The Deadlock in European GM Crop Authorisations as a Wicked Problem by Design

A need for Repoliticisation of the Decision-making Process

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PREFACE

When I started working at the Netherlands Commission on Genetic Modification (COGEM), I was aware that controversial technologies were not simply resolved through more scientific knowledge. But as with most problems, it is easier to identify what doesn't work than to come up with strategies that might prove effective. Working for a scientific advisory body, I have experienced throughout the years how resilient certain patterns in discussions and problem solving have become. But it wasn't until the 'alarming study' published by Séralini, that the apparent unresolveability really started to dawn on me.

And this is where I got fascinated by the entanglement and dynamics of different factors in science, society and regulations. This dissertation analyses the role and limits of decision-making in each of these fields, with GM crops as a case study. The analysis allowed me to build my argumentation for the importance of decision-making in situations of (scientific) uncertainty, a plurality of conflicting views in society and a legal framework that can provide the rules but not determine the outcome. Analysing each of these factors calls for different methodologies and expertise. For me this has been a struggle and, hopefully, finally also a strength in the process of compiling this thesis. A background in both science and philosophy teaches you how to translate knowledge, cross bridges and close gaps, but you don't really belong in either of these fields. Taking up a PhD meant finding myself again in an unknown world; the one of Philosophy of Law. Leaning on the limited legal knowledge I had, the GMO regulations, questions about my methodology and theoretical framework have moreover left me puzzled. On the other hand, being challenged and questioned continuously to justify my choices from different perspectives has also increased my understanding and sharpened my analysis. It challenged me to use a variety of tools to analyse and study GM crop authorisations as a wicked problem by design. I hope this thesis is able to cross boundaries to reveal some of the dynamics of the GM crop issue that rise above the limits of the separate fields of expertise.

I would like to thank my supervisors for accepting me as an external PhD candidate and supporting me throughout this process with both critical questions and motivating appraisals that helped me to structure my thoughts. I also want to thank those - you know who you are - who took me on crazy (mud) runs and self-organised marathons, endless bike rides and freezing open water swims to balance the all-night writing sessions, those inviting me for English tea and creative LEGO sessions in the country that I kept refusing because I was always too busy, and those meeting me for beers & loud music to forget about all the brilliant things I thought I came up with.

LIST OF ABBREVIATIONS AND ACRONYMS

ATMP	Advanced Therapy Medicinal Product
Bt	*Bacillus thuringiensis*
CA	Competent Authority
CAP	Common Agricultural Policy
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
Commission	European Commission, EC
Council	Council of the European Union, Council of Ministers
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DNA	Deoxyribonucleic acid
EBP	Evidence Based Policy
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENGL	European Network of GMO laboratories
ENSSER	European Network of Scientists for Social and Environmental Responsibility
EP	European Parliament
EPEC	European Policy Evaluation Consortium
ERA	Environmental Risk Assessment
EU	European Union
EURL GMFF	European Union Reference Laboratories for GM food and Feed
GE	Genetic Engineering
GMO	Genetically Modified Organism
GRACE	The 'GMO Risk Assessment and Communication of Evidence' project
G-Twyst	The 'Genetically modified plants Two Year Safety testing' project
IARC	International Agency for Research on Cancer
IFOAM	International Federation of Organic Agriculture Movements
IR	Implementing Regulation
JRC	Joint Research Centre of the European Commission
LMO	Living Modified Organism
MS	Member State
NGO	Nongovernmental Organisation
NPBT	New Plant Breeding Techniques

NRL	National Reference Laboratories
OECD	Organisation for Economic Cooperation and Development
PAFF	Standing Committee on 'Plants, Animals, Food and Feed'
PP	Precautionary Principle
RNA	Ribonucleic acid
SAM	Scientific Advice Mechanism / Group of Chief Scientific advisors (SAM)
SEC	Socio-Economic Consideration
TALENs	Transcription activator-like effector nucleases
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
WHO	World Health Organisation
WTO	World Trade Organisation
WTP	Willingness To Pay

CHAPTER 1

BIOTECHNOLOGY GOVERNANCE: WHY, HOW AND BY WHOM?

R. Mampuys

The first three chapters of this thesis provide the problem description and analysis, the main research question and my hypothesis. These are followed by a set of five chapters consisting of published articles that deepen this analysis. This thesis is concluded with a final chapter to answer my research questions and substantiate my hypothesis. This first chapter introduces biotechnology as the object of this thesis. It illustrates both the potential and challenges of using and regulating biotechnology through a) a brief overview of applications, definitions and a general characterisation of the discussion in this field and b) an overview of the European regulatory framework in both theory and practice. A practice where market authorisation decisions on GM crops are systematically delayed and stalling. From there, I will present two concepts that I will use to illustrate and characterise the problem: 'alarming studies' and 'wicked problems'.

1. INTRODUCTION

The introduction of molecular biology in the 1970s can be marked as the birth of modern biotechnology, enabling the altering of the genetic code of living organisms. This process is also known as genetic modification, genetic manipulation or genetic engineering.

Over the years different techniques have been developed to modify the hereditary material (DNA) of living cells, aimed at improving the efficiency, precision and accuracy of the desired genetic changes. Starting in the 1930s with inducing random mutations through radiation and mutagenic chemicals, it is now possible to change single nucleotides[1] in the DNA of living organisms (Natarajan 2005 and Rees & Liu 2018). The newest techniques such as CRISPR-Cas[2] are versatile and used as a one-size-fits-all tool in agricultural, environmental, medical and industrial biotechnology. Genetic modification was initially applied only in micro-organisms, but soon after the field has been broadened to plants and animals, including humans.

Agricultural applications focus on the development of new plant varieties to increase production by improving insect- or disease resistance, herbicide

1 Nucleotides form the basic structural unit of nucleic acids such as DNA.

2 CRISPR-Cas is an abbreviation of Clustered Regularly Interspaced Palindromic Repeats with a CRISPR Associated Protein (Cas). It is one of the newest tools used to alter DNA sequences and modify gene function because it acts like a programmable pair of molecular scissors that is able to cut strands of DNA, remove DNA and insert new pieces of DNA with added functionality. The alterations possible with this technique vary from singe point mutations to inserting or removing entire (parts of) genes.

tolerance, or resilience to climatological changes and other stress factors (ISAAA 2018). Other developments focus on agricultural product quality such as composition, size and appearance. In the field of veterinary science, biotechnology is used for genetics research to aid the animal breeding process and for the development of veterinary vaccines. Cloned animals, such as the sheep dolly (Callaway 2016), and genetically modified animals, such as the bull Herman (Mackenzie & Cremers 1992), have been developed in the 90s but these applications never became steadily integrated into animal breeding so far. The only commercial application of a GM animal is a fast growing GM salmon developed in Canada. It was developed in the late 90s and took almost 20 years to get authorised for human consumption (Nature 2017). The development of GM animals is back into the picture since a few years because new techniques were developed that overcome several technical hurdles of modifying animals (Nature 2016a,b). Contrary to commercial applications, the development of genetically modified laboratory animals (i.e. rats, mice) to function as disease and testing models for human medicine have been common practice for a long time. In the medical field, biotechnology is used for preventative, diagnostic and therapeutic purposes. Preventative purposes include the development of vaccines for common diseases like seasonal flu as well as vaccines for outbreaks such as Ebola (FDA 2019) or COVID-19 (Stoye 2020). Biotechnology is used in diagnostics to identify hereditary diseases or develop personalised treatments, and gene therapy is increasingly used to treat cancer or metabolic disease (Cornel 2019). Industrial biotechnology refers mainly to the production of substances in GM micro-organisms, ranging from food additives (i.e. vitamins), pharmaceutical products (i.e. insulin), biofuels (i.e. ethanol) and raw/fine chemicals (fibers, plastics, lubricants) (for an overview see Rodrigues & Rodrigues 2017).

The developments in biotechnology continue to expand and they may have a growing and more substantial impact on our health, food production and environment in the future, such as the possibility to change human characteristics with germline modification, the production of meat without animals or the elimination of an entire population of pest insects with gene drives.[3] Furthermore, biotechnology increasingly converges with

3 In 2015 Chinese scientist Jiankui He announced the birth of two girls, genetically modified to be HIV resistant, opening a worldwide debate on germline modification of humans (Nature 2018); the term gene drive is used for a genetic mechanism that modifies the inheritance pattern of a specific characteristic in such a way that it spreads in the population faster than normal. This can be used to insert a lethal gene in pest or disease-spreading insects to eliminate for example malaria (Nature 2019) and the so called 'impossible burger' is a plant based burger that 'bleeds' and tastes like regular meat products because of the presence of 'heme' that is produced in GM yeast (Nature Biotechnology 2019).

other technologies such as nanotechnology, 3D printing, computer science, neuroscience, robotics and engineering, creating a landscape of seemingly futuristic applications.[4]

This broad variety of applications also triggers diverging views on the role this technology should play in our lives. And this in turn creates a multitude of challenges for the governance of biotechnology on a national, European and global level (see Chapter 8). Governance[5] is a broad term that in my view can be best described as the whole process of 'dealing with' (technological) developments on different levels, ranging from society, science, industry and regional, national or international governments and institutions. 'Dealing with' can, for example, concern public debate and participation, aiming for responsible innovation by science and industry or designing and enforcing regulations by policy makers.

For many technological/scientific applications that vary in appraisal in society (e.g. smartphone use, automobiles, industrial agriculture, animal testing), existing governance approaches seem to be sufficient to manage their implementation in society. This doesn't mean there is no debate, but the existing systems of governance enable using or avoiding the technology in a way that facilitates the needs of different stakeholders such as consumers, producers, science and industry without too much upheaval i.e. without substantial protests or the blocking of regulatory processes.

But somehow, for genetically modified organisms (GMOs) the governance mechanisms in place do not seem to work in the same way and genetic modification is considered controversial (e.g. European Commission 2010, Tosun & Schaub 2017). This is particularly the case in Europe, where Member States (MS) cannot agree on the safety of GM crops despite clearance from the European Food Safety Authority (EFSA) and where a majority, but not all, of

4 Choi *et al.* 2020 describe nanoparticles that deliver 'suicide gene' therapy to brain tumors; Goulart 2019 announces the printing of a functional mini-liver; Koch *et al.* 2019 present the results of research into storing data in DNA; El-Shamayleh & Horwitz 2019 manipulate the neural activity in monkeys with genetic constructs responding to light; Kriegman *et al.* 2019 created a living self-healing robot from frog cells and Heveran *et al.* 2020 invented self-healing bricks with the help of GM bacteria.

5 Political scientist Mark Bevir described governance in general as 'all forms of social coordination and patterns of rule' and more in particular as 'all processes of governing, whether undertaken by a government, market, or network, whether over a family tribe, formal or informal organisation, or territory, and whether through laws, norms, power or language' (Bevir 2012). In academic literature, numerous levels, types and styles of governance are described such as global, public or private governance, corporate, environmental or regulatory governance, participatory, contract or collaborative governance.

the 27 MS have voted to ban GM crops based on non-safety arguments (see Smart *et al.* 2015 and New Scientist 2015). The controversy is also reflected in public opinion research, recurring debates in media and politics and hampered decision-making on market authorisations as well as regulatory reforms.

This thesis aims to analyse what is not working, why it is not working and what could be done to improve the situation in Europe with regard to regulatory decision-making on the authorisation of GM crops. First, we need to define what we mean when we are talking about biotechnology and GMOs.

2. VARYING DEFINITIONS OF BIOTECHNOLOGY AND GMOs

Several definitions of biotechnology and GMOs are in use that vary depending on the context in which they are used (i.e. general, political, scientific or legal). Starting with biotechnology, one of the most used general definitions is the one from the Organisation for Economic Cooperation and Development (OECD):

> *'The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.'* (OECD 2005, p.9)

The OECD description covers all biotechnology, including more traditional activities such as brewing and cheese making. To distinguish between traditional and modern biotechnology, the OECD added a list-based definition, consisting of seven categories of techniques in modern biotechnology, last updated in 2018:

1. *DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology; large-scale DNA synthesis, genome- and gene-editing, gene drive.*
2. *Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signalling, identification of cell receptors;*
3. *Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation; marker assisted breeding technologies, metabolic engineering.*
4. *Process biotechnology techniques: Fermentation using bioreactors, biorefining, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biosensing, biofiltration and phytoremediation; molecular aquaculture*

5. *Gene and RNA vectors: Gene therapy, viral vectors;*
6. *Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology; and*
7. *Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.*
   (OECD 2018, p.8)

The focus of this thesis is on modern biotechnology and more specifically on organisms whose genetic material (DNA) has been altered, called living modified organisms (LMOs) or GMOs. One of the main international treaties covering the use biotechnology, the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (hereafter: Cartagena Protocol) uses the term LMO, which is defined as:

> *'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'* (CPB, Art. 3)

The Cartagena protocol also defines living organism and modern biotechnology.[6] In addition, it recognises that in everyday usage LMOs are usually considered to be the same as GMOs but notes that definitions and interpretations of this term vary widely (Cartagena Protocol, FAQ). In the European regulatory context, the term GMO is the standard, defined as:

> *'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'* (Directive 2001/18/EC, Art. 2)

While most definitions of 'biotechnology' show relatively small variations in wording and interpretation,[7] the definition 'GMOs' and 'LMOs' and of

6 The Cartagena Protocol defines a 'living organism' as 'any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids'; modern biotechnology is defined as 'the application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family' (CPB, Art. 3).

7 See for example the UN convention on biological diversity who defines biotechnology as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use' (CBD, Art. 2) or the Novel feeds regulation Canada which defines biotechnology as 'the application of science and engineering to the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms' (Feeds regulations 1983, Art. 2).

'genetic modification' or 'genetic manipulation' varies more substantially.[8] To illustrate, the Cartagena protocol has a focus on 'novel combinations' of genetic material, while the European legal definition emphasizes the 'non-naturalness' of the recombination. While there seems to be an overlap, novel and non-natural are not necessarily the same and this may lead to different interpretations and implementations of regulations.

In addition, numerous definitions and metaphors have been introduced, and contested, to mediate public understanding of biotechnological techniques. See for example O'Keefe (2015) and McLeod & Nerlich (2017) who analyse and discuss the use of some of these metaphors. I will briefly summarise some examples of language differences and metaphors here. In general, the notion of 'genetic modification' is mostly used in a scientific context, whereas 'genetic manipulation' is more common in a political/societal context from a critical perspective on these techniques. With regard to specific techniques, the term 'synthetic biology' was introduced early 2000 for modified organisms that were, basically, no different from GMOs.[9] Synthetic biology was presented by scientists as a means of precise and highly controllable ways to achieve genetic changes (other wordings used in the context of synthetic biology are 'designing life' and 'rewriting the code of life'). In contrast, it was named 'extreme genetic engineering' or 'GMOs on steroids' by stakeholders and organisations with a more critical attitude towards GMOs, such as ETC Group (2007) and Friends of the Earth (2012). The struggle for defining biotechnology developments is also illustrated on a policy and regulatory level, where the European Commission (EC) appointed three scientific committees to come up with a single definition of synthetic biology. Literature research and international surveys resulted in 35 published definitions, out of which the following 'operational definition' of synthetic biology was distilled:

8 See for example the European legal definition of a GMO as 'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination' (Dir. 2001/18/EC, Art. 2) versus the Canada novel feeds regulation that defines genetic modification as 'to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation' (Food and Drug Regulations, B28.001). The EU definition has a focus on modern biotechnology, while the Canadian definition would include all biotechnology applications. In addition, Canada regulates plants with novel traits (PNTs) that include most GMOs but also some products of conventional plant breeding that are not considered GMOs in Europe (Directive 94-08).

9 The term synthetic biology was first used in 1910 in Stephane Leduc's publication 'Théorie physico-chimique de la vie et générations spontanée', but nowadays refers mostly to the introduction of a series of new techniques around 2000 that allow for the creation of synthetic biological circuits to control cells (see Garder *et al.* 2000 and Elowitz 2000).

> *'The application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms.'* (SCENIHR, SCCS, SCHER 2014, p.30)

But synthetic biology surely wasn't the last metaphor to be introduced. Since a few years, the introduction of 'gene editing techniques'[10] suggest an even more controllable process of creating genetic changes (O'Keefe 2015). And this terminology too is subject to criticism. Environmental nongovernmental organisations (NGOs) such as GMWatch (2018b) and Beyond GM (2016) criticise these metaphors because in their view it unfairly suggests a safe precision technology and it tries to steer away from negative connotations or associations with GMOs.

For the purpose of this thesis, it is not necessary to discuss what is the 'right' or one true definition of biotechnology, GMOs, synthetic biology or gene editing. From the variety of definitions and metaphors, it is important to remember that a diversity of definitions exist and that these can be used in different contexts or with different purposes. Furthermore, the identified diversity of terminologies seems to hint at a level of disagreement on how GMOs should be perceived and regulated.

3. RECURRING THEMES IN DISCUSSIONS ABOUT BIOTECHNOLOGY

The application of biotechnology brings forward questions to individuals and societies on how they want to relate themselves to its use with regard to acceptance and desirability. These questions may be a topic of conversation by the general public when confronted with information and news from (social) media or with consumer goods such as GM food, but they are also discussed in academic literature, in legal and policy areas and in political debates.

This section provides a non-exhaustive overview of recurring themes in these discussions, gathered from my experience at the Netherlands Commission on Genetic Modification (COGEM). COGEM is an independent scientific advisory body of the Dutch government that advises on the risks to human health and the environment of the production and use of GMOs and informs the government of ethical and societal issues linked to genetic modification. The advisory task of COGEM focusses in essence on regulatory science, whereas its

10 Gene editing refers to a series of new recombinant DNA technologies such as Zinc Fingers, Transcription activator-like effector nucleases (TALENs) and CRISPR-Cas. These techniques can be used to precisely cut, replace or add DNA without leaving traces of modification.

informing task uses regulatory knowledge including legal, moral and economic knowledge. This thesis is therefore written from the perspective of this type of science. Regulatory science concerns the use of scientific knowledge to justify regulations and substantiate the safety of applications that are subject to regulations (see Section 2.2). Regulatory science is a part of regulatory knowledge, which may in addition include legal, procedural, moral, economic and other knowledge, see Faulkner & Poort (2017). All these types of knowledge are reflected in the themes that play a role in discussions about biotechnology. An overview will be given below. For a more extensive analysis of the history, character and dynamics of the GM debate, see for example Bovenkerk (2010, Chapter 2) and COGEM (2017).[11]

An (ideal typical) distinction can be made between themes relating to moral views towards biotechnology (is the technology acceptable or not?), themes relating to risks and benefits (is it safe and useful (enough?) and themes relating to broader issues that play a more general role in technology discussions (e.g. socio-economic issues). This distinction is somewhat artificial, as terms like risk, harm or damage as well as benefits also relate to moral perspectives. For example, risks can relate to obvious and measurable harms like toxicity to humans or animals, but also to the loss of biodiversity or a specific food production system that is valued by a part of society. Or as Stirling (2012) phrased it: 'much of the controversy over genetically modified organisms concerns not the likelihood of some agreed form of harm, but fundamentally different understandings of what harm actually means.' What is considered harm or acceptable risk may vary from person to person and is also related to what one considers valuable or worth protecting.

3.1 FUNDAMENTAL MORAL PERSPECTIVES

For some, genetic modification is no different from other ways in which mankind changes its environment to achieve desired goals.[12] According to these type of views, plant breeding or animal breeding is all the same, regardless of the technologies used, whether they be conventional breeding methods or genetic modification. This does not necessarily mean that people holding these

11 COGEM (2017). Gentechdebat op scherp: invalshoeken voor een vruchtbare dialoog (available in Dutch) is a book based upon policy reports written mainly by the author of this thesis in her role as a scientific secretary of the Subcommittee on Ethics and Societal Aspects. The reports were re-edited by Mampuys and reflected on by a variety of experts to reassess their value and contribution to the GM debate.

12 Tosun & Schaub (2017) describe a pro-GMO coalition consisting of amongst others agro-chemical companies, biotech research institutes, big farming, and selected (European) Member States who ask for the authorisation of new GM products.

views approve of all types of applications, but they do not distinguish between the technologies used. For others, altering the DNA of living organisms is fundamentally different from other techniques.[13] It conflicts with the 'naturalness'[14] and integrity of processes in living organisms. From this perspective, the use of GMOs is therefore unacceptable. This view can have religious as well as non-religious moral or ethical reasons. Both views reflect people's conceptions of 'a good life', i.e. what people consider a valuable way of life. Obviously, a variety of perspectives exists between the two extremes of embracing the technology or fully rejecting it. These may vary in the level of technology interference or control over nature people feel comfortable with or that they believe is contributing to their view on 'a good life'. Fundamental moral perspectives are not per se always articulated as such but may also be reflected by intuitive feelings or emotions. For example, public opinion research has shown that the idea of GMOs gives some people a general feeling of unease or disgust. This is also known as the 'yuk' factor (see Midgley 2000).

3.2 ATTITUDES ON RISKS/BENEFITS

Technologies are developed and applied because they are perceived by at least some people to provide certain benefits. From this perspective, biotechnology has a potential to contribute to the quality, quantity and sustainability of food production, new therapies to improve health and welfare and the production of a wide variety of components for industrial use. On the other hand, there may also be risks or negative (side) effects to the use of technology. The risks can relate to accidental and unintended risks to humans and the environment (biosafety) as well as risks that the technology could inspire misuse in the form of bioterrorism or biowarfare (biosecurity).[15] The safety of humans and the environment is considered important on a collective level and most countries have regulations in place that safeguard the risk of technologies in society. The potential risks of GMOs are being studied in scientific research and mandatory risk assessments are a part of the regulatory approval process.

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13 Tosun & Schaub (2017) describe an opposing camp against GMOs consisting of amongst others citizens, consumer-protection groups, and environmental NGOs who demand GMOs to be regulated more strictly or even banned.

14 The word naturalness has different meanings and is often used differently depending on context. In this context it refers to the meaning of naturalness as 'whole' and 'pure', 'without human interference'. For an overview of the ethical debate on naturalness in discussions about plant-biotechnology, see Van Haperen *et al.* (2012).

15 Biosafety aims to prevent the *accidental or unintended misuse* of the life sciences while Biosecurity aims to prevent the *deliberate misuse* of the life sciences by non-state actors. For a review of biosafety and biosecurity issues in synthetic biology see Gómez-Tatay & Hernández-Andreu (2019).

While some reviews of scientific literature conclude that GM crops are as safe as traditionally bred crops (Nicolia *et al.* 2014, National Academies of Sciences Engineering and Medicine 2016, European Commission 2010b), others fear we cannot oversee or predict the consequences of genetic modification and the way it could, perhaps even irreversibly, damage our health or the environment (GMWatch 2016, ETC Group 2014). Both perspectives refer to science, but where one points at the absence of evidence of harm, the other points at the uncertainties or the unknown consequences of the technology on the long term and emphasises the need for evidence of safety. As noted before, individuals, collectives, cultures and nationalities may differ on the question what should be considered harmful or what risks are acceptable. In addition, recurring doubts and discussions about the benefits, risks or downsides of biotechnology use also relate to the level of trust in authorities that are assigned to safeguard the use of this technology. From there, we arrive at the broader themes relating to biotechnology.

3.3 BROADER ISSUES

Besides fundamental views on biotechnology and attitudes towards risk and safety, broader themes play a role relating to issues that are not necessarily biotechnology specific. An example can be found in debates on sustainability, where some argue that biotechnology can contribute to sustainable agriculture (a decrease of insecticide use with insect resistant GM crops, see Oliver 2014), whereas others are of the opinion that GM crops indirectly facilitate unsustainable agricultural practices (an increase in pesticide use with herbicide tolerant crops, see Zdjelar & Nikolic 2013). Friends of The Earth (2014) criticised the production of vanilla in GM microorganisms being promoted as ‘natural’ and ‘sustainable’ while it is in their view unnatural, unsafe and it replaces natural production in developing countries, causing local workers to lose their jobs and income.

Additionally, there may be alternative solutions to problems in the agricultural and medical field that, according to some perspectives, are more suitable to address the problem. People may argue for example that vegetarianism is a better solution than producing more feed for cattle intended for meat production. This is a balance that can be made in different ways depending on both people’s moral fundamental views (i.e. views on ‘the good life’) as well as attitudes towards risks and benefits.

Broader themes in biotechnology discussions can also relate to institutional and socio-economic questions about authority, autonomy, access to technology, ownership, fairness and equity and geopolitical / distributional issues regarding food, health and welfare (for an overview of socio-economic aspects of GM crops, see Chapter 7). For example, the National Academies of Sciences Engineering and Medicine (NASEM) (2016) and the International Service for the Acquisition of Agri-biotech Applications (ISAAA) (2018) argue that biotechnology holds promises for farmers and citizens in developing or malnourished countries. A well-known example is Golden Rice,[16] a GM rice variety created to alleviate Vitamin A deficiency in developing countries. On the one hand the rice is described as a key example of a technology that contributes to alleviate hunger and malnutrition.[17] On the other hand Friends of the Earth (2011) argue that this GM rice does not solve the actual problem of food distribution and access to a varied diet. Or that accepting this technology may be a first step in making farmers (financially) dependent on multinational companies that are trying to control the food chain.

The themes mentioned give a broad overview of the perspectives on biotechnology. Because there is a plurality of views that are conflicting on various levels, it is not surprising that these lead to debates in science, society and in the regulatory and political sphere. As mentioned earlier, conflicts about technology use are not uncommon, which is why there are regulations in place and policies are developed to address these differences in the best possible way. For biotechnology however, these conflicts have shown a remarkable resilience to being solved or mitigated, especially in the area of the commercial applications of GM crops. Since 2003, the European authorisation procedures for commercial release of GM Crops systematically resulted in delayed or stalled decision-making and several MS have called a ban on the cultivation of GM crops. This makes European market authorisations of GM crops an case study. To gain more insight into the potential cause(s) of the conflict over GM crops, we first need to zoom in on the way GMOs are regulated. In the next section, an overview is provided of the GMO regulatory framework.

4. REGULATORY FRAMEWORK FOR GMOs IN EUROPE

GMOs are subject to regulations in most countries worldwide. After the discovery of recombinant DNA technology in 1973, scientists set up a meeting

16 For an overview of the Golden Rice history and discussion see Kettenburg 2018.

17 See the project website URL: www.goldenrice.org (Accessed 14 July 2020)

to discuss its implications. At the Asilomar conference in 1975 an international community of scientists acknowledged that GMOs could potentially pose a risk to humans and the environment.[18] This eventually triggered the initiative for national and international legislation to assess the risks of GMOs in laboratory experiments. Initially, regulations were focused on genetic engineering (GE) of microorganisms in the laboratory, as this was the only field that GE was applied to at first. Over time, GE started to be applied in plants, animals and human health research, both in the laboratory and in the field. This resulted in composing and implementing additional regulations for introduction into the environment (field trials and commercialisation or deliberate release).

Regulatory frameworks applying to scientific developments and technological applications determine amongst others who decides about what and based on which grounds. The grounds on which GMOs are regulated are similar to the way we deal with other technologies that may have potential risks to humans and the environment, such as novel foods, pharmaceutical products or pesticides. This means an experiment or product needs to be assessed and if it meets the safety requirements, it can be approved. Regulatory frameworks for GMOs worldwide are quite similar with regard to the risk assessment, but there are differences in the way the regulations are set up and implemented.[19] These differences are not relevant to the topic of this thesis and will not be discussed in detail. Other differences can be found in the division of decision-making power; i.e. who decides about what. The approval itself can vary from an administrative act to a political voting procedure and depends on the type of application and national regulations. With relevance to this thesis, the focus of the rest of this section is on the EU regulations for GMOs.

The EU regulates GMOs based on a definition of a GMO (see Section 2), supplemented with a list of processes and techniques that result in a GMO, a list of processes that do not result in a GMO and a list of processes that do result in a GMO but are exempted from the regulatory requirements of

18 The Asilomar Conference on Recombinant DNA (February 1975) was an influential conference about potential biohazards and regulation of biotechnology. An international group of professionals (biologists, physicians, lawyers) participated to draw up voluntary guidelines to ensure the safety of recombinant DNA technology (see Berg 2008).

19 The main difference highlighted in academic literature is whether the trigger for regulating a product is 'product' or 'process' based, i.e. whether it looks at the characteristics of the end product or at the way the product was made. Canada is the most prominent example of a strictly 'product' based regulation, whereas Europe is known for its predominantly 'process' based regulation. Both systems have their own benefits and downsides, for an overview and comparison see COGEM (2019).

the regulations, such as a safety assessment (see Directive 2001/18/EC resp. Annex IA, part 1, Annex IA, part 2 and Annex IB). European regulations provide requirements which EU MS need to implement in their own legislation. There are Directives and Regulations[20] for different applications such as contained use (i.e. laboratory experiments), deliberate release into the environment (i.e. field trials with plants) and commercialisation (i.e. market authorisation of GM crops, pharmaceutical products and gene therapy). For the purpose of this thesis I will not discuss all GMO Directives and Regulations, but zoom in on the relevant regulations for market authorisations of GM crops.

Market authorisation of GM crops (import as food/feed and/or cultivation) is regulated on a European level and based predominantly on an assessment of food/feed and environmental safety (Directive 2001/18/EC and Regulation (EC) No. 1829/2003) and requirements for traceability (for food safety purposes) and labelling (Regulation (EC) No 1830/2003). When applying for market approval, applicants are required to provide data substantiating the food and environmental safety of their product, including reference material and a detection method that enables tracing the product in the food chain. The food and environmental safety are assessed by the EFSA[21] and competent authorities (CA) of the EU MS. Labelling and traceability requirements are assessed and validated by the by European Union Reference Laboratories for GM food and Feed (EURL GMFF).[22]

In addition, in 2015 a Directive has come into force which, in addition to and separately from the safety assessment, enables MS to ban or restrict cultivation of GM crops on their territory based on non-safety arguments, such as socio-economic aspects or environmental policy objectives (Directive (EU) 2015/412).

20 Directives lay down results that must be achieved by MS but they are free to decide how to transpose those directives into National Laws. Regulations have binding force throughout every MS and enter into force on a set date.

21 The European Food Safety authority is a European agency funded by the European Union that operates independently of the European legislative and executive institutions (Commission, Council and Parliament) and EU Member States. EFSA provides independent scientific advice and communicates on existing and emerging risks associated with the food chain, including the commercial application of GMO's. EFSA conducts food safety and environmental risk assessments of GM crops that are applied for market authorisation in the European Union.

22 The core tasks of the EURL GMFF are the scientific assessment and validation of detection methods for GM Food and Feed as part of the EU authorisation procedure and the provision of support to the National Reference Laboratories (NRL) for GMO control in the EU Member States. The EURL GMFF is supported by the ENGL, the European Network of GMO Laboratories, and hosted by the Joint Research Centre (JRC) of the European Commission.

To facilitate producers' freedom of choice, MS are encouraged and facilitated in taking appropriate measures for coexistence of conventional/organic crops with GM crops with the aim of preventing admixture or inadvertent presence of GM crops in other products (Commission Recommendation of 13 July 2010).[23]

Together, these regulations set the requirements (food and environmental safety, traceability and labelling) and optional restrictions (coexistence measures and non-safety arguments) to determine which GM crops can be allowed to be cultivated by farmers and to be used in food for human consumption and feed for livestock animals. The next section goes into more detail of how decisions about market applications are made. The market authorisation procedure of GM crops can be roughly divided in two steps: 1) an environmental and food safety assessment (i.e. the grounds on which a decision is made) and 2) regulatory decision-making based on European comitology procedures (i.e. determining the decision-making power: who decides about what and how). After describing both steps, I will reflect on how they work out in practice.

4.1 PREREQUISITE: AN ENVIRONMENTAL RISK AND FOOD SAFETY ASSESSMENT

The principles and data requirements for the environmental risk and food safety assessment are described in detail in the regulations (e.g. Annex II and Annex III of Directive 2001/18/EC). The risk assessment takes into account a broad variety of potential effects and the risk assessment principles. Summarised these principles focus on the following nine topics for the environmental risk assessment: the persistence and invasiveness of the GM plant, selective advantages or disadvantages of the GM plant, the chances and possibilities of gene transfer to sexually compatible plants, impact of the interaction of the GM plant with target organisms, impact of the interaction of the GM plant with non-target organisms, effects on human and animal health, effects on animal health, effects on biogeochemical processes and impact on cultivation, management and harvest techniques used. The food safety assessment in addition requires a toxicological, allergenicity and nutritional assessment.

23 GM crops can accidentally comingle with conventional or organic crops during production and transport, or their genes can outcross into these varieties in the field. This is particularly a problem for the organic sector that prohibits the use of GM. Coexistence measures aim to prevent admixture and outcrossing of GM crops. The Commission Recommendation of 13 July 2010 provides guidance to MS for the development of coexistence measures, including in border areas. The recommendation encourages MS to cooperate with each other to implement appropriate measures at the borders between MS so as to avoid unintended consequences of cross-border contamination (European Commission 2010c).

This means the GM plant needs to be characterised geno- and phenotypically[24] and its effects on the environment are compared to a similar non-GM plant in field trials. For the food safety assessment, the molecular composition of the plant is tested for potential toxic or allergenic effects. The assessment also includes mandatory 90 day feeding studies with rodents (see Section 5). Besides food and environmental safety assessments on specific applications, EFSA also publishes (non-binding) guidance documents on specific aspects of the risk assessments to assist applicants who want to file for market authorisation. Some of these guidance documents have been translated into legally binding texts.[25]

Applications for market authorisations are also sent to EU MS who get the opportunity to assess the application and send their conclusion, remarks and questions to EFSA. Eventually, this results in a scientific opinion from EFSA that is sent to the EC (European Commission 2015).

4.2 REGULATORY DECISION-MAKING: COMITOLOGY

Eventually, decision-making about GM crop authorisation lies not with the EFSA but with European and national government representatives. If the EFSA concludes that the product does not pose a risk to human health or to the environment and that additional requirements (such as traceability and labelling) have been met, the EC submits a draft implementing decision of authorisation to a committee made up from representatives of the MS. Here, a voting takes place that officially has to be scheduled within three months after publication of the EFSA scientific opinion.

MS representatives vote under the rule of 'qualified majority'[26] or system of weighed voting defined in the Lisbon Treaty (EPRS 2014). Comitology refers to a set of procedures that give MS a say in the implementing acts of the EU. To understand the challenges of the comitology procedures with regard to GM crop authorisations, the working mechanism and role of comitology in Europe have to be explained first.

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24 Genotype is constituted by an organisms' entire DNA (its hereditary information), its phenotype are the properties that we can observe such as morphology, development and behaviour in the environment.

25 Implementing regulation (EU) No. 503/2013 in accordance with Regulation (EC) No. 1829/2003.

26 A measure will be approved if it is supported by 55% of the Member States (15 out of 27), provided they represent 65% of the EU population.

When legislative acts[27] have been adopted by the Council of the European Union (i.e. the Council of Ministers, hereafter: the Council) and the European Parliament (EP), a system of MS committees oversees the execution of EU laws (the non-legislative acts): this is operationalised through the comitology system. For an overview of types of EU law see **Figure 1**.

The European Union Comitology system (hereafter: comitology) was established in the late 1950s and early 1960s. For an overview of the origins of the EU comitology see for example Blom-Hansen (2008).

The comitology system has undergone several reforms over the years, the last significant overhaul resulted in the Lisbon Treaty. Most reforms had to do with the division of power between the EC, the Council, the EP and the MS.

The Lisbon Treaty became effective in 2009 and formalised most of the proposals on comitology in articles 290 (Delegated acts) and Article 291 (Implementing acts) of the Treaty on the Functioning of the European Union (TFEU).[28] For an overview of the differences before and after the Lisbon Treaty see Stratulat & Molino (2011). In this introductory chapter, it is sufficient to summarise the current working mechanism of the comitology procedures and some main differences to the older procedures.

Delegated acts (Article 290, TFEU) deal with specifications of technical details or amending specific parts of legislation. They are defined as 'non-legislative acts of general application' whose aim is to 'supplement or amend' certain 'non-essential elements' of legislative acts. Article 290 makes the EC solely responsible for drafting and adopting delegated acts. Delegated acts work through expert groups and draft proposals can be objected by the EP and/or Council. This means that the EP and the Council can oppose the delegated act on any grounds or revoke the delegation. The EP can do so based on a majority, the Council can do so based on a qualified majority, see Georgiev (2013).

Implementing acts (Article 291, TFEU) aim to create uniform conditions in the MS. Stratulat & Molino (2011) explain that, when a 'legally binding Union act [...] identifies the need for uniform conditions of implementation',

27 Legislative acts refer to the joint adoption (so called co-decision) by the EP and the Council of a regulation, directive or decision on a proposal from the Commission (Article 289 (TFEU))

28 The TFEU is one of two treaties forming the constitutional basis of the European Union. The other one is the Treaty on European Union (TEU).

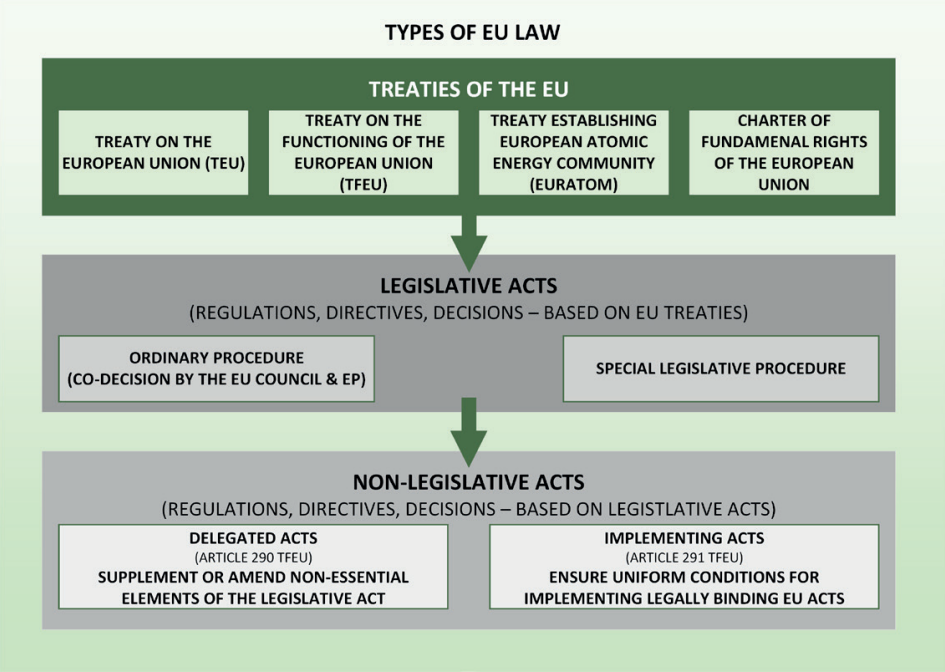

Figure 1: The types of EU law can be divided into primary legislation (the Treaties of the EU) and secondary legislation (legislative and non-legislative acts). Non-legislative acts can be either delegated or implementing acts.

it can require the adoption of implementing acts, which are of a 'technical and administrative nature' (p.2). These acts are adopted by the Commission, i.e. the EU executive, and overseen by the Member States, i.e. the 'national' executives'. The detailed procedures for the Member States' control of the Commission's executive powers are set out in Regulation (EU) No 182/2011.[29]

The regulation distinguishes between an 'examination procedure' and an 'advisory procedure'. In both cases, committees formed by representatives of MS are in charge of scrutinising the proposed implementing acts. The committees include one representative from every EU country and are chaired by the EC. Each committee decides its operating procedures, based on standard committee rules of procedure. The voting results and summary record of the committee meetings are published in the comitology register.

29 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

The advisory committee issues non-binding opinions based on a simple majority of the MS, whereas the examination committee acts through a binding qualified-majority vote on draft measures presented by the EC. The result of this voting round under a qualified majority can be 'positive', 'negative' or 'no opinion'. If the result is 'positive' the EC has to adopt the implementing act. If the voting results in a 'negative' opinion, the EC can 1) amend the proposal or 2) send it to an 'appeal committee'. The appeal committee is also made up of EU countries' representatives, but is intended to have a higher level of political representation. It is also chaired by the EC and follows the same voting rules of a qualified majority. If the result is 'no opinion' the EC can also amend the draft or, in specific cases, has no choice but to refer the act to the appeal committee. This is mandatory if the measure concerns specific matters, i.e. taxation, financial services, the protection of human, animal or plant health, or definitive multilateral safeguard measures. In the appeal committee, if the qualified majority voting is positive, the act is adopted, if the outcome is negative, the act has to be rejected. In case the second voting is also inconclusive, the EC may veto a decision.

Implementing acts cannot be vetoed by the EP or the Council. However, Stratulat & Molino (2011) point out that Article 291 'grants the EP (alongside the Council) the right to intervene by submitting a non-binding resolution when it considers that the EC has overstepped its execution competences.'

GM crop authorisations are implementing acts that fall under the responsibility of the examination committees which require a qualified majority voting. They are discussed in one of the Standing Committees on Plants, Animals, Food and Feed and environmental safety (PAFF), either in the specialised commission on 'genetically modified food and feed and environmental risk' (for authorisations through Regulation (EU) No 1829/2003 on import as food/feed) or in the 'Regulatory Committee 2001/18/EC' (for authorisations through Directive 2001/18/EC on cultivation). Since these are matters concerning the protection of human, animal or plant health, a voting result of 'no opinion' has to be referred to the appeal committee. If again the result is 'no opinion', the EC may adopt a final decision on the authorisation based on the original recommendation.[30]

30 Pursuant to the comitology rules, the EC is no longer obliged to adopt a final decision in case of disagreement i.e. when the outcome is 'no opinion' in both the Standing Committee and in the Appeal Committee ('shall adopt' was replaced by 'may adopt'), see Regulation (EU) No 182/2011, Art. 6(3).

Market authorisations for GM crops are valid for 10 years, after which the applicant has an obligation to update the application dossier with any new scientific information with regard to safety of the GM crop and monitoring reports. The renewal dossier is again assessed by EFSA and the MS. Renewals have to go through the comitology procedures again. The decision-making process for GM crop authorisations in Europe is visualised in **Figure 2**.

With relevance to this thesis, three things are important to keep in mind about the comitology procedures for GM crop authorisations. First, unless the MS reject the proposal with a qualified majority, the EC ultimately has the decision-making power to authorise or reject a GM crop application, or postpone that

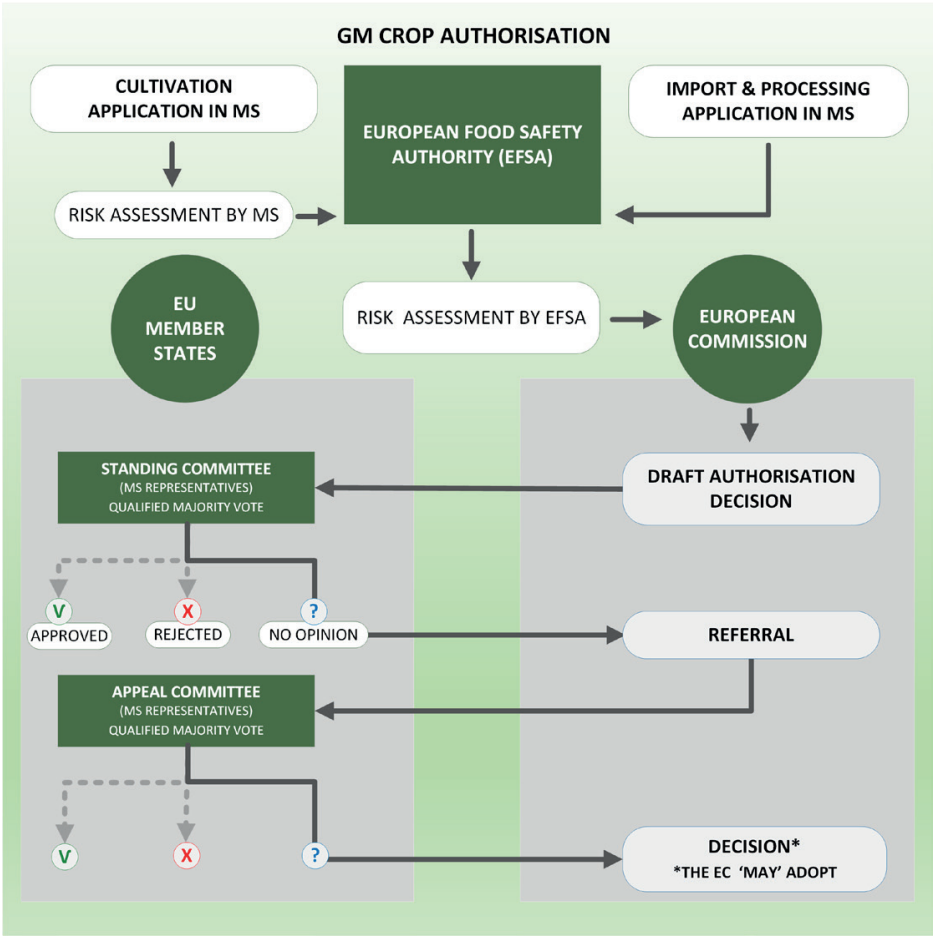

Figure 2: EU regulatory decision-making process of the authorisation of GM crops. Adapted from COGEM (2019).

decision. Second, the Council and EP can protest, but have no compelling means to influence the decision. Third, there is a so called 'sunset clause' (i.e. the authorisation needs to be renewed after specified period of time), but while awaiting a new decision, the old one does not expire or become invalid. This differentiates GM crops from, for example, authorisations for pesticides, which legally expire after a specified timeframe and become illegal to use. Together, these characteristics limit the number of parties who determine the final decision on GM crop authorisations and they can lower the urgency for decision-making itself since consequences seem to be limited.

4.3 DECISION-MAKING IN PRACTICE

After the first EU regulations had entered into force in 1990, several GM crops were approved for market release. A British company (Zeneca seeds) was the first one to bring a GMO product to the consumer market, which was a tomato puree, with a voluntary GM label. The authorisation process seemed unproblematic until the first import of GM crops from the United States of America (USA) arrived in 1996. The company responsible for the GM soybean (Monsanto) refused to label the product as GMO (Stephan 2012). Upon arrival in Europe, NGOs such as Greenpeace organised protests against GM crops, also initiating a public debate about safety and freedom of choice (e.g. Jasanoff 2005, Kurzer & Cooper 2007). Around that time, decision-making under the comitology procedures also became problematic and the EC started to approve GM crop authorisations without support of the MS. In 1997 Austria, Italy and Luxembourg banned GM maize Bt 176 (see Tiberghien 2009 and Randour 2014). The request of the EC to lift the bans was rejected by the Council. More national bans were installed later by Greece and France (see Punt & Wesseler 2016). In 1999 five MS (Denmark, France, Greece, Italy and Luxembourg) declared in a meeting of the Council of Environmental Ministers of the EU that they would suspend further approvals of GM crops until new legislation on the labelling and traceability of GM foods came into force (i.e. 'the declaration of five', see Punt & Wesseler 2016). The declaration was supported by other EU MS, leading to a majority of 12 of the 15 MS that refused to decide on new authorisation requests (see Tiberghien 2009).

This resulted in a *de facto*[31] moratorium on GM crops between 1998 and 2004. Since it was not an official moratorium no formal reasons for the moratorium were given. Stephan (2012) mentions political-economic protectionism,

31 Lieberman & Gray (2006) discuss different interpretations of the moratorium from the perspective of intergovernmentalism and supranationalism: 'The moratorium was not an official policy adopted by the EU, but a default outcome of deadlock in the regulatory committee and the Council of Environment Ministers, which the Commission chose not to resolve.' (p.602).

institutional (GM crop decisions are political in Europe, while mandated to a bureau of experts) and cultural factors[32] as reasons that eventually led to the moratorium. He criticises the link that is often made between the GM crop moratorium and food safety incidents in Europe (e.g. dioxine, Creutzfeld Jacob disease), and points out that safety incidents were also happening in the USA at the time. On both continents this undermined the regulatory credentials of responsible actors such as governments and scientific advisory bodies. In addition, NGOs in de USA also set up anti-GMO campaigns (see Thompson 2015). These events did however not affect the regulatory decision-making process on GM crop authorisations in the USA like it did in Europe.

The European *de facto* moratorium was upheld until a broad set of measures was agreed on to improve the risk assessment, transparency and the (political) legitimacy of the decision-making process of GM crop authorisations. For detailed overview of the political process of arriving at these changes, see Skogstad (2003) and Morris & Spillane (2010). In summary, the negotiations between the EC, the Member States, the Council and the EP resulted in three new regulations: Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, Regulation (EU) 1829/2003 on genetically modified food and feed and Regulation (EU) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. In addition, and independent scientific advisory body was installed: the EFSA. With these regulatory changes, scientific considerations were no longer the only determinant of decisions on GM crop authorisations. The precautionary principle was explicitly endorsed in the new regulations and the final decision about the authorisation is left to political authorities 'who will use the scientific advice provided by the EFSA not as 'absolute truth' but as 'knowledge with a confidence interval' (Haniotis 2000, see also Skogstad 2003). The Commission reasoned that different from risk assessment, risk management is a 'political decision' that 'involves judgements not only based on science but on a wider appreciation of the wishes and needs of society' (European Commission 2000a, p.14) and therefore 'all interested parties should be involved to the fullest extent possible' (European Commission 2000b, p.16). As a result, GM crop field trials and risk assessments had to be made public and an option for public consultation regarding experimental and commercial releases of GM products was created.

32 Stephan (2012) identifies traditionalist culinary preferences that 'remain more influential in many European societies than the US and notes that discourses are successful in mobilising citizens when they resonate with pre-existing cultural values and identities' (p.115).

In 2003, new applications that had been considered safe by EFSA were scheduled for voting again.[33] Meanwhile, several MS (e.g. Austria, Bulgaria, Hungary, Germany, Greece, Luxembourg, Italy and France) continued to ban GM crops (e.g. Christiansen & Polak 2009 and Anyschenko 2013). Some of these bans (e.g. Austria and Poland) have been challenged in court.[34] Smart *et al.* (2015) have shown that since 2003 there has only once been a qualified majority in favour of a draft Commission Decision on market authorisation of a GM crop. Several authorisation decisions (only importation) have been adopted by the EC without the support of the MS for both economic and legal reasons. Europe depends heavily on the importation of soybean products from elsewhere in the world, mainly for the purpose of feed (soy is the main source of protein in animal feed). In addition, the *de facto* moratorium resulted in an international trade conflict. In 2006, the World Trade Organisation (WTO) ruled that Europe had violated international trade rules by blocking the import of GM food and that Austria, France, Germany, Greece, Italy and Luxembourg also had no legal grounds to impose their own unilateral import bans.[35]

Nevertheless, the one sided authorisation decisions by the EC have been protested by the EP, who have systematically been opposing the EU commission plans to authorise imports of GMO products through non-binding resolutions (European Parliament 2020).[36] In these resolutions the MEPs point to amongst others the risks of GM crops,[37] the risks of high pesticide levels of herbicide tolerant GM crops, the link between GM crops and unsustainable agriculture (such as the link between soybean production and deforestation) and repeated criticism over the (non-democratic) authorisation process of GM crops in Europe.

33 An overview of the proposals and decisions during the *de facto* moratorium can be found on the website of the Financial Times. URL: https://www.ft.com/content/624a88c6-97db-11da-816b-0000779e2340 (Accessed 14 July 2020).

34 Austria tried to legally ban GMOs in part of the country to protect organic agriculture, see Joined Cases T-366/03 and T-235/04 Land Oberösterreich and Republic of Austria v Commission of the European Communities (Rec.2005, p.II-4005); and Joined Cases C-439/05 P and C-454/05 P Land Oberösterreich and Republic of Austria v Commission of the European Communities (Rec.2007, p.I-7141). In 2008 Poland tried to ban GM crops based on ethical and religious grounds (case C-165/08 Commission v Poland). The Court concluded that Poland failed to fulfil its obligations under Directive 2001/18/EC.

35 WTO dispute DS291 European Communities – measures affecting the approval and marketing of biotech products.

36 Since 2016 the EP has adopted over 40 resolutions objecting the authorisation of GM crops (both importation and cultivation). For an overview see European Parliament (2020).

37 The resolutions refer to amongst others alarming studies and related publications from NGO's opposing GMOs.

Despite these resolutions, the EC went ahead with the approvals for import (see the European GMO register).[38]

Authorisation decisions about cultivation have been completely halted and no decisions have been taken by the EC since 1998. Three cultivation applications on which the voting outcome of the appeal committee was 'no opinion' are pending since 2018. Only one GM maize has been authorised for cultivation in Europe. This is an insect resistant maize (MON810) that has been authorised in 1998.[39]

Most applications in the system are considerably delayed in either the risk assessment phase or in the voting procedures. The average timeline for risk assessment had increased from 2 to 5 years, with extremes of 8 years (for an overview of these delays and a comparison with authorisation procedures in the US, see Smart *et al.* (2016). In 2017, in a complaint filed by three associations representing companies which market genetically modified food and feed (EuropaBio, COCERAL and FEFAC), the European ombudsman concluded that the delays of twenty applications of GM food/feed were unjustified.[40] This however, did not result in an improvement of the decision-making process, as delays in the approval process continue.

Even when authorised, GM crops can still be scrutinized and measures can be taken to revoke its legal status. MS can invoke the safeguard clause (Directive 2001/18/EC, Art. 23) or apply emergency measures Regulation (EC) No1829/2003, Art. 34 to ban authorised GM crops based on new scientific information that indicates an overlooked risk associated with GM crops. Eight MS have used these measures in the past (Austria, Bulgaria, Germany, Greece, Hungary, Italy, Luxembourg and Poland). In these cases, EFSA is requested by the EC to reassess the studies on their scientific rigor and draw a conclusion on the question whether there is indeed a reason for concern. Thus far, EFSA has concluded all safeguard clauses to be scientifically unfounded (e.g. EFSA

38 European GMO Register, see URL: https://ec.europa.eu/food/plant/gmo/eu_register_en (Accessed 14 July 2020).

39 Market authorisations are valid for 10 years. In 2008 a renewal of the cultivation application for MON810 was submitted. EFSA published a positive opinion on the renewal in 2009. The draft implementing decision was scheduled for voting twice in 2018 with 'no opinion' as a result. There is no expiration date on the cultivation as long as the renewal application is pending.

40 Case 1582/2014/PHP, 'Decision of the European Ombudsman closing the inquiry into complaint 1582/2014/PHP on the European Commission's handling of authorisation applications for genetically modified food and feed' European Ombudsman, 15 January 2016

2004, 2005, 2006, 2008, 2012f, 2013 and 2014). However, most national bans remain in place, because the Council has rejected the Commission's proposals to lift them.[41] In this situation the comitology procedures did result in a clear outcome, but one that goes against the Commission's proposal.

In 2011, the European Policy Evaluation Consortium (EPEC) evaluated the EU legislative framework for GMOs, concluding that the regulatory process is both rigorously scientific and dysfunctional as a consequence of a complex set of factors, both external and internal to the authorisation process (EPEC 2011). In an attempt to solve the deadlock in decision-making in the comitology procedures, the EC proposed another new Directive in 2010 that gives individual MS the option to ban or restrict GM crop cultivation on their territory based on broader arguments, in addition to the safety assessment. Directive (EU) 2015/412 came into force in 2015. As reasons for the new Directive, the text reads:

> *'In the past, in order to restrict or prohibit the cultivation of GMOs, some Member States had recourse to the safeguard clauses and emergency measures [...]. In addition, the decision-making process has proved to be particularly difficult as regards the cultivation of GMOs in the light of the expression of national concerns which do not only relate to issues associated with the safety of GMOs for health or the environment. (8) In that context, it appears appropriate to grant Member States, in accordance with the principle of subsidiarity, more flexibility to decide whether or not they wish to cultivate GMOs on their territory without affecting the risk assessment provided in the system of Union authorisations of GMOs [...]The grant of that possibility to Member States is likely to improve the process for authorisations of GMOs and, at the same time, is also likely to ensure freedom of choice of consumers, farmers and operators whilst providing greater clarity to affected stakeholders concerning the cultivation of GMOs in the Union. This Directive should therefore facilitate the smooth functioning of the internal market.'* (Directive (EU) 2015/412, Consideration 7)

By separating safety and non-safety arguments and giving MS the opportunity to 'opt out', the EC aimed to improve the decision-making process on market authorisations on a EU level. In the first voting on a market authorisation of cultivation, a majority of the MS used this Directive to ban cultivation on

41 Under the old pre-Lisbon treaty comitology, the Council served a similar function as the current appeal committee.

their territory,[42] but the outcome of the last voting in the appeal committee on several GM crop authorisation requests for cultivation in March 2017 again resulted in 'no opinion' (European Commission 2017b). In Chapter 6 of this thesis, Poort and I provide a normative analysis of this regulatory strategy that was intended to improve the decision-making process on GM crops. We conclude that the Directive could work in theory but identify several user and design factors that limit the potential success.

In conclusion, there is a regulatory framework that aims to facilitate both the safety of GM crops and that leaves room for individual decision-making (by MS, regions, producers and consumers) based on broader arguments. By adopting the directives and regulations that are into force, MS representatives have agreed that safety for humans and the environment is the main criterion to authorise GM crops for market release. Additionally, traceability and labeling requirements have to be met as well as putting into place effective measures to facilitate co-existence on a MS level. And finally, MS can opt out of cultivation on their territory based on non-safety arguments.

However, when the EC presents a draft proposal based on a positive safety assessment by EFSA, MS have reasons not to comply with the expected outcome of the voting under the comitology procedures. The standard outcome is 'no opinion' because no qualified majority can be reached due to abstentions from voting and negative votes. Official reasons mentioned for the negative vote or abstention have been amongst others: no agreed national position, negative public opinion, political reasons, risk of harm to the national agri-food industry, uncertainties in risk assessment, safety concerns for the environment, the precautionary principle and the lack of comprehensive data on long-term potential impact of GMOs (European Commission 2017b). Several of these arguments that relate to safety are supposed to be covered by the existing safety regulations discusses in this Section. In addition, MS with a negative public opinion or other concerns, have the opportunity to opt out on a national level. Instead, they choose to abstain from voting or cast a negative vote. Additionally, the EC who is mandated to force a decision or take it herself, is not doing so. The lack of decision-making can be illustrated by the market

42 It should be noted that MS who used the Directive to opt out from cultivation, did so for varying reasons. Dobbs (2017) points out that some MS used the directive to provide time to evaluate the situation and consider whether to facilitate GM crops. 19 Other Member States and regions had a range of reasons for availing the clause, including a 'green image', distrust of GM technology, public opinion, environmental concerns and concerns over the challenge to prevent the presence of GMOs in non-GM crops (admixture).

authorisation timeline of GM maize MON810, the only GM crop authorised for cultivation in Europe. This GM maize was approved for cultivation in 1998 and the applicant filed for a renewal 10 years later in 2007. EFSA issued a positive opinion on the renewal in 2009. It took until 2017 for the renewal to be brought up for voting. The result of the first and second voting in the appeal committee was 'no opinion'. As of 2020, no decision has been taken on the renewal of the authorisation for cultivation of GM maize MON810. Until a decision has been made, the original authorisation remains valid. Three other GM maize cultivation applications are pending for a decision since 2018. As for now, this means decision-making about market applications for cultivation is completely stalled. For an overview of timelines for GM crop authorisations see Smart *et al.* (2015).

At a first glance, an apparent disagreement about the safety of GM crops seems to be the cause of the problem. Food and environmental safety are the cornerstones of the regulatory framework for GMOs, which has been implemented by using regulatory science. To understand the dynamics of this type of science a theoretical framework is needed to describe a very specific characteristic of debates within this field: the recurring unrest or alarm that is being raised by scientific studies challenging the safety of GM crops. This unrest is used, amongst others, as a reason for MS to ban GM crops on a national level. Based on a series of case studies, Brom and I have introduced the concept of 'alarming studies' to describe these dynamics.

5. ALARMING STUDIES: A CASE OF CONFLICT ON SCIENCE?

The concept of 'alarming studies' was introduced in a report I wrote at the COGEM (2013). Based upon that report Brom and I introduced this concept in the academic literature in 2015 (Mampuys & Brom 2015a,b). The core idea of 'alarming studies' is that studies claiming significant risks of genetic modification to human health or the environment provoke a recurring pattern of discussions, arguments and governance responses. This section provides an introduction to the concept of alarming studies. The identified patterns in argumentation and governance responses are analysed in depth in Chapter 4 and Chapter 5 of this thesis.

We defined alarming studies as 'scientific or other studies claiming that a technological innovation (e.g. a GM crop) poses a threat to human health or the environment which has not been acknowledged by the existing governance

system' (Mampuys & Brom 2015b). There have been several examples[43] of such studies about the risks of GM crops since 1999 and the resulting discussions about these studies have shown a similar pattern in societal, scientific and political debate. One of the most prominent examples of such a study will be discussed here to illustrate the resilience of the conflict over GM crops.

5.1 THE SÉRALINI STUDY

A study from 2012 (hereafter: the Séralini study) concluded that GM maize NK603[44] caused cancer when fed to rats (Séralini *et al.* 2012). In this study, rats (male and female) had been fed with GM maize over a period of 2 years. The results were published in a peer reviewed scientific journal, accompanied by a press conference, and the publication of a book and documentary titled 'Tous Cobayes?' to inform the general public (translated 'all of us guinea pigs now?'). The publication and media package that was released generated a significant amount of uproar, particularly the explicit graphic material of rats with enormous tumors.[45]

The study results alarmed the authorities responsible for food safety, because the maize that was used in the study (NK603) had been authorised for market release (food and feed)[46] in the European Union (EU) since 2004. Feeding trials with rodents had been part of the application to draw conclusions on food safety, and these had not given any reasons for concern. In addition, all MS had been involved in the risk assessment of maize NK603 and had sent their comments to the EFSA, who advises the European Commission (EC) about

43 The cases studied in Mampuys & Brom (2015a,b) were Séralini *et al.* (2012) who concluded rats fed GM maize developed cancer, Ewen & Pusztai (1999) who investigated adverse effects of GM potatoes on rats, Rosi-Marshall *et al.* (2007) who studied ecosystem effects of transgenic crop byproducts, Huber (2011) who wrote a letter to US Secretary of Agriculture Vilsack ed. to warn about a new pathogenic organism arising from GM crops and Carman *et al.* (2013) who found adverse effects of GM soy and maize on pigs.

44 GM maize NK603 is a herbicide tolerant maize variety with a decreased binding affinity for herbicides containing the active ingredient Glyphosate. This trait facilitates easy herbicide application for farmers. Both GM maize and Glyphosate are a topic of discussion for being associated with adverse effects on health i.e. carcinogenicity.

45 An overview of media attention can be found on a website dedicated to the work of Séralini (URL: www.gmoseralini.org/category/media-coverage (Accessed 25 July 2020). It should be noted that this website, founded by author of other anti-GM websites such as GMWatch, GMOEvidence and GMOJudyCarman, displays a one-sided overview of the media attention. Chapter 4 of this thesis provides an overview and discourse analysis of both sides of the debate about this study.

46 The term 'food' refers to food intended for human consumption, whereas 'feed' is intended as food for animal husbandry.

market authorisations of GM crops. In an overall opinion sent to the EC, EFSA concluded that the consumption of this GM maize posed no significant risks to human health (EFSA 2004). After consulting a draft proposal for market authorisation with the MS, the EC approved the maize for market release. Logically, the main question after the Séralini publication was: had something been overlooked in the risk assessment or approval process?

The Séralini study was reassessed for its scientific rigor by academic peers, competent authorities of MS and by the EFSA (a summary of these reviews can be found in Chapter 5). Scientists discussed the methodology and results of the study as well as the quality of the peer review process of the publication. Are the conclusions justified based on the methodology used? Had the peer review process been adequate? Regulatory authorities on MS and EU level investigated whether the conclusions were reason to revoke the market authorisation. In addition to these discussions, questions arose on public fora such as news websites and social media about broader issues relating to GM crops and about the motivations and independence of the author's team (for a discourse analysis of the discussion on this and other alarming studies, see Chapter 4). Séralini and his team had a reputation of being critical towards GMOs and their work was partially funded by the organic industry (who don't allow GMOs). But suspicions also rose about those reassessing the results such as EFSA. Are they sufficiently objective to reassess their own previous judgement and would they change it if needed?

After investigation, the EFSA (2012c) stated that the conclusions of the Séralini study were insufficiently substantiated by the used methodology.[47] Therefore, the results were deemed inconclusive, providing no valid/justified reasons to revoke the EU market authorisation of GM maize NK603. In 2013, Elsevier announced the retraction of the article from the journal because of insufficient scientific quality (Elsevier 2013). However, Séralini and his team were sticking to the validity of the results. In 2013 they published a detailed response to the various criticisms in a newly established scientific journal (Séralini 2013). Soon after, the original paper was republished with some minor adjustments in that same journal (Séralini *et al.* 2014). And this was not the end of the debate

47 Issues were identified with amongst others a) the strain of rat used (Sprague-Dawley rats are prone to developing tumours during their life, independent of their food and particularly if their food intake is not restricted), b) inadequate controls, c) deviations from standard international protocols for carcinogenicity and toxicity feeding studies, d) the number of experimental animals used in each group, e) inadequate statement of objectives of the experiments, f) absence of data on the composition and intake of food during the experiment and questionable statistical analysis.

because actors on both sides continued to either defend or dismiss the results of the study. The main question was whether the conclusions of the Séralini study were unjustified because there was no significant risk (false positive), or whether there was a risk but the study methodology was of insufficient quality to substantiate this (false negative).

5.2 EU FUNDED RESEARCH TO SOLVE THE DISCUSSION

Despite the conclusions on the Séralini study from the EFSA and several national and international authorities, the debate was sufficient reason for the EC to fund two research projects. The first project looked into the value and methodology of rat feeding studies to assess the food safety of GM crops in general and the second one aimed to reassess the specific food safety risk of GM maize MON603. In addition, a third project was funded by the French Government. Coincidentally, the first project merged with another ongoing discussion: about the need for mandatory rat feeding studies in GMO risk assessment.

In December 2013, Regulation (EU) No 503/2013 in accordance with Regulation (EC) No 1829/2003 entered into force in the EU, providing detailed instructions for the risk assessment of GM food/feed, including a mandatory 90-day-feeding study in rodents in whole GM food/feed. These instructions were not new, but had previously been part of the guidance documents from EFSA, that had no legal or mandatory status. In an editorial of the EFSA Journal, Waigman *et al.* (2013) describe the background, novelties and challenges of this regulation. It had been the outcome of a discussion[48] between the MS and the EC with the aim of incorporating the existing EFSA guidance for the risk assessment of food and feed from GM plants into a binding legal text. In addition to the original text, some elements were newly introduced by the MS and the EC based on their particular views and the desire to improve consumer confidence in GM plants. The regulation was endorsed by a qualified majority of EU MS after a lengthy discussion. According to Devos *et al.* (2016), the mandatory nature of the 90-day feeding studies was not unanimously accepted on scientific grounds by various stakeholders. There were doubts about the

48 The last paragraph of the editorial in EFSA Journal (2013) reflects the difficulties in this process, stating: 'The safety and usefulness of GM plants is subject to an intense political and societal debate, characterised by widely diverging positions in different EU Member States. Considering that the IR was endorsed by the Member States with a qualified majority, one expectation is that risk assessment requirements outlined in the IR will satisfy the majority of Member States, and allow them to support safety conclusions on GM Plants, where appropriate. The future will show whether the IR will fulfil this expectation and contribute to a convergence of Member States views on the safety of GMOs.'

value of conducting these kind of studies without a hypothesis. Article 12 of the regulation obligated the EC to review the requirement on the basis of new information before 30 June 2016.

The legal requirement for review of regulation (EU) No 503/2013 and the controversial debate about scientific findings on the safety of GM plants were mentioned as the main drivers for the first project: 'The GMO Risk Assessment and Communication of Evidence (GRACE)' project (GRACE 2015). The project was running from 2012 to 2015 and had two main work streams: (1) Improving the interpretation of 90-day rat feeding trials, clarifying their added value and exploring alternative approaches to reduce or substitute animal trials, (2) developing and testing an approach to systematically gather and evaluate the quality of existing evidence on the impact of GM plants.

In addition, the project developed and implemented opportunities for stakeholder participation in all key stages of the project. The reason for this, can be found in the executive summary of the report nothing that, despite an extensive amount of existing research on GM crops, *'the outcomes are not consistently and comprehensively considered by stakeholders, general public, or in decision making'*. Therefore, *'A primary objective of GRACE was to improve the accessibility and presentation of the scientific information in order to provide better understanding for all stakeholders and the general public'*. With this approach, the project seemed to aim for a robust research design and results that would be supported and acknowledged by as many stakeholders as possible. The project summary recognises that this aim was not fully achieved but states that '*stakeholder requests that could not be realised (e.g. due to limited resources) as well as controversial discussions were documented to allow future consideration of the issues raised'* (GRACE 2015, executive summary).

After 3 years, four 90-day feeding trials with rats and an extended feeding study lasting 1 year were done with GM maize MON810.[49] The final results: *'...showed that non-targeted*[50] *feeding studies may lead to randomly generated significant differences between animals fed with the GM test material and animals fed*

49 GM maize MON810 is an insect resistant 'Bt' maize, expressing an insecticidal protein to fight Lepidopteran pests. Bt is an abbreviation of *Bacillus thuringiensis*, which is a soil bacterium that naturally expresses this protein. This is the only GM maize that is authorised for cultivation in the EU, therefore this maize was already chosen for the GRACE project.

50 Non-targeted means without a hypothesis or an indication that a specific GM crop could have a harmful effect. This means that a broad as possible set of parameters is measured and compared to a situation where rats are fed non-GM maize to find differences in effect. In these situations it can be challenging to draw conclusions on the significance of identified differences.

with a control diet. Such results are not informative for risk assessment. GRACE data support the scientific reasoning that only in case a trigger is available from the initial molecular, compositional, phenotypic and/or agronomic analyses, feeding trials with whole food/feed may provide an added scientific value for the risk assessment of GM crops' (GRACE 2015, executive summary).

Despite the involvement of stakeholders in all stages of the project, these results were met with critique. NGOs opposing GMOs such as GMWatch (2015 and 2018a) and Testbiotech (2015) pointed out that the GRACE project had been done with a different type of maize (MON810 instead of NK603), a different type of rat[51] and it did not look beyond 90 days or a year (i.e. Séralini studied rats for two years, which is their approximate life span). Although these differences may seem an omission, we should not forget that the Séralini study was dismissed because of critique on its scientific method. Therefore, an agreement had to be found to conduct feeding studies in a scientifically 'more robust' way. All GRACE data had been made available for public/stakeholder scrutiny and debate and the research methodology had been adjusted moreover during the project. But apparently, this turned out to be insufficient to agree on the methodology and outcome. Fortunately, another project had also been funded with a slightly different objective that to an extent addressed the critique on the GRACE project.

The second project, 'GM plants Two Year Safety Testing' (G-TWYST), ran between 2014 and 2018 and was also funded by the EU. The study included rat feeding studies with GM maize NK603 of 90 days, one year and two years. It used the same GM maize as the Séralini team and took into account the same time span of two years. The overall conclusion of the G-TWYST project was that no adverse effects were observed related to the feeding of the NK603 maize for up to two years (Steinberg *et al.* 2019).

Finally, the third project titled GMO90+ was initiated by the French government, investigating potential harmful effects of Maize MON810 and NK603 when fed to rats for six months. The final results were published in 2018 and it was concluded no adverse health effect could be attributed to the consumption of GM maize diets in comparison with the consumption of their non-GM controls (Coumoul *et al.* 2018).

51 Experimental animals such as rats are bred by specialised companies. To improve the robustness of the research, the rats should be genetically alike as much as possible. There are several types of laboratory rats with different characteristics on for example growth or food conversion or susceptibility to disease. One of the critiques on the Séralini study was that they used so called 'Spraque-Dawley rats' that are known for their susceptibility to develop tumours during their lifespan. The GRACE project used 'Wistar rats' and vice versa got criticised for using different rats that would not be susceptible enough to reflect the risk of tumour growth.

5.3 REGULATIONS REMAIN UNCHANGED AND THE DEBATE CONTINUES

In each of the projects it was concluded there were no significant health risks reported of feeding GM maize to rats. In addition, the GRACE project concluded that the need for mandatory feeding studies in the absence of a hypothesis was not supported from a scientific perspective because of a lack of added value. These conclusions were not shared by all stakeholders. On the one hand, the European biotech sector and several scientists supported the results and emphasised the need to 'reinstate science in GMO safety assessment and eliminate unnecessary animal testing' (EuropaBio 2018a,b).[52] On the other hand, several NGOs and other scientists criticised the results and the stakeholder process. In a 2015 report, German NGO Testbiotech criticised the results of the feeding study and highlights conflicts of interest at GRACE and flaws in the process of publication (see Testbiotech 2015a, Testbiotech 2015b). Woegerbauer *et al.* (2016) criticised the GRACE project to have 'refrained from communicating uncertainties which intrinsically affect any scientific analysis and subsequently the quality and validity of the drawn conclusions'.

It seems there are insurmountable differences in views on how 'good' science on this type of research should be done and by whom. Almost 8 years later, Séralini stands by his results and criticises the outcomes of the EU funded studies in a detailed and extensive article (Séralini 2020). GMWatch published a news item titled 'EU-funded rat feeding studies do not refute the Séralini study' (GMWatch 2018). The Séralini study is still cited, either directly or indirectly, as proof GM maize poses significant risks to human health in NGO reports, Communications of the European Parliament (EP) and academic literature (e.g. Testbiotech 2019, European Parliament 2020, Then & Bauer-Panskus 2017, Robinson *et al.* 2016). Furthermore, the EC has not changed the mandatory regulatory requirements regarding feeding studies. Referring to scientific uncertainty, in January 2017 the EC presented its conclusion to the MS that the requirement for conducting 90-day feeding studies would not be revised (European Commission 2017a).

These outcomes raise several questions, especially since the Séralini study was so controversial and a significant amount of funding, time and number of

52 In addition, the Alliance for Science headlined 'European studies disprove Séralini's GMO maize tumor claims' (Alliance for Science 2018) and the French plant biotechnology association stated that the EU studies 'refute the main conclusions drawn from the Séralini studies' (AFBV 2018).

partners had been involved in the research projects.[53] Why is it so difficult to reach an agreement on a scientific study and its results? What kind of research is needed to provide robust answers to questions of safety? Why did the EC never formally respond to the results? Why did she not acknowledge or confirm the conclusions of the projects that she commissioned herself?[54] Or the other way around, why did she neither dismiss the results nor revoke any market authorisations of GM crops? Even more confusing, in the summer of 2019, the market authorisation for GM maize NK603 (the maize investigated by Séralini, G-Twyst and GMO90+ with different conclusions on food safety) was renewed in the EU concluding that the risks for humans and the environment from the consumption of this maize are negligible.

The discussion about this alarming study illustrates a disagreement about the safety of GM crops and about the way GM crops are assessed in the regulatory procedures. This conflict seems to be present on more than one level: among scientists (e.g. Séralini's team versus other scientists supporting the outcomes of the EU projects), Member States (e.g. not all of them were in support of the mandatory feeding trials) and stakeholders (e.g. the biotech sector versus environmental NGOs). In addition, at least a level of ambiguity can be seen on a European level with regard to the ECs response to the research results of commissioned projects, safety testing requirements and market authorisations. Finally, the discussion also seems to suggest that only safety is taken into account in the regulation of GM crops, which may be insufficient in the view of stakeholders with fundamental objections or broader arguments against GMOs. In Chapter 4 a discourse analysis illustrates that broader arguments are systematically brought to the fore in discussions about alarming studies. The complexity and entanglement of both fact- and value-related factors in the discussion about GM crops combined with its resilience to problem solving, have been identified in academic literature as characteristics of a 'wicked problem' (e.g. Jelsma 2001, Durant & Legge 2006b, Bovenkerk 2010, Inghelbrecht *et al.* 2014, Newman & Head 2017, Daviter 2011 and Weimer 2014). In the next section, the concept of wicked problems is used to characterise the

53 The GRACE project took 3 years, cost almost 8 million euros and involved 19 partners from 13 countries, over 1700 experimental rats were used. The G-TWYST took 4 years, cost almost 4 million euros and involved 8 partners from 6 EU countries.

54 Careful reading of Regulation (EU) No 503/2013 shows that the EC was not formally obligated to respond, see Article 12. Ad 1 which states that 'the Commission shall in particular monitor the outcome of the research project called GRACE under the 2012 work programme of the seventh Framework Programme for Research (FP7).'

problem of GM crop authorisations and make a first inventory of proposed ways of dealing with these kind of issues.

6. BIOTECHNOLOGY AS A WICKED PROBLEM

The term 'wicked problem' was introduced by Rittel & Webber (1973) to describe complex problems that lack a shared problem definition and are extremely difficult to solve.[55] Instead, attempts to solve wicked problems only seem to introduce new ones. The notion of 'wicked problem' suggests that these problems are unresolvable and can only be managed or coped with (Roberts 2000). In this section I will look at the GM crop conflict through the lens of wicked problems to draw conclusions on whether the concept fits the characteristics of this type of problem. This will provide direction for problem mitigation strategies that will be discussed later in this thesis.

6.1 RITTEL & WEBBERS' WICKED PROBLEMS

The term 'wicked problem' was introduced by Rittel & Webber (1973) who used it to describe solution-resistant policy problems in urban planning. In their view, wicked problems differ significantly from purely engineering problems in urban planning because they involve societal factors as well and are therefore, more complex, unpredictable or even impossible to solve.[56] In other words, they were implying that societal factors are the cause of problems in technical areas.

Over time, the notion of 'wicked problems' became used in other contexts and has been used for a wide variety of issues that seem generally resistant to solutions. Termeer & Dewulf (2019) summarise the application of the wicked problem concept in fields in environmental and urban science and beyond such as economics, computer science and health, relating to problems such as climate change, poverty, digital warfare and biodiversity loss. The problems in these fields emerge at the policy making level and have been widely studied in this field with the main question of what can be achieved in terms of dealing with their wickedness (see Roberts 2000, Durant & Legge 2006b, Head 2008, Levin *et al.* 2012).

55 Rittel & Webber (1973, p.160): wicked problems 'are never solved'.

56 Rittel & Webber (1973, p.160) societal problems '... are inherently different from the problems that scientists and perhaps some classes of engineers deal with' 'As distinguished from problems in the natural sciences, which are definable and separable and may have solutions that are findable ... Social problems are never solved' (p.160).

Rittel & Webber (1973) originally listed ten characteristics of wicked problems, some of which are partially overlapping and have been condensed by other authors to smaller sets (e.g. Roberts 2000, Xiang 2013, Head & Alford 2015). In my view the most relevant characteristics of wicked problems adapted to the issue of GMO's are the following: a) the lack of a definitive problem formulation, b) the absence of a stopping rule, c) solutions are not true or false, but good or bad, d) attempts to solutions result in unintended and unexpected effects and e) there is no opportunity to learn by trial and error (e.g. the issue owner has no right to be wrong). I will use these criteria to characterise the GM crop problem.

Firstly, there is the lack of a definitive problem formulation. The GM crop issue has a wide variety of different problem formulations: for some the issue is related to environmental or food safety risks (see Section 5), for others it is about the integrity of life (i.e. organic agriculture),[57] the power of big agricultural companies in the food chain, the facilitation of industrial agriculture and pesticide use in general, the indirect effects of GM crops on biodiversity or sustainable land use (i.e. GMWatch 2018, see also Friends of the Earth).[58] The diversity of these issues reflect disagreement about both facts and values and results in different problem definitions. The issue of problem framing has been addressed amongst others by Helliwell *et al.* (2017) who concluded that NGOs opposition to agricultural biotechnologies is rooted in skepticism about the framing of problems and solutions, or Parfit & Dunn (2013) who argue hunger needs a political solution and not a technological one like the development of GM rice with high levels of vitamins. The diversity of problem formulations is not limited to facts versus values, but also present within the field of scientific research and particularly in the field of environmental risk and food safety assessments (illustrated by the case of alarming studies, e.g. Section 5, see also Tepfer *et al.* 2012).

Secondly, there is no stopping rule, no definition or criteria of when 'the GMO conflict' has been solved since it is entangled in a system of related problems. This can be illustrated by the attempts of the EC to solve the problem by

57 The integrity of plants and production systems is one of the key principles of organic agriculture. From this perspective they forbid the use of genetic modification since it is at conflict with these principles, see the norms of The International Federation of Organic Agriculture Movements (IFOAM) for organic production and processing.

58 NGO Friends of the Earth state on their website that 'Genetically modified (GM) crops bring unnecessary risks to both humans and nature. They increase the corporate control of the food chain, whilst placing heavy economic burdens upon conventional and organic food sectors aiming to avoid contamination.'

introducing additional regulations. After the initial protests and debate caused by the first import of GM crops in Europe in the late 90s, additional regulations and data requirements were put into place in 2003 to strengthen the risk analysis, and mandatory labeling was put into place to facilitate freedom of choice for consumers. This however, did not result in a smooth decision-making process, instead additional problems came to the fore: (new) uncertainties in the risk analysis emerged, and not all food was labeled in a satisfactory way to all stakeholders (such as products from animals that have eaten GM food, or substances produced by GM microorganisms).[59]

The third criterion states that proposed 'solutions' for the biotechnology conflict are not true or false, but depending on one's perspective of the problem: good or bad. There is a wide variety of positions towards biotechnology, but the two most voiced in the debate are often characterised as two extremes: pro- and anti-GMO; either advocates or critics.[60] On the one hand there is a Pro-GM group that embraces biotechnology and sees it as an important or even essential technology towards food safety and security and new medical and industrial innovations (e.g. EuropaBio, ISAAA, see also Tosun & Schaub 2017). For this group, the European regulatory framework for GM crops is seen as overly cautious, extremely burdensome in terms of time and costs and disadvantageous for the plant breeding sector (see also Amman 2014, Tagliabue 2017, Tagliabue & Amman 2018). On the opposing side, there is a group that can be characterised as anti-GMO, GM skeptics or critics. They see biotechnology as a risky technology with negative moral and socio-economic consequences. They also consider the current regulatory system to be insufficient but from their perspective, risks are overlooked or even dismissed and ignored (e.g. Testbiotech, ENSSER, GeneWatch UK,[61] see also Tosun & Schaub 2017). From

59 The reasoning behind what should be labeled is linked with detection limits. Animals that have eaten GM feed do not become modified themselves and cannot be distinguished from animals that have eaten non-GM feed. The same holds true for substances such as vitamins that are produced by GM micro-organisms and are purified (not containing any traces of the micro-organisms). From a fundamental moral perspective of objecting GMOs, this is insufficient as GMOs have been involved in the food production process.

60 Examples can be found on the websites of biotechnology industry websites who name 'anti-GM-activists or -campaigners' whereas NGO websites against GMOs speak of 'Pro-GMO lobbyists, -countries and - campaigners.

61 In 2019 the results of a joint research project titled RAGES (Risk Assessment of Genetically Engineered Organisms in the EU and Switzerland) were published that criticised the EU risk assessment of GM crops. The project was a collaboration of Testbiotech, the European Network of Scientists for Social and Environmental Responsibility (ENSSER), its Swiss branch CSS (Critical Scientists Switzerland) and GeneWatch UK, see also Testbiotech 2019.

their perspective, the last thing that should be done is deregulate certain GMOs (e.g. Euractiv 2019).

Scientific advisory bodies and the EC acknowledge that the current regulatory framework is not ideal. The EC aims for a 'clear', 'proportionate' and 'robust response' to developments in plant biotechnology (Euractiv 2019a). But part of the problem is that the 'right' interpretation of such a system is differs among stakeholders in the field. Given the conflicting positions, regulatory decisions that move towards the desired direction for one group and are considered 'good', are usually considered 'bad' by the other. This is also illustrated by the regulatory decisions on GM crop authorisations. Interestingly, decisions in the GMO conflict are often not directly labeled as good or bad. Instead, the discussions are framed as true (good) or false (bad), hiding under the veil of 'objective' science. This can be illustrated by the following quotes. On the one hand, Beat Späth, Director of Agricultural biotechnology at industry advocacy group EuropaBio says in an opinion piece for European news website Euractiv (2019c): *"The European Food Safety Authority (EFSA), the European Commission, and more than 280 scientific and technical institutions around the world have all declared that genetically modified crops (GMOs) are at least as safe as conventionally bred crops",* referring to amongst reports from the European Commission (European Commission 2010b), the European Academies Science Advisory Council (EASAC 2013) and the National Academies of Sciences, Engineering, and Medicine (NASEM 2016). On the other hand, a book titled 'GMO myths and Truths' from Robinson *et al.* (2014) of NGO GMWatch quotes: *"Genetically modified (GM) crops are promoted on the basis of a range of far-reaching claims from the GM crop industry and its supporters. ... However, a large and growing body of scientific and other authoritative evidence shows that these claims are not true"* referring to amongst other a statement from 300 Members of the European Network of Scientists for Social and Environmental Responsibility that cite a list of publications that 'prove' the risks of GMOs (ENSSER 2013).

The fourth criterion of wicked problems is that proposed solutions may trigger unexpected or unintended consequences. Three examples will be provided to illustrate such consequences for GM crops; the unexpected long trajectory of the development of GM golden rice and the unintended consequences of the regulatory framework on (access to) innovation. A GM rice variety ('Golden Rice, because of its purpose and color) was developed in the 1990s to express a high level of carotenoids that could help developing countries reduce vitamin A deficiency. From a scientific perspective, Golden Rice was expected to be a

key example of how GM crops could be beneficial for consumers in relation to urgent global nutritional problems (in contrast to most existing GM crops which provided advantages for farmers' production processes). Nearly 30 years later, the rice is still not on the market and the debate has spiraled into arguments about dignity and human rights, equity and empowerment, local culture, health and well-being, biodiversity and holism and systems thinking (See Kettenberg 2018, Scott 2011 and Parfitt & Dunn 2013 for an overview of the Golden Rice debate).

The second example illustrates unintended effects of the regulatory system for innovation. The regulations for GM crops were supposed to guarantee the safety of these products on the market, but they also have at least three unintended effects on innovation. First, because of the time and costs associated with going through the regulatory procedures, only multinational companies are able to afford bringing products to the market (for estimations of the costs see studies by amongst others Kalaitzandonakes *et al.* 2007, McDougall 2011 and EuropaBio 2015). Because of the costs, non-staple crops are less attractive to invest in from a business perspective, as they will not return the investment after commercialisation. This means smaller breeding companies do not bring GM crops to market and only a limited amount of different GM crops (bulk or staple such as maize, soy, cotton, and rapeseed) are developed. A third unintended effect can be found in trade politics. African countries seem to adapt strongly to the European GM regulatory framework and are reluctant to authorise GM crops for cultivation, because this may limit their export market to Europe (for examples of effects of EU regulation in developing countries, see World Politics Review (2019) and Zaidi *et al.* (2019).

In the 'GMO conflict' there are different problem definitions, solutions are not true or false, but good or bad. This makes problem mitigation more difficult as proposed strategies by one side are deemed unreliable and bad by the other side and vice versa. In addition, attempts to solutions have unintended and unexpected effects that change or shift the problem or that introduce new problems. Finally, this also means a trial and error approach for steps forward (the fifth criterion e) is difficult and any change or proposal will likely be resisted by one side or the other. All together, these elements characterise the authorisation of GM crops as an example of a wicked problem.

Over time, other typologies have been introduced to characterise, explain and solve wicked problems, such as intractable disagreements (Schön & Rein

1994), intractable controversy (Hisschemöller & Hoppe 1995) or ill-structured problems (Simon 1973, 1977). The typology proposed by Hisschemöller & Hoppe is also widely used in academic literature and will be briefly discussed here. They proposed a perspective on structuring of policy problems based on a distinction between uncertainties and consensus about facts and values in policy problems. Their idea was a response to the tendency in policy development to focus on 'conventional scientific rigor combined with political neutrality' (Hisschemöller & Hoppe 1995). They concluded that this focus is unfit to address the underlying value dimensions of most policy issues. It only works for so called structured problems with a consensus on both the facts and the values at stake. To improve dealing with more complex issues, they identify three other types of problems: moderately structured problems with a consensus on scientific facts but not on values or vice versa and unstructured problems that involve uncertainty and disagreement on both facts and values. They proposed different strategies to deal with each of them. According to the problem types identified by Hisschemöller & Hoppe (1995), the GMO issue can be classified as an unstructured problem, given the variety of different moral views (see Section 3) and lack of consensus on facts and values (as illustrated by the scientific disagreement on alarming studies in Section 5).

When I started analysing the GM crop issue with a focus on 'alarming studies' (2015), I predominantly used the concept of unstructured problems. Perhaps inspired by my background in the beta sciences, this typology of 'unstructuredness' suggests a solution can be found in 'structuring' efforts. Later, further research made me realise that while structuring is essential for decision-making, it is likely still unable to truly 'solve' the issue. This is why I use the typology of 'wicked problems' as an overarching identifier of the GM crop conflict in Chapters 1-3 and 9 of this thesis. Framing GM crops as a wicked problem suggests that a) it is biotechnology itself that is a problem and b) the issue is impossible to solve because of its wickedness. This means the bar of problem 'solving' may have to be lowered to 'resolving' the issue through dealing, coping or managing the problem in an acceptable way.

6.2 WICKED PROBLEMS: CONSEQUENCES FOR PROBLEM MITIGATION

In the last part of this section, I will reflect on what it means for biotechnology to be a wicked problem from the perspective of 'resolving' the issue. I will discuss criticism on the concept of wickedness and reflect on proposed strategies to mitigate these types of problems. Based on these insights, the 'wickedness' of the biotechnology problem can be reassessed.

Despite being considered unsolvable, strategies have been proposed in academic literature deal with wicked problems. Daviter (2017) reviews these strategies and categorises them as coping, taming and solving strategies. In addition, the concept of wicked problems has been challenged in academic literature, creating room for alternative strategies to mitigate them. I will highlight some of the main and relevant criticisms in view of this thesis. For a more general overview of literature challenging the concept of wicked problems, see Turnbull & Hoppe 2018, Head 2019 and Termeer *et al.* 2019.

Termeer *et al.* (2019) note that the expansive use of the term wicked problem for a wide variety of complex problem in different fields ranging from environmental and urban problems to societal and economic issues has undermined its conceptual definition. They also argue that there is no strict separation between wicked and tame[62] problems and point out that recent work on wicked problems tends to conceptualise it as a matter of degree. This was also recognised by Turnbull & Hoppe (2018) but they approach the wicked/tame distinction from another perspective. They argue that the wicked/tame distinction was originally used to differentiate between societal problems and problems of natural sciences, claiming that the latter are usually the wicked ones. Referring to literature from the field of Science and Technology Studies (STS), they substantiate that the natural sciences too are far from a mechanistic reasoning about tame problems. This has also been recognised by amongst others Newman & Head (2017).

With relevance to this thesis, the case description of alarming studies in Section 5 illustrates how a 'simple' scientific question about the safety of a GM crop can become extremely complicated to answer. Turnbull & Hoppe (2018) also criticise the problem/solution approach. By categorising a problem as wicked, it is 'assumed to have an autonomous, unique nature of its own' (p.6), which can be discovered and then solved. This was also recognised and pointed out by Head (2019) and Daviter (2017) who conclude that the concept of wickedness has quarantined complex or wicked problems as a special category that requires special and equally complex and iterative approaches. This isolates the problem from the surrounding context which may very well be part of the problem. With

62 Rittel & Webber (1973): 'the problems that scientists and engineers have usually focussed upon are mostly "tame" or "benign" ones. As an example, consider a problem of mathematics, such as solving an equation; or the taks of an organic chemist in analysing the structure of some unknown compound; or that of the chessplayer attempting to accomplish checkmate in five moves. For each the mission is clear. It is clear, in turn, whether or not the problems have been solved, (p.160).

relevance to this thesis, this can be illustrated by the problematic decision-making process on GM crop authorisations. The European context of decision-making (i.e. comitology) cannot be seen separately from the 'wickedness' of biotechnology. This is also recognised by Nie (2003) who makes a distinction between *wicked by nature* and *wicked by design*. He argues that whilst the nature and context of some issues can have a certain potential for political conflict, they can also be made (more) wicked by design, when used by political actors as a surrogate to debate larger and more controversial problems. Applied to the issue of biotechnology, the broad (moral, technological and economic) implications of this technology certainly have a potential for political conflict. In addition, the importance of context can be illustrated amongst others by the fact that GM crop authorisations seem to be more problematic in Europe than elsewhere in the world and that medical applications[63] of biotechnology generally have a higher acceptance, i.e. are less wicked, than food applications. The relevance of decision-making actors is illustrated by the increasing difficulties in the decision-making process on GM crops as more actors with more and diverse expertise, interests and perspectives become involved (e.g. applicant, EFSA, EC, comitology committees).

Despite this multidimensionality, Termeer *et al.* (2019) also note that 'new and existing governance approaches have often been unproblematically proposed as ways to solve wicked problems, while only imperfect solutions, partial solutions or small wins are achievable in practice'(p.1). This has also been pointed out by Hisschemöller & Hoppe (1995) who noted that policy makers have a tendency, deliberately or not, to move away from or deny these type (i.e. unstructured) of problems through limiting the number of participants in a policy arena (economic reasoning / maximising effects for the largest number) or by limiting the range of acceptable arguments (technocratic reasoning). Both 'strategies' can be seen in the conflict over GM crops where decisions on authorisation are taken based on a qualified majority and where non-safety arguments are dismissed or put in the private sphere. In addition, Termeer *et al.* (2019) conclude that when the concept of wicked problems is used in policy practice, they 'tend to provoke either paralysis or an overestimation of what policy can do about wicked problems' (p.1).

63 With the exception of human germline editing. For a long time this option was only theoretical and gained minimal public attention. The unexpected announcement of the first GM babies in China in 2015.

From the field of policy sciences, Head (2019) highlights problem framing, policy design, policy capacity[64] and the context of policy implementation as useful approaches for 'mainstreaming' wicked problems. He then focusses on constructivist approaches emphasizing the role of dialogue and conflict resolutions. Endorsing problem framing and the importance of dialogue are also in line with the learning strategy proposed by Hisschemöller & Hoppe (1995). This strategy is inspired by the concept of frame reflection from Schön & Rein (1994). Frame reflection can be characterised by a focus on the controversy and stimulating participants to reflect on their own and other participants' perspectives. Hisschemöller & Hoppe (1995) propose a learning strategy through problem structuring[65] and 'a reasoned problem choice'.[66] Problem structuring involves 'the confrontation, evaluation and integration of as much contradictory information as possible' (p.63). Recognising that problem structuring is no guarantee for a broad consensus on the nature of the problem, it can at least form the foundation of a reasoned choice of a problem frame, according to Hisschemöller & Hoppe (p.64). As such, this strategy does not focus on consensus or problem solving, but on problem finding. In 2001 Hisschemöller & Hoppe elaborated on the value of problem structuring, describing it as a mutual learning process amongst societal actors that interact and deliberate on their perceptions of the problem and its potential solutions. With regard to structuring, Hoppe (2010) later criticised the tendency to structure problems by dividing them into separate issues and questioned whether it is possible to solve messy issues by converting them into 'technically controllable' issues (p.88). Similarly, Head (2019) emphasises that wicked problems cannot be tamed or fixed by dissolving them into multiple elements which are then reassembled. At the same time, it has been argued that wicked and even unstructured problems cannot be solved, and therefore strategies should focus on coping or managing wicked problems through partial, temporarily and imperfect solutions. In my view there is a fine line between partial/temporarily solutions and the conversion and reassembly of sub–issues. In other words, complex problems may require complex solutions or mitigation strategies, but these too need a starting point.

64 According to Head (2010), policy capacity links the success of policy making not solely to the effectiveness of the policy instruments, but also to the perceived legitimacy of the leaders in the decision-making process.

65 Hoppe continued to develop this structuring approach further, See Hoppe (2018).

66 In the view of Hisschemöller & Hoppe, policy problems are social and political constructs and as such problem structure is a matter of choice: 'Choosing' the wrong kind of problem and its accompanying solving strategy, may result in the emergence of intractable controversies or unstructured problems.' (p.53).

At a first glance, GM crop authorisations are temporarily (they have a validity of 10 years), a partial decision on the authorisation does however not seem feasible. There is either an authorisation or there is not. One could argue that the latest Directive (EU) 2015/412 that allows MS to restrict the cultivation of a GM crop resembles a partial decision, but as we have seen, this did not improve the yes / no decision on the EU authorisation of GM crops. What the concept of wicked problems means in the specific context of GM crop authorisations needs to be further investigated, both in terms of problem finding and in terms of possible ways of dealing with this issue. In this thesis I aim to contribute to this process.

7. PROBLEM DEFINITION

Biotechnology is a broad and multidimensional technology that can have a significant impact on humans and the environment. In addition, the societal acceptance of different applications of this technology, such as GM crops or GM medicines, varies widely. People's attitudes towards biotechnology are formed by moral views, perceptions on risks and benefits and broader arguments relating to scientific, socio-economic and ethical grounds. The abundance of different perspectives about the safety and desirability of biotechnology applications leads to a plurality of conflicting views. Therefore, a regulatory framework has been developed in Europe that aims to ensure safe applications, freedom of choice for consumers and producers and a functioning market.

For the authorisation of commercial applications of GM crops however, the regulatory framework is not working adequately. Decisions about market authorisations are structurally delayed or even stalling. There is a deadlock in the European decision-making on the authorisation of GM crops. Based on its characteristics, the issue can be classified as a wicked problem. There is conflict on both facts and values, the problem lacks a shared problem definition and different views exist on solutions to the problem. If we accept that GM crops are indeed a wicked problem, it follows that the situation is extremely difficult or even impossible to resolve. Nevertheless, in regulatory practice, attempts have been made to improve the decision-making process on GM crop authorisations. The question is whether these attempts can and will work to improve the situation. The concept of wicked problems has also been criticised in academic literature, resulting in alternatives for problem mitigation by acknowledging different degrees of wickedness, and a multidimensional aspect that focusses on the context and the actors involved. Proposed mitigating strategies have been amongst others focused on learning and problem framing, dialogue and

conflict resolution and on policy design and capacity. Both theory and practice on problem (re)solving of wicked problems need to be critically analysed.

In Chapter 2, I will discuss and analyse technocratic, participatory and regulatory strategies to evaluate their contributions to mitigating the GM crop conflict. I conclude that these strategies alone or together have been insufficient to improve the decision-making on GM crop authorisations. This substantiates that GM crop authorisations are indeed a wicked and thus unsolvable issue. Unless something has been overlooked. It is from this perspective that I will formulate my research question. Finally, I will further investigate this question in Chapter 3 to build my hypothesis.

CHAPTER 2

TECHNOCRATIC, PARTICIPATORY AND REGULATORY MITIGATION STRATEGIES INSUFFICIENT TO RESOLVE THE DEADLOCK

R. Mampuys

1. INTRODUCTION

Different perspectives on the safety and desirability of GM crops result in a plurality of conflicting views about facts and values (see Chapter 1). Therefore, a regulatory framework has been developed that aims to facilitate individual, national and European decision-making regarding safety as well as broader (value) related aspects of GM crops (see **Table 1**).

In brief, the European Food Safety Authority (EFSA) and the Member States' authorities perform an environmental and food safety assessment for GM crop applications for importation and/or cultivation. If the GM crop is considered safe, the European Commission (EC) consults the Member States (MS) through a voting procedure with a draft proposal for authorisation. In addition to and separately from the European marketing authorisation based on safety, MS can restrict or ban cultivation of GM crops on their territory based on non-safety arguments. Finally, food products made of, or containing GMOs need to be labelled to facilitate consumers' freedom of choice. For GM crop cultivation, appropriate measures need to be taken by the MS to facilitate coexistence with conventional and organic agriculture.

Table 1: The main GM crop regulations in Europe and their objectives

Directive 2001/18/EC	Protect human health and the environment when carrying out the deliberate release of GMOs into the environment (i.e. the cultivation of GM crops) or placing on the market of GMOs.
Regulation (EC) No 1829/2003	Provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market.
Regulation (EC) No 1830/2003	Facilitate accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.
Directive (EU) 2015/412	Restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory based on non-safety arguments such as environmental or agricultural policy objectives, town and country planning, land use, socioeconomic impacts, coexistence or public policy (optional).

Yet, decision-making about market authorisations of GM crops is stalling because the comitology's voting procedure in either the standing or the appeal committee never results in a qualified majority in favor or against the proposal: the standard outcome is 'no opinion' (Smart 2015). The EC, who is mandated to take a decision in these cases, is reluctant to do so. With significant delays, authorisations for importation are eventually approved by the EC. Authorisations for the cultivation of GM crops have been completely halted. A majority of 19 out of 27 MS has opted out of cultivation of GM crops on their territory based on Directive (EU) 2015/412. In addition, several MS uphold national bans based on the safeguard clause or emergency measures provided in Directive 2001/18/EC and Regulation (EC) No 1829/2003. Over the years, GM crops have become an example of failed European decision-making on a supranational level. In Chapter 1 I have argued that the 'wickedness' of biotechnology is a likely cause of this problem (see Chapter 1, Section 6). In brief, wicked problems are complex problems that seem resistant to being solved, they lack a shared problem definition and involve disagreement on both facts and values. Attempts to solve these problems seem fruitless and moreover introduce new problems.

This chapter explores the cause(s) of the resilience of the problem of EU-decision-making on GM crop authorisations by looking at mitigation strategies that have been proposed and applied. In Section 2, I will discuss and evaluate three mitigation approaches that are common in the field of regulatory science: improve the science, involve the general public or change the regulations. These result in what I categorise as technocratic, participatory and regulatory strategies. Although the word 'strategies' suggest that these are deliberately and purposefully thought out approaches designed by a specific actor, this is not necessarily the case. I have chosen these because political actors, policy-makers and stakeholders in the field of GMOs repeatedly refer to these three factors as problematic and in need of improvement. I will evaluate the contributions of technocratic, participatory and regulatory strategies and argue that these have been insufficient to improve decision-making on the authorisation of GM crops in Europe. Based on this analysis, I will formulate my research question and provide an outline for this thesis.

2. MITIGATING THE BIOTECHNOLOGY CONFLICT

Regulatory decision-making on GMOs and GM crops is strongly based on a scientific safety assessment (Berg 2008, see also Chapter 1, Section 4). The role of science in policy and regulatory processes has been discussed in

academic literature since the 60s (e.g. Brooks 1964) and later became known as 'regulatory' or 'mandated' science (e.g. Rushefsky 1986 and Salter 1988).[1] For an overview of the development of regulatory science and scientific advice see Jasanoff (1990) and Irwin *et al.* (1997). Jasanoff (1990) explained the growth of scientific advising as a response to 'a growing public concern about technological hazards, accompanied by diminished trust in government and ambivalence about the place of experts in political decision-making' (p.2). The role of science was to 'rationalise politics', to add 'competence and critical intelligence into a regulatory system that otherwise seems all too vulnerable to the demands of politics' (p.1). While recognising the need for scientific knowledge in policymaking, Jasanoff also criticised the dominant role of this factor in the overall process. She promotes the need for 'socially robust knowledge' in policy-making. This type of knowledge not only includes scientific expertise, but also acknowledges normative and societal perspectives, in other words it provides a contextualisation of scientific knowledge (for more on socially robust knowledge see amongst others Nowotny 2003, Jasanoff 2003 and Jasanoff & Hurlbut 2018). The importance of (public) participation and deliberation in support of regulatory science for policymaking has gained significant attention over the years, illustrated in both literature (see a review by Spruijt 2014) and empirical research (Spruijt 2015).

Taking into account the origin and developments in regulatory science, it is not surprising that proposed mitigation strategies for technology related problems tend to focus on three areas: science, (public) participation and regulation. This is also the case for GM crops, where increasing scientific knowledge, public participation and adding or changing regulations have been promoted to mitigate the conflict. Technocratic and participatory strategies are not explicitly proposed to result directly in decision-making on the authorisation of GM crops but as will be illustrated in this chapter, stakeholders suggest that removing barriers such as scientific uncertainty or societal dissensus could make this process a lot easier. When this seemed to be difficult or even impossible, regulatory strategies have been applied that aim for a legal solution by acknowledging scientific uncertainty and societal disagreement.

The focus areas of the mitigation strategies I will discuss are also reflected in the reasons given by Member State representatives for abstaining from voting

1 Salter (1988) argued that mandated science differs from normal science in two ways: 1) because of the ways in which society uses the two bodies of knowledge and 2) because scientific and policy considerations are closely integrated at every step in its production and use.

on market authorisations of GM crops. The summary report of the appeal committee of 27 March 2017 lists the following reasons provided by MS: 'no agreed national position', 'negative public opinion', 'political reasons', 'risk of harm to the national agri-food industry', 'uncertainties in risk assessment', 'safety concerns for the environment', 'the precautionary principle' and 'the lack of comprehensive data on long-term potential impact of GMOs' (European Commission 2017b).[2]

At a first glance, several of these arguments are supposed to be covered by the existing regulations on environmental and food safety (i.e. Directive 2001/18/EC and Regulation (EC) No 1829/2003), suggesting something is amiss with the safety assessment. Some of the arguments go (or seem to go) beyond the scope of the regulations that the voting applies to. However, these are addressed in other regulations that facilitate individual and national diversity in choosing to use GM crops or not (i.e Regulation (EC) No 1830/2003 and Directive (EU) 2015/412. The fact that these arguments are brought to the fore as reasons to abstain from voting suggest that these elements too are insufficiently addressed in the current regulatory framework.

The summary of arguments illustrates both the interrelatedness and the relevance of the focus areas (science, society, regulations) of the strategies that I will discuss. The regulatory framework cannot be separated from science itself, as it includes technical definitions and techniques, as well as a detailed list of requirements for the risk assessment (see Chapter 1, Section 4). As such, the regulatory framework relies to an important extent on (regulatory) science and scientific expertise. In addition, the regulatory framework presumes deliberation and participation, as it explicitly leaves part of the decision-making to MS representatives in the comitology procedures. This reflects that the authorisation of GM crops is not just a technocratic or administrative handling, but it suggests room for a broader deliberation that, in practice, goes beyond the safety objective of the regulations: MS refer to aspects that assume deliberation and participation of stakeholders and the general public (e.g. 'political reasons', 'no agreed national position', 'negative public opinion'). And finally, scientific research and the resulting commercial applications such as GM crops are subject to EU regulations, but this framework leaves room for national differences between MS, some of which have been legally challenged

2 The same or similar reasons can be found in all summaries of the joint meetings of the standing committee on plants, animals, food and feed and the regulatory committee under directive 2001/18/EC as well as the summaries of the appeal committees.

or debated in formal complaints and opinions.[3] As such, strategies that look into improving the scientific and societal / stakeholder input or that look into improving the regulatory framework, could in theory contribute to the overall decision-making about GM crop authorisations. And given interrelatedness of scientific, societal and regulatory factors, it seems that they all need to function 'adequately' for the system to work. This seems logical from the perspective of a functionalist input-output model of the decision-making process. After all, if the scientific facts on the safety of GM crops are unambiguous, if society would agree on its use, and if the regulatory framework is fit for purpose, applying it to decide about market authorisations should in theory be a piece of cake. This ideal logic thinking about technology implementation processes has however also been criticised as naïve by amongst others Sarewitz (2004), Wellstead (2018), Cairney (2017) and Biesbroek *et al.* (2015). In this section I will discuss strategies that have been applied or suggested to mitigate the GM crop conflict and I will evaluate them based on their outcome and insights from academic literature.

2.1 TECHNOCRATIC STRATEGIES

The main objective of the market authorisation regulations of GM crops is safety for humans and the environment. Against this background a technocratic approach makes sense. If no agreement can be reached about the outcome of the safety assessment and the proposed decision to authorise a GM crop on the market, the problem could lie with the quality or robustness of this assessment. We see this technocratic tendency reflected in the reasons MS give for abstaining from voting: 'uncertainties in risk assessment', 'safety concerns for the environment' and 'the lack of comprehensive data on long-term potential impact of GMOs'. At a first glance, these are issues that science could solve or contribute to solving.

3 See for example Joined Cases C-58/10 to C-68/10 of Monsanto and others against emergency measures in France, Case 111/19 of the Confédération paysanne and Others versus Premier ministre and Ministre de l'Agriculture, de l'Agroalimentaire et de la Forêt about the legal status of mutagenesis in the GMO regulations, Case C-165/08 Commission v Poland which dealt with the prohibition on placing on the market of GMOs based on ethical and religious grounds, joined cases C-439/05 and C-454/05 land oberosterreich and Austria v Commission about a temporary ban on the use of GMOs in Upper Austria to protect organic agriculture, Case 1582/2014/PHP regarding a joint complaint of several applicants at the European Ombudsman about the delayed European authorisation procedures and WTO dispute DS291 about the EU violating international trade by blocking the import of GM crops. A last example of regulatory differences are unilateral decisions of EU member states (Sweden, Finland, the UK, Germany, Belgium) to exempt certain GMOs from their legislation, based on their own interpretation of the EU definition of a GMO, for an overview see Eriksson (2018).

Technocratic strategies seem to be based on the assumption that better science and more knowledge (and reducing uncertainties) will lead to better decision-making. Technocratic strategies are usually directed at framing the problem as a more technical one, so it can be 'solved' from a scientific or technical perspective (Newman & Head 2017). Pielke (2007) connects this view to a linear model of science, where 'agreement on scientific knowledge is a prerequisite for a political consensus to be reached and policy action to occur' (p.13). Technocratic responses seem to have become an automated status-quo type of reaction to problems about technology applications. In the next sections I will discuss and evaluate three examples that cover commonly used technocratic strategies in the conflict about GM crops: 1) reducing uncertainties with scientific knowledge or additional research, 2) including scientific expertise in policy- and regulatory decision-making and 3) proposing technological solutions. Together these strategies give a general overview of the value and limitations of technocratic approaches.

2.1.1 REDUCING UNCERTAINTIES

Scientific research and data requirements to reduce the uncertainty of risks related to GM crops have been one of the most common strategies to mitigate the conflict about GMOs. First, I describe the use of this type of technocratic strategy in the policy and regulatory arena and then I will place this strategy in a theoretical perspective.

To start with, the environmental and food safety assessment of GM crops in itself can be viewed as a technocratic strategy. This process only takes into account safety aspects and does not look at potential benefits or socio-economic impacts. It aims to reduce the risk that unsafe products enter the market. A risk assessment for GMOs is standard practice worldwide, so this is a common strategy. However, Europe is mentioned as having one of the strictest regulations with extensive data requirements and a strong focus on precaution (e.g. Amman 2014, Smart *et al.* 2015, Punt & Wesseler 2015 and Tagliabue 2017).

The EU risk assessment should take into account all direct and indirect, immediate or delayed effects, including potential cumulative long-term effects associated with the interaction of the GM crop with other GMOs and the environment. Annex II of Directive 2001/18/EC describes in detail the steps involved in the environmental risk assessment, while Annex III describes the data requirements. Additional requirements for a food a food safety assessment

can be found in Regulation (EU) 503/2013. The decision to maintain the mandatory rodent feeding trials in this regulation (see Chapter 1, Section 5), is exemplary of the European focus on reducing uncertainties, as illustrated by the Commissions' response to the GRACE project:

> *'The Commission explained that developments in scientific knowledge on replacement, reduction and refinement of animal use in scientific procedures are not at present sufficient to allow for the replacement of the 90 day feeding study in rodents by alternatives. In addition, there remain difficulties to define, with the necessary precision, the level of uncertainties in the application safety data package which would trigger the requirement for the 90-day studies on a case by case basis.'* (European Commission 2017a, A.03)

The question that the Commission does not answer here is when scientific knowledge would be sufficient and what level of uncertainties should trigger feeding trials. The (continuing of the) mandatory animal feeding trials has been criticised because it would undermine the credibility of the risk assessment process. Amongst others, Devos (2019) and EuropaBio (2018a,b) have argued that when the Commission emphasises uncertainty without a strategy to solve it, this undermines its own existing regulatory system.

Uncertainties are acknowledged to be an inherent part of science and risk assessment on the one hand, but at the same time authorities try to manage, reduce and control them. EFSA even issued guidance documents on uncertainty analysis (EFSA 2018) and communicating uncertainties (EFSA 2019a). These and other guidance documents by EFSA provide further detail to the regulations and their requirements. Over the years, EFSA published more than 20 scientific guidance documents[4] to aid applicants who want to apply for a market authorisation of GM crops to compose an application dossier. These documents describe in detail what kind of information and data is needed for the environmental and food safety assessment in general, and separate guidance documents have been published for specific components of the risk assessment (e.g. molecular characterisation, agronomic and phenotypic characterisation, allergenicity, monitoring) or for specific GM organisms (e.g. animals, mammals, birds, fish, insects). Besides *ex-ante* data requirements, *ex-post* measures are applied to reduce uncertainties regarding risks. European regulations require annual monitoring reports and an authorisation renewal

4 For an overview, see http://www.efsa.europa.eu/en/applications/gmo/regulationsandguidance (Accessed 15 July 2020)

after ten years. In comparison: most countries outside of the EU de-regulate a GM crop once it has been assessed for safety and approved for commercial release. The characteristics of the EU risk assessment procedures illustrate the way Europe strives to reduce uncertainties. However, the increasing data requirements and precautionary measures have not led to expeditious decision-making on market authorisations of GM crops.

The strategy of more research and data production to reduce uncertainty can also be recognised in the standard policy response to 'alarming studies'. A common response from the government and from the scientific field is to review the study's methodology to judge its scientific rigor. However, despite the scientific review of the EFSA and several MS authorities, the discussion lingered on and the EC eventually commissioned additional research to get more certainty on the outcomes of these feeding trials. As illustrated in Chapter 1, this did not resolve the discussion on alarming studies and the food safety of GM crops. Reducing uncertainty through more research and other characteristic governance responses to alarming studies are analysed in more detail in Chapter 5.

When we put the strategy of reducing uncertainties by adding scientific research in perspective of academic literature, the findings about their limited success are not surprising. Collingridge & Reeve (1986) concluded that scientific knowledge is insufficient to advance rational policymaking. They noted that when science is used in policy, it will always encounter either an under-critical or an over-critical environment, reducing its impact on policy decisions. Another prominent author on the role of science in policy, Daniel Sarewitz, emphasized that scientific uncertainty is not 'a lack of scientific understanding' but a 'lack of coherence among competing scientific understandings' (Sarewitz 2004, p.386). He introduced the term 'excess of objectivity' to explain that given the enormous and diverse body of scientific information, facts, theories and hypotheses, basically any value-based position in a controversy can be substantiated by 'a supporting set of scientifically legitimated facts' (p.389). The abundance of scientific facts and its use in policy and politics to defend different and often conflicting views has also been pointed out by other scholars such as Levidow (2001), Pielke (2004) and Daviter (2017). They emphasize that science cannot provide definite answers to policy questions.

Academic literature also addresses the role of communication and transparency about uncertainties. On the one hand scholars emphasize the importance of

communicating transparencies because this could increase understanding on how experts use evidence in their assessments and the limits thereof (Frewer 2002 and Miles & Frewer 2011). In addition, transparency and open communication could help build trust among the broader public in science and science-based decisions. EFSA acknowledged this, but also points out the potential downside of being transparent about uncertainties, which may result in crumbling trust of a science that fails to provide certainties (EFSA 2018, 2019a).[5]

Research has shown that transparency about uncertainties doesn't necessarily end debates and may even fuel them. Since complex issues will inevitably involve certain levels of uncertainty, both the knowns and unknowns can be contested as an argument in the discussion. Böschen *et al.* (2010) discussed the political use of science based non-knowledge. In line with Sarewitz, he argues that scientific nonknowledge (i.e. uncertainty) is not a certain state of knowledge waiting to be uncovered but that it results from science itself and that it is 'multifaceted' and 'socially constructed and negotiated'. He argues that societal conflicts over the correct assessment of what is known and not known cannot be resolved by the routine appeal to available evidence. He illustrates this with an example of the risks of GM plants:

> *'When we find, for instance, no empirical facts indicating harmful effects of a certain GM plant, this situation can be evaluated in two contradictory, yet equally reasonable ways: either in terms of reliable knowledge that there actually are no harmful consequences or in terms of possible unknown unknowns—which means that we are unsuspecting where, when, and how hitherto unforeseen effects might occur'* (Böschen *et al*. 2010, p.786).

This is a striking example reflecting the tension between knowns and unknowns playing a recurring role in the discussion over the safety of GM crops. Uncertainties are often highlighted to emphasize potential risks and consequently, promote a precautionary approach for the use of GM crops. See for example Myhr & Traavik (2002) who conclude that 'the obvious lack of data and insufficient information calls for application of the precautionary principle (PP) in the decision-making process' (p.74). In other words, uncertainties are used as an argument to halt the development of GMOs. NGOs opposing GMOs

5 EFSA (2019) 'will trust increase because EFSA is open and transparent about its conclusions or would such openness have the opposite effect, because people may wrongly infer that the conclusions of EFSA are not reliable?' (p.51).

(e.g. GM Watch, Testbiotech, Greenpeace) often emphasize that absence of proof is not proof of absence, suggesting that the absence of GMO risks can be proven through more scientific data. Searching for closure of the debate through more (reliable) data can however turn into an infinite process, since scientific uncertainty is endemic and the absence of risks cannot be proven. Therefore, more scientific data is unlikely to resolve the debate or remove all uncertainties.

2.1.2 USE OF SCIENTIFIC EXPERTISE

It has been common practice to use scientific expertise in European policy and decision-making processes. In an analysis on how scientific experts frame the discourse in European policy discussions, Gornitzka & Sverdrup (2008) have shown a strong increase in Commission-organised expert groups since the nineties.[6] First, I will show how this approach is used in the GM crop regulatory arena and then I will place this technocratic strategy in a theoretical perspective.

The use of expert knowledge is called upon in situations where complex interdisciplinary research with a high level of uncertainty or data needs to be assessed. With regard to biotechnology and GM crops, scientific experts have come to play a significant role in the decision-making process, both on a MS level and the European Level.

The GMO expert panel at EFSA performs a risk assessment of GM crop authorisation applications. An equal process takes place on a MS level, where national food and environmental safety authorities and scientific advisory bodies assess the applications. They send their comments and conclusions to the EFSA who uses this input to finalise her opinion for the European Commission. Given the complexity, interdisciplinarity and size of GM crop authorisation scientific dossiers, there is inevitable room for variation of judgement. For example, the submitted comments by MS and the EFSA response illustrate differences on the data and the level of detail and certainty needed in the GMO risk assessment (see for example Annex G of EFSA 2019b). The EFSA (i.e. the GMO expert panel) also reviews new information on the risks of GM crops (brought to the fore by MS in safeguard clauses or by alarming studies in scientific literature). Several MS have invoked the safeguard clause based on new scientific information, which has been concluded to be unfounded by

6 Gornitzka & Sverdrup (2008) counted 1237 expert groups in 2007, compared to 851 expert groups in 2000 and 602 in 1990.

the EFSA expert panel. Here too, we see differences in expert judgement. In addition, these differences are used in the political arena e.g. resolutions from the EP on proposed market authorisations have moreover pointed out that critical MS comments had been insufficiently addressed by EFSA in her final opinion (see also Chapter 1, Section 4.3).

Besides reviewing applications and new scientific information, experts are involved in shaping policies and regulations. Various expert groups have been discussing the potential risks and legal status of new plant breeding techniques (NPBTs).[7] The first working group on NPBTs was active between 2007 and 2011 and could not reach a consensus on the status of all techniques. In addition, the EFSA GMO panel adopted scientific opinions on the safety of three techniques (EFSA 2012d, EFSA 2012e). Over the years, more techniques were added to the list of NPBTs. Separate expert working groups on synthetic biology were set up upon request from the EC, focusing on the definition, risk assessment methodologies and safety aspects (SCENIHR, SCCS, SCHER (2014), SCENIHR, SCCS, SCHER (2015a), SCENIHR, SCCS, SCHER (2015b). However, neither of these processes and reports resulted in decision-making by the EC about the legal status of NPBTs (GMO or not?). Instead, more scientific expertise was brought to the table by consulting a newly established advisory body: the Group of Chief Scientific advisors (SAM) that provides independent advice to the EC to inform policy making and recommendations to improve the interaction between policy-making and scientific advice. They issued a scoping paper and explanatory note on NPBTs in 2016 and 2017 and a statement on the regulation of gene editing in 2018 (Scientific Advice Mechanism 2016, 2017, 2018). As of 2020, decisions about the status of NPBTs haven't been taken, and the Council of the EU has requested another study from the EC to clarify the legal situation of NPBTs after a ruling of the European Court of Justice on a technique called mutagenesis (Council of the European Union 2019).[8] According to news site Euractiv (2019b) the Council argued that the ruling brought legal clarity, but 'it also raised practical questions which have consequences for the national competent authorities, the Union's industry,

7 These techniques are more specific and precise compared to older techniques and cannot always be easily distinguished from plants created with conventional breeding techniques or natural variants. This triggered the question whether the resulting plants should be seen as GMOs from a legal and scientific perspective and whether they should require a risk assessment.

8 Case No 111/18 ruled that organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive. For a legal analysis of this case, see Bergmans *et al.* (2020) or Vives-Vallés & Collonnier (2020).

in particular in the plant breeding sector, research and beyond' that need answering. Part of the proposed study includes stakeholder views on the use of NBPTs in the MS (see also participatory strategies in Section 2.2). The results of this study are expected in 2021. These examples illustrate that scientific expertise does not necessarily result in unambiguous and irrefutable advice.

The limitations of scientific expertise in regulatory decision-making have been extensively discussed in academic literature. The use of scientific expertise in the governance of GM-crops fits within the concept of so called 'post normal science' a term that was introduced by Funtowicz & Ravetz (1993) to describe the use of science in situations with high (scientific) uncertainty, disputed values, high stakes and the urgent need for decision-making. Here, regular applied science no longer suffices. This calls for professional consultancy and scientific expertise that goes beyond 'simple' knowledge provision and includes uncertainty management and transdisciplinarity (Funtowicz & Ravetz 1993, Konig *et al.* 2017). Besides an exchange of knowledge between different fields of scientific expertise, this approach promotes extended peer review which is a process that also includes lay people and policy decision-makers. Although heralded at first, the concept later became criticised when it 'failed' to resolve complex policy issues in particularly environmental science (Ravetz 2006, Goemine 2011). Others argued that post-normal science tended to turn into politics presented as a new way of doing science since the issues that require expertise are often closely linked to normative questions (Wesselink & Hoppe 2011).

Academic literature also pointed out that scientific expertise cannot be inserted directly into the policy decision-making process. Firstly, because scientists and policy makers have a different perspective or scope: 'policymakers seek certainties and solutions while scientists offer probabilities, uncertainties and multiple scenario's' (Spruijt 2014, p.17). This so called 'science-policy gap' has been discussed by scholars such as Bradshaw & Borchers (2000), Choi (2009) and Wellstead *et al.* (2018). Secondly, scientific expertise cannot produce decisive evidence on risks, while policymakers keep asking for conclusive evidence (pointed out by amongst others Levidow *et al.* 2005). Van Asselt & Vos (2006) called this 'the uncertainty paradox' (p.5).

The changing and challenging role of science and scientists as experts in decision-making procedures under uncertainty has been reflected on by amongst others Jasanoff (1990) who argued that scientific expertise is

insufficient to resolve complex policy questions since they are too narrow-focussed on science and not representative of broader societal values. Pielke (2007) and Weiss (2003, 2006) provided respectively four and five typologies of the roles experts can have in policy advising, varying in different levels of policy advocacy and uncertainty tolerance. Based on a literature review, Spruijt *et al.* (2014) identify the following factors that will influence an expert's role: type of issue (uncertainty/complexity), type of knowledge (education, experience, objectivity); core values (normative beliefs); organisation; societal context and an expert's ability to learn and change his or her viewpoint. These aspects indicate that adding scientific expertise in complex situations does not (automatically) lead to pure and objective conclusive answers or directions for a solution. It inevitably also makes experts vulnerable to questions about authority or political accountability in situations of controversy, an issue that has been discussed by amongst others Bijker *et al.* (2009) (i.e. 'the paradox of scientific authority') and Weingart (1999). When science advice changes from data driven and peer reviewed 'certainties' to expert judgements, the experts as persons become vulnerable for criticism. This issue also plays a role in the field of GM crops, where experts reviewing authorisation applications or alarming studies are systematically criticised and questioned on their authority and integrity (see Chapter 4). Reflecting on the examples and academic literature in this section, it seems unlikely that adding scientific expertise will resolve the conflict over GM crop authorisations.

2.1.3 SEARCH FOR TECHNOLOGICAL SOLUTIONS

A technocratic strategy that searches for technological solutions is commonly known as a 'technological fix'. It refers to the development of new products or applications to mitigate part of a problem. Here we do not necessarily talk about scientific knowledge, but also about applications that have been developed based on this knowledge. Scott (2011) notes that the term 'technological fix' was originally used as a recommendation for a positive course of action. It was introduced by Weinberg (1969) who characterised it as the solution to a problem that results from reframing a social problem as a technological one. According to Weinberg, 'the availability of a crisp and beautiful technological solution often helps focus on the problem to which the new technology is the solution' (Teich 1993, cited in Scott 2011, p.209). Later however, the term became used as a rhetorical tool to dismiss or criticise technologies or technological developments (Rosner 2004). Technological fixes and their criticisms can both be recognised in the field of agricultural biotechnology. This strategy is conceptually more complicated: in the policy and regulatory

arena one cannot label or mention this strategy as such, because that would automatically organise its opposition: therefore it cannot be explicitly found in the policy and regulatory arena. I will therefore combine its presentation with a theoretical perspective based on indications of and criticisms on certain developments that could be viewed as a technological fix. I will use two examples: NPBTs as a technological solution for the opposition to GMOs based on the argument of 'naturalness' and 'Golden rice' as a technological solution for the opposition to GMOs based on the argument that GMOs only serve the interests of industrial western agriculture.

The insertion of foreign DNA into an organism is considered as 'unnatural' by many opponents of GMOs. This problem can, from a scientific perspective, be solved by making only 'naturally' occurring changes to the DNA (i.e. by using DNA from related crossable species (i.e. 'cisgenesis') or making only very small changes without adding new DNA through (i.e. gene-editing, see Chapter 1). These techniques have been promoted by scientists and stakeholders from industry as an acceptable alternative to 'real' GMOs. Although this may be the case for some, this reasoning has also been criticised as a technological fix, as the use of scientific reasoning to resolve a moral argument. The 'technological fix' has been criticised from a philosophical perspective because it misunderstands the relationship between humans and nature (Scott 2011). GMWatch (2019a) issued an article titled 'Natural GMOs hype debunked' in response to an article from the Alliance for Science (2019) titled 'Many plants are naturally GMO'. Similarly, in the debate over the legal status of cisgenic plants, Van Hove & Gillund (2017) point at the complex socio-ecological, legal and political dimensions of technological development that should be taken into account, instead of just a technological perspective to determine whether a GM plant should be regulated or not. This view reflects the call for a broad and inclusive regulatory framework (see Section 2.3.2). In addition, argumentation to view certain GMOs as 'natural' is not only motivated from the viewpoint of normative acceptance of technology, but also has legal and economic implications (and stakes). Some stakeholders arguing NPBTs such as gene editing are 'natural' also hope to exempt these type of GMOs from the strict, costly and time-consuming regulations in Europe (e.g. EuropaBio 2019).

The second example of a technological fix concerns Golden rice, a GM rice variety that has high levels of beta-carotene. Scott (2011) identifies a second type of technological fix criticism that focusses on the practical side instead of

a philosophical perspective. Practical criticisms focus on the ambiguous nature of technological fixes, their inherent defects and limitations. The lack of GM crops that provide a benefit for consumers has been mentioned moreover as one of the reasons for opposition against GM crops. The majority of commercialised GM crops are herbicide tolerant or insect resistant, providing solely a benefit for the producer. Golden rice was supposed to contribute to solving an urgent nutritional problem in developing countries (Kettenburg *et al*. 2018). It has been presented as a form of responsible innovation, as it may contribute to solving malnutrition because it uses existing and available food crops (rice) with changed characteristics. Here I note that 'responsible' innovation also relates to moral values and what is considered 'responsible' by one, can be seen differently by others (see for example Biddle (2017) or McNaghten (2016) on the ambiguous relation between GM crops and innovation). The development of Golden rice has been heavily criticised, one of the arguments being that this is a technological fix that may alleviate a symptom of the problem (vitamin A deficiency) but not the root cause of the problem (food production and distribution). The example of Golden rice can be generalised in broader claims about biotechnology being an essential technology in solving the worlds agricultural and food production problems. These claims have been criticised pointing out the technology is not a 'silver bullet' solution (e.g. Parfitt & Dunn 2013, Hoffman 2013).

2.1.4 IMPLICATIONS OF TECHNOCRATIC STRATEGIES

In this section I have discussed three examples of technocratic strategies to resolve issues about GM crops. I have discussed examples of these strategies from the field of GM crops and discussed academic insights on their potential contributions and challenges in resolving conflict.

Summarising, the three technocratic strategies of reducing uncertainties, adding scientific expertise and searching for technological solutions (i.e. technological fixes), seem to be a standard response to situations of conflict about GMOs, whether they be about alarming studies, authorisation processes or the regulation of new techniques. But although broadly applied, their success seems to be limited. The debates about alarming studies remain and reignite when new ones are published, scientific expertise has not resulted in decisions about the regulatory status of NPBTs, nor have technological solutions provided generally accepted answers to questions about naturalness or benefits of GM crops. A strong focus on adding science can even have an adverse

effect, leading to discussions about reproducibility, integrity and legitimacy of science and scientific experts (i.e. 'the science crisis').[9] The discussion about uncertainties, objectivity or naturalness also illustrate the interrelatedness of scientific, normative and legal factors, providing an argument of why scientific input alone is unlikely to resolve the conflict on GM crops.

2.2 PARTICIPATORY STRATEGIES

In the voting procedures on GM crop authorisation, MS mentioned several reasons to reject or abstain from voting that were related to public and stakeholder perspectives such as 'no agreed national position', 'negative public opinion' and 'risk of harm to the national agri-food industry'. Calls for public participation seem to suggest that taking stakeholders into account can result in a collective vision on the way forward, or at least a shared or common ground on which decisions can be built. A variety of different wordings is used to reflect a role for the broader public or specific stakeholders in technology development and decision-making, such as public participation, involvement, engagement, consultation, debate or dialogue. These terminologies are not always consistently used and may have different meanings in different contexts.

Although public consultation (e.g. on EFSA opinions) and stakeholder participation (e.g. EU projects discussed in Chapter 1) are part of the decision-making process on GM crops, their role and function are not always explicitly defined or too diverse to distinguish them as separate strategies. However, public participation strategies have been extensively discussed in academic literature, also with reference to the GMO debate. Therefore, I will turn this section around and start with a reflection on participatory strategies from academic literature and I will use examples from the GMO debate to evaluate them.

First of all, broadening the level of participation in regulatory decision- or policy-making has not always been common practice. In academic literature on deliberative democracy, Dryzek (2010) and Ercan (2015) describe an evolution of deliberative strategies that have moved from a formal setting of constitutional

9 Saltelli & Giampietro (2017) summarise the following causes of this crisis: the generation of new data/publications at an unprecedented rate; the compelling evidence that the majority of these findings will not stand the test of time; a tension between good scientific practice and the desperation to publish (or perish); the multi-facettedness of the issue with no singular problem owner or solution. See also Saltelli & Funtowicz (2017).

courts towards taking into account a broader forum and also to an expansion of legitimate speech styles (from rational arguments to storytelling or rhetoric). Nowadays, it is more common to use public participation processes to form new policies or regulations or to gather information on what 'society' wants or what stakeholders want regarding the use of technology. As pointed out by Stirling (2008) 'Worldwide policy attention is refocusing on new frameworks and methods for fostering engagement with stakeholders and the public in the governance of science and technology' (p.263). As such, there is a connection between participatory and regulatory strategies, since the first category of strategies contributes to the legitimisation of the latter. In other words, in democratic societies input from participatory activities can be seen to form the basis of regulations and policy decisions. They contribute to characterise notions of 'goods', 'a good life' and 'a good society'[10] by identifying values, hopes and fears that may need to be addressed in regulations. These are characteristics of deliberative democracy, described by Bovenkerk (2012) as a political model in which political decisions are legitimate when they are reached through free and uncoerced debate between equals in the absence of power structures.

Different participatory strategies can be found that all have their basis in different forms and aims of participation and deliberation. Stirling (2008) summarises several aims of these strategies mentioning 'inclusion' (Brown 2002), 'discursivity' (Dryzek 1990), 'deliberation' (Leib 2005), 'pluralism' (Bohmann 1996), 'reflexivity' (Voß *et al*. 2006), and 'participation' (Pellizzoni 2001). Other goals of participation can be found in other literature, such as learning (e.g. Schön & Rein 1997, Hisschemoller & Hoppe 1995) or deepening and broadening of the problem (e.g. Poort 2012, Castle & Culver (2013). For the purpose of this thesis I do not need to discuss all of them in detail. With a focus on their potential contribution to the decision-making process about GM crops, I will limit myself to differentiate between participatory strategies with a focus on either consensus or dissensus (controversy) and I will merge other strategies. These may focus on inclusion, reflection or learning without a predefined outcome.

10 Van der Burg & Brom (2009) differentiated between three categories of the good: 'goods', 'a good life' and 'a good society'. They argue that the state cannot be neutral with regard to conceptions of 'goods' (e.g. diversity of the cultural and natural environment) and 'a good society' (e.g. valuable ways of arranging a society), amongst others since these are to a certain extent reflected in the law, but the state should be neutral regarding conceptions of 'a good life' (e.g. valuable ways of life), which belong in the individual domain.

2.2.1 INCLUSION AND ENGAGEMENT

Several scholars have been cautious towards the power of scientific expertise in policy processes, they warn this may to be too narrow to legitimise policy decisions in complex situations (the need for 'socially robus knowledge', e.g. Jasanoff 1990). The need for broadening of the decision-making process in cases of uncertainties about knowledge is also part of the post-normal science concept presented by Funtowicz & Ravetz (1993). In situations of scientific uncertainty, they identify a need for scientific expertise (Section 2.1.2), but also for what they call 'extended peer review'. The trustworthiness of authorities to take decisions in complicated situations can be increased by an extension of public participation. They emphasize the need for multidisciplinarity and public participation as an extended peer review.

What these typologies of participation have in common is that they do not seem to have an intended outcome of the participation in terms of consensus or dissensus. This is also in line with the learning strategy of Hisschemöller & Hoppe (1995) to cope with unstructured policy problems. Their ideas have been inspired by the concept of frame reflection from Schön & Rein (1994) and have been further investigated by amongst others Jelsma (2001) and Bovenkerk (2012) who argue that the inclusion of different viewpoints is initially more important than the aim of consensus. According to Bovenkerk public debate should not be restricted to expert committees or depoliticised bodies, but it should take place on different levels and should include a broad variety of different types of knowledge: not only values should be a topic of discussion, but also scientific evidence and the status of scientific knowledge.

Public consultation is part of the regulatory framework for GM crops and can be seen as a way to include the broader public into the decision-making process. Public opinion is mentioned moreover in Directive 2001/18/EC and Regulation (EC) No 1829/2003 and EFSA opinions are open for public consultation. However, there is a restriction on the type of comments that are taken into account. Only comments that are within the scope of the relevant Directive or Regulation (i.e. environmental and/or food safety), are 'considered' and taken into account. Although this makes sense from a legal perspective, dismissing arguments based on emphasising boundaries between science/non-science can also be seen as a way not to deal with other/broader or difficult comments. Van Asselt & Vos (2010) refer to the restriction of arguments as 'boundary work' (a

concept of Gieryn (1999)).[11] The limitations of the public commenting option in the regulatory framework on GM crops has been criticised by amongst others Ferretti (2007), who argued it provides a false promise of public participation. With the entering into force of Directive (EU) 2015/412, other, non-safety reasons, can be invoked by MS to restrict or ban a GM crop for cultivation. However, this directive does not have an explicit option for public consultation, nor does it encourage MS to start a participatory process on a national level (a more in depth analysis of the deliberative potential of this Directive can be found in Chapter 6). In terms of inclusion, learning and multidisciplinarity, the current forms of public consultation do not seem to facilitate a broad and inclusive debate where different viewpoints and types of knowledge are taken into account.

2.2.2 CONSENSUS BUILDING

While some conclude that the involvement of stakeholders is in itself a goal, other forms of deliberation aim for consensus as the desired outcome of the process (e.g. Habermas 1989, Elster 1998, Cohen 1997). The importance of societal consensus came up in the 80s and resulted in a growing popularity of so called 'consensus conferences' (see Joss & Durant 1995 and Einsiedel *et al.* 2000). In these conferences, citizen panels are facilitated in gaining a basis understanding of the issue at hand, followed by interactive sessions with experts and amongst themselves to exchange views in order to form a substantiated view on the issue that is then discussed with policy- and decision-makers. The popularity of these conferences diminished over time and has been criticised based on both the methodology (system) and its users (the public). One of the main critiques was that consensus thriving masks differences in opinion as these are removed from the debate during the process (see amongst others Kelly 2003, Horst & Irwin 2010). This criticism has a focus on the system of consensus conferences, but there is also criticism on the public taking part in these participatory activities. Misconceptions about biotechnology and GMOs are often pointed at as one of the reasons that prevents consensus (scientific actors in particular tend to argue that if only people would understand the science, they would accept the technology). For example, McHughen (2010) acknowledges that not all anti biotech sentiments are based on the ignorance

11 Van Asselt & Vos (2010) describe Gieryn's notion of boundary work as a strategic and purposeful act in which boundaries are drawn between realms, for example, between science and non-science and between science and politics. Boundary work involves drawing and maintaining contrast through selective attributions, which effectively demarcate in order to construct 'self-evident justification' and 'superiority in designated terrains' (p.288).

of agriculture or DNA, but points out a series of 'real' misconceptions on the topic.[12] He concludes that with the rise in technical knowledge and scientific literacy of European schoolchildren, 'eventually knowledgeable and critical thinking consumers will make informed choices' (p.727). In addition, Inghelbrecht *et al.* (2014) also emphasize that 'consumers must better understand the process of agriculture and food production' in relation to the controversy over GM crops (p.68).

However, I note that even amongst knowledgeable and critical thinking scientists, arriving at a consensus based on scientific data is already a problem, let alone for the general public. Chapter 1 described the involvement of stakeholders in scientific research to reassess the food safety of GM crops and to evaluate the methodologies in conducting this type of research. Through stakeholder involvement, the project aimed to arrive at a consensus on the way this type of research can be done best and ideally, also agree on the results of the study (Schiemann *et al*. 2018). But this did not work out as planned and disagreement on the safety of GM crops remained. For this reason, Christiansen *et al.* (2017) even argue that involving the general public in participatory activities about controversial science is not supported from the perspective of democratic legitimacy.

Most individuals in society are not trained to understand complex scientific studies or judge the quality of science. People's views on risk and safety are formed thought different factors and in new situations, they in general seek information that adds to their existing view (i.e. confirmation bias). Scientific knowledge is often used in a different way than intended by scientists (see for example Daviter (2017) on the political use of knowledge) and scientific consensus is not necessarily embraced by societal actors in the same way (e.g. Kahan 2010). The other way around, Aklin & Upperlainen (2013) argued that scientific dissent can undermine public support for environmental policy. Summarising: participatory strategies with a focus on consensus building about GM crops seems an unlikely goal to achieve.

2.2.3 ACKNOWLEDGING CONTROVERSIES

One of the main critiques of consensus conferences has been that differences of opinion are removed from the debate, denying the presence of a pluralism

12 McHughen (2010): 'The genomes of many crop species, when analyzed, show remnants of DNA originating in other species, so the concept of an inviolable 'natural species barrier' is demonstrably, flatly, unequivocally, wrong' (p.725).

of conflicting views in society. Amongst others Mouffe (1999) argued that consensus-seeking tends to exclude interests that are not seen as 'rational' from the perspective of ideal deliberative democracy.[13] These interests are put into the private sphere and set aside from the debate. In response, academics have also been investigating and promoting the opposite of consensus seeking: acknowledging controversies.

The importance of pluralism and controversy has been extensively discussed by Mouffe (1999), who argues that a recognition of the conflict will do greater justice to the conflicting nature of pluralism. Work on strategies that focus on the acknowledgement of controversies has been done by amongst others Poort (2013) and Castle & Culver (2013). The main reasoning of Poort behind the emphasis on controversies is that value conflicts should not be silenced or removed from the debate, but should be acknowledged and used to rethink the problems at stake. In particular for intractable disagreements (i.e. wicked problems), acknowledgement of the conflict may help to establish a regulatory framework that manages disagreements instead of trying to control them or hide them under a veil of consensus. Castle & Culver (2013) argue that dissensus can be a better way for structuring policy problems, and developed a 'method of contested exchange': a strategy that aims to disclose the knowledge and values needed to structure policy problems. This suggest that contested or controversial problems can be structured and hat this could contribute to problem mitigation.

To my knowledge, there are no explicit or direct examples of this type of strategy that have been applied in the GM crop conflict. Examples of dismissing controversies from the debate can be found in the regulatory framework for GMOs. Individual differences in opinion are acknowledged in the EU regulations and operationalised through a labelling requirement for food containing GMOs. However, similar to consensus conferences, this action places broader non-safety arguments in the realm of individual choice and dismisses them in the overall decision making process. Similarly, Directive (EU) 2015/412 acknowledges the existence of non-safety arguments about the cultivation of GM crops and allows MS to ban these applications. This too however, can be seen as a way to dismiss instead of deepening the understanding of the controversy, since these bans require no further deliberation or debate.

13 A consensus from the perspective of endorsers of ideal deliberative democracy (e.g. Habermas) should be built on rational arguments that are based on knowledge and values that are generally accepted by all people in society.

2.2.4 IMPLICATIONS OF PARTICIPATORY STRATEGIES

Defined in terms of contribution to regulatory decision-making processes, the success of participatory activities around biotechnology has been limited. They do not (and are not always intended to) result in a broad societal consensus providing a direction for decision-making. Participatory strategies aimed at involving stakeholders and the broader public to make an inventory of their opinions usually display a wide variety of different and conflicting viewpoints. The way these results are 'considered' or 'taken into account' often remains unclear or input is dismissed by concluding it is 'outside of the scope' of the regulations. The inclusion of stakeholders as a goal in itself risks to be part of the decision-making process as a 'check-box' instead of actually having an influence on the decisions that are made (e.g. Ferretti 2007, Weimer 2010).

In cases of conflict where stakeholders are involved with a predefined goal such as a consensus, they have shown to be unsatisfied with the process, those involved in the process or the outcome of it. Stakeholders sometimes refuse to participate, step out during the process or they eventually distance themselves from the results and present their own conclusions in a separate process. An example is the European GRACE project (see Chapter 1, Section 5), which involved stakeholders throughout the entire process (Schiemann 2014). Nevertheless, critique on the outcome and process remained and hampered broad support for the final conclusions (Woegerbauer 2016, Testbiotech 2015 and GMWatch 2019).

The challenges and difficulties of implementing participatory strategies have also been recognised in academic literature. Weingart (2008) criticised the notion of 'socially robust knowledge' for being too vague to be operationalised. Bovenkerk & Poort (2008) concluded that participation and deliberation are valuable and necessary in debates about controversial technologies, but are in themselves insufficient to arrive at decision-making. Participatory strategies can be used by policy makers to identify perceived hopes and threats of a technology in order to design new policies or adjust existing ones, but these will not result in ready-to-use directions on the way forward. Christiansen *et al.* (2017) criticise the use of public participation in controversial science in general because (1) it assumes that the public has (partially) shared and substantiated reasons to accept or reject technology and (2) it assumes that there is clarity on other aspects of technology use, such as its efficacy and safety. In the case of GM crops, there is no such a shared knowledge base that is broadly shared in the scientific field nor in other fields.

Despite the availability of experience and critical academic literature on public participation, the call for a broad societal consensus[14] is still emphasised in discussions about (new) contested technologies, especially in the field of biotechnology. Numerous initiatives, global observatories, dialogues etc. have been set up over the years, but viewpoints remain diverged and the (intended) use of the outcome of participatory strategies in decision-making on regulations and authorisations is often implicit, providing difficulty to identify or measure the positive results of participatory strategies. Finally, in my view mutual understanding or acceptance of different viewpoints is relatively easy when nothing is at stake. In reality, processes seem to go smoothly until actual decisions have to be made on a single course of action (e.g. a yes/no decision on the authorisation of GM crops).

2.3 REGULATORY STRATEGIES

Regulatory strategies to mitigate the conflict on GM crops may focus on defining clear rules and boundaries on risk assessment or through legally acknowledging value disagreements regarding GM crops. When discussing regulatory strategies in this thesis, I am not referring to the process through which these regulations have been formed (in which participatory strategies can play a role, as mentioned in Section 2.2), but to the scope and implications of the (proposed) regulations themselves. The regulations themselves have been criticised and adapted moreover throughout the years to improve the conflict over GM crop authorisations in Europe and MS refer to the regulatory framework and its underlying principles (e.g. 'the precautionary principle') as a reason for abstaining from voting in the regulatory process. The precautionary principle (or PP) is a legal principle that plays an important role in discussions about GM crops. The PP is leading to conflict because of different interpretations on how it should be interpreted and used in a regulatory context (e.g. Stirling 2007, Steele 2006, Weimer 2010 and Tosun 2013). The first two regulatory strategies I will discuss should be understood against the background of these different interpretations. Therefore, a brief introduction is given on the background of the PP (see **Box 1**).

14 For example, the National Academies of Sciences, Engineering and Medicine stated after the first international summit on human gene editing in 2015 that 'It would be irresponsible to proceed with any clinical use of germline editing unless and until (i) the relevant safety and efficacy issues have been resolved, based on appropriate understanding and balancing of risks, potential benefits, and alternatives, and (ii) there is broad societal consensus about the appropriateness of the proposed application.' (NASEM 2015).

Box 1. The precautionary principle

The precautionary principle originates from German and Swedish law (Löfstedt 2004) and aims to enable policy makers to take regulatory action before risks materialise in order to prevent unnecessary harm (Eckley & Selin 2004). The PP was formally adopted with the Maastricht Treaty (the Treaty on the European Union (TEU) and is laid out in Article 191(2) of the Treaty on the Functioning of the EU (TFEU). Originally the PP was focused on enabling precautionary action in the environmental field, but it now applies to all areas of human, animal or plant health and safety (Zander 2010). The main document that explains the EU's approach to the PP is the 'Communication on the Precautionary Principle' from the EC (European Commission 2000b). According to this document, the PP is 'relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data'. The document defines that precautionary measures shall (1) be proportional to the chosen level of protection, (2) be non-discriminatory, (3) be consistent with comparable measures already in place, (4) be based on a cost–benefit analysis of action and non-action, (5) be subject to review when new scientific data becomes available, and (6) facilitate the production of the scientific evidence necessary for a more comprehensive risk assessment.

There is a significant amount of academic literature about the PP as a legal principle that will not exhaustively be discussed here. For this thesis it is important to be aware that the PP has different legal interpretations,[1] different uses in risk assessment practices (e.g. Myhr & Traavik 2002) and different uses in political-decision-making on GMOs (illustrated in this section).

The PP is explicitly mentioned in Directive 2001/18/EC as an underlying principle for the environmental risk assessment of deliberate release of GMOs. Because there may be risks involved, GM crops need to be assessed for food and environmental safety. The PP is further embedded in amongst others the safeguard clause or emergency measures that can be invoked to ban authorised GM crops exemplify another use of precaution, the mandatory monitoring reports and the limited validity of market authorisations of 10 years. As an underlying principle, it allows for precautionary measures in case of overlooked, uncertain or unexpected indications of harm of GM crops. However, the European approach on the PP leaves room for a narrow and a broad interpretation of its use. The narrow interpretation emphasises the role of science in regulatory decision-making, including the inherent presence of uncertainties. In this view, uncertainties are acknowledged and should be reduced where possible, but they are not necessarily a reason to stop technological applications or decision-making. The broad interpretation tends to use the PP to guide risk management choices in case-by-case decision-making when encountering scientific uncertainty (see Weimer 2010, p.633, p.637 and p.656) or to refer to broader non-safety risks that should be included in regulatory frameworks.

1 Zander (2010), cited by Tosun (2013) identifies at least three: Sweden interprets the PP as a fundamental principle that compels governments to act in a precautionary manner. The UK uses it as an enabling principle that allows governments to act in a precautionary manner. Finally, the US uses it as a basis for regulatory action; in other words the fact that a risk assessment is required, reflects the use of the PP.

Regulatory strategies, i.e. (proposed) adjustments of the regulatory framework or legal decision-making, seem to be based on the assumption that 'better' rules and regulations will facilitate better-decision-making. Regulatory strategies can be focused on stretching and challenging of the existing regulatory framework, or on establishing a novel or additional regime (Faulkner & Poort 2017). Both types of adjustments can be recognised in (proposed and actual) changes that have been made to the current GMO regulatory framework. Interestingly, these (proposed) changes seem to follow two opposite directions; they either focus on a more science or evidence-based regulatory framework or they focus on a more precautionary & broader regulatory framework that includes non-safety aspects. These two goals of regulatory reform have been discussed by amongst others Skogstad (2003) in her analysis of the first regulatory reform that took place during the *de facto* moratorium (1998-2004). I will describe and illustrate both strategies based on examples from the GMO regulatory framework and place them in a theoretical perspective. Finally, I will discuss a third strategy that doesn't focus on the GMO specific regulatory framework, but on the decision-making rules in the comitology procedures.

2.3.1 AN OBJECTIVE SCIENCE-BASED REGULATORY FRAMEWORK

Several (natural) scientists and stakeholders (mainly from industry), but also scientific advisory bodies have emphasised the importance of evidence or science-based policy (EBP) and regulations. This view assumes that policies and regulations can be improved if decision-makers have access to better, more objective, information and were more likely to absorb this information (Stoker & Evans 2016). The European Commission's Scientific Advice Mechanism (SAM) recently said:

> *"there is a need to improve EU GMO legislation to be clear, evidence-based, implementable, proportionate and flexible enough to cope with future advances in science and technology in this area,"* (Euractiv 2019a).

This narrow interpretation of the PP is strongly linked to a focus on evidence-based policy or EBP. EBP originates from the field of medicine and refers to decisions that are informed by rigorously established objective (scientific) evidence (Cairney & Oliver 2017). This idea originates from the proposition that 'reliable knowledge is a powerful instrument for advising decision-makers and for achieving political success' (Head 2010, p.78). The concept of EBP has been incorporated in the existing regulatory framework for GM crops, reflected in the environmental risk and food safety assessment that strongly rely on scientific evidence. Guidance documents have been developed by EFSA to provide detailed instructions on the type and form of scientific evidence that should be included in market applications (see Section 2.1.1). Comments from

the Member states and the broader public on EFSA opinions that relate to non-safety aspects are dismissed arguing that these are outside of the scope of the regulations i.e. not science-based.

However, the role of scientific evidence is getting under pressure with the introduction of new techniques that allow to make genetic changes in plants that are no longer detectable. For some advocates of EBP, this is a reason to exempt these GMOs and their products from the regulations. For example, Amman (2014) and Davison & Amman (2017) reject the conception that GMOs are fundamentally different from other crops. As such, they condemn the justification of a precaution for GM crops in the regulations. Along the same line, Tagliabue (2017) and Tagliabue & Amman (2018) deem the term 'GMO' scientifically meaningless and semantically dubious. It should therefore be abandoned. They recommend a product-based approach for the GMO regulatory framework, which according to them is more science-based because it looks at the end product, irrespectively of how it is made.[15] A product based regulatory framework has been promoted by other authors as well, see for example Podevin *et al.* (2012, 2013), and Wolt *et al.* (2010, 2015). In addition, Ramessar (2010) highlights the coexistence regulations in Europe as too precautionary, irrational and scientifically unjustifiable.[16] He also suggests adopting the US and Canadian product based systems that are based on scientific principles. Masip (2013) also emphasises rationalising, evidence-based and science-based solutions to resolve EU's problems in agricultural policies. Advocates of EBP are not necessarily of the opinion that other non-scientific arguments are invalid, but they belong in the realm of individual or political decision-making.[17]
The concept of science-based policies and regulations has been criticised in academic literature. Cairney (2016) argues that because of bounded rationality,

15 Tagliabue & Amman (2018) promote 'a new crop legislation based on sustainability criteria that apply to all varieties regardless of breeding methods used. That is, instead of focusing on whether a crop has been developed through genetic modification or conventional breeding methods the legislation would departure from the values that are central to achieving a sustainable development within plant breeding.'(p51). With regard to broadening to regulatory framework, they point out that 'In democratic societies, governed as regulated free markets, the preferences of groups can be expressed, also in terms of consumer choices, but such orientations should not become rules for everybody'(p.47).

16 'Not only are the thresholds for adventitious presence far stricter than for conventional crops, but the isolation distances implemented to achieve such thresholds are arbitrary, excessive and appear to be politically motivated rather than to reflect scientific reality' (Ramessar 2010, p.135).

17 In a news item of Euractiv (2014), Ann Glover, the former chief scientific advisor of the, at the time outgoing, president of the EC was cited saying "the incoming commission must find better ways of separating evidence-gathering processes from the 'political imperative".

it is impossible to take all evidence into account. Saltelli & Giampietro (2017) refer to the myth of rationality from Collingridge & Reeve (1986) that 1) policy action can be predicated on the accumulation of facts and the taming of uncertainty; and 2) science has the power to provide dispassionate facts to adjudicate controversies (see also Sarewitz 2000 and Benessia *et al.* 2016).

The limits of EBP is illustrated by amongst others Head (2010) who notes that a) a strong evidence base is not always available, b) policymakers and political leaders responsible for the implementation and decision-making, are influenced by many other factors and c) even where a scientific basis is available, this is usually not 'fit' to the practical needs of policy and program managers as it often encompasses detailed / expert knowledge. In addition, Saltelli & Giampietro (2017) warn that too strong a focus on scientific evidence may result in 'a dramatic simplification of the available perceptions, in flawed policy prescriptions and in the neglect of other relevant worldviews of legitimate stakeholders.' (p.62). They warn that science-based strategies such as EBP can be used instrumentally (see also Sarewitz' excess of objectivity) or to exclude certain (normative) viewpoints that are not backed up by a strong scientific evidence base. In this light, a strong focus on evidence based regulations might worsen controversies instead of mitigating them.

Finally, the argument that a product-based trigger for GMO regulations is more science-based than a process-based and should thus be the preferred option for a better regulatory framework does not necessarily hold up. In a policy report I wrote for COGEM in 2019, the possible implications of a product based regulatory framework for GM crops in Europe have been investigated based on desk research and interviews in The Netherlands and Canada. In the context of this thesis it is worth noting that the Canadian regulations apply to 'plants with novel traits'. Where Europe debates the question 'What is a GMO?' in Canada similar discussions arose about the question 'What is a novel trait?'. Similar to discussions about what 'naturally occurring changes' to the DNA are, the Canadian situation triggers not only a scientific, but also a normative discussion about 'novelty'. COGEM (2019) concluded that a simple change of the trigger for regulations, is unlikely to resolve the discussions about GM crops in Europe and would likely just exchange one discussion for another.

2.3.2 A PRECAUTIONARY AND INCLUSIVE REGULATORY FRAMEWORK

The notion of precaution is widely used in (academic) literature and policy/ political debates about biotechnology, often without specifying which

interpretation is followed. In a societal context the concept seems to be stretched beyond the legal interpretation to point out broader non-safety risks such as socio-economic risks or risks related to the loss of normative, religious or cultural values in agriculture. This illustrates the variety of interpretations of precaution that can easily get mixed up in debates and discussions. In addition, precautionary and inclusive in this section should be understood as extensions of each other and should not be confused with inclusive legal approaches that focus on participation. Regulatory strategies focused on a broad interpretation of the PP tend to use the principle as a decision rule and broaden the scope of the regulatory framework from scientific safety arguments to normative and value related aspects.

Elements of a broader interpretation of the PP can be found in the existing regulatory framework for GM crop authorisations. For example, the two step process of a risk assessment and a voting procedure by the MS, leaves implicit room for additional considerations or different risk perceptions. In addition, since the initial risk based regulatory regime in the 1990s, a trend can be observed to include broader elements into the regulatory system. Over the years, regulations and guidelines have been implemented on food labeling (Regulation (EC) No 1830/2003), coexistence measures (Regulation (EC) No 1829/2003, consideration 28, see also European Commission 2010a) and in 2015 a directive was introduced that allows individual MS to ban GM crop cultivation on their territory based on non-safety arguments such as environmental or agricultural policy objectives, or other compelling grounds such as town and country planning, land use, socioeconomic impacts, coexistence and public policy (Chapter 6 provides a normative analysis of the background and impact of this Directive).[18]

There is a tension between those supporting the view that only scientifically demonstrable differences in a GM crop should qualify to legitimise regulatory decisions (narrow focus on the PP and a strong focus on scientific evidence), and those that are of the opinion that the 'process' and broader (normative and/or socio-economic) implications of genetic modification should be the trigger and legitimisation for regulatory measures and decisions.

18 A similar regulation was proposed (2015/0093 (COD) by the EC in 2015 on the import of GMO food and Feed, but this was rejected by the European Parliament. They expressed concerns this regulation would be unworkable, it would lead to conflicts with WTO or that it would lead to the reintroduction of border checks between pro- and anti-GMO countries. The EP rejected the proposal and called on the Commission to withdraw its position.

For example, advocates of evidence-based regulations may reject the principle of labelling because it is not related to scientific safety (the labelling requirements facilitate freedom of choice). In addition, the diminishing detection possibilities for the use of NPBTs in GM crops (ENGL 2019) provides an argument to exempt these crops from the regulations from the perspective of evidence-based regulations. Advocates of the second strategy want the labelling requirements to be broadened to include products from animals (meat, eggs, and dairy products) that have been fed GMOs (e.g. Inf'OGM 2015, see also Moses & Brookes 2013). They argue this would be more in line with a process-based regulatory framework that reflects normative reasons to reject GM crops. To facilitate these preferences, some MS have acknowledged additional labelling initiatives: 'gentechnikfrei' (Austria), 'ohne gentechnik' (Germany) and 'sans OGM' (France).

Edvardsson Björnberg *et al.* (2018) illustrated that some EU MS have included wider socio-economic considerations in their national GM legislations in addition to the environmental risk assessment, such as Sweden, France and Norway. These regulatory provisions have been criticised because they would further delay the licensing process. Chapter 7 identifies a series of quantification and normative issues that illustrate the challenges of including socio-economic considerations in regulatory frameworks. Most regulatory measures that refer to broader non-safety aspects (such as ethical aspects, socio-economic considerations or sustainability) are non-mandatory, additional or optional to the main regulatory framework that is predominantly focused on a scientific risk assessment.[19] A GM crop can be allowed onto the market if it is considered safe, and in addition there are regulations facilitating producers' and consumers' choice to avoid these products based on other arguments. It places these arguments in the realm of notions of 'a good life' on an individual level, while some members of society are of the opinion these arguments should play a more prominent role in a view on 'a good society' on a collective level.

The importance of inclusion of broader/non-safety arguments into the regulatory framework has been discussed by amongst others Carr & Levidow (2000) who emphasize the importance of acknowledging uncertainties as well as normative considerations, Myhr (2010) who promotes sustainability

19 E.g. Considerations 9, 57, 58 and 60 of Dir. 2001/18/EC, consideration 42 of Regulation (EC) No 1829/2003. See also Directive (EU) 2015/412

as a normative standard for GM crops and Steele (2006) who argues that a precautionary approach appeals to ethical ideals associated with sustainable development. These perspectives criticise the regulatory framework for being too narrow and science based, while emphasizing that biotechnology has important moral, ethical and socio-economic implications that should be incorporated in the process. Tosun (2013) notes that the PP can facilitate transparent policy making as it requires policy makers to be explicit about their decisions and the extent to which these are driven by scientific evidence, economic or societal reasons. She also warns however, that a strong focus on the broad interpretation of the PP can set sail for an incredibly complex regulatory framework that takes into account an almost endless amount of factors that are difficult or even impossible to compare and balance due to normative differences, which can further complicate decision-making on GM crop authorisations.

The integration of broader normative aspects in regulatory frameworks has also been discussed in legal theory (e.g. Black 1998, Van der Burg & Brom 2000 and Poort 2013). These authors mainly focus on the importance of interaction, communication and dynamics in developing regulatory frameworks and less on the outcome of these regulations. This connects their work also to deliberative theories mentioned in Section 2.2. These authors emphasize that the development of legal frameworks should remain to a certain extent dynamic to leave room for norm development and problem reframing. In their view this approach does justice to a complex pluralist society and to rapidly developing technologies. While I sympathise with this perspective from a theoretical perspective, it seems unfeasible in reality. Regulatory strategies focusing on the process of design and problem formulation are best applicable when norm development is still ongoing, both in the legislative and in the implementing process. The difficulty, however, is that the phase of problem formulation for GMOs seems to be long past and the different positions are firmly established. In addition, the current regulatory framework for GMOs is also embedded in an international context, which limits flexibility and dynamics on rigorous changes. Nevertheless, in my view these dynamics will become more important when looking at the latest technological advances of biotechnology integrating with other technologies and in other fields (see Chapter 8). While the impact of biotechnology broadens to other working fields and applications, the 'scientific' and 'regulatory' visibility of the GM-technologies diminishes as the use of the technology is no longer detectable or falls outside of the legal scope of the current GMO regulations. When GM technology gets integrated

in new converging technologies it develops characteristics that call for a more flexible and dynamic regulatory framework.

2.3.3 COMITOLOGY REFORM: CHANGING THE RULES OF THE GAME

The last regulatory strategy I will discuss does not aim to provide a (re)solution for the disagreement about GM crops, but it aims to change the rules of the decision-making procedures in such a way that undecisiveness is no longer an option (in theory).

In 2017 the EC submitted a proposal for an amendment of the Comitology procedures in Regulation 182/2011 (European Commission 2017c). The amendments are based on four measures: 1) making the voting positions of the MS in the appeal committee public, 2) discounting abstentions in the calculation of qualified majorities, 3) creating a higher-level variant of the appeal committee and 4) asking the relevant composition of the Council of Ministers for a non-binding advisory opinion. The proposal provides motivations of which some relate directly to the situation of GM crops:

> *'This initiative follows up on a statement by the President of the Commission in his State of the Union address to the European Parliament in September 2016 when he said: 'It is not right that when EU countries cannot decide among themselves whether or not to ban the use of glyphosate in herbicides, the Commission is forced by Parliament and Council to take a decision. So we will change those rules – because that is not democracy'* (European Commission 2017c, context of the proposal)

> *'On several occasions concerning the adoption of acts which are subject to the comitology procedure, the Commission has found itself in the past years in a situation where it is legally obliged to take an authorisation decision in the absence of a qualified majority of the Member States taking position (either in favour or against) in the committee. This 'no opinion' situation is in the Commission's view particularly problematic when it concerns politically sensitive matters of direct impact on citizens and businesses, for instance in the field of health and safety of humans, animals or plants.'* (European Commission 2017c, context of the proposal)

According to Guéguen (2017), increasing transparency on the voting positions can reinforce MS political accountability for their decisions. The second amendment would push MS to take a position, since not doing this will have

their position ignored. Upscaling the political level of the appeal committee would already be possible under the current regulation, as the regulation does not specify the political level of the representatives. The last proposed amendment calls for a non-binding advisory opinion from the Council of Ministers which would push individual MS to make their national position explicit. As of 2020, the proposal still lies with the Council and the Parliament. It seems to be too early to draw conclusions on the implications of this strategy since the proposal has not yet been adopted. However, the fact that it already takes 3 years for the proposal to be discussed, might be another symptom of the 'wickedness' of the GM crop issue. In theory, if adopted, the measures could or are even likely to impose decision-making. However, as we have seen with other regulatory changes, there is nearly always a certain amount of leeway for alternative use. In addition, if users themselves to not stick to their responsibilities, regulations will not work as intended.

Looking at the proposal, I can already think of a way the amendments could further delay decision-making instead of improving it: the last amendment would require a non-binding advisory opinion from the Council. This could stimulate national discussions and push for explication of national and collective positions of the MS. However, if this process is deadlocked or stalling, because MS are reluctant to discuss the sensitive issue on a national level, it will only add to the timeline for EU decision-making.

2.3.4 IMPLICATIONS OF REGULATORY STRATEGIES

Regulatory strategies focusing on scientific evidence on the one hand and broader precautionary aspects on the other hand have been applied to change the regulatory framework. As a result, the current EU framework for GMOs has both characteristics of precautionary and evidence-based systems. The first two regulatory strategies promote different views on the type of knowledge[20] that is necessary for a 'good' regulatory framework. There is a tension between those that see science as the only legitimate source of knowledge for a regulatory framework and those that promote the inclusion of other perspectives (such as contextual, political, cultural, and socio-economic factors). The current regulatory framework seems to aim to satisfy both needs at the same time, leading to a situation that dissatisfies both sides. Promotors

20 Faulkner & Poort (2017) define regulatory knowledge as: 'relevant knowledge for deciding about appropriate new assessments and measurements of emerging biotechnologies'. These contain 'besides scientific knowledge, also knowledge about the perceived moral desirability of a new technology, knowledge about the broader policy setting, procedural knowledge about political processes and cultures, knowledge of the economy and industrial sectors, and relevant social values' (p.227).

of the first type of strategy will find the current framework too vague and precautionary while those endorsing the second strategy argue the system is not precautionary enough and too focused on 'hard science'. Choosing either one of these strategies does not seem like a constructive solution. While the value of objective and science-based facts for policymaking and law development seems evident, too much emphasis on scientific evidence tends to simplify the problem by separating scientific, fact-based arguments from broader ethical, socio-economic and other arguments. More or less: an evidence-based focus says: back to the (scientific) facts! But with that, it also directly or indirectly dismisses other arguments. A focus on a broad precautionary framework that takes into account non-safety arguments may lead to a complex framework that takes into account factors that are difficult or impossible to measure and compare due to normative differences.

Stirling (2007) argues that the dichotomy between purely 'sound science' and precaution is smaller than often assumed and ideally, they could complement each other. However, I note that while both precaution and scientific evidence are emphasised and incorporated in the regulatory framework, they do not seem to complement each other. Instead, these concepts seem to be used as ammunition against each other in regulatory science, political and stakeholder debates. Van Asselt & Vos (2006) argue the PP easily becomes politicised when used either to amplify or attenuate uncertainty in order to further their own interests. Along this line of reasoning, Weimer (2010) argues the EU has fallen into an 'extreme of combining a non-functioning ideal of purely science-based decision making with a decision-hampering highly politicized precautionary rhetoric' (p.626).

Lastly, both strategies encounter practical challenges on implementation. Science-focused regulatory frameworks are based on the assumption that 1) there is sufficient scientific evidence and 2) there is agreement about this evidence. As we have seen in the previous section on technocratic strategies, this is not necessarily the case. The same holds for a broader regulatory framework and agreement on normative aspects such as sustainability and socio-economic aspects and how to include them into the framework. Therefore, it seems that regulatory strategies in themselves, but also in combination with technocratic strategies (scientific evidence) are insufficient to resolve the conflict over GM crops.

3. RESEARCH QUESTION

In the first chapter a problem description has been provided for the European authorisation process of GM crops: decision-making on these authorisations is delayed or even stalling. Based on the characteristics of the discussions about GM crops the issue has been classified as a wicked problem. These type of problems are considered extremely difficult or even impossible to resolve.
Nevertheless, mitigation strategies have been suggested and applied to resolve the conflict. In this chapter I have discussed and evaluated three types of strategies that are directed at improving the scientific, societal and regulatory aspects of the decision-making process about the authorisation of GM crops. They aim at creating more certainty about the risks from scientific research, at finding a common ground in the societal and stakeholder debate and at providing a fit-for purpose regulatory framework which protects rights and liberties of producers and consumers of GM crops and those that prefer to avoid them.

An extensive amount of theoretical and applied research has been performed on technocratic, participatory and regulatory strategies. Scientific research continues to produce more data on the environmental risks and food safety of GM crops, but arguments that refer to scientific uncertainty persist and continue to be brought forward to reject GM crops. Academic literature has extensively discussed the need and methodologies for participatory processes that include the general public and stakeholders, but despite their potential and application, a plurality of conflicting views remains. Regulations have been adapted and proposed to reflect a legal framework that facilitates objective and science-based decisions on the one hand, and acknowledges broader non-safety arguments on the other hand.

Overall, despite valuable insights that can be derived from these strategies, there haven't been substantial improvements in the decision-making process on the authorisation of GM crops since the late 90s. This is illustrated by the continuing delays in market approvals, the voting outcomes that systematically result in 'no opinion' and a continuous pattern of requests for more scientific research, regulatory reforms and public participation.

This brings me to the following research question for this thesis:

Why is there a deadlock in decision-making on the authorisation of GM crops in Europe and how can it be addressed?

To provide an answer to this question, the following sub questions need answering:

I. **What kind of problem is the deadlock in decision-making about GM crops and why?**
(Addressed in Chapter 1, 4 and 5)

II. **Why is the deadlock in decision-making a problem?**
(Addressed in Chapter 1, 7, 8, 9)

III. **Has the issue been addressed and how?**
(Addressed in Chapter 2, 6 and 7)

IV. **Did this resolve the issue and why (not)?**
(Addressed in Chapter 2, 3 and 9)

V. **How can the issue be addressed to improve the situation?**
(Addressed in Chapter 9)

4. OUTLINE

I have now concluded the first two chapters of my thesis providing a general introduction, problem description and analysis and research question. These provide the theoretical background against which the subsequent chapters should be seen. In Chapter 3 I will build my hypothesis and as such, this chapter can be seen as an overarching argumentation of Chapters 4-8 which add to exploring and deepening my argumentation for the hypothesis. These chapters consist of published articles based on a mix of methodologies ranging from empirical research, literature reviews and legal analysis. An outline of Chapters 3 – 9 will be provided below.

Chapter 3 GM crop authorisations: indecisiveness caused by political conflict

In this chapter I will deepen the problem analysis and develop a hypothesis on why decisions on EU level about the authorisation of GM crops are problematic. I will do this through a normative analysis of the contributions from scientific, participatory and regulatory input in the decision-making process. After looking into the general characteristics of decision-making and the type of decisions that can be identified in the authorisation process of GM crops in Europe, the role and limitations of each of these decision-making steps is

evaluated. I will argue why technocratic, participatory and regulatory strategies alone or combined cannot be sufficient to arrive at decision-making about the authorisation of GM crops (partially answering sub question IV of this thesis whether proposed strategies resolved the issue and why (not).

Finally, I will present my hypothesis that a lack of political judgement in the decision-making process on the authorisation of GM crops could be an underexposed bottleneck in the problematisation of GM crops. I will explore the role of decision-making in a political context and identify indicators of the political character of the conflict over the authorisation of GM crops.

Chapter 4 Ethics of dissent: a plea for restraint in the scientific debate about the safety of GM crops

2

Published article / Authors: Mampuys R & Brom F.W.A. / Journal: Journal of Agricultural and Environmental Ethics 28, 903-924 (2015)

This chapter provides an in depth overview of the different arguments and conflicting values that are at stake in the agricultural biotechnology debate. Through a discourse analysis of the debate that follows after publication of alarming studies, it illustrates the underlying values and broader arguments that play a role in a seemingly scientific debate. The chapter is based on a series of case studies of 'alarming studies' published between 1998 and 2015. The timespan shows that over and over, the same type of arguments play a role in the debate. Three main categories of argument types can be found: specific arguments related to the methodology, results and conclusions of the study, contextual arguments about GMOs and their benefits and risks in general and arguments that focus on the credibility of the stakeholders involved. The case studies illustrate that the debate about GM crops usually takes place in the context and language of science, while it actually goes beyond safety and scientific facts. The analysis in this chapter contributes to the characterisation of the GM crop issue as a wicked problem and provides a more in depth answer of sub question I of this thesis (what kind of problem is the deadlock in decision-making about GMOs and why?).

Chapter 5 Governance strategies for responding to alarming studies on the safety of GM crops

Published article / Authors: Mampuys R & Brom F.W.A. / Journal: Journal of Responsible Innovation 2(2) 201-219 (2015)

This chapter analyses the governance of alarming case studies as strategies to mitigate the conflict over GMOs. These strategies have a strong focus on

science: more research, more facts and less uncertainties. The analysis shows that science alone is not sufficient to resolve conflicts about alarming studies. Despite being dismissed on a scientific basis by peers, competent authorities, governmental advisory bodies and representatives on a MS and EU level, these studies continue to revive the debate or block decision-making about GM crops. This analysis adds to the problematisation by illustrating that focusing on the science component from a governance perspective is not a fruitful strategy to arrive at decision-making on GM crops. Alarming studies are a recurring issue in the biotechnology debate and more science will not provide a definitive answer. This chapter contributes to answering sub question I in more depth to characterise what kind of issue the GM crop conflict is.

Chapter 6 Controversy first: factors limiting the success of Directive (EU) 2015/412 for national decision-making on the cultivation of GM crops
Published article / Authors: Mampuys R & Poort L.M. / Journal: Journal of Law, Innovation and Technology 11(2), 175-202 (2019)

Chapter 6 provides an in depth normative analysis of a regulatory strategy to mitigate the GMO conflict (contributing to answering sub question III of this thesis). It is a normative analysis of Directive (EU) 2015/412 that was supposed to improve decision-making on GM crops. By creating the opportunity for MS to ban GM crops based on non-safety arguments in addition to the market authorisation process that focusses on safety, the EC tried to separate scientific arguments from other, broader arguments. It hoped that MS would be able to arrive at a consensus on safety when they had the option to ban a GM crop on their territory. Thus far, the new directive is only used by MS as an additional means to block the decision-making process on GM crops. The analysis illustrates why adjusting the regulations does not necessarily provide a solution for the conflict and disagreement on biotechnology, even if the regulation in itself seems fit and reasonable.

Chapter 7 Socio-economic Considerations in Regulatory Decision-making on Genetically Modified Crops
Published article / Author: Mampuys R / Journal: Collection of biosafety reviews 10 (2018)

The growing adoption of GM crops worldwide can have socio-economic benefits for society and farmers, including increased farm profitability, income stability and ease of operation, along with decreased labor and pesticide use, crop losses, and exposure to toxic chemicals. Thus, in addition to national and international regulations on biosafety, countries are increasingly aware of

the importance of formalising the inclusion of socio-economic considerations (SECs) into regulatory decision-making. In practice, the complex and varied character of SECs can lead to technical and procedural challenges, which can further complicate the current conflict in GM crop decision-making. The potential and the challenges of SECs regulatory systems contribute to answering sub question II and III in more depth. Market introductions of biotechnology products have inherent microeconomic and competitive benefits and drawbacks. Socio-economic impacts can be positive or negative: in most cases, both occur but are not necessarily specific to GM crops. Socio-economic analyses generally compare the resources used or gained by a project with either (1) the prevailing situation or (2) an alternative scenario to determine the better option. SECs are highly dependent on context, especially the type of GM crop, the geographical location of use and the type of users. The distribution of benefits and costs amongst growers, consumers, food manufacturers, retailers and technology developers can make impact assessment rather complex. Modern biotechnology and its regulation are subject to public and political debate in many parts of the world. On top of environmental safety assessments, socio-economic assessments can contribute to balanced decision-making on market releases, future investments in research and development, and technology deployment. However, systematic and clearly outlined procedures and data/information gathering are needed to guide policy formulation and decision-making on biotechnology applications. This article (1) reviews the role of SECs in biosafety decision-making and (2) discusses the opportunities and challenges of integrating SECs into regulatory decision-making.

Chapter 8 Emerging crossover technologies: how to organise a biotechnology that becomes mainstream?

Published article / Authors: Mampuys R & Brom F.W.A. / Journal: Environment Systems and Decisions 38, 163-169 (2018)

Chapter 8 highlights the urgency of decision-making about agricultural (and other) biotechnological applications, contributing to answering sub question II of this thesis. It illustrates that undecideability in the EU will not stop the developments in an international setting. This descriptive analysis adds another layer of complexity to the problem characterisation of the biotechnology debate. It illustrates how biotechnology and its applications no longer fits within its strictly defined borders but integrates horizontally and vertically within other techniques and fields of application. As a consequence, the legal governance component of regulations no longer fits the scientific state of the art.

Science will continue to create new opportunities and challenges for itself (with more knowledge also come new questions and uncertainties), for societies (public opinion) and for the regulatory framework (fit for purpose and future proof?). This further emphasizes the role politics and political decision-making should play when uncertainties and disagreement will remain and regulatory frameworks in itself are insufficient to compel decision-making.

Chapter 9 European decision-making on GM crop authorisations: repoliticisation is evaded but needed

In this final chapter I substantiate my claim that repoliticisation of the biotechnology issue is needed in Europe to mitigate the problems with decision-making (providing an answer to sub question V). This chapter revisits the initial problem analysis of biotechnology as a wicked problem and zooms in on the role of political judgement and decision-making. Or in my view: the avoidance of political judgement in the current decision-making processes on GM crops.

In the absence of political urgency, evading decision-making on complex issues could be justified from a strategic political perspective. However, in view of the normative nature of the conflict about GM crops and the role and responsibility of the political decision-making actors, I will argue that avoiding decision-making on GM crops does not do justice to either GM crop opponents or proponents from a democratic perspective. This substantiates my hypothesis that repoliticisation of the decision-making process is needed to resolve the deadlock in decision-making about GM crops. I conclude with a brief reflection on the implications of repoliticisation of decision-making about GM crop authorisations with a focus on the importance of issue ownership and political priority.

Finally, in this chapter I will revisit and answer my research questions and formulate recommendations on future research. I argue that decision-making on GM crop authorisations in Europe is a wicked problem by design in which decision-making is evaded through delegating responsibilities to scientific, societal and legal actors and systems. Whilst science, participatory activities and a regulatory framework each contribute to the decision-making process, political judgement and decision-making are eventually needed decide in cases of conflict. Not doing so and upholding the illusion of a working system, does not do justice from a democratic perspective to both proponents and opponents of GM crops.

CHAPTER 3

GM CROP AUTHORISATIONS: UNDECISIVENESS CAUSED BY POLITICAL CONFLICT

R. Mampuys

1. INTRODUCTION

Based on the strategies that have been discussed and evaluated in Chapter 2, the systematic problems in regulatory decision-making on GM crops may point out that a) academic literature has not been (sufficiently or correctly) translated into practice; or b) the proposed insights and applied strategies are not the right ones to resolve the issue; or c) the problem does not (solely) lie within the technocratic, participatory or regulatory arena.

An exhaustive evaluation of whether and how all of the approaches have been applied, might be informative but is unfeasible within the context of this thesis. Based on the current situation however, it is possible to draw some general conclusions on their outcomes and success. In practice, there has been a strong focus on science and regulations to mitigate the conflict. Most changes or attempts to mitigate issues on GM crops that have been implemented focus on additional (technical) scientific research and adjusting or designing new regulations. Science can feed into the decision-making process by providing information on safety or risks, but as we have seen, science is also inherently uncertain and produces an excess of objectivity. Regulations and changes to them can directly influence decision-making (rules), but there are conflicting perspectives on the 'right' type of regulations. Participatory strategies have also been employed, but mostly without directly measurable outcomes with regard to decision-making on GM crop authorisations. Participation processes often involve a broad variety of (different) viewpoints, concerns and demands, and while these may inform decision-making processes, they do not dictate how or which decision is best. Given the endurance of the GMO conflict since the 90s and the broad variety of strategies that have been proposed and applied over the years, I don't consider it fruitful to add new variations to these categories. I choose to take a different approach and will zoom in on the specific role of decision-making, because this specific element seems to be problematic. In this chapter, I will analyse the types of decisions that are being exercised in a scientific, societal and regulatory context. From there, I will elaborate on how they can contribute to decision-making about the authorisation of GM crops to explore if and which factor(s) are missing in this process.

First, I will provide a brief overview of some general characteristics of decision-making and discuss the contributions and limitations of scientific, societal and regulatory input into the decision-making process.

Second, I will investigate why the mitigation strategies focussing on these inputs have been insufficient with an analysis of the normative role and limits of decision-making in a scientific, regulatory and societal context. This can teach us something about the extent to which solutions proposed in each of these fields can, in theory, contribute to improve decision-making. The analysis sheds light on whether there is a problem with the input into the decision-making process (science, public opinion) or the rules of the process (regulations) or with the execution of the decision-making process. I will argue that the technocratic, regulatory and participatory strategies contribute to the decision-making process but are by themselves or together insufficient to arrive at explicit and effective decision-making on a European level.

Third, I will present my hypothesis that the role of politics may be an overlooked element in the problematic decision-making about the authorisation of GM crops. In the last part of this chapter I discuss the role of politics in the decision-making process about the authorisation of GM crops in Europe and point out a series of indicators that add to the plausibility of my hypothesis.

2. DECISION-MAKING ON GM CROPS

First, the concept of decision-making has to be clarified with relevance to this thesis. The characteristics of a decision can relate to the grounds on which it is taken, its content or its consequences. Decisions can be characterised as digital or non-digital (0-1 or yes/no versus multiple alternatives and/or based on certain terms and conditions.), simple or complex (unambiguous, discrete and bounded versus conflictual and multi-outcome), objective or subjective (facts versus values), certain or uncertain (predictable versus unpredictable outcomes). In addition, decisions can be legitimate, justified or proportional or not, and from a normative perspective decisions can also be good or bad. The last distinction begs the question what are good or bad decisions and who is the judge of that? And what kind of decisions play a role in the authorisation process of GM crops? The decisions that are made in science are of a different nature than the ones made in society or in a legal setting. This section briefly looks into some of those differences.

2.1 A BRIEF OVERVIEW OF CHARACTERISTICS OF DECISION-MAKING

Lasswell & Kaplan (1950), described decision-making as 'forward looking, formulating alternative courses of action extending into the future, and selecting among alternatives by expectations of how things will turn out' (cited by Pielke 2007, p.54). From this perspective, decision-making seems

to be straight forward and objective, influenced by factual information and (legal) boundaries that can be extrapolated to potential decisions in the future. Pielke (2007) adds a normative element to decision-making by describing good decisions as 'those that more reliably lead to desired outcomes. But as there are a multitude of interests and perspectives: there is rarely a consensus on desired outcomes and the means to achieve those outcomes'(p.29).

This indicates decision-making requires a certain direction or preference of the type of future one is looking for. This can be a view on a good life, a view on good agriculture or food production, but also views on good scientific research or regulations. As such, the definition of Lasswell & Kaplan doesn't explicitly address the point of intentionality. We need to know where we want to go in order to form a judgement about the options for decision-making. Intentionality is a first characteristic that is of importance for decision-making, and one that also adds a normative element. Decision-making is not only influenced by the status of objective information, societal consensus and legal boundaries, but also by conflicting and dynamic values (such as those expressed in society) and diverging perspectives on what the future should look like. Secondly, decision-making marks a specific point in time where alternatives to the decision are left behind. Hisschemöller & Hoppe (1995) argue that by making a decision or choice, policy makers close the process of structuring and participation: 'although a decision is always necessary to prevent the political process from becoming paralyzed, there always remains a tension between the tendency to decide and the desirability to further integrate alternative views and contradictory information about the problem' (p.65). Third, the element of exclusion is what characterises decision-making as a political process. The political character of decision-making has been discussed by amongst others Mouffe (2000), Laclau (1996) and Poort *et al.* (2013). It presumes the decision-maker has the power or mandate to make a choice that also has a normative element (one thing is chosen over another). Fourth, Laclau (1996) notes that deciding requires a situation 'where discourses are articulated in particular ways and discursive struggles are waged, leading to particular outcomes' (p.92), indicating that decision-making requires argumentation.

Summarising, decision-making requires input of different sources of information, a sense of direction (aim or goal of the decision) and should ideally be substantiated by argumentation. In addition, in a formal or legal setting it also requires a predefined process to arrive at a legitimate decision. In other words, functional decision-making requires clear guidelines on who

is mandated to decide about what and based on what conditions and terms. With this in mind, we take another look at the decision-making process in the authorisation procedures of GM crops.

2.2 CONTRIBUTIONS AND LIMITATIONS OF DECISION-MAKING IN A SCIENTIFIC, SOCIETAL AND REGULATORY CONTEXT

The regulatory framework and the decision-making procedures for GM crops have been described in Chapter 1. Each Directive or Regulation has an objective which defines what it aims for, and lists the requirements or rules on how, based on what grounds, this objective should be met. Together, these reflect what a legitimate decision is in the context of the particular Regulation or Directive.

The European regulatory framework has been proposed and approved though a co-decision or ordinary legislative procedure by the European Commission, the European Parliament and the Council of ministers, representing respectively Europe (the executive), European citizens and the governments of the 27 EU countries. In the European parliamentary democracy, these actors have the power and responsibility of decision-making that should reflect a broadly shared view on 'goods' and 'a good society'.

The GMO regulations have also been subject to this process. As such, based on the objectives of the regulatory framework for GM crops, legitimate decisions are those that ensure safe applications for humans and the environment as well as the effective functioning of the internal market while facilitating national and individual freedom of choice (see Chapter 2, Table 1). The following key decisions and responsible actors can be identified in the regulatory framework for GM crops (see **Figure 1**).

The good news is, at first sight there is a regulatory system in place that facilitates clear (i.e. there is a single definition of a GMO and lists of techniques that result or do not result in a GMO) – objective (i.e. there are legal requirements for authorisation based on scientific evidence and quantifiable traceability and labelling) - digital (i.e. the outcome is a simple yes/no) decision-making about the authorisation of GM crops. The intended outcome of the authorisation process of GM crops should be 'yes' (authorised for market release) if the objectives of the regulations are met and 'no' (rejected) if they are not.

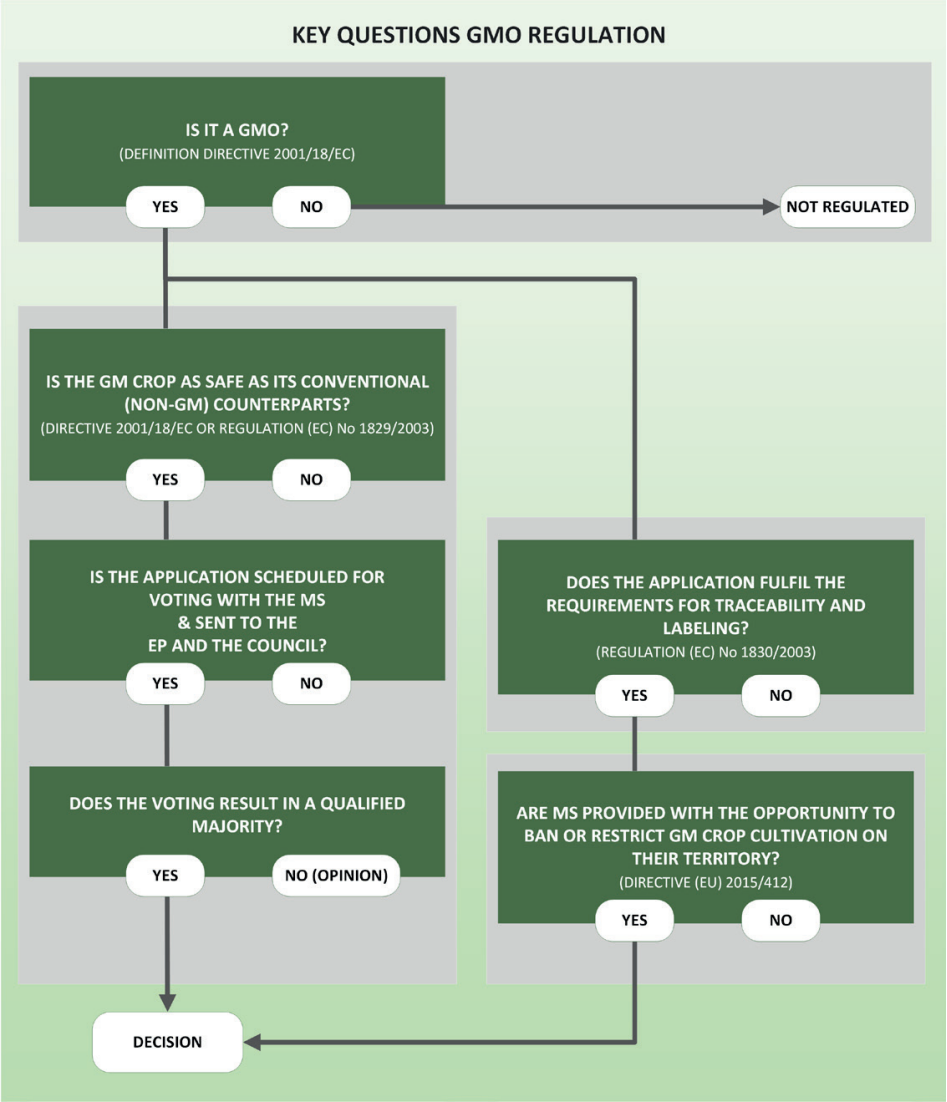

Figure 1: Key questions in EU regulatory decision-making on GM crops. If these questions are all answered with a 'yes', they will result in a final decision on the authorisation of a GM crop application.

However, this decision is preceded by a series of other steps that also involve decision-making. These are decisions related to scientific, societal and regulatory matters. In Chapter 2 I have discussed technocratic, participatory and regulatory strategies for mitigation of the GM conflict, concluding that these strategies have not led to definitive answers or directions for decision-making

with regard to safety, agriculture & food production or regulatory frameworks. The question is whether such definitive answers are feasible in the first place. In the next sections I will discuss the characteristics of decision-making in a scientific, societal and regulatory context based on an ideal typical perspective. Using examples from the case of GM crops, I will reflect on what we can and cannot expect from their contributions in the overall decision-making process.

2.2.1 SCIENCE DOES NOT COMPEL ACTION

Science can be described as the systematic pursuit of knowledge. Ideal typically, science follows objective rules and guidelines (the scientific method) and tries to separate facts from opinions by investigating hypotheses and theories (e.g. McNaughton 1999, Kreutzberg 2004). Science informs expectations about choices and their possible outcomes. It can draw conclusions on the likelihood of hypotheses being true or false, but in general it will not tell us what to do based on that conclusion. Regulatory science or scientific advice may take it a step further, but is usually still separated from political decisions.[1] This means science does not compel action; no matter how objective and convincing scientific conclusions may be, they will usually not point in the direction of the 'right' regulatory decision.

Regarding risks, decision-making requires a normative judgement based on what is seen as an acceptable level of harm or risk (e.g. Pielke 2004, Oreskes 2004, Jasanoff 1987 and Wynne 1991). Therefore, decisions about authorising or rejecting GM crops depend on where one wants to go with regard to agriculture and food production, on what is perceived as worth protecting and what risks are worth taking. In addition, scientific evidence about risks always involves a level of uncertainty. In an analysis of the role of science in public policy, Oreskes (2004) pointed out that science 'does not produce logically indisputable proofs about the natural world. At best it produces a robust consensus based on a process of inquiry that allows for continued scrutiny, re-examination, and revision' (p.369). Scientific information provides an 'excess of objectivity' that can be used as an endless resource to substantiate or argue for a variety of decisions. As such, scientists' influence on the use of their knowledge is limited (e.g. Daviter 2015 and Böschen *et al*. 2010). Finally, science is not value-free. The characteristic 'true or false' distinction of scientific hypothesis is based on what 'good' science is. As pointed out by Carr & Levidow (2000), 'science-based decisions are not value free. For example, value judgements are involved in deciding what impacts to include and leave out of the risk assessment, and

1 E.g. EFSA may conclude there are no significant risks for human health or the environment associated with a GM crop, but it does not advise or take the decision to authorise the crop.

what counts as environmental harm'(p.32). And here, there are differences of opinion as illustrated by the case of alarming studies in Chapter 1. In addition, scientists are increasingly expected to interact and cooperate with society, the private sector, policy makers and politicians. A conflict arises when science is expected to be value free and objective on the one hand, and justified and accountable on the other hand.

For these reasons, science will not provide an unambiguous objective answer that dictates political decision-making on GM crops, illustrated by Newman & Head (2017) who argue that 'political dynamics [...] cannot be neutralised by a dose of evidence, no matter how relevant or powerful' (p.419). With regard to decision-making itself, Head (2010) noted that 'in a democracy, evidence cannot make those policy choices on the deliberators' behalf (p.80.). Nevertheless, there are many examples where policy makers and politicians turn to science to reduce uncertainty and provide a clear line of action, such as the debate about global warming (discussed by amongst others Rayner & Malone 1988, Sarewitz & Pielke 2000 and Lempert 2000), pesticides (Tosun *et al.* 2018, Bazzan & Migliorati 2020 and Arcuri & Hendlin 2020) and GMOs (Chapter 1, Section 5).

2.2.2 PUBLIC OPINION COMPELS VARIOUS AND CONFLICTING ACTIONS

Society can indirectly influence regulatory decision-making through the expression of their opinion and through supporting, rejecting or protesting technology applications. Individuals, groups and society as a whole can express their opinion in their actions trough consumer behavior, organising themselves in groups to use collective effort to highlight issues to fellow citizens,[2] industry, policymakers or politicians.[3] This input can be used as a resource for marketing or lobbying goals, to defend political standpoints or to motivate or justify policy changes and decisions. Vice versa, governmental actors can actively engage the general public to express their opinion through public engagement activities. Society can also influence technology decisions by objecting (e.g. public consultations on EFSA opinions) or protesting them (e.g. the March against Monsanto, see an article in newspaper The Guardian (2015)) and in extreme cases, by using vandalism (such as the destruction of GM crop field trials, see for example Kuntz 2012 or Romeis *et al.* 2013).

2 E.g. NGO websites opposing or expressing critical views on biotechnology/genetic modification, such as GMWatch, GMFreeze, Testbiotech, Friends of the Earth, ETC Group, GMO free Europe etc.

3 The European Citizens' Initiative (ECI) is a European Union mechanism aimed at increasing direct democracy by enabling EU citizens to participate directly in the development of EU policies, introduced with the Treaty of Lisbon.

The question is when there is (in) sufficient societal support for a regulatory decision? This also depends on how policy-makers take public views into account. Christiansen & Gunnar-Hallsson (2017) describe three perspectives on how public views should be taken into account in decision-making that may result in different outcomes of those decisions: 1) public policy should be responsive to the preferences of citizens, 2) policies should be reasonably acceptable for all those subject to them or 3) public should directly participate in policy making through public deliberation.

Different views on public involvement also contribute to the GM crop conflict. The EC may reason that the regulations are reasonable and responsive to the preference of citizens who want to avoid GM food by providing labeling of food products. GMO opposing NGOs may be of the opinion that the general public should have a more explicit and direct influence on GM crop authorisations, as illustrated by their own initiative of creating GMO-free regions (for an overview and analysis of the GMO-free Regions network see Tosun & Shikano 2015). This initially small-scale initiative grew out to an international network, illustrating how public actors aim to influence or oppose decisions on GM crops.

Society can be described as a community of people living in a country or region having shared customs, laws, and organisations. At the same time 'the society' or 'the public' is not a singular or uniform entity. Individuals in a society are heterogeneous and can hold a wide variety of values and beliefs with regard to views on goods, a good society and a good life. Individuals in society can take decisions that suit their interests as long as they fit within the regulatory framework on what is considered acceptable and desirable. However, society can't make decisions as an entity, because it is a collective of individuals with a broad spectrum of different and often conflicting views, as is the case with GM crops.[4] Therefore, a collective agreement or consensus on the authorisation or rejection of GM crops seems unfeasible.

2.2.3 REGULATIONS DO NOT DETERMINE THE OUTCOME: LAW IN BOOKS # LAW IN ACTION

The regulatory system determines the outline or borders for decision-making in society. The law can be described as a system of rules which a particular

4 There has never been an overwhelming majority in favor or against biotechnology. A 2019 Eurobarometer indicates that the level of concern of EU citizens about genetically modified ingredients in food or drinks is on average 27% (similar to food hygiene concerns (32%), food poisoning (30%) and animal disease (28%) and varies from 45% in Lithuania to 13% in Finland (European Commission 2019). These numbers also change over the years. For a similar question in a 2010 Eurobarometer, 66% of respondents were very or fairly worried about 'Genetically modified organisms found in food or drinks'. (European Commission 2010d)

country or community recognises as regulating the liberties, rights and actions of its members. Regulations contribute to decision-making by assigning responsibilities to who decides about what and on which grounds. Regulatory decisions reflect views on goods and a good society based on a parliamentary democratic majority. However it can't possibly reflect all conceptions of a good life when these are conflicting in nature. Regulations have (limited) flexibility in terms of scope, pacing and language. Flexibility within the scope of regulations may vary and has both benefits and downsides. Very strict and detailed definitions makes regulations prone to be overhauled by scientific developments (e.g. NPBTs, see also Chapter 8)[5] while a broad definition makes regulations vague providing leeway for legal disputes. In addition, language differences between different disciplines[6] and nationalities[7] may lead to ambiguities in the interpretation of and execution of regulations in the form of decisions.

Most importantly, regulations do not determine the outcome of its execution, i.e. they don't determine the outcome of the decision. They can define the type of decisions which can be made within the scope of a regulation (i.e. safe or not, authorised or not, no opinion) or who can overrule who in the decision-making process (i.e. the power of the EC, Council, EP, standing or appeal committee to intervene or veto a decision). But eventually, a legal framework on its own will not be sufficient to arrive at its intended outcome without commitment and appraisal from those who are assigned the responsibilities to do so. The intended use of regulatory frameworks cannot be enforced if its users decide not to stick to the rules or use whatever leeway room there is in the regulations to avoid or delay decision-making (e.g. abstaining from voting, upholding bans, delaying voting procedures).

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5 In this chapter Brom and I illustrate how scientific developments stretch the boundaries of law, and at the same time put pressure on a broader debate on how to organise innovation, safety and societal embedding of a contested technology.

6 The regulatory definitions of a GMO and techniques leading to GMOs are legal/scientific constructs which may lead to differences in interpretation by scientific and legal experts or even between experts from the same field. Some MS unilaterally exempted experimental introductions into the environment (field trials) for new techniques from the national GMO legislation, based on their scientific interpretation of the EU regulations (see Eriksson 2018). The ECJ ruling of 2018 (Case C-528/16) reversed/overruled some of these decisions.

7 The European regulations apply to 27 Member States and are translated into 24 languages. This may lead to (slightly) different implementations of Directives on a national level or to different interpretations of regulations.

3. UNDECISIVENESS ABOUT GM CROPS AS A POLITICAL CONFLICT

In the previous section I have reflected on the contributions that can be expected from science, society and regulatory frameworks in the decision-making on the authorisation of GM crops. I have argued that these sources of input can directly and indirectly inform the decision-making process, but they don't compel the singular action (either yes or no) that is needed for the decision on GM crop authorisations. At best, they provide arguments. Arguments that need to be weighed and balanced in one way or another to justify a political decision. Without such a decision, the process remains in a deadlock. I will defend that this makes clear that there is an essential role for political judgement in regulatory decision-making. In the last section of this chapter, I will take a next step in building my hypothesis by providing and discussing indicators illustrating it is the political nature of decision-making that is an overlooked or underexposed factor in the conflict about GM crop authorisations. I aim to illustrate and argue that the most commonly proposed and used strategies that focus on science, participation and regulatory reform even contribute to avoiding political judgement. These indicators substantiate my hypothesis that the GM crop conflict is (also) a political one that cannot be resolved by scientific, regulatory or societal input alone.

3.1 POLITICS = DECISION-MAKING IN CASES OF CONFLICT

Political decision-making means decision-making in cases of conflict. After all 'if citizens had the same values and preferences, collective decisions would be easily achieved and the institution of complex democratic procedures would be redundant' (Biale & Liveriero 2017, p.580). The purpose of politics is generally described as to enable the members of a society to collectively achieve important human goals they cannot otherwise achieve individually. For example, it would be impossible for individuals to assess the safety of GM food or to test whether products contain GM ingredients. Therefore, these decisions are organised on a collective level. In Europe, decisions have been made to reflect different views on biotechnology (applications) in a system where decisions are taken on a collective (governmental) level to ensure safe applications and where individual preferences are facilitated through measures providing transparency (such as labelling).

Political actors use different types of knowledge and input to argue, negotiate and bargain to move towards a desired change, to reject or resist change and uphold the status quo. This seems straight forward, but the reality of politics is complicated, or as several authors have phrased it 'messy' (e.g. Weible &

Cairney 2018,[8] Sarewitz 2004). Political decision-making actors often have to make simple, digital decisions on complex matters, based on a broad variety of input from both objective and subjective sources and in a situation with a variety of interests and uncertainties. This is exemplified by the decisions on GM crop authorisations: the decision is simple (authorise or reject), but the information and circumstances preceding that decision are not. I will briefly discuss two factors that illustrate the complicatedness: bounded rationality and the ambiguity of national interests.

As pointed out by amongst others Millstone *et al.* (2015) and Daviter (2015), scientific knowledge is used differently in a policy and political context[9] than it is in a scientific context. But aside from that, given the extensive amount of scientific evidence and other sources of knowledge that can be used as input into the decision-making process, it is inevitable that policy-makers and politicians face 'bounded rationality' (Cairney & Weible 2017).[10] This limits their ability to pay attention to, understand, and respond to the policy problems for which they are responsible. There is simply too much and complex information, resulting in ignoring most of the available information. This could also explain why adding complex scientific research has had limited influence on decision-making processes about GM crop regulations and authorisation decisions (such as rodent feeding trials).

Political decision-making actors operate in an environment where the input from society and science and the boundaries of the legal framework are used creatively and strategically to serve national, political and sectoral interests. To complicate things further, these interest are dynamic over time and are not necessarily understood or represented in the same way at different political levels. In an analysis of MS voting behavior on GM crop authorisations Mühlböck & Tosun (2017) address these different notions of national interests, starting from the formal position that the Council represents the Member

8 Weible & Cairney (2018): 'the policy process is inherently messy and marked by a sticky resistance to change. It is also diverse across contexts and constantly evolving over time' (p.194).

9 To differentiate between politics and policymaking, political representatives decide on the goals of policies, after which it is up to policy-makers to implement and execute / translate these decisions into policies or proposals for (adjustments of) regulations. While the politics (deciding) versus policy-making (doing) seems clear, the boundaries between them cannot always strictly be made.

10 Cairney & Weible (2017): 'there can be no 'comprehensive rationality' in which policy makers can understand their context fully and process all policy-relevant information, to turn their values into a coherent and consistent set of objectives. Rather, they possess incomplete information and face bounded rationality (p.622).

States (TEU, Article 10). Mühlböck & Tosun cite Benz (2003, p.83) who argues this implies there should be an 'unbiased transmission' of the interests of Member States from a national to a European level through the governmental representative (in the Council this is the Minister responsible for the specific dossier). The question is however, what or better which, interests are meant here. Hagemann *et al*. (2016) interprets national interests as representing public opinion, while Treib (2010) sees party-political actors in national governments as representative of the national interests. Moravcsik (1998) and Scharpf (1996) argue that sectoral interests determine national interests. In their article Mühlböck & Tosun illustrate that each of these interests, in different national constituencies play a competing role in voting behavior. Given the economic, political, societal and cultural differences in European MS, this inventory of different views on the meaning of interests may also to a certain extent explains the differences in MS voting behavior on GM crops.

3.2 INDICATORS OF POLITICAL CONFLICT IN BIOTECHNOLOGY

Based on the above mentioned challenges of political decision-making, I will discuss a series of indicators which in my view substantiate that not science, or societal factors or regulations need change in the regulatory decision-making about GM crops, but political judgement. In other words, these indicators illustrate the political nature of the conflict on GM crops.

The first indicator of political conflict on GM crops is the difference between decisions on importation and cultivation. Both types of application go through the same regulatory system and require an environmental and/or food safety risk assessment. Both types of application are assessed positively by EFSA and put through the same voting system, which for both systematically results in 'no opinion'. Only one GM crop has ever been authorised for cultivation in Europe. No decisions are taken in the comitology procedures about cultivation. However, the situation for importation is different and the EC eventually approves importation authorisations in the absence of a qualified majority by the MS. This may have more than one reason, some of which are legal (the EU can face legal issues with the WTO for protectionism if she refuses to allow GM crops that are scientifically considered safe), as well as economic (the EU heavily depends on the importation of soy and maize for animal feed). Overall, clearly a balance is made between scientific and economic interests, indicating a political judgement.

Similar differences in the authorisation of agricultural and medical biotechnology applications provide a second indicator of political conflict. Medical therapies that contain GMOs (such as gene therapies and vaccines) require a risk assessment for both patient and environmental safety. Market authorisations of these products (called Advanced Therapeutic Medical Products or ATMPs) also follow European procedures for risk assessment (by the European Medicines Agency (EMA) and national authorities of the MS) and go through the comitology voting procedures for implementing acts. The voting procedures for ATMPs typically follow the scientific advice that inspired the draft proposal of the EC. This difference may be explained by a shared vision on the benefits of medical products while a goal and the means of reaching that goal in agriculture is more divided amongst MS (who have different views and interests in agriculture and food production). A balancing of benefits and risks is also typically one that requires political judgement.

A third indicator can be found in decisions by MS on a national and European level. Interestingly, some countries that oppose market authorisations of GM crops on a European Level, do authorise the deliberate release of GM plants on their territory (for example Switzerland, see Science Magazine (2013)). Deliberate release of GM plants concerns field trials for the purpose of scientific research. A possible explanation might be that deliberate release applications are less centralised (national level, not EU) and less political (deliberate release applications are assessed and approved by a national competent authority).

Finally, the avoidance of political behavior itself can be seen as a fourth indicator of political conflict. Although the controversial character of GM crops would ultimately qualify the topic for political discussion, it seems that systematically, strategies are chosen where political judgement is avoided. In other words, the situation is being 'depoliticised' (e.g. Poort *et al.* 2013) by delegating the issue to other contexts such as science, society or regulations. First, the main regulations on market authorisation themselves can be seen as avoiding political judgement. GM crops that are considered safe after an environmental and food safety assessment can be authorised for market release. There is no appraisal for small, moderate or big risks if for example these applications would offer significant benefits. Still however, differences of opinion exist on what is safe (enough), indicating this too is a normative decision that requires political judgement.

Other regulations applicable to GM crops do acknowledge and facilitate normative decisions, but these are optional and generally delegate decisions and responsibility to a lower (political) or individual level. Directive (EU) 2015/412 that allows MS to ban or restrict GM crop cultivation acknowledges non-safety arguments, but can also be seen as putting these on a side track and dismissing them from the European discussion.

In the regulatory procedures, a significant part of the decision-making seems to be delegated to science. The EFSA provides the basis for regulatory decision-making about the market authorisations of GM crops. The political decision-making process that is 'left' is limited to a digital decision that is restricted to a voting procedure under the comitology procedures. Since the Lisbon Treaty (2011) an appeal committee replaces the Council (of Ministers) for a second voting when the first round results in 'no opinion'. With this change, the voting system has been downgraded from higher level politics (Ministers as representatives) to lower level politics (MS representatives and experts). In addition, the influence of the EP has also been reduced since the Lisbon Treaty (Georgiev 2013). The EP has can only issue non-binding resolutions against draft authorisation decisions. The fact that these resolutions have been systematically submitted but ignored, also indicates a political conflict. The comitology system has been criticised moreover because it would move decisions towards the Commissions preferred outcome instead of those of the Council (Ballman *et al.* 2003). On the other hand, Böhling (2009) notes that there is no ideal way for the EC to safeguard MS interests in policy implementation, since the preferences and interests of MS differ significantly. Since 27 political cultures in Europe unavoidably complicate political agreement on decisions, this may explain to an extent why the EC seems to avoid political behavior when possible.

Nevertheless, in this thesis I argue there is an essential role for political judgement in regulatory decision-making about GM crops. In my view, the EC has exhausted scientific and legal means to resolve the conflict on GM crops. More scientific research, scientific and legal working groups, expert advice and even court cases have not led to decision-making on EU level. Neither science, nor public opinion, nor overarching regulatory frameworks can overcome the differences in political culture. This requires acknowledging the political nature of decision-making and acting according to it.

4. HYPOTHESIS

The authorisation of GM crops is problematic in Europe, resulting in stalling decision-making on a top down governance level. Over time, several strategies to mitigate this issue have been proposed and applied. These have mainly focused on technocratic, participatory and regulatory strategies. These strategies have contributed in different ways, but they have not significantly improved eventual decision-making on the authorisation of GM crops. This is problematic because biotechnology developments outside of Europe continue, and pose increasing challenges for Europe to uphold its current regulatory framework and justify the outcomes. In addition, the lack of decision-making is at conflict with several basic legal principles such as legal certainty for developers, and results in international conflicts about trade and scientific innovation. In this chapter I have argued that technocratic, participatory and regulatory strategies by itself or altogether have not been sufficient to mitigate the conflict on regulatory decision-making about GM crops. And even if these strategies would have been perfectly executed, they could not have resulted in a singular action or direction for decision-making. Besides technocratic, regulatory and societal input into the decision-making process, political judgement is needed in cases of conflict. This is an underexposed factor in the deadlock in decision-making about the authorisation of GM crops.

Based on the problem analysis and first steps in answering my research questions, I arrive at the following hypothesis:

Technocratic, participatory and regulatory input in the decision-making process are insufficient if political actors renounce or are unable to take up their own role in the decision-making process; which is to decide in case of conflict. An explicit repoliticisation of the decision-making process about GM crops is needed to get out of the current deadlock.

CHAPTER 4

ETHICS OF DISSENT: A PLEA FOR RESTRAINT IN THE SCIENTIFIC DEBATE ABOUT THE SAFETY OF GM CROPS

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1. INTRODUCTION

The use of genetically modified (GM) crops within Europe has been subject to regulations since 1990.[1] These regulations originate from the scientific consensus that GMOs could potentially present a risk to humans and the environment and should be regulated (Berg 2008). The European and most GMO regulations in other countries mainly focus on safety aspects, whereas other issues (such as principal, ethical or socio-economic aspects) are considered an individual or market choice. These aspects are covered by European Labelling regulations for GM food and feed.[2][3]

Companies, universities and research institutes are investigating the risks and short- and long-term effects of existing and new GMOs on humans and the environment (Nicolia *et al.* 2014). The results of this research, whether published in scientific literature or not, form the basis for safety assessments carried out by regulatory bodies such as the European Food Safety Authority (EFSA). Market approvals for GM crops are subject to an extensive environmental and food safety assessment prior to commercial approval (EFSA 2010). Following market approval, monitoring is implemented to identify any indirect or unanticipated adverse effects on the environment. The dominant consensus in the biotech sector and regulatory community is that the current risk assessment practice is adequate and that GM crops that are approved for market release are safe. However, among scientists, the nature and status of this consensus is a recurrent topic of discussion (e.g.Hilbeck *et al.* (2015)). To date there have been no confirmed incidents in which GM crops approved for market release have caused direct harm to the environment or to human health (Nicolia *et al.* 2014).

1.1. ALARMING STUDIES CHALLENGE THE CURRENT RISK GOVERNANCE

The regulatory consensus on the safety of GM crops is challenged by studies which conclude that certain GMOs do cause harm to human health or the environment. The authors of these studies suggest that the current assessment procedure might overlook fundamental problems regarding the safety of

1 Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms.

2 Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

3 This article is written from within continental Europe and our conclusions are consequently more relevant in this context.

GM crops (e.g. (Carman *et al*. 2013; Séralini *et al*. 2012)). We propose to call those studies 'alarming studies' because they alarm scientists, risk assessors, governments and the broader public of unknown risks that are possibly being disregarded in the existing system.

As pointed out by Thompson (1997), developments in food biotechnology are not just the concern of scientists and manufacturers. Recent decades have shown a significant increase in frequency and scope of ethical debates surrounding science and technology (Brom *et al*. 2015). The European debate on GMOs in agriculture is a well-documented example of the 'ethicization' of the public discourse on science, technology and innovation (Bovenkerk 2012). Although alarming studies usually are (scientific) publications directed at the scientific community, they are characterised by the fact that they also address a broader public and a wider set of issues. These wider issues revolve around the topic of GMOs and they actively come into play when an alarming study is published. The concatenation of texts on GMO safety over time has created a public (and counterpublic) with a specific discourse that is addressed by alarming studies (see also (Warner 2002)).

The discussion following publication of these studies is usually handled as a problem that fits within the current governance structure and discourse of risk assessment. The publications are responded to by a standard procedure of the responsible governmental agencies: they ask their scientific advisory bodies to reassess the study and decide whether the results justify revising their opinion about a GM crop (EFSA 2012c; FSANZ 2013; BAC 2012; NVWA 2012). Until now, regulatory bodies have not been convinced that a revision in response to an alarming study was necessary. For those who endorse the current risk assessment practice this signals the end of the debate, but not for those who are of the opinion that important issues (e.g. long term effects, effects of GM crop associated herbicides, socio-economic impacts and power structures of big agricultural companies) are disregarded in the current decision making system for GM crops. Consequently, the debate continues with undiminished vigour. The discussion will fade over time, only to be reignited by the appearance of the next alarming study.

1.2. ALARMING STUDIES

In this article, we propose to define an alarming study in general as a scientific or other study, claiming that a technological innovation (e.g. GM crop) poses a threat to human health or the environment which has not been acknowledged

by the existing governance system. We emphasize that the term 'alarming study' refers to the claim made and does not say anything about the veracity or otherwise of the study. Not all case studies in this paper originate from peer reviewed research articles, they also include a personal letter of concern and a retracted and republished study. We will illustrate that regardless of the validity or status of the claims, alarming studies provoke fierce debates which leads to considerable upheaval and anxiety. Despite the lack of scientific rigour we believe that these studies, claims and letters are an important part of the debate outside of the scientific community. Furthermore, from a scientific point of view it cannot be excluded that some of these 'early warnings' may turn out to be valid after all. This does not mean that every claim or shout out should trigger governmental action. It means that the scientific status of a letter/paper/journal or the reputation/background/previous work of a scientist should not play a determining role in the decision for further investigation.

Alarming studies about the safety of GM crops have been appearing since GM crops were authorised for placing on the market (Ewen and Pusztai 1999). Because discussions about the value and position of these studies are open-ended, they re-occur and accumulate in the debate whenever new 'alarming studies' make the news. They are therefore one of the main triggers to reignite the GM debate.

A key example of an alarming study is a paper by a French scientist about the health effects of the consumption of GM maize (Séralini *et al*. 2012). The Journal Food and Chemical Toxicology published the results of a study in which rats were fed GM maize and various concentrations of a glyphosate containing herbicide for a period of two years. Séralini and his team concluded that the rats fed with the GM maize and herbicide developed more and more serious tumours than the control group, and they developed the tumours earlier in their lives. Because the GM maize variety they used has been on the market for several years, the publication led to an international debate and several national authorities and scientific advisory bodies looked into the results to see if there was a need to revise their opinion that this GM maize was safe for consumption.

They concluded that the study contained methodological shortcomings and that the conclusions could not be justified. Although the study was dismissed as unsound and incorrect by advisory bodies and the EFSA (2012c), several NGOs and scientists disagreed and the debate in Europe continued. Eventually,

the Séralini paper was retracted by the editor and later it was republished in another journal (RetractionWatch 2014). Despite the formal outcome, this study is moreover referred to as proof that the consumption of herbicide tolerant GM maize causes cancer and other adverse effects (GMOSeralini 2014).

We will analyse the discussion about the Séralini paper and use examples of other studies regarding the safety of GM crops to illustrate the repetitive character of the debate about these studies over time (Ewen and Pusztai (1999), Rosi-Marshall *et al*. (2007), Huber (2011), and Carman *et al*. (2013) (**Table 1**).

Table 1: Examples of alarming studies and their publication status

Authors	Effect claimed	Status
Ewen S.W.B. and Pusztai A. (1999)	Rats fed diets containing GM potatoes expressing the lectin Galanthus nivalis agglutinin (GNA) had variable effects on different parts of the rat gastrointestinal tract, such as the proliferation of the gastric mucosa.	Peer-reviewed research letter, published with disagreement among reviewers
Rosi-Marshall E.J. *et al.* (2007)	Feeding caddis fly larvae Bt maize in laboratory tests resulted in growth reduction and increased mortality rate.	Peer-reviewed
Huber D. (2011)	A new pathogen originating from glyphosate tolerant GM crops causes plant infections and infertility and fetal losses in cattle fed GM feed.	Personal letter to US secretary of Agriculture - scientific paper announced - no publication as of 2015
Séralini G.E. *et al.* (2012)	Rats fed GM maize and various concentrations of a herbicide for a period of two years developed more and more serious tumours than the control group, and developed the tumours earlier in their lives.	Peer-reviewed, retracted & republished in other journal
Carman J.A. *et al.* (2013)	Pigs fed with GM maize for several months developed significant higher levels of stomach inflammation and some had an enlarged uterus.	Peer-reviewed

1.3 ATTEMPTS TO SEPARATE FACTS AND VALUES FUEL THE DEBATE

Governments attempt to isolate the discussion about facts (the 'scientific' discussion) from the discussion about values (the 'political' or 'societal' discussion) by treating the debate about alarming studies as 'simple' or

'structured' problems (Hisschemöller and Hoppe 1995). However, in the debate regarding GM crops 'political values' and 'scientific facts' are strongly intertwined. Separating them and only taking 'scientific facts' into consideration when it comes to decision-making fuels the ongoing discussion. Consequently, the debate about GMOs escalates and becomes polarised. A seemingly simple discussion about a scientific study (e.g. the Séralini paper) that goes against the existing safety evaluation of a GM crop develops into a chaotic debate that goes far beyond scientific research. We believe that further analysis is needed to investigate if and how it is possible to get past this repetitive cycle.

We use an overview and qualitative analysis of arguments used between 1999 and 2013 by stakeholders in a selection of representative alarming GM crop case studies to illustrate this pattern. We analyse the dynamics and interaction of the arguments to illustrate that there is and probably will be a permanent difference in viewpoints because there is disagreement about facts as well as values and their interconnectedness. Therefore, the situation cannot be solved by reassessing the study or conducting more research because this will only create more facts while the value conflict remains. The focus of the debate should be on these fundamental differences about values and making them explicit and manageable in the discussion.

2. ARGUMENT ANALYSIS

Discussions following the publication of an alarming study roughly follow the same pattern. After publication, the discussion starts within the scientific community with detailed arguments about the research design and methodologies used. Soon however, the audience widens and the discussion drifts off towards arguments about GMOs in general and their role in agricultural practice (Bovenkerk 2012). Finally, prejudices, personal attacks and accusations about conflicts of interest start to increasingly influence the debate that ends in a deadlock without a definitive outcome.

Based on an overall inventarisation we identified three broad categories of arguments that play a role: specific arguments about the alarming study or publication; contextual arguments relating to the underlying discussion; and arguments about personal credibility. From there, we found twelve re-occurring subcategories of arguments (**Figure 1**).

The research in this paper is based on a content analysis of arguments used in scientific papers, opinion pieces, news articles, blogs and comments regarding alarming studies (**Table 1**). Citations were identified by means of a systematic

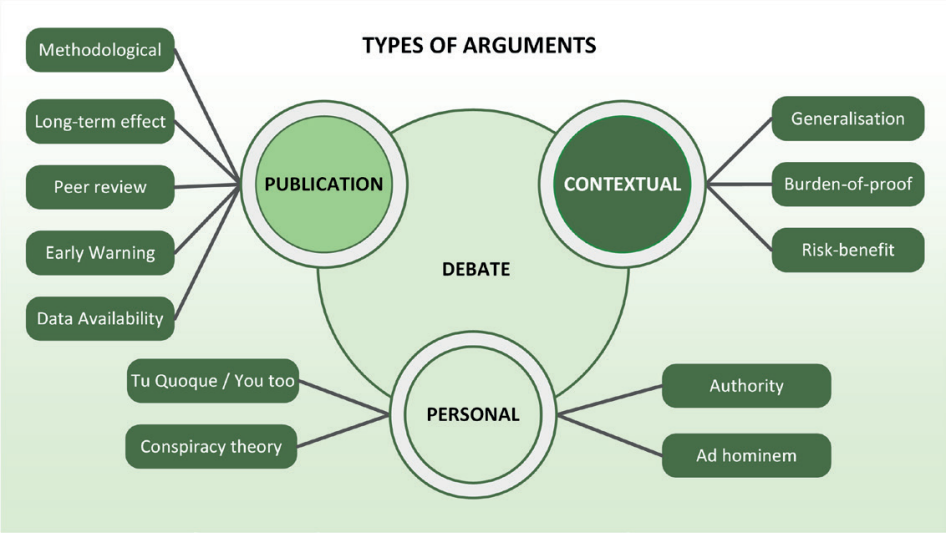

Figure 1: Clustering of arguments: the arguments in the discussion about alarming studies can be divided into three categories and twelve subcategories.

English search engine query based on the study's author name and snowball search sampling to get a representative image of the debate from different sources.[4]

Clustering of arguments in this article is an ideal-type[5] one and it should be noted that many citations contain elements from specific, contextual and personal arguments and the subcategories within these categories (**Figure. 1**). The arguments were categorised according to the degree to which they are representative of a certain type of argument. Additionally, the categories to which the arguments are assigned do not imply any judgement about their veracity. The goal of the classification is to draw conclusions about the influence of different arguments on the course of the debate. Personal details, company names and GMO variety specifications have been anonymised. Furthermore, the list of citations is not exhaustive, but provides an indication of the arguments that play a role in the debates about alarming studies. An extensive list of citations can be found in the appendix of a report of The Netherlands Commission on Genetic Modification (COGEM 2013). Ongoing research in view of this article resulted in an extension of the existing list.

4 The SAGE Encyclopedia of Social Science Research Methods pp. Atkinson and Flint (2004): snowball sampling.

5 Stanford Encyclopedia of Philosophy. pp. Max Weber (5.2: Ideal Type).

2.1 SPECIFIC ARGUMENTS

Specific arguments contain research details of the alarming study. These arguments focus on the experimental design, hypothesis and methods used, but they also discuss the scientific and administrative procedures surrounding the publication of research results in (peer-reviewed) journals. Specific arguments theoretically appeal to scientific facts and the practice of scientific research, but they also entail an underlying discussion about 'good science'. We divided specific arguments into five subcategories: methodological, peer review, early-warning, data availability and long-term effect arguments.

2.1.1 METHODOLOGICAL ARGUMENTS; THE EXPERIMENTAL DESIGN

Methodological arguments are an important element in the initial debate following publication. The aim of these arguments is primarily to verify the scientific validity of the results and evaluate, confirm or refute the scientific credentials of the research and lead researcher(s). This usually results in a detailed discussion about the methodological setup of the experiments, as illustrated by two examples from the Séralini paper which was both criticised and defended:

> *The [author] article claims to address the toxicity of herbicide-tolerant GM maize in the diet, with or without Roundup herbicide, and of Roundup alone when administered in drinking water at levels equivalent to 50 ng/L, 400 and 2,250 mg/L of glyphosate. Since the water consumption was not measured it is not possible to calculate the real exposure to glyphosate from these concentrations.* (Arjo *et al.* 2013)

> *We have replicated, extended and thus improved the experiments conducted by [author] and colleagues by measuring outcomes from 3 instead of 2 feed doses and more crucially for a period 8 times longer in duration (...) with 11 blood and urine measures of around 50 parameters, 34 organs instead of 17, etc., in order to ascertain if the statistical findings (...) were biologically relevant or not in the long term.* (Séralini *et al.* 2013)

A Similar exchange of arguments can be found in the other alarming case studies mentioned in **Table 1.** An illustrative overview of arguments per type and per case study can be found in Additional table 1.

2.1.2 PEER REVIEW ARGUMENTS: SCIENTIFIC QUALITY

Peer review arguments are used to emphasise, verify or evaluate the scientific quality of a publication. Both the value and limitations of peer review have been profoundly discussed in literature (Jennings 2006; The Economist 2013; Bohannon 2013; Nature 2006). Peer review is considered by both proponents and opponents of alarming studies to be a hallmark of good research, but they draw different conclusions. As a result the peer review system itself becomes part of the debate; proponents say the research was peer reviewed and thus good, whereas opponents say the peer review process was flawed and the study should be retracted, as illustrated by the following citations from the Séralini case (citations from the other cases, see Additional table 1):

> *A dangerous case of failure of the peer review system, which threatens the credibility not just of the journal but of the scientific method overall.* (Reuters 2012)

> *More than 26 international scientific peer-reviewed papers by the team with the lead author on the topic in the last 5 years, and 11 in toxicological journals on the same period only in PubMed....None of the papers was considered as flawed by the scientific community.* (Séralini *et al.* 2013)

2.1.3 EARLY-WARNING ARGUMENTS: SERIOUSNESS OF THE FINDINGS

A third specific argument focuses on the seriousness of the findings. These early-warning arguments highlight the effect and can have a major impact particularly in the public domain. This differs from the scientific domain where emphasis is usually placed on the methodological underpinnings, probability and validity of the claims. The 'early-warning potential' of arguments is also politically important in terms of policy response because ignoring potentially severe effects could have major consequences. Early-warning arguments create a sense of urgency. By stressing the seriousness of the situation (and broadening its scope) the sense of urgency to take action can be heightened. These arguments are likely to be magnified by media releases with shocking images, such as photos of rats with enormous tumours as an acclaimed result of GM food consumption (photos from the Séralini *et al*. (2012) paper were moreover reproduced in news articles e.g. CBSNews (2012)). The following are examples of early-warning arguments from the Séralini case (citations from the other cases, see Additional table 1):

> *Study linking GM maize to cancer must be taken seriously by regulators. Trial suggesting a GM maize strain causes cancer has attracted a torrent of abuse, but it cannot be swept under the carpet.* (Vidal 2012d)

This is the main cause of your and your kids health problems and the monstrous obesity in the country. So if we do not start educating ourselves on GMO and do not demand our government now to stop pretending that they have no idea about what is going on with the notorious biotech industry, which is exterminating the US citizens as they do with their masterpieces super-weeds or super-bugs, then your kids and your grandchildren lives are in the greatest danger ever in the entire history of the planet Earth. (GMOSeralini 2013)

2.1.4 DATA AVAILABILITY ARGUMENTS: TRANSPARENCY

The availability of data provided in the publication is a recurring argument in the discussion about alarming studies on the safety of GM crops. One of the aims of these arguments is to remove uncertainty where possible and to verify and validate the conclusions of the research. It is ostensibly a factual discussion suggesting that the solution can be found by providing the missing data, but there may also be an implicit accusation that the owner of the data has something to hide or does not want the data to be checked by third parties. In practice, more data does not necessarily result in a final outcome; it can also reignite the (same) discussion. Here, we illustrate two examples of data availability arguments from the Séralini case (citations from the other cases, see Additional table 1):

At this level, a full debate is biased if the toxicity tests on mammals of [GM crop variety] and [herbicide] obtained by [name] Company remain confidential and thus unavailable in an electronic format for the whole scientific community to conduct independent scrutiny of the raw data. (Séralini *et al.* 2013)

Following a written request by Professor [name], [regulatory agency] has today given the researcher access to all available data relating to the Authority's evaluation of genetically modified (GM) maize [variety] carried out in 2003 and 2009. (EFSA 2012a)

2.1.5 LONG-TERM EFFECT ARGUMENTS: UNQUESTIONED

The long-term effect argument is theoretically irrefutable. These arguments are a given in the debate about GM crops and other controversial technologies: long-term research is useful and important because it can provide more certainty about the safety of a new application. The long-term effect argument emphasises the importance of long-term research and usually points out the shortcomings of current safety research. Consequently, these arguments are used to disqualify the results of studies presented in the regulatory risk assessment of GM crops. They cast doubt on the value of existing findings and current standard in the risk assessment process. Interestingly, long-

term effect arguments are often used in a self-evident way while remarks on the design complexity, interpretation and the use of the results of these experiments are seldom addressed in discussions about alarming studies. We illustrate two examples of long-term effect arguments from the Séralini case (citations from the other cases, see Additional table 1):

> *[Author]'s is the first long-term peer-reviewed toxicity study on the health impacts of GM [variety] maize and the commercial herbicide formulation it is engineered to be grown with. GM food crops are authorized on the basis of short (a maximum of 90-days) feeding studies, usually carried out in rats. Long-term studies are not required by regulators anywhere in the world. (...) This shows that the 90-day tests routinely done on GM crops are not long enough to detect serious health effects that take time to develop, such as cancer and organ damage.* (GMOSeralini 2012)

> *A point that I keep bringing up...is that every research animal in the US has been eating GMOs for well over a decade. These animals are closely monitored in animal colonies by trained professionals that include veterinarians and pathologists and biomedical researchers. If there were problems in their food, that would be obvious.* (Worstall 2012)

Specific arguments are an essential part of the scientific discussion and valid within their scientific context, but they do not provide an answer to contextual or personal arguments (Section 2.2 and 2.3) that are triggered by alarming studies. Furthermore, arguments about peer review or long term effects also illustrate that the contents of what 'good science' entails, is not set in stone. This underpins our claim that science on its own cannot provide answers about the safety or desirability of GMOs.

2.2 CONTEXTUAL ARGUMENTS

The second category of arguments is focused on GMO related themes, such as the safety in general and other more fundamental issues (Marris 2001). We classify them as contextual arguments. They include wider issues based on the political, cultural and moral consequences of GM technology. Contextual arguments often say something about the direction in which society should be heading and are partially subject to personal preferences. Facts and values are strongly intertwined in this category. Therefore, issues relating to these arguments are usually not addressed in legislation. The government limits its

role to ensuring safety and freedom of choice (e.g. labelling in the EU). Wider issues are thus privatised and placed in the realm of individual responsibility (Swierstra and Te Molder 2012). The arguments in this category are about topics such as sustainability, biodiversity and naturalness, but also monopolisation of the food supply chain and the power of biotechnology companies. There are several types of contextual arguments; in this article we highlight three subcategories: generalisation, risk-benefit and burden-of-proof arguments.

2.2.1 GENERALISATION ARGUMENTS: BEYOND THE DETAIL

Generalisation arguments increase the sense of urgency by broadening the scope of alarming studies and those affected by it. From a scientific perspective, an individual study on a GM crop only says something about that specific crop, or at most something about GM crops containing the same genetic modification induced by the same genes. The results of such studies are therefore not per sé representative for all GMOs. However, both proponents and opponents frequently draw opposite conclusions from the same results – namely that all GM crops are good/bad or safe/unsafe. In the public domain, it is difficult to make a distinction between specific and generic conclusions, in part because news reports often already include an element of generalisation. They stretch the implications of research findings beyond their original context. For example, some media extrapolate the results of feeding studies with animals to effects on humans and speak of GM crops in general instead of the specific GM crop. The scientific data are lifted out of the modelled context of science and dropped into the everyday world as a generally applicable finding. In the process, the findings are stripped of some or all context in which they were valid (COGEM 2005). This is illustrated by citations from the Séralini case where the entire regulatory system is dismissed or it is generally emphasised that 'all' GM foods are safe (citations from the other cases, see Additional table 1):

> *[Author]'s findings revealed that industry and regulatory claims of biological irrelevance of effects found in 90-day tests are invalid. They showed further that the regulatory system for GM foods is inadequate and cast into question the safety of all commercialized GM foods.* (Robinson 2013)

> *(...) that concluded the opposite about the effect of GM foods on animals: that such food was as safe, or safer, than regular non-GM food and feed.* (McHughen 2013)

2.2.2 RISK-BENEFIT ARGUMENTS; BROADER CONTEXT

People use risk–benefit arguments to point out the wider consequences of a technology and the balance between risks and benefits. The use of risk–benefit arguments broadens the debate beyond issues that can be solved by the specific alarming study alone. Stakeholders make selective use of scientific reports on GM crops to demonstrate either the benefits or the lack of them. These arguments can be linked to the generalisation argument: either the benefits and safety of GMOs in general are emphasised, or all GMOs are said to be harmful and pose risks to humans and the environment, as illustrated from the Séralini case (citations from the other cases, see Additional table 1):

> *But my bigger concern is the well-established environmental downside of GMO crops. Biodiversity is damaged and pesticide resistance increases. (...) Far from enabling us to produce more food with less environmental damage the opposite is proving to be the case.* (Entine 2012)

> *As for genetic manipulation – that's got lots of potential benefits for food and feed production. The number of mouths to feed is increasing rapidly and the capacity to feed them, given climate change, is dropping.* (Vidal 2012b)

2.2.3 BURDEN-OF-PROOF ARGUMENTS: INDEPENDENT RESEARCH

Burden–of–proof arguments question the independence of GM safety research. These arguments disqualify the opposition as a reliable discussion partner and trusted supplier of information, and often overlap with arguments about personal credibility (Section 2.3). The burden–of–proof issue in GM safety research seems to be a fundamental sticking point in the debate. The (political) decision to make companies legally responsible for demonstrating product safety has proved to be contentious. Obviously, the company given this responsibility has an interest in the approval of the product. At the same time, it can be argued that companies have nothing to gain by placing an unsafe product on the market, because there is a fair chance they will eventually receive claims for damages. Nor would everyone be in favour of the taxpayer footing the bill for safety studies of GM crops, especially those who have moral objections towards the technology itself. The burden–of–proof argument is used against biotech companies, but also against scientists who are considered as anti–GMO. Inevitably, these arguments have a strong link with *ad hominem* arguments (Section 2.3.3). We illustrate two examples of burden–of–proof arguments from the Séralini case (citations from the other cases, see Additional table 1):

> *We recall that in the regulatory assessment of GMOs, chemicals and medicines, tests are conducted by the applying companies themselves, often in their own laboratories. As a result, conflicts of interest exist in these cases.* (Séralini *et al.* 2013)

> *[Regulatory agency] had recommended approval of [company] Roundup-tolerant maize in 2009 without first conducting or insuring any independent testing. They admitted in their official journal that they relied on 'information supplied by the applicant'(...).* (Engdahl 2012)

Contextual arguments are equally important and valid as scientific arguments. They address society and say something about the direction in which we should be heading and how decisions about (technological) developments should be made and by whom. At the same time, perspectives about society and the role of technology differ and are influenced by factors such as cultural, religious and personal preferences as well. Therefore, they belong in a sociopolitical context instead of a scientific debate about the safety of a specific GMO. Interestingly, there seems to be no designated platform for these discussions and governments usually employ safety as the only criterion for market release.

2.3 ARGUMENTS ABOUT PERSONAL CREDIBILITY

The last overarching category is formed by arguments about personal credibility. These arguments focus on the opponent in the discussion, often resulting in a strong pro-contra debate. From this point on, the discussion is likely to derail into a fierce and personal discussion that is no longer related to the specific question (the validity and consequences of an alarming study). The fact that several participants have been active in the GM debate for many years easily reignites old accusations and suspicions. We identify four subtypes of arguments in this category: *tu quoque*, authority, *ad hominem* and conspiracy theory arguments.

2.3.1 TU QUOQUE ARGUMENTS: YOU TOO

Tu quoque arguments ('you too') are used to bring the opponent down to the same level by pointing out that they have acted in the same way and are therefore no better. These arguments avoid discussing the substance of the issue in detail and seek to disqualify the discussion partner. Tit-for-tat accusations exacerbate the polarisation and uncompromising nature of the debate. *Tu quoque* arguments are widely used and often intertwined with other arguments, as illustrated by these citations from the Séralini case (citations from the other cases, see Additional table 1):

If we argue that [author]'s study does not prove that the GM food tested is dangerous, then we must also accept that industry studies on GM foods cannot prove they are safe. (GMOSeralini 2013)

[Website] is one of the most rabidly anti-GM sites out there, so I don't think they're anyone to be pointing fingers and accusing people of not being 'impartial judges'. (Vidal 2012a)

2.3.2 AUTHORITY ARGUMENTS: EXPERT OPINION

The effect of the authority argument is ambiguous. Authority arguments are used initially to increase the value of an opinion given by a person, organisation or journal. However, an inherent problem with the authority argument is that discussions should be foremost about what someone says and not who says it. Then again, the authority of experts in a certain field does play a role in the debate. Their views deserve to be given more weight and recognition in the debate than those of others, not only because they have relevant qualifications or experience, but because they have demonstrated that they deserve this authority in their field (Slob 2006). A point that should be made on authority claims is that specialists from different areas of expertise weigh evidence differently and this can lead to diverging conclusions from authorities which cannot be compared easily (Sarewitz 2004; Oreskes 2004). Authority can also be compromised and parties involved usually have some sort of interest which shapes their response to evidence. Therefore it is legitimate to inquire into those interests (Oreskes 2004; Etzkowitz 1996). However, if a debate is already polarised, it will be almost impossible to invoke authority unchallenged. Consequently, these arguments are employed to improve one's own stature or to dispute the authority and expertise of the discussion partner, as illustrated by the Séralini case (citations from the other cases, see Additional table 1):

He's not a toxicologist and hasn't studied or published any papers on the health effects of GMOs, so I am not sure how he is qualified to comment on a study by [author]'s team, who have published many such studies. (Vidal 2012c)

The journal, one of the best toxicological journals, did not retract the study, despite relentless pressure to do so. (CRIIGEN 2013)

2.3.3 AD HOMINEM ARGUMENTS: PLAYING THE MAN

Ad hominem arguments or 'playing the man, not the ball' cast suspicion on other stakeholders in the debate. It is an umbrella argument that is often

intertwined with other arguments, from methodological and peer review arguments to burden-of-proof and authority arguments. *Ad hominem* arguments do not address the substance of the criticism, but cast doubt on the right of the other party to make a comment at all. *Ad hominem* attacks are considered a disturbing trend in the GMO discussion (Arjo *et al*. 2013). The aim of *ad hominem* arguments is to disqualify the opponent as a discussion partner and to divert attention from the matter at hand. They encourage tit-for-tat accusations, leading to a polarised debate. Here, we illustrate two examples of *ad hominem* arguments from the Séralini case (citations from the other cases, see Additional table 1):

> *Since [person] is tied in closely with GM corporations he is not an impartial judge of [author]'s study.* (Vidal 2012c)

> *Towards the end of September, shocking headlines ricocheted around the world, claiming eating GM food caused cancer. But the truth is much darker: an anti-GM scientist overtly manipulated scientific process and the media to get those headlines.* (Finkel 2012)

2.3.4 CONSPIRACY THEORY ARGUMENTS: DISTRUST THE SYSTEM

Conspiracy theories attribute an event to the actions of powerful people or organisations that are said to be trying to hide their involvement from the outside world (Sustein 2009). Although it cannot be excluded that some stakeholders in the field of GM technology have coordinated their activities, there are usually no direct sources to confirm this and commentators tend to repeat each other's claims in blogs and social media. More importantly, conspiracy theories divert the attention from the social, scientific and political issues and above all generate mistrust of the parties involved (Van der Linden 2013). We illustrate two examples of conspiracy theories that were mentioned in the Séralini case (citations from the other cases, see Additional table 1):

> *This revolving door of corrupt ties between powerful private industry lobby groups and the EU Commission was in full view recently with the ruling of the [regulatory agency] trying to discredit serious scientific tests about the deadly effects of a variety of [company] GMO corn.* (Engdahl 2012)

> *It is much better for the economy to have both GMO and GMO chemical sales AND the cost of curing the impact from the GMOs. That becomes the sticky issue in all this because German & Swiss pharmaceutical giants are heavily invested in cancer technology. Almost a conflict of interest.* (Bardocz *et al.* 2012)

Arguments about personal credibility have become a persistent part of the GMO discussion (Arjo *et al*. 2013). Instead of contributing to a constructive debate about a scientific or sociopolitical issue, these arguments usually have an opposite effect. They result in a 'blame game' that reduces trust in all parties involved and increases polarization and escalation of the debate.

3. DYNAMICS OF THE DISCUSSION ABOUT ALARMING STUDIES

Based on the argument analysis in Section 2, we conclude that a selection of arguments is used repeatedly in the discussion initiated by alarming GM crop studies between 1999 and 2013. These dynamics are also seen in other applications of genetic modification such as animal biotechnology (Meijer and Brom 2009). From our analysis, conclusions can be drawn on the influence of the arguments on the direction of the discussion.

3.1 A HOTCHPOTCH OF ARGUMENTS

The GM debate is characterised by multi-level disagreements about definitional, factual, scientific, interest-based, value-based, moral and metaphysical aspects (Bovenkerk 2012). Disagreements about definitions and facts have been attributed merely to science, whereas interest-based, value, moral and worldview disagreements belong to the realm of politics and the public domain. In practice however, scientific disagreements are usually not solely about facts and political disagreements do not strictly originate from values. But even after years of recurring debates about alarming studies science is still pointed at to provide a final solution.

Although a theoretical distinction can be made between the various arguments 1) most of them contain a mix of elements from several types, and 2) the same arguments are often used by different parties from a different perspective (e.g. peer review arguments, seriousness of the findings, authority arguments). Some of the arguments have a clear purpose in the discussion; they aim to reassure, alarm, make value judgements or convince the opponent. Other arguments however, do not link directly to the specific alarming study. In this article, we identify them as contextual or personal arguments. We argue that these arguments are important indicators for the underlying debate about values triggered by new technologies. In our opinion, the recurrence of contextual arguments points towards urgent questions about food production and agriculture in general. The question is whether they belong in this debate about specific alarming studies or in a broader debate about what sort of society we want and which technologies are desirable to get there.

3.2 CONTEXTUAL ARGUMENTS HAMPER DECISION MAKING

The debate about alarming studies is hampered by contextual arguments that address wider issues such as risk-benefit, socio-economic aspects and issues relating to burden-of-proof. Because a solution for these wider issues cannot be found within the specific situation these arguments make it more complicated to reach an agreement on the significance and consequences of an alarming study.

In the debate about GMO safety, arguments about personal credibility appear to be on the increase in both the scientific and the social domain. These arguments divert attention from the main issues and are foremost geared to disqualify the opponent as a discussion partner (Slovic 2000). They do not contribute to the discussion and lead to polarisation, a hardening of attitudes and escalation of the debate.

3.3 GOVERNANCE SHOULD ACKNOWLEDGE BOTH FACTS AND VALUES

In the political and policy-making domain, the tensions and discrepancies between the different stakeholders and arguments are a focus point. It is a political task to evaluate all arguments and decide on actions to be taken. The outcome must be based on the appropriate expertise and facts but it should also do justice to wider concerns raised among the public. Mampuys and Brom (2015) provide an in depth analysis of governance options for dealing with alarming studies.

The current governance structure attempts to separate the 'scientific' discussion about 'facts' from the 'political' discussion about 'values'. We have shown in our argument analysis that this separation cannot be made and that scientific facts won't provide a solution as long as there is an underlying discussion about the values that form the foundation of the risk assessment framework. A vicious cycle has arisen partially because governments keep pointing at science to provide final answers.

3.4 STRUCTURING MULTI-LEVEL DISAGREEMENTS

Hisschemöller & Hoppe (1995) presented a distinction into four types of problems based on the level of agreement about the facts and values: agreement about facts and values (structured problem), agreement about one of them (moderately structured problem – either technical (agreement about the problem, not the solution) or merely political (agreement about the solution, not the problem)) – and agreement about neither (unstructured problem) (Hisschemöller 1993; Hisschemöller & Hoppe 1995). Our classification of specific, contextual and personal arguments can also be attributed to these categories (**Table 2**).

Table 2: Characterisation of problems based on scientific and normative consensus. Adapted from: Hisschemöller and Hoppe (1995) and Bovenkerk (2012).

		VALUES	
		CONSENSUS	NO CONSENSUS
FACTS	CONSENSUS	Structured problem Agreement about means & ends Focus on specific publication related arguments Experts or bureaucrats	Moderately structured problem Disagreement about ends (agreement about solution) Contextual AND specific publication related arguments Consensus conferences
	NO CONSENSUS	Moderately structured problem Disagreement about means (agreement about problem) Specific publication related AND contextual arguments Expert committees	Unstructured problem Disagreement about means & ends Specific publication related AND contextual AND personal arguments Socio-political debate

For each type of problem, a different solution is suggested by Hisschemöller & Hoppe (1995). Stakeholders approach the GM debate persistently as either a structured problem or a semi-structured problem where science will remove uncertainties and provide pragmatic solutions that will lead to a definitive outcome. Other aspects that relate to underlying values, morals and worldviews are directed to individual choices. Our argument analysis confirms the conclusion that GM crops are a wicked or unstructured problem (Termeer *et al.* 2013). A wicked problem can be defined as a dynamic problem without clear demarcation or definition which is continually redefined and reproduced, making previous solutions no longer workable while defining new problems

and questions (Rittel & Webber 1973; Batie & Schweikhardt 2009). Additional research and more data production will fuel this process.

The situation can only improve if an explicit discussion is facilitated about the value framework in which the scientific assessment has to function. If this value framework is 1) articulated and 2) endorsed and defended by political actors, science can play its role in the response to alarming studies. However, given the many different levels of disagreement about GM technology, it seems unlikely that an agreement can be found any time soon. A broader conversation about the value framework regarding agriculture and food production is needed but won't solve the issue of alarming studies because the value question of GM crops will continue to differ on an individual level.

4. DISCUSSION & CONCLUDING REMARKS

Alarming studies about the safety of GMOs have reignited national and international debates because they constitute a public (Warner 2002) that's overflowing with issues that cannot play a formal role in the current decision making process for GM crops. Scientists, risk assessors, companies, NGOs, citizens, politicians and policymakers compete for attention in a wide variety of arguments expressed in scientific papers, statements, news reports, blogs and comments.

The dynamics and characteristics of these debates on the safety of GMOs are not unique. Similar debates take place about other controversial technologies or developments that affect social values. Examples are shale gas, nuclear energy or vaccination programs. Drawing on several GMO case studies, this article presented an overview of the arguments used in these debates: specific, contextual and personal arguments. We have shown that the debate about these studies follows a similar and recurring pattern. Based on the analysis of these case studies, we believe that alarming studies will continue to reignite the GMO debate because there are different viewpoints on both the scientific process and the context of application of GMOs in agriculture.

4.1 ADDITIONAL SCIENTIFIC ASSESSMENT NO REMEDY

Our analysis has shown that the current regulation of GM crops does not (sufficiently) take into account the fact that the implementation of this technology in society is an unstructured problem. Stakeholders point at scientific uncertainties as the core of the problem and scientists are expected to remove these uncertainties. This causes a shift in political decision making

towards the scientific domain, making it part of the wider debate about GM crops. This wider debate can't be solved by science alone.

Worldwide, national and international governments evaluate the safety of GM crops. The dominant regulatory consensus is that so far there are no reasons to doubt the possibility of applying GM crops in agriculture with a negligible risk to humans and the environment. Despite the recurrence of alarming studies, to date there have been no confirmed incidents with GM crops approved for market release (Nicolia *et al*. 2014). Therefore, it seems fair to conclude that the current regulatory consensus on the risk assessment procedures is valid.

We want to emphasise the importance of continuous and critical validation of the status quo in risk assessment procedures. It is not possible to determine straight away whether the results and claims of alarming studies are valid. We are of the opinion that these studies should always be investigated from a scientific point of view. This fits the regular model of scientific developments being confirmed, refuted or corrected by additional research and building a body of evidence for a specific finding. Therefore, it is important that regulatory actors are vigilant of the risk of bias towards the validity of new research findings. To a certain extent, definitional, factual and scientific disagreements can be solved here. However, it also means that those involved will have to accept disagreement on the wider issues relating to GMOs and restrain themselves in the specific discussion about alarming studies.

4.2 ADDRESSING WIDER ISSUES OF BIOTECHNOLOGY

We emphasize that the scientific assessment is 'only' a part of the political and public debate about the desirability of GMOs. Therefore, stakeholders should be hesitant to look solely at scientific research to provide answers in the GM debate (Blankesteijn *et al*. 2014). The scientific risk assessment may deal with the safety issues, but interest-based, value, moral and worldview disagreements play an important role in the discussion about GMOs as well.

Our analysis of the debate surrounding alarming GM crop safety studies makes clear that the safety debate is fueled in a non-productive way by contextual issues. Although these studies trigger a broader debate on social and political elements of GM technology, they are unsuitable vehicles for a wider democratic debate. We believe that these issues should not be addressed in an ad hoc way in response to alarming studies, but during the normal course of research and development and as part of the ongoing debate about what kind of society we

want and what kind of technologies can contribute. The underlying discussion about food production and agriculture involves a multitude of values that go beyond GM specific arguments and these require a separate discussion. Governments can play an important role in facilitating this discussion, but they don't necessarily carry sole responsibility for the outcome. There are valid reasons for placing certain decisions regarding the production of food in the private domain, since they involve personal preferences that permanently differ between individuals, groups, religions, nationalities and cultures. As a final conclusion we want to emphasize the importance of making fundamental differences in viewpoints explicit in a wider discussion about agriculture and food production.

CHAPTER 5

GOVERNANCE STRATEGIES FOR RESPONDING TO ALARMING STUDIES ON THE SAFETY OF GM CROPS

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1. INTRODUCTION

Alarming studies initially highlight a specific technological risk that is possibly being disregarded in the existing governance system. Governments therefore usually address the issue as a structured and case-specific scientific problem. Secondly however, these studies trigger a broader debate on the social and political elements of the technological debate. These issues cannot be addressed in the context of a response to the alarming study. In this paper we analyse government responses to cases of alarming studies to underpin our claim that alarming studies are unsuitable vehicles for a wider democratic debate about technology. We identify a series of recommendations on how to respond to alarming studies within the current governance structure, while our main and overarching point is that that other platforms are needed to enable conversations about responsible innovation.

The dynamics of the debate ignited by alarming studies are not technology specific; there are strong similarities in the debate around different controversial technologies such as shale gas, nuclear energy, genetically modified (GM) crops or vaccination programmes. In this paper, we will use GM crops as our main subject.

The use of genetic modification in agricultural applications has been subject to strict safety regulation for a long time. These regulations originate from the scientific consensus that genetically modified (GM) crops could potentially present risks to humans and the environment. The European regulations therefore focus on safety aspects, whereas other aspects (such as principal, ethical or socio-economic aspects) are considered an individual or market choice and are therefore secured by European labelling regulations for GM food and feed.[1] It should be noted that this article is written from within continental Europe and our analysis conclusions will therefore be more relevant in this context than outside of Europe.

Companies, universities and research institutes look into the potential risks and short- and long-term effects of GMOs on humans and the environment (Nicolia *et al*. 2014). The result of this research, whether published in scientific literature or not, forms the basis for the safety assessments by licensing authorities. Market approvals for GM crops are subject to an extensive

1 Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

environmental and food safety risk assessment before being approved or denied for commercial release (European Commission 2001, 2003). After market approval, monitoring is implemented as an additional safety net to identify any indirect or unexpected adverse effects on the environment. The dominant consensus in the biotech sector and regulatory community is that the current risk assessment practice is adequate (or even too strict) and thus that GM crops that are approved for market release are safe. Among scientists, the nature and status of this consensus are recurrent topics of discussion (e.g. Hilbeck *et al*. (2015)). To date there have been no incidents confirmed by governments or competent authorities in which GM crops approved for market release have caused direct harm to the environment or human health (Nicolia *et al*. 2014). This consensus is extended and reconfirmed by enlarging the body of evidence about the safety of GM crops through ongoing research.

1.1 ALARMING STUDIES REIGNITE DISCUSSION

Although the vast majority of research indicates that no significant adverse effects can be expected from the use of GM crops approved for commercial release, studies concluding that certain (approved) GMOs do cause harm to human and animal health or the environment do crop up occasionally. We propose to call those 'alarming studies' because they alarm other scientists, risk assessors, governments, companies and the broader public of unknown risks that are possibly being disregarded in the existing system. Although these (scientific) publications seem to be directed at the scientific community, they are characterised by the fact that they address a broader public (and set of issues). This public evolves around the topic of GMOs but actively comes into 'existence' when an alarming study is published. The concatenation of texts on this subject over time has created a public (and counterpublic) with a specific discourse that is addressed by alarming studies (see also Warner (2002). Alarming studies provoke fierce debates and can lead to considerable disquiet and anxiety. More importantly, the debates are open-ended because those involved ultimately cannot agree on the significance of these studies or the consequences that should be attached to them.

Governments have a duty to safeguard human and environmental safety, which means that society expects them to respond to reports that one of these is at risk. In other words: governments must respond in one way or another to alarming studies. This is usually done by a reassessment of the study by scientific advisory bodies. However, the acceptance of the outcome of the assessment is severely hampered by the fact that the appearance of

an alarming study will also reignite a broader discussion about the value of GM technology. Disagreements about these aspects will not and cannot be solved by reassessing an alarming study. Thus, underlying questions remain unanswered and the answers provided are not acknowledged, resulting in frustration for all stakeholders involved. As a result, the status quo in the GM debate seems to get worse.

1.2 BIOTECHNOLOGY DEBATE CHARACTERISED BY MULTI-LEVEL DISAGREEMENTS

Despite the dominant consensus, not everyone agrees with the current governance structure for GM crops. The debate about the implementation of GM crop technology in society is characterised by multi-level disagreements about definitional, factual, scientific, interest-based, value-based, moral and metaphysical aspects (Bovenkerk 2012). Definitional, factual and scientific disagreements have been classified to be merely attributed to science, whereas interest-based, value, moral and worldview disagreements belong to the realm of politics[2]. In practice however, these elements are strongly intertwined in discussions about GM technology. We would like to add, perhaps redundantly, that scientific disagreements are usually not solely about facts and political disagreements don't strictly originate from values. The roots of these multi-level disagreements are based on differences in views on science, society, nature and food production. This has been illustrated amongst others by a report of the Netherlands Commission on Genetic Modification (COGEM 2013). The report illustrates that there is no general agreement about the facts or about the values regarding GM. Neither is there agreement about the goal this technology could serve or about the means that should be used otherwise to reach this goal.

For the purpose of this article, we integrate the broader means / ends separation with a commonly used distinction between four types of problems. It is based on agreement about the facts and values (structured problem), agreement about one of them (moderately structured problem – either technical or merely

2 When referring to politics in this paper, we address both the socio-political debate in the public realm on the impact of GM-technology as well as the regulatory-political debate related to the governance of GM-technology. Based on the description of Jeremy Waldron ('that the felt need among members of a certain group for a common framework or decision or course of action on some matter, even in the face of disagreement about what that framework, or decision or course of action should be, are the circumstances of politics'(Waldron 1999) and Chantal Mouffe ('to envisage politics as a form of 'agonistic pluralism' in order to stress that in modern democratic politics, the crucial problem is how to transform antagonism into agnonism' (Mouffe 2000), we are of the opinion that the 'regulatory-political debate' cannot be untangled from the 'public socio-political debate' that takes place outside of the regulatory framework. Wherever we refer to one of those in particular, this will be made explicit in the text.

political – and agreement about neither (unstructured problem) (Hisschemöller 1993). Furthermore, depending on the type of problem, different solutions are proposed to best fit the characteristics of the dispute (Hisschemöller & Hoppe 1995) (**Table 1**).

The rhetoric of the debate about GM crops should be understood as an unstructured problem *(*Mampuys & Brom 2015a*)*. From a European perspective, we will show that stakeholders persistently keep approaching the problem as either a structured problem or a moderately structured problem in which scientific experts or expert committees will remove uncertainties and provide pragmatic solutions that will lead to a definitive outcome. The reigniting discussion after the publication of so-called 'alarming studies' about the safety of GM crops proves over and over that this is not the case.

We think that further polarisation and escalation of the debate have to be prevented in order to give future discussions about the value of GM technology a chance. Therefore, we investigate potential improvements in responding to alarming studies from a governance perspective. In this article we look into the

Table 1: Characterisation of problems based on scientific and normative consensus Adapted from: (Hisschemöller & Hoppe 1995) and (Bovenkerk 2012).

		VALUES	
		CONSENSUS	NO CONSENSUS
FACTS	CONSENSUS	Structured problem Agreement about means & ends Experts or bureaucrats	Moderately structured problem Disagreement about ends (agreement about solution) Consensus conferences
	NO CONSENSUS	Moderately structured problem Disagreement about means (agreement about problem) Expert committees	Unstructured problem Disagreement about means & ends learning strategy / public debate

options for action (such as monitoring, initial response, adopting measures, selecting experts/advisory bodies, national and international alignment, follow-up actions and communication) open to governments and advisory bodies in response to the appearance of an alarming study. The options each have their own benefits, risks and pitfalls, from which lessons and pointers can be drawn. These are looked at in more detail and recommendations are made on how to respond to alarming studies with a focus on doing justice to both the facts and the values that play a role in the debate and the role of political decision-makers vis-á-vis the societal political debate. With these recommendations, we aim to at least restrain the widening gap between the different frames of facts and values about GM technology.

2. ALARMING STUDIES

We propose to use the term 'alarming study' for a scientific or other study, the results of which may or may not have been published in a peer-reviewed journal, from which it can be concluded that a technological innovation (such as a GM crop) poses a threat to human and/or animal health and the environment. The term 'alarming study' refers only to the claim made and does not say anything about the veracity or otherwise of the study.

Alarming studies have been appearing since the first GM crops were authorised for placing on the market. We concluded before that the GM debate should be understood as an unstructured problem, leaving discussions about the value and position of alarming studies open-ended. Consequently, the names of these studies recur and accumulate in the debate whenever new 'alarming studies' make the news. In terms of Warner (2002), these studies address both a scientific and regulatory public as well as a broader (counter)public consisting of other stakeholders such as companies, NGOs, citizens and consumers. Alarming studies are therefore one of the most important triggers to reignite the GM debate and that is why we analyse them to assess the effect of governance response strategies on the GM debate. A key example of an alarming study is a paper by a French scientist about the health effects of the consumption of GM maize (**Text box 1**).

Other examples of alarming studies that we analysed for the purpose of this article are Ewen & Pusztai (1999), Rosi-Marshall *et al*. (2007), Huber (2011) and Carman *et al*. (2013) (**Table 2**).

Box 1. Example of an alarming study

In September 2012 the Journal Food and Chemical Toxicology published the results of a study by Séralini *et al.* (2012) in which rats were fed GM maize and various concentrations of a glyphosate containing herbicide for a period of two years. Séralini and his team concluded that the rats fed with the GM maize and herbicide developed more and more serious tumours than the control group, and they developed the tumours earlier in their lives. Because the GM maize variety used in this research has been on the market for several years, the publication led to an international debate and several national authorities and scientific advisory bodies looked into the results to see if there was a need to revise their opinion that this GM maize was safe for consumption. They concluded that the study contained methodological shortcomings and that the conclusions could not be justified. Although the study was dismissed as being unsound and incorrect by advisory bodies and the European Food Safety Authority (EFSA (2012b)), several NGOs and scientists disagreed and the debate in Europe continued. Eventually, the Séralini paper was retracted by the editor and later it was republished in another journal (RetractionWatch 2014). Despite the discussion and formal outcome, this study is moreover referred to as proof that the consumption of herbicide-tolerant GM maize causes cancer and other adverse effects (GMOSeralini 2014b).

The discussion following the publication of an alarming study appears to have a repetitive character that can roughly be described as follows: the author(s) and opponents of GMOs point to the alarming publication as proof that GM crops pose a risk and some argue that measures should be taken (immediately). Governments usually respond in a procedural manner by referring the study to their scientific advisory bodies. These assess the publication according to the agreed research protocols and methods based on EU and international regulations and come to the conclusion – so far – that the research does not pass the test of scientific credibility and that there is no reason to revoke or postpone authorisations for GM crops:

> *Taking into consideration Member States' assessments and the authors' answer to critics, EFSA finds that the study as reported by Séralini et al. is of insufficient scientific quality for safety assessments. EFSA concludes that the currently available evidence does not impact on the ongoing re-evaluation of glyphosate and does not call for the reopening of the safety evaluations of maize NK603 and its related stacks.*
> EFSA statement on final review of Séralini *et al.* (EFSA 2012c).

Table 2: Examples of alarming studies.

Author	Alarming effect claimed
Ewen and Pusztai (1999)	Rats fed GM potatoes show abnormalities digestive tract
Rosi-Marshall *et al.* (2007)	Harmful effects of GM maize in aquatic insects
Huber (2011)	New pathogen from GM crops
Séralini *et al.* (2012)	Rats fed GM crops develop cancer
Carman *et al.* (2013)	Pigs fed GM feed show harmful effects

> *Overall, the data presented in the paper are not convincing of adverse effects due to the GM diet and provide no grounds for revising FSANZ's conclusions about the safety of previously approved glyphosate-tolerant and insect-protected GM corn lines and glyphosate-tolerant GM soy lines.*
> Australia New Zealand Food Standards' response to a feeding study in pigs by Carman *et al*. (FSANZ 2013).

For the government and those in the scientific community who endorse the current risk assessment frame, this appears to be the end of the matter. However, those who are of the opinion that the results are (another) reason to ban GM crops are disregarded and they continue to pursue the debate with undiminished vigour. Characteristic for this discussion on GMOs is the broadening of the debate to wider issues like the safety of GM crops in general, distrust in biotech companies, the power of multinationals over global food production and the desirability of current practice in agriculture (Marris 2001). Implicitly and explicitly, multi-level disagreements come to the surface. Some examples of arguments in this debate are:[3]

> *With regard to biodiversity, there have been too few long term, properly controlled studies of the effects of GM crops to make much comment.*
> Rosi-Marshall case (Fitzsimons 2009).

> *Séralini's findings revealed that industry and regulatory claims of biological irrelevance of effects found in 90-day tests are invalid. They showed further that the regulatory system for GM foods is inadequate and cast into question the safety of all commercialized GM foods.*
> Séralini case (Robinson 2013).

3 A systematic overview of the arguments used in the debate can be found in a report of the Netherlands Commission on Genetic Modification: COGEM report CGM/131031-01.

> *This is highly sensitive information that could result in a collapse of US soy and corn export markets and significant disruption of domestic food and feed supplies. On the other hand, this new organism may already be responsible for significant harm.*
> Huber case (Huber 2011).

> *There are a lot of things that are wrong with GMOs, but not on a biological level. Rather, it's the question of intellectual property and patent laws that are a huge disadvantage to small farmers.*
> Carman case (Gorski 2013).

> *There is a real problem for us here, and that is that you say that it is not right to discuss unpublished work; as I understand, all of the evidence taken by the advisory committee in that report comes from the commercial companies, all of that is unpublished.*
> Ewen and Pusztai case (Williams (1999).

Similar (underlying) arguments are described by Sarewitz (2004) with regard to a 'vicious' debate that unfolded after the publication of Quist and Chapela (2001) about the introgression of transgenic DNA into traditional maize events in Mexico. This case could also be considered an alarming study. Under current policies, the debate on the authorisation of GM crops concentrates on demonstrating their safety. Although the existence of uncertainties in the environmental risk assessment is acknowledged, governments urge scientists and advisory bodies to come up with answers that can dispel these uncertainties (Van Asselt and Vos 2010, Wardekker *et al*. 2008). A standard model is that if uncertainties are removed, the correct course of action will be apparent (Sarewitz 2004). This suggests that governments assume that uncertainties about risks lie at the heart of the public debate on GM crops (Marris 2001), and it hopes that removing these uncertainties will settle the debate. Two issues can be identified in this approach.

Firstly, it disregards the diversity in scientific disciplines resulting in different and sometimes competing views on science and nature, as also demonstrated by Sarewitz (2004). According to Sarewitz, these differences reflect the *"richness of nature, and the consequent incapacity of science (...) to develop a coherent, unified picture of "the environment" that all can agree on".* He concludes that *"uncertainty is in part a manifestation of the disunity of science and the plurality of institutional and political players (...) involved in the conduct and interpretation of scientific research"*

(Sarewitz 2004). Therefore, even ruling out conflicts of interest and ideological commitments to look at *"what the science is really telling us" can be a meaningless exercise"* (Sarewitz 2004).

Secondly, governments limit their role to ensuring public health, environmental safety and freedom of choice (e.g. labelling in the EU). This means that they hardly take non-safety issues into account in decision-making on GMOs, whereas the sentiment is largely concerned with just these issues. This changes the focus of the safety aspect, because scientific research and risk assessment themselves become the subjects of a critical political discussion in which broader arguments are intertwined with safety issues.

Given the recurring debate about GM crops, it seems that the current (risk) assessment framework and governance structure is controversial because it does not take into account broader issues that relate to environmental concerns and food production. We think that other platforms are needed to enable conversations about responsible innovation. However, a definitive solution that will settle all levels of disagreement does not seem close on the short term, if possible at all. Meanwhile, some practical solution has to be found within the current governance frameworks. Therefore, we identify a series of recommendations on how to respond to alarming studies within the current realm of technical debate about alarming studies.

3. GOVERNANCE OPTIONS

Within the force field of different arguments that are put forward in response to an alarming study, national governments are looked at for a solution. Given their responsibility towards those who rely on the existing framework such as consumers, but also companies, researchers and investors, governments have to respond to alarming studies the best they can. This is a challenge, because those involved have different ideas about the knowledge and actions necessary to solve the problem (Sarewitz 2004, Wynne 1989). Experiences from cases of alarming studies from the past can throw light on the effect of various options open to government and advisory bodies as a learning opportunity for the future. The government's response will depend on various factors, such as the status of the research, the nature and intensity of the debate and the stage it is in.

In this article, we distinguish four phases (I – IV) in which the government and advisory bodies have an opportunity to make choices: preparation (monitoring),

first response (timing and opening gambit), obtaining advice (gather expertise and data) and finally the phase of response (communication and follow-up actions) (**Table 3**). For each phase, we will discuss the possible consequences of government actions and we will identify pointers and pitfalls.

3.1 MONITORING (I)

Preparing for discussions about alarming studies is usually done by means of monitoring via civil servants, assessment agencies and advisory bodies. Through their work and (inter)national networks they are naturally informed of new developments and ongoing research. By monitoring scientific developments, governments can avoid being confronted unexpectedly with an alarming study making the news and they will be able to respond rapidly. Monitoring can also support a learning process on recognising emerging discussions. A possible pitfall for agencies interpreting monitoring results is that results that go against the dominant scientific consensus are not picked up as quickly after repeated false claims (by the same author). This makes it important to remain open to new developments and unconventional research methods. Another possibility is that researchers themselves inform governments about 'alarming' results at an early stage. Regardless the veracity of alarming results, the course of the debate and monitoring thereof can also influence the decision and timing for a response from the government.

3.2 TIMING AND OPENING GAMBIT (II)

After publication of an alarming study, governments have to decide about their (initial) response to the event. First, relevant questions have to be answered such as: What is the status of the publication and are immediate measures, such as a moratorium, justified? Answering these questions is difficult, especially

Table 3: Governance of alarming studies: phases & questions

Phase		Policy questions
I	**Preparation:** *Monitoring*	Monitor scientific developments? Monitor societal debate?
II	**First response:** *Timing & opening gambit*	Respond or ignore? Moratorium or other measures?
III	**Obtain advice:** *Expertise & data*	Choice of advisory bodies? Coordination with European advisory bodies?
IV	**Response:** *Communication & follow-up actions*	Attune communication to stakeholders? Follow-up actions: further research?

when there are uncertainties about the scientific value of the publication. Ignoring an alarming study or responding too late can lead to suspicion and dissatisfaction with the conduct of government, but an ad hoc response from governments invoking precautionary measures will give the impression that the situation must be serious, which can also lead to a (possibly unjustified) escalation of concern.

3.2.1 INITIAL RESPONSE

Alarming studies can lead to national or international debates about the safety of GMOs, and in most cases it is not possible to determine straight away whether the results and claims in such studies are valid, regardless whether the study is published in a peer reviewed journal or not (**Text box 2**).

In the already polarised debate about GMOs, alarming studies are very likely to make the news. With the chances of considerable media attention, the EFSA decided to respond instantly to the publication of the Séralini paper (EFSA 2012a). In a statement, EFSA acknowledged the existence of the study and announced an assessment of the paper's relevance. The fast response demonstrated an effective monitoring of scientific developments. On the other hand, to those who are less familiar with the regulatory framework it can also invoke questions about the working methods and function of the organisation such as: are there GMOs in our food and are they safe? Is this the first time that EFSA looks into the safety of this maize?

Box 2. Peer review as a criterion for assessment.

Several alarming studies have put forward the question whether the government should respond to peer-reviewed studies only or to unpublished but alarming research results as well. Peer review is considered by both proponents and opponents of specific studies to be a hallmark of good research, but they draw different conclusions: proponents say the research was good, whereas opponents say the peer review process was flawed. Both the value and limitations of peer review have been profoundly discussed in literature (Bohannon 2013, Jennings 2006, Nature 2006, The Economist 2013). In addition, it should be noted that applications for marketing authorisation of GM crops can also contain unpublished and non-peer-reviewed information. Although these studies undergo a type of review in the form of appraisals by competent authorities and advisory bodies this could become a pitfall that makes the government come across as biased. Peer-review seems therefore not a decisive argument whether or not to further investigate an alarming study.

Governments and governmental bodies usually limit their role to ensuring certain requirements are met, such as safety standards and (specifically for Europe) freedom of choice with regard to food products by means of labelling. The underlying objectives and methods for decisions about these issues are often implicit or largely unknown to the public. This goes in particular for choices that have been made before alarming studies gather media attention, such as the regulatory approval of GM crops. If people are not aware of the existence of safety regulations for the commercialisation of GM crops, the acknowledging statement mentioned above may not have the contemplated effect. The decision making process of GM crops in Europe has moreover been deemed indistinct and complicated by scientists, companies and (non-EU) regulators / policymakers (Dunwell 2014, Masip *et al*. 2013). Besides a lack of transparency, these complexities have led to several problems in international trade (Meester, Berkhout and Dries 2013). This likely makes it even more difficult for people to get a grasp on who decides when about GM crops and based on what kind of data and considerations.

Studies about consumer attitudes to GM food support the idea that providing clear and convincing information about managing the risks of a technology is more effective than promoting the benefits (and thereby ignoring concern about potential risks) (Durant & Legge Jr 2006, Hess *et al*. 2013). The availability of transparent and understandable information about procedures and regulations could therefore be helpful to answer relevant basic questions the moment an alarming study hits the news. Obviously, the more complex or political procedures are, the more difficult it will be to translate this information outside a group of experts involved in the regulatory framework itself.

3.2.2 MORATORIUM

Based on the results of an alarming study, governments have to decide whether or not immediate (precautionary) measures should be taken, such as a moratorium on the import and/or cultivation of a GM crop or even retrieving products from the supermarket shelves. Changing existing procedures or declaring a moratorium are only possible if there is a justifiable ground for concern regarding human or environmental safety. However, in the early stages of a study that goes against the dominant regulatory consensus, there are usually several uncertainties about the seriousness of the situation. Given the body of evidence about the safety of GMOs that have been approved for market release, a single alarming study or publication will seldom provide

indisputable evidence of an acute risk that justifies immediate action. Additionally, a moratorium can have far-reaching consequences for political relations and commerce. For these reasons, the various interests at stake and the risks involved have to be carefully considered before taking restricting measures.

However, it should be noted that in risk perception, the seriousness of the effect is often considered of greater importance than its probability. While this can be a sign of 'irrationality' ('probability neglect' (Sustein 2005)), it may be morally justified. For example in the case of a catastrophic risk such as a nuclear meltdown, the consequences can be enormous, even though the chance of occurrence is low. This can justify that people find it an unacceptable risk (Roeser 2002); also given that risk estimates involve uncertainties (Hansson 2004, Slovic 2000). Feelings of concern regarding food safety can incur emotions that are likely to be magnified by media releases with shocking images, such as photos of rats with enormous tumours as an acclaimed result of GM food consumption (photos from the Séralini *et al*. (2012) paper were moreover reproduced in news articles e.g. Castillo (2012)). Emphasising the safety of a GM crop and pointing towards the existing safety assessments for market approval are unlikely to contribute to the acknowledgement of these emotions.

Besides national or European measures such as a moratorium, there are other ways to enable people to act according to feelings of concern in relation to GMOs. In the EU, GM labelling in food provides a means for people to choose whether to consume GMOs. The effectiveness of these measures lies in the availability of transparent and understandable information about regulations such as those for labelling and traceability (Section 3.2.1).

3.3 EXPERTISE AND DATA (III)

In most cases, the government will only be able to make a decision about any measures to be taken after establishing with sufficient certainty if the study justifies these actions. In the current assessment framework of GM crops, this is usually done by having the study reviewed by scientific advisory bodies.

3.3.1 CHOICE OF ADVISORY BODIES

Various (inter)national advisory bodies are appointed to assess the environmental and food safety aspects of GMOs and provide advice to their

government. Therefore, it seems evident to ask them for a reassessment. However, asking the same bodies that have assessed the GM crop in the first place for advice on an alarming study about that same crop can incur resistance because of the possibility of bias or prejudice (GMWatch 2012a). This is one of the reasons why the Belgian Biosafety Council chose to install an ad hoc advisory committee to examine the Séralini study (Belgian Biosafety Advisory Council 2012). The decision to either lay down the request with the appointed advisory body or install an ad hoc committee each has its own advantages and disadvantages.

Appointed advisory bodies have relevant expertise and experience and the resources to respond rapidly. Additionally, their visibility and 'raison d'être' are enhanced in the process. However, the provision of advice by the established advisory bodies also has pitfalls. The ability to remain sensitive and alert to new research methods and or results may be constrained, because established bodies usually work with specific research protocols and methods, based on EU and international regulations. Moreover, in the interests of consistency and reliability, professional organisations may be reluctant to retract earlier advice, given that their reputation and credibility is an important factor in how their advice is regarded. Scientific knowledge is subject to change, whereas a certain degree of consistency is also important in risk assessment and evaluation. Constantly changing the risk assessment can lead to a loss of confidence among companies (legal certainty) and other stakeholders, whereas waiting too long to make changes can also damage confidence. Furthermore, when advisory bodies become (or are seen to be) part of the established system that represents a dominant but disputed paradigm, their advice may not provide useful input, and may even exacerbate the controversy (GM-FreeCymru 2012, GMWatch 2012b).

Obtaining advice from a different or ad hoc advisory body can provide a fresh perspective and may be more easily accepted. However, by establishing an ad hoc committee the government also risks putting the value of the acknowledged advisory bodies in doubt. It could even disqualify them in the eye of the public. Furthermore, putting together an ad hoc committee is time-consuming and there is a risk that the government will be accused of cherry picking from the pool of available expertise to influence the outcome. The decision to consult an established advisory body or an ad hoc advisory body is namely a political one.

3.3.2 COORDINATION WITH NATIONAL AND EUROPEAN ADVISORY BODIES

Where food and environmental issues surrounding GMOs have international ramifications it is customary to consult with other (inter)national advisory bodies about the quality and availability of the research data (**Text box 3**) and the validity of the conclusions (EFSA 2012c, NVWA 2012).

The advantage of (international) consultation is that use can be made of a wide variety of available expertise. If it is possible to come to a common position, coordination has the potential to achieve international agreement, which can in turn increase acceptance and support for the outcome.

A risk of (international) coordination is that the agreements made will look like consensus while they are in fact a compromise. Given the different positions within Europe about the authorisation of GM crops, some points will be subject to negotiation: the evaluation and measures proposed may be too cautious for some and too rigorous for others. Presenting compromises in a consensus document can be conceived as a selective form of transparency in which minority opinions are not visible. Furthermore, there is a risk of tunnel vision among those in agreement. A risk of limiting consultations to national coordination is that the final outcome may not be in agreement with international (EU) policy or that different outcomes fuel the GM debate leading to further polarisation.

Box 3. Availability of research data as a criterion for assessment.

The availability of (raw) research data of alarming studies as well as safety assessment data from biotechnology companies is a recurring topic in the GMO discussion. While we will not elaborate on this point in detail here, we want to point at the limitations of the persuasive power of data. Interpreting third-party raw data is difficult and time-consuming and if, after all the hold-ups and delays to provide this data, this does not lead to a definitive judgement about an alarming study, stakeholders may not be forgiving (given the sense of urgency and concern). Furthermore, the data debate suggests that providing missing information will lead to a final solution and that there is a single truth waiting to be uncovered. It should be noted that the disagreement about GMOs is not solely about the data itself but merely about the interpretation and relevance of these data (and who provides it).

To the broader public, international coordination can be seen as an obscure process, making it easy for critics to dismiss it as a conspiracy or orchestrated response (GM-FreeCymru 2012). In addition, it may increase a defensive position of the authors of the paper and decrease the possibility to have an open and fruitful discussion. The integrity and authority of the negotiators is therefore of importance during international coordination. As borders fade, international orientation and coordination is often essential (or even obligatory within the EU), but it does not relieve national governments of the duty to explicitly form their own judgement.

3.4 COMMUNICATION AND FOLLOW-UP ACTIONS (IV)

Once the assessments by scientific advisory bodies are carried out, governments have to decide on the value of the alarming study and any consequences that should be attached to it. Sometimes, politics invoke scientific uncertainties as a reason to justify taking or not taking action in relation to controversial technologies when in fact underlying issues or values play a role (Sarewitz 2004). A recent article by Holbrook and Briggle (2014) also elaborates on the complicated relation between knowledge and action. Amongst others, they underline the importance of addressing or even confronting the underlying values as an essential part of responsible innovation and decision-making. This puts up the question whether and which other arguments apart from science the government should consider and what channels they should use to communicate their view on an alarming study.

3.4.1 COMMUNICATING ABOUT THE ASSESSMENT OF ALARMING STUDIES

In the first instance, alarming studies about the safety of GMOs have a bearing on safety policy. Governments respond by asking their advisory bodies to investigate whether the results of the study are accurate and valid. After a scientific assessment, they will have to make a statement why they will or will not take measures.

These statements usually reconfirm the dominant consensus about the safety of GM crops approved for market release. So far, it was concluded that there is no reason to revoke or postpone authorisations for GM crops based on the results of the alarming study. On the one hand, this response addresses the primary question about the initial trigger for the discussion: the alarming study. On the other hand, it does not clarify which arguments are considered in the formal decision-making on GMOs (e.g. biosafety) and which are not (wider issues) and why. Usually, communication is limited to pointing out the

relevant procedures ('we have asked our advisory bodies to assess or reconsider the study') and issuing a press release on the findings of these advisory bodies. While this is relevant and important, it all too easily comes across as 'these are the facts and you'll have to accept them' (Te Molder 2011). It remains unclear why other arguments, for example in a broader debate on agriculture and food production, are not taken into account.

Contextual arguments regarding GMOs are part of the political debate about the type of society we want and the technologies we need to get there. They concern topics such as sustainability, biodiversity and naturalness, but also monopolisation of the food chain and the power of biotechnology companies. These arguments frustrate the dialogue because a solution to these wider problems cannot be found within the specific situation of an alarming study. Ad hoc situations, such as the appearance of an alarming study, are therefore by definition unsuitable vehicles for these arguments and discussions. Nevertheless, political arguments are out of necessity triggered by the appearance of alarming studies because they cannot be addressed elsewhere. Platforms that enable conversations about responsible innovation are urgently needed and the government can reinforce its position as a public's source of information by establishing a platform where political arguments regarding GMOs can be aired. However, the responsibility to establish these platforms is not confined to the government. There are different options for the form this platform could take, such as forums, 'thinking laboratories' (a cross between closed expert committees and open public debates) (Ruivenkamp and Jongerden 2010) or a broader (inter)national debate on food production in general. We emphasise that addressing wider issues involves more than setting up a discussion forum; it also obligates those involved, including government, to take the outcome serious and act on the results. Moreover, contextual arguments and wider issues are in fact a political discussion in which the role of public policy including regulation is at stake.

3.4.2 FOLLOW-UP ACTIONS

Alarming studies present new results that go against the dominant consensus on the safety of GMOs. The usual response to contradictory results is to establish whether they can be confirmed or refuted by existing studies or by conducting further experiments. However, if the experimental design and method differ from standard tests and broadly recognised research protocols, it proves difficult to find studies to compare results with (DeFrancesco 2013). Moreover, when the majority of scientists in the field consider a study to

be methodologically flawed or incorrect, repeat studies will always lead to further discussion. Furthermore, from a scientific point of view a biased or methodologically dubious safety study (accidentally or on purpose) should not be an incentive to conduct further research with public sector funding (**Text box 4**). In such cases, the responsibility should lie with the researchers themselves to improve and rectify their study. This can be problematic because it is not always unequivocally clear whether a study is scientifically sound or not or whether the findings are unreliable due to misconduct or honest error (Hayes 2013).

Undertaking further research confirms that the issue is taken seriously and it can bring an element of calm to the debate, at least temporarily. On the other hand, commissioning further research may also cause a public stir, because then there is 'apparently' reason for concern. Referring to existing and repeatedly confirmed research results is faster and can emphasise the existing body of evidence. However, because comparative research results are not abundant, there is a risk that the government and advisory bodies will be accused of cherry picking the results that suit them. It should be noted that study designs for complex research such as feeding trials differ to varying degrees. This will easily ignite another discussion about methods, execution and results.

If repeat or follow-up research is being undertaken, stakeholders will probably try to influence the design of the additional studies and the composition of the research team. More importantly, they may withdraw support during the process if they disagree with the chosen approach. These situations already occurred with follow-up research of the findings of Séralini *et al*. (2012), initiated

Box 4. Time & funding as a criterion for follow-up research

Government funding for replicating a study branded by the scientific community as being methodologically weak can meet with incomprehension and resistance from the scientific field. Furthermore, counter-research into safety studies of GMOs found to be safe for placing on the market is not interesting for most researchers because of the high costs and limited publication potential. Additionally, it can be regarded as a waste of time, money and experimental animals. The compulsory post-market monitoring of GM crops should be sufficient to bring to light any unanticipated adverse effects following marketing authorisation. Furthermore, commercial activities may be put on the backburner as a precaution when follow-up research is initiated.

by the French government (GMOSeralini 2014a) and the EU GRACE project.[4] If involvement of important stakeholders is lost, support for the final outcome of the research will also crumble. Given the polarised discussion about GMOs, there is a significant chance that when the results of additional research are published, the debate will reignite and escalate all over, whatever the results (Bauer-Panskus and Then 2014, Schiemann 2014). Points to consider when referring to already existing research results include identifying clear criteria or a quality model for selecting alternative studies to refute or confirm the alarming study. Things that require careful attention when commissioning further research include the choice of researchers and the transparency of the decision-making process.

There seems to be no 'right choice' in conducting additional research or not. If no repeat studies are carried out and no comparable results can be found, the study will remain unique and, despite the criticisms, references to the results will remain. It may therefore be advisable to repeat studies to overcome the limitations of the previous one. Although this will not solve the issue indefinitely, the potential for scientific improvement remains open and communication between stakeholders is encouraged.[5]

4. DISCUSSION & CONCLUDING REMARKS

The lack of and focus on consensus about the significance and consequences of alarming studies makes these events important catalysts in the recurring debate about GMOs. They reignite a broader discussion about GMOs where conflicts of interest, quality of scientific research, government responsibility, transparency of safety research, influence of biotechnology firms and monopolisation of farming practices play an important role. There are multi-level disagreements about the value and contribution of GM technology to food production.

With the analysis of government responses to alarming studies, we have shown that the scientific assessment is part of the regulatory and socio-political debate about the safety or desirability of GMOs but it does not cover all its aspects. We consider it important to emphasize that scientific research on the safety of GMOs including follow-up studies will never produce indisputable proof. In this context, we would like to acknowledge two authors who have paraphrased the role of science in an excellent way. According to Oreskes (2004), science

4 www.grace-fp7.eu/en/home

5 http://www.grace-fp7.eu/en/content/open-scientific-forum-public-debate-90-day-feeding-study-mon810-maize

can at best produce *"a robust consensus based on a process of inquiry that allows for continued scrutiny, re-examination and revision".* Sarewitz (2006) describes science as an excess production of objectivity: "S*cience seeks to come to grips with the richness and complexity of nature through numerous disciplinary approaches, each of which gives factual, yet always incomplete, views of reality*". It is ultimately up to politicians to decide at what point science provides a sufficient basis to make a decision and to accept responsibility for this (Sarewitz 2004).

In practice, the formal process determining decision-making about GM crops strongly focusses on depoliticising the issue at hand and treating it as a technical 'scientific' or structured 'factual' problem. There is an extensive framework for the (risk) assessment of GMOs in Europe, but it seems that despite broad agreement amongst part of the stakeholders, others disagree with this governance structure. The recurrence of alarming studies and current response strategies of EU governments leads to further polarisation and hardening of the GM debate.

From the recurrence of alarming studies, it becomes clear that the current framework is controversial, but a quick fix for the complex problem of GM technology is not nearby. Given the complexity and duration of the GMO debate, it seems clear that there is no ideal recipe or roadmap on how to handle alarming studies about the safety of GM crops. Therefore, solutions have to be found within the existing framework and governance structure. To restrain and limit the widening gap of the facts & values discussion about GM crops, governments should improve their response strategies. This article discusses the various options for governments and advisory bodies in responding to alarming studies about the safety of GMOs. Based on an analyses of the dynamics of past debates, lessons, pointers, risks and pitfalls are identified that can help the government prepare for and anticipate future situations (**Tables 4- 6**).

Our first conclusion is that alarming studies about the safety of GMOs will always make the news because the GM debate has never settled due to multi-level disagreements about facts and values. Scientific and political disagreements both play a role amongst the public, including the regulatory framework and among scientists themselves. To prevent unexpected confrontations with alarming studies, governments should monitor the developments in scientific research by means of their network of civil servants, assessment agencies and advisory bodies. Providing insight into the rules and regulations regarding

safety of GMOs after an alarming study hits the news, will not be embraced easily or even be regarded with suspicion. Therefore, it is important that transparent and understandable information about both the scientific and political procedures regarding decision making of GMOs is already available. This kind of continuous transparency and disclosure gives structure to the debate and provides a better background to understand the actions taken or not taken as a consequence of an alarming study.

Secondly, because it is not possible to determine straight away whether the results and claims in alarming studies are valid or not, their credibility and validity will always have to be investigated. An instant response or statement that the government is aware of the situation and visualisation of their priorities in responding to the alarming study can contribute to transparency and trust. Additionally, governments could redirect questions to existing information sources about food & environmental safety of GMOs and the decision-making process.

Table 4: Governance of alarming studies: preparation

Phase		Lessons & pointers
I	Preparation	• Monitor scientific developments • Remain alert and open to new or even unconventional research • Ensure access to information about decision-making GMOs

Given the polarised discussion on GMOs and the strong pro-/contra atmosphere, advisory bodies must beware of rigid thinking and tunnel vision and keep an open mind towards new or unconventional research methods and results. Governments should be aware of both a potential bias of conventional advisory bodies as well as the risk of disqualifying them by installing an ad hoc commission by establishing criteria for a second opinion in addition to the advice from the formally responsible bodies. This should make sure that the second opinion adds to the credibility of the system instead of discrediting it. In addition, advisory bodies and governments should be aware of the effect of international alignment on the escalation and polarisation of the debate.

Third, a (re)assessment by scientific bodies of the study or the GMOs concerned is not sufficient to bring the debate to a satisfactory closure. In the process, we claim it would be advisable to make a distinction between the information

and communication needs of the different stakeholders, which will help the government and advisory bodies to devise appropriate communication strategies for different stakeholders. This also means the public sector must have in-house expertise on science and science communication to ensure that it can meet the information needs of the various stakeholders. Furthermore, communication should not start when an alarming study is published, but beforehand. That is part of what responsible innovation entails in our opinion.

Table 5: Governance of alarming studies: response and advisory requests.

Phase		Lessons & pointers
II	First response	• Respond • Acknowledge situation and explain governmental priorities • Redirect to existing and understandable information sources • Emphasise importance of openness towards research results
III	Advice	• Establish criteria for a second opinion • Visualise individual positions in international alignment

Responsible innovation means integrating societal and ethical considerations in science and technology research and development (Van Oudheusden 2014). Therefore, governments should not only communicate the safety issues in their response. Such a procedural reaction does not do justice to the political discussion about the context of GMOs that is brought to the table repeatedly. Although an (unmanageable) broadening of the debate could hamper the chance of reaching a consensus on the scientific value of the alarming study, government should acknowledge the position and role of both scientific and political aspects in decision-making.

Furthermore, although more research will unlikely solve the issue of alarming studies and GM technology indefinitely; repeating a study to overcome its limitations keeps the potential for scientific improvement open. Despite the different viewpoints, communication between stakeholders should be continuously encouraged and an effort should be made to prevent withdrawal of important stakeholders from the process.

We think that the reigniting discussion about alarming studies on GMOs is an indicator in a broader debate about agriculture and food production, given the fact that many contextual arguments are not GMO specific. Governments should therefore continue to monitor social trends and developments and

remain cognisant of the contextual arguments about GMOs. Forcing the discussion into a safety debate format leads to frustration and dissatisfaction. For various reasons, some cannot accept the conclusion that GMOs authorised for market release are found to be safe by scientific advisory bodies. At the same time, governments and scientists become frustrated because the public will not accept 'the facts' about the safety of GMOs.

Table 6: Governance of alarming studies: response and follow-up.

Phase		Lessons & pointers
IV	Response	• Acknowledge both specific and contextual aspects • Make explicit which issues are not addressed and why • Repeat and improve study to overcome limitations • Be realistic about the outcome

It is essential to indicate which arguments will be considered in the decision-making on GMOs and which will not. More importantly, it should be made clear where these other arguments may contribute to policy making, for example in a broader debate on agriculture and food production. This could partially discharge the scientific debate from normative questions regarding the desirability of GMOs. The first steps towards such a system were already taken in 2010 when the European Commission announced plans to give individual member states the freedom to veto cultivation of GM crops in their country (European Commission 2010a). In 2015, this resulted in an amendment of Directive 2001/18/EC aiming to combine a community authorisation system regarding safety with additional freedom for Member States to decide whether they wish to cultivate GM crops on their territory based on non-safety arguments[6].

It is ultimately up to politicians to decide when scientific evidence is 'good enough' to make a decision and stand for it. With this, the debate should shift towards the issues that are really at hand in the GMO discussion. Aside from procedural decisions, we conclude that it is necessary to put the political debate back on the agenda with regard to unstructured problems such as GM crops. To cite Sarewitz & Pielke Jr (2000).

6 Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

> *"No longer able to hide behind scientific controversy, politics would have to engage in processes of persuasion, reframing, disaggregation, and devolution, to locate areas of value consensus, overlapping interests, or low-stakes options (...) that can enable action in the absence of a comprehensive political solution of scientific understanding".*

Transparency and visibility of political decision-making is crucial, as scientific information alone will never rule out all uncertainties. In the introduction of this article, we classified GM crops as an unstructured problem characterised by disagreement about both facts and values, and about both the means and the ends of the technology. As probable solutions to this type of problem, a learning strategy and public debate were proposed (**Table 1**). We conclude that (formal) political debate should be added to this list. Based on the findings of this article, we endorse the claim of (Van Oudheusden (2014)), who emphasized the (leading) role of politics in responsible innovation. Finally, we note once more that the dynamics and characteristics of the debate on the safety of GMOs are not unique. Similar debates arise around other controversial technologies or developments that affect social values (e.g. shale gas, nuclear energy or vaccination programs). The pointers and pitfalls identified in this article can therefore also be useful in the (political) debate about other controversial technologies.

CHAPTER 6

CONTROVERSY FIRST: FACTORS LIMITING THE SUCCESS OF DIRECTIVE (EU) 2015/412 FOR NATIONAL DECISION-MAKING ON THE CULTIVATION OF GM CROPS

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1. INTRODUCTION

The use of genetically modified (GM) crops within Europe has been subject to regulation since 1990.[1] The regulation originates from the scientific consensus that genetically modified organisms (GMOs) could potentially present a risk to humans and the environment (Berg 2008). The resulting legal framework is based on an extensive environmental and food safety risk assessment. To date there have been no incidents confirmed by governments or competent authorities in which GM crops approved for market release have caused direct harm to the environment or human health (Nicolia *et al*. 2014). Nevertheless, among scientists, politicians and the broader public, the nature and status of the adequacy of the regulatory assessment remain topics of ongoing discussion. Recurring alarming studies[2] on the food and environmental safety of GM crops trigger the existing conflict about GM crops. Additionally, consistently more general concerns have been expressed regarding GM crop cultivation, such as those related to industrial agriculture and the use of pesticides. The divergent views on scientific, ideological, political, social and cultural elements classify the GM crop discussion as an intractable conflict or wicked problem (Schön & Rein 1994, Rittel & Webber 1973 and Mampuys & Brom 2015b). As a consequence, decision-making about the cultivation of genetically modified (GM) crops in the European Union (EU) has become a laborious process (Smart *et al*. 2016 and Mühlböck & Tosun 2017).

Commercialisation of GM crops in Europe requires a market authorisation approval on a European level for both importation and cultivation.[3] GM crops have to 1) pass a risk assessment procedure and 2) be approved by the Member States (MS) based on qualified majority voting or by the European Commission (EC).

Decision-making on the authorisation of GM crops for cultivation in Europe has been troubled for many years, because MS are unable to reach a qualified majority either in favour of, or against, the market authorisation (step 2). In all cases, the application had already passed the risk assessment procedure with a positive result i.e. it was concluded that the GM crop is safe for humans

1 Council Directive 90/220/EC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms.

2 A scientific or other study claiming that a technological innovation (e.g. a GM crop) poses a threat to human health or the environment which has not been acknowledged by the existing governance system (see Mampuys & Brom 2015).

3 Directive 2001/18/EC and Regulation (EC) No. 1829/2003.

and the environment (step 1). Although the EC is mandated to autonomously take a decision in these cases, it seems hesitant to do so because of the political sensitivity of this topic. As a result; decision-making on the cultivation of GM crops in Europe came to a halt and applications are piling up. The discussion is deadlocked and both MS who want to cultivate GM crops as well as MS who want to legally restrict cultivation cannot have their way.

The EC concluded that the safety framework might be (mis-)used to object to licensing because there was no framework available to express other, national concerns that relate to non-safety issues associated with GMOs.[4] In 2015 Directive (EU) 2015/412 (hereafter: Directive) was adopted which – in addition to and separately from the safety assessment - enables MS to restrict or prohibit the cultivation of GMOs in their territory based on considerations other than safety. The new Directive was supposed to remove the deadlock in decision-making on the EU market authorisations of GM crop cultivation and give individual MS autonomy to legally restrict cultivation of these crops.

As of 2018, however, it seems that this new approach has not worked out in the way it was intended. A majority of MS did use the new Directive to opt-out from GM crop cultivation on their territory[5], but at the same time this did not change the voting behaviour of MS regarding the overall EU market authorisation process. The last voting in March 2017 on two pending cultivation applications and one renewal did not result in a qualified majority either in favour of, or against, the GM crops (European Commission 2017). Was it a faulty solution to the actual problem? Or a solution to the wrong problem? Or both?

In this paper, we argue that the new European Directive 2015/412 could function adequately if it would do more justice to the deeply rooted conflict about GMOs. To illustrate this, we use an alternative lens of an 'ethos of controversies', that, in a nutshell, emphasises that decision-making builds on temporary political agreement, and, thus, not necessarily signals the end of ideological, religious or cultural conflict. This approach claims that even when dealing with value-

4 Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

5 European Commission 'Restrictions of geographical scope of GMO applications/authorisations: Member States demands and outcomes' <http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en> Accessed 16 April 2018.

orientated disagreements it is in theory possible to come to an adequate and reasonable regulation. Structuring the issue by exploring and acknowledging the controversies, does more justice to the diverging viewpoints and can be a first step towards decision-making on intractable disagreements such as GM crops.

We start by exploring the European struggle for a comprehensive assessment framework for GM crops (Section 2) and will zoom in on the latest attempt of the EC to end the deadlock on decision-making about the market authorisation of GM crop cultivation (Section 3). Then we will introduce and explain the theoretical framework of an interactive legislative approach (Section 4). This approach can be understood in the context of the interactionist paradigm of law-making (Van der Burg 2014). The interactionist paradigm contains a gradual shift from top-down law-making towards law-making building on co-operative effort in which law is made by various stakeholders (Van der Burg 2016). Poort's approach claims that even when dealing with value-orientated disagreements it is in theory possible to come to an adequate and reasonable regulation (Poort 2013). By using an ethos of controversies, this approach structures a first step towards decision-making by exploring and acknowledging the controversies that characterise the issue.

We will use this theoretical lens to identify several factors that limit the potential success of the new Directive on GM crop cultivation (Section 5). This Directive provides a unique example of how the existing controversies are not only acknowledged, but how non-safety considerations are also given an explicit legal status in regulatory decision-making. Finally, we propose a strategy, using an ethos of controversies, which could unlock the potential of the new Directive as a window of opportunity for decision-making about GM crop cultivation.

2. THE EUROPEAN STRUGGLE ON GM CROP CULTIVATION AUTHORISATION

Market authorisation of GM crops (import and/or cultivation) is regulated Europe-wide and based on an assessment of food/feed and environmental safety and decided on by means of a qualified majority voting by the MS. In brief, the European Food Safety Authority (EFSA) conducts an environmental and food safety assessment of the GM crop. All EU MS get the opportunity to assess the application and send their conclusion, remarks and questions to EFSA. Eventually, this results in a scientific opinion that is sent to the

EC.[6] If the EFSA concludes that the product does not pose a risk to human health or to the environment, the EC submits a draft implementing decision of authorisation to the MS, represented in either the Standing or the Regulatory Committee.[7] Voting officially has to be scheduled within three months after publication of the EFSA scientific opinion.

Under the comitology procedure[8], MS vote under the 'qualified majority' defined in the Lisbon Treaty (see EPRS 2014). If MS vote 'Yes', the EC adopts the draft decision. If they vote 'No', or if the result of the vote is 'No opinion' (no qualified majority in favour or against), the EC submits the draft decision to the Appeal Committee.[9] Here, MS vote a second time on the draft decision. A qualified majority in favour or against respectively results in the approval or rejection of the draft decision. If again the result is 'No Opinion', the EC is itself required by the GMO legal framework and by the Charter of Fundamental Rights to adopt a decision on the application.

Only once since 2003 there has been a qualified majority in favour of a draft Commission Decision on market authorisation of a GM crop (Smart *et al.* 2015). Several authorisation decisions (only importation) have been adopted by the Commission without the support of the MS. Many applications in the system have however contracted a considerable delay (Smart *et al.* 2015) and authorisation decisions about cultivation have been completely halted, even when the European ombudsman concluded that these delays were unjustified.[10] Additionally, the incoherence of Europe on GM crop cultivation

6 European Commission, 'Review of the decision-making process on GMOs in the EU: questions and answers.' (2015) Memo 15-4779_EN, Brussels, 22 April.

7 Applications submitted under Regulation (EC) No. 1829/2003 are presented for voting in the Standing Committee on the food chain and animal health (SCFCAH), Applications under Dir. 2011/18/EC are presented for voting to the Regulatory Committee. Both committees are composed of governmental representatives of the relevant ministries of the MS.

8 European Commission, 'Proposal for a regulation of the European Parliament and of the council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers' COD (2017) 85 final.

9 In the Appeal Committee, usually an attaché of the permanent representation (Foreign Affairs) in Brussels represents the MS in the voting.

10 Case 1582/2014/PHP, 'Decision of the European Ombudsman closing the inquiry into complaint 1582/2014/PHP on the European Commission's handling of authorisation applications for genetically modified food and feed' European Ombudsman, 15 January 2016; European Commission 'Proposal for a Council Decision concerning the provisional prohibition of the use and sale in Austria of genetically modified maize (Zea mays L. Line MON810) pursuant to Directive 2001/18/EC of the European Parliament and of the Council', COM(2009)56.

versus importation has moreover led to critique and incomprehension within and outside of Europe (Tagliabue 2016, Wager & McHughen 2010). To capture the origins of this disagreement, we go back to the beginning of GM regulation in Europe.

2.1 HISTORICAL OVERVIEW OF THE LEGISLATIVE STRUGGLE

After the Asilomar conference[11] in 1975 it was globally acknowledged that GMOs could potentially pose a risk to humans and the environment (Berg 2008). This trigger eventually resulted in national and international legislation to assess the potential hazards of GMOs in all laboratory experiments, field trials and market authorisations. In Europe legislation for commercial release of GM crops was put into place in 1990. Initially, several GM crops were authorized for commercialisation.

However, when the first GM crops (corn and soy) were actually exported from the USA to Europe in 1996/1997, this led to considerable media attention, public concern about safety, demonstrations and boycotts.[12] Several MS invoked the safeguard clause and put a ban on GM crops.[13] MS and the EC continued to discuss which scientific data was needed to conduct the risk assessment and what kind of effects should be considered as adverse. Regulatory reforms, additional regulations[14] and increasing data requirements have however proven insufficient to facilitate decision-making and reach a qualified majority for market applications (see Box 1). Since 2004, the EC has utilised its mandate to approve several GM crops for market release (only import food/feed). Nevertheless, the tedious process resulted in stalling applications (Smart *et al* 2016), complaints at the World Trade Organisation (WTO) and court cases.[15]

11 The Asilomar Conference on Recombinant DNA (February 1975) was an influential conference about potential biohazards and regulation of biotechnology. An international group of professionals (biologists, physicians, lawyers) participated to draw up voluntary guidelines to ensure the safety of recombinant DNA technology.

12 The elevated level of concern of EU citizens in the late 90s is often linked to a more general mistrust in the government caused by regulatory failures with regard to mad cow disease, an incident of dioxin-contaminated Belgian food and the spreading of infectious animal diseases such as hoof and mouth disease.

13 Member States may invoke a safeguard clause (art. 23 Dir 2001/18/EC or art. 34 Regulation (EC) No.1829/2003) to temporarily restrict or prohibit the use and/or sale of a GMO within their territory if they have justifiable reasons based on new information to consider that the approved GMO constitutes a risk to human health or the environment.

14 European Commission, 'Proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms' COM (1998) 85.

15 See for example: WTO (dispute DS291) and Pioneer v. Commission (Case T-164/10); see also Euractiv, 'EU GMO ban was illegal, WTO rules' (2006), 12 May 2006.

Box 1. Market approval of GM crops in Europe

As of 2018, in total 63 GMOs are authorised in the EU for food and feed uses (covering maize, cotton, soybean, oilseed rape, sugar beet).[1] Another 23 applications for GM crops are pending, all of which have a positive EFSA opinion (published between 2006 and 2017). The EU depends on imports for over 80% of its vegetable proteins, largely provided by GM soybean. Over 36 million tons of GM soybean are imported to feed EU cattle.[2] Only one out of two crops[3] that have ever been approved for cultivation in the EU is actually being produced: maize MON810.

Maize MON810 has been genetically modified to produce a specific protein (Bt) that protects it against the European corn borer, a pest insect. This GM maize variety was originally approved in 1998. MON810 is being cultivated in five EU countries (Spain, Portugal, Czech Republic, Slovakia and Romania). At the same time, 9 MS (Austria, France, Germany, Luxembourg, Hungary, Greece, Bulgaria, Poland and Italy) used the safeguard clause to ban this GM maize variety. According to European regulations, a market approval renewal is needed after 10 years.[4] This application for renewal of MON810 was filed in 2007 according to Regulation 1829/2003 on genetically modified food and feed. The EFSA issued a positive opinion on this renewal in 2009 (EFSA 2009). Voting took place in March of 2017 but MS could not reach a qualified majority on a decision about the renewal and no Commission decision has been taken yet. The authorisation from 1998 remains valid until a decision is taken. In total there are 6 pending applications for GMO cultivation in the EU, including the renewal of MON810.

1 European Commission, 'Register of authorised GMOs' <http://ec.europa.eu/food/dyna/gm_register/index_en.cfm> Accessed 16 April 2018.

2 European Commission, 'Fact sheet: questions and answers on EU's policies on GMOs' <http://europa.eu/rapid/press-release_MEMO-15-4778_en.htm> Accessed 16 April 2018.

3 In 2010 a GM starch potato named 'Amflora' was authorised in the EU. This authorisation was annulled, see <http://europa.eu/rapid/press-release_CJE-13-160_en.htm> Accessed 16 April 2018.

4 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

2.2 DIVERGING VIEWPOINTS OF AND WITHIN EU MEMBER STATES

The lack of consensus between MS in favour of, or against, the commercial release of GM crops – despite a positive safety assessment – illustrates that MS in the EU have broadly diverging viewpoints with regard to GM crops. These differences are expressed in MS voting behaviour on the EU level and

in national bans on specific GM crops.[16] Furthermore, the fact that the EC is extremely hesitant to use its mandate to veto a final decision emphasises that this is a highly contested topic. In this Section, we will go into more detail about the specifics of the diverging viewpoints.

The EU regulation for GM crop authorisation is predominantly based on safety aspects, while other elements are considered a national, individual or market choice and responsibility. These are therefore secured by amongst others labelling regulations and coexistence guidelines.[17] Both Directives for market authorisation mention ethical implications[18], but these do not have an actual weight in the decision-making process in practice. Ethical principles may be taken 'into consideration' by MS or an advice from the European Group on Ethics could be obtained, but these steps are non-committal. A consultation period for the public is mandatory, however comments are to be 'taken into consideration' and only risk-related arguments are taken into account.

Scientific studies that indicate that certain risks of GM crops might have been disregarded ('alarming studies'), cause considerable disquiet and anxiety.[19] Not only because there might be safety concerns, but also because they trigger the underlying debate about non-safety arguments against GM crops. Additionally, the scientific debate about the interpretation of these studies for policy decisions, indicates that science alone cannot be used as an unambiguous and objective ground for decision-making on GM crops or other contested technologies (Mampuys & Brom 2015b, Sarewitz 2004). In fact, it seems that even if alarming studies are formally dismissed as scientifically unsound and

16 European Commission, 'Questions and Answers on EU's policies on cultivation and imports of GMOs' (2013) EC (2013). MEMO-13-952_EN.

17 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC; see also European Commission, 'Commission Recommendation on Guidelines for the Development of National Co-Existence Measures to Avoid the Unintended Presence of GMOs in Conventional and Organic Crops' (2010) C200/1.

18 Art. 9 of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and Art. 42 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

19 For example Séralini *et al.* 'RETRACTED: Long term toxicity of a roundup herbicide and a roundup-tolerant genetically modified maize' (2012) 50(11) *Food and Chemical Toxicology* 4221–4231.

unjustified, they continue to play a role in the ongoing debate. The discussion about these 'alarming' studies symbolises the underlying debate about the value and desirability of GM crops in our food production system (Mampuys & Brom 2015).

Alarming studies have been used by several MS to invoke the safeguard clause and put a ban on GM crops. By 2013 eight EU countries had submitted such clauses to prohibit the cultivation of maize MON810 on their territories. Most safeguard clauses submitted to EFSA have been declared scientifically unfounded[20], but none of them have been lifted[21], which can be interpreted as an acknowledgement of underlying issues and respect for national autonomy of MS.[22]

Besides the broad upheaval of alarming studies and bans in some MS and not others, the diverging viewpoints are reflected in regulatory delays and the voting behaviour of the MS on the draft decision of the EC. The draft decision is based on the EFSA scientific opinion that is in turn compiled by both EFSA and MS competent authorities and scientific advisory bodies. Only positive assessments are sent to the Commission, because a GM crop that poses risks to humans and/or the environment cannot be authorised for market release. Despite the positive scientific safety assessment, some MS always vote in favour, some always oppose or abstain and some MS shift between positions. Official reasons mentioned for the negative vote or abstention have been amongst others: no agreed national position, negative public opinion, political reasons, risk of harm to the national agri-food industry, uncertainties in risk assessment, safety concerns for the environment, the precautionary principle and the lack of comprehensive data on long-term potential impact of GMOs (European Commission 2017). Obviously, several of these objections do not relate to safety and go beyond the scope of the European regulatory framework for market authorisation.

20 European Commission (n 20).

21 Tarja Laaninen 'Member States' bans on GMO cultivation' European Parliament Research Service, 5 January 2015, PE 545.708 <http://www.europarl.europa.eu/EPRS/EPRS-AaG-545708-Member-State-bans-on-GMOs-FINAL.pdf> Accessed 16 April 2018

22 For an overview of safeguard clause concerning the cultivation of GMOs, see Giovanni Tagliabue, 'The EU legislation on "GMOs" between nonsense and protectionism: An ongoing Schumpeterian chain of public choices' (2017) 8(1) *GM crops Food* 57-73.

Over the years, it became 'the norm' for decision-making on GM crop authorisation that the dossier is returned to the Commission for a final decision (European Commission 2015a, Bergmans *et al.* 2016). Despite a legal timeframe of three months between the EFSA scientific opinion and a 1st voting in the Standing Committee, scheduled voting and final decisions were moreover postponed leaving several applications in 'regulatory limbo'. For GM food/feed products approved between 2011–2013, the EC took on average 19 months to take products through the voting system. An average of 48 months was calculated from application submission to the Commission's final decision for import of a GM product (Ernst & Young & EuropaBio 2014).

Over the years the EC has made an effort to overcome the diverging viewpoints from MS by reforming the legislation and proposing practical solutions. Issues about the environmental and food safety assessment have resulted in increasing data requirements and detailed guidance documents for applicants. Disputes about freedom of choice have been solved by introducing labelling for GM food and feed ingredients. To deal with adventitious presence of GMOs due to accidental contamination, threshold values have been agreed on to specify when labelling should be applied. To prevent contamination of conventional / organic crops and GM crops, several EU rules and national pacts/treaties with regard to coexistence measures were put into place.[23] Finally, to prepare for any unanticipated adverse or long-term effects, a time-limit of 10 years was introduced for authorisations. After 10 years a re-evaluation has to be done based on monitoring reports and ongoing research.

It can be concluded that MS are still not satisfied with the regulatory changes that have been made; for some the regulations are too strict and hamper innovation while for others they do not go far enough. The earlier reforms and changes (before Dir. (EU) 2015/412) have something in common; they are strongly based on reducing scientific uncertainty or ensuring freedom of choice for European citizens. They look for solutions in a quantitative/factual approach: asking for more data, setting up labelling requirements and threshold values for contamination. Consequently, the reforms disregard the underlying arguments about moral values with regard to agriculture and food production. The fact that these reforms have been unsuccessful in improving GM crop decision-making, again confirms an underlying cause for the disagreement about GM crop cultivation.

23 European Commission 'Coexistence of genetically modified crops with conventional and organic agriculture'< https://ec.europa.eu/agriculture/gmo/coexistence_en> Accessed 16 April 2018.

The desirability of GM crop cultivation has national, regional and local dimensions to it, and is linked to social, ideological and cultural values relating to land use, (local) agricultural systems and the protection of specific landscapes. For example, these values can be reflected in a national, regional or local preference for organic agriculture or a strong position of Green Parties in a country. But values are also expressed by the activities of NGOs (such as the European network of GMO-free regions or the March against Monsanto) and representative organisations for biotech companies (such as EuropaBio). The last European opinion poll about biotechnology, the 2010 Eurobarometer, showed that on average opponents outnumber supporters by three to one and that, in no MS, is there a majority of supporters (Gaskell *et al*. 2010). Motivations for this attitude do not only relate to safety but also to a perceived feeling of unease, the association with 'unnaturalness' or (the lack of) direct benefits for consumers. Mühlböck & Tosun (2017) investigated whether and how voting behaviour on GM crop authorisations in the Council of Ministers[24] reflects national interests. They concluded that ministers' voting behaviour is influenced most by national factors such as public opinion, followed by party politics and sectoral interests. Other political and economic motivations for MS voting behaviour have been mentioned by among others Tagliabue (2016).

The influence of national, regional and local dimensions and interests regarding GM crop cultivation explains why it seems unlikely that the European decision-making could be based on solely the outcome of the scientific environmental risk assessment from EFSA. The (science-based) Directives on GMO market authorisation and the (political) users/authorities of these Directives seem to be in conflict here. This finding would plead in favour of the new Directive, which was created to facilitate multilevel governance and give room to diverging national interests other than safety.

3. NEW REGULATION GM CROP CULTIVATION

In an effort to resolve the long-standing issue around market authorisation decisions on GM crop cultivation, the EC made an extraordinary move in 2010. It announced plans to add an optional step to the science-based assessment framework for the market authorisation of the cultivation of GM crops. The goal of this proposal was twofold: it was supposed to provide MS with the possibility to 1) allow GM crops that meet the set safety criteria to be cultivated

24 Under the old comitology procedure, voting would go to the Council of Ministers after voting in the standing committee if the result was 'no opinion'. Since 2014 the second voting takes place in the appeal committee.

OR 2) restrict or prohibit cultivation of GMOs in their territory based on considerations other than safety.[25] This partial decentralisation step could facilitate a form of multilevel governance in which more justice is done to local and regional factors while others, such as safety, remain centrally organised (see also Dobbs 2016).

3.1 REGULATORY AIMS OF THE NEW REGULATION

With this proposal, the EC explicitly acknowledged the role of and differences in national concerns which do not only relate to issues associated with the safety of GM crops for health or the environment. Therefore, the new approach was, according to the EC, likely to improve the centralised process for authorisations of GM crops and, at the same time, ensure freedom of choice of consumers, farmers and operators whilst providing greater clarity to affected stakeholders concerning the cultivation of GMOs in the Union. This Directive should therefore facilitate the smooth functioning of the internal market. The proposal for a partial renationalisation of GM crop cultivation was discussed and amended several times from 2010 to 2014. In 2015 Directive (EU) 2015/412 came into effect.[26]

The working mechanism of the new Directive is a two-step plan. First, during the authorisation or renewal procedure of a given GM crop, a MS may request from the applicant that the geographical scope of the authorisation be adjusted to exclude the territory of that specific MS from cultivation (Article 26b.1). No formal argumentation is needed for this step. If the applicant does not actively deny the demand (i.e. if he confirms or ignores the request), the adjustment of the geographical scope shall be implemented. Second, if the applicant denies the MS request for exclusion from the geographical scope, a MS may adopt measures restricting or prohibiting the cultivation of a GMO in all or part of its territory (Article 26b.3). The measures taken must be in conformity with Union Law, reasoned, proportional and non-discriminatory. The Directive states that the measures must be based on compelling grounds such as, but not limited to, those related to a) environmental policy objectives, b) town and country planning, c) land use, d) socioeconomic impacts, e) avoidance of GMO presence in other products without prejudice to Article 26a, f) agricultural

25 We note that that media coverage of the new proposal in most cases only highlight the possibility to restrict or prohibit GM crop cultivation.

26 Directive (EU) 2015/412; see also a similar proposal from April 2015 by the EC to restrict the use of GM food/feed (2015/0093(COD). This proposal has different and more complex ramifications concerning international trade and is not a part of our analysis.

policy objectives or g) public policy. The non-exhaustive list of grounds in the Directive can be used individually or in combination, but may never conflict with the environmental risk assessment carried out under the usual procedure under Directive 2001/18/EC or Regulation (EC) No 1829/2003. This also means that even if MS decide to use Directive (EU) 2015/412, they are still required to vote on the safety of a GM crop.

In summary, MS can ask the applicant to exclude their territory from the geographical scope of the application. If the applicant actively denies this request, the MS can adopt measures to restrict or prohibit the cultivation of a GM crop on a national level based on non-safety arguments that have to be substantiated in official writing to the applicant and the EC. This second step has to be implemented in national legislation. The Directive has been in place since April 2015. As of 2018, only a few MS (i.e. Germany, Italy) have (nearly) completed the implementation, are working on new legislation (The Netherlands, Croatia) whereas some MS (Finland, Sweden) have decided not to implement the new Directive.[27] Research of both Dobbs (2017) and Tosun & Hartung (2018) looked into the motives of and challenges to MS to implement the Directive. MS name different reasons for availing the clause. Some claim to have no specific objections to GM crops but need more time to consider whether or not to facilitate GM agriculture, other MS mention their 'green image', distrust of GM technology, public opinion, environmental concerns and concerns on coexistence within MS. It should be noted that MS cultivating GM crops always have to put in place coexistence measures at their borders with non-cultivating countries.[28]

27 Global Agricultural Information Network (GAIN) report of November 4th: German Cabinet presents draft legislation to ban GE cultivation; Italy: Legislative Decree No. 227 of November 14, 2016, Implementing Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015, Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of Genetically Modified Organisms (GMOs) in Their Territory (Law No. 227), GAZZETTA UFFICIALE (G.U.)(Sept. 8, 2016), NORMATTIVA (in Italian); personal communication.

28 European Commission 'Adoption of national legislation in accordance with Article 26a (1a) of Directive 2001/18/EC' <https://ec.europa.eu/food/sites/food/files/plant/docs/plant_gmo_auth_nat-measures_summary-cross-border-national-measures.pdf > Accessed 16 April 2018.

3.2 DISAPPOINTING INITIAL RESULTS

Despite major dissatisfaction with the deadlock / standstill in decision-making regarding GM crop market authorisations, the responses from NGOs as well as industry to the new Directive were, from the start, quite pessimistic.[29]

As the proof of the pudding is in the eating, the Directive's initial success or absence thereof can be illustrated by actual voting on pending applications. In January 2017, the EC scheduled a voting on 2 new cultivation applications that received a positive EFSA opinion and on the renewal of MON810 (see Box 1). Nineteen of twenty-eight MS requested to be excluded from the geographical scope of these applications.[30] The applicant did not object and these requests were honoured. For all three applications, the vote's outcome was 'no opinion' because no qualified majority was reached. Most MS who used step one of the new Directive, still voted against or abstained from voting on the market authorisation, with the exception of The Netherlands[31], Italy and Lithuania who voted in favour.[32] A second voting took place at the end of March, with the same result.[33] In conclusion; the new Directive has been successful in providing MS with the autonomy to decide on cultivation of GMOs in their territory, but it has not succeeded with the other goal: namely, allowing GM crops that meet the set safety criteria to be cultivated in other MS.

29 See for example: Greenpeace (Euractiv.com, 22 April 2015), 'The Commission's proposal is a farce because it leaves the current undemocratic system untouched. It would allow the Commission to continue ignoring major opposition to GM crops, despite president Juncker's promise to allow a majority of EU countries to halt Commission decisions on GMOs'; and, EuropaBio (Euractiv.com, 22 April), 'This proposal would limit the choice for livestock farmers and threaten their livelihoods. It would also set the alarm off for any innovative industry subject to an EU approval process in Europe. Failing to uphold the EU-wide approval of safe products will damage jobs, growth, innovation and competitiveness.'

30 European Commission 'Restrictions of geographical scope of GMO applications/authorisations: Member States demands and outcomes' <http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en> Accessed 16 April 2018.

31 Awaiting implementation of Dir. (EU) 2015/412 in Dutch law, NL opted out from the geographical scope of the market applications, but voted in favour on the proposal for market authorisation in the light of the safety assessment.

32 GMWatch 'EU countries say No to GM crops but not quite loudly enough' (GMWatch, 27 January 2017). <http://gmwatch.org/en/news/latest-news/17441-eu-countries-say-no-to-gm-crops-but-not-quite-loudly-enough>

33 Louis Gore-Langton 'MEPs appose GM approvals but Commission will have the final say' (Foodnavigator, 27 March 2017). <https://www.foodnavigator.com/Article/2017/03/28/MEPs-oppose-GM-approvals-but-Commission-will-have-the-final-say> Accessed 16 April 2018.

Plans for a reform of the comitology procedures have been announced as a potential solution.[34] Additionally, some stakeholders recently even promoted an opt-in regulatory system instead of an opt-out strategy.[35] Before jumping to other solutions, we suggest first investigating why the new Directive is not working the way it was intended. We will do this using the theoretical lens of an ethos of controversies, which will be explained in the next Section.

4. THE INTERACTIVE LEGISLATIVE APPROACH: AN ETHOS OF CONTROVERSIES

This Section explores our theoretical framework, which builds on Poort's earlier work: the interactive legislative approach. This approach can be understood in the context of the interactionist paradigm (Van der Burg 2014). The interactionist paradigm contains a gradual shift from top-down law-making (vertical structures) towards law-making building on co-operative effort in which law is made by various stakeholders (horizontal structures) (Van der Burg 2016). Poort argues that the interactive legislative approach can be a more adequate legislative approach to complex issues with a strong moral impact (Poort 2031). These issues are characterised by uncertainties about knowledge, rapid developments and a profound moral pluralism. Hisschemöller & Hoppe (1995) define these complex issues as unstructured problems.

The openness of the legal norms of interactive legislative approaches ensures that they can adapt to new developments in the field. Especially for issues that are characterised by rapid changes, responsiveness to these changes is relevant. Otherwise rules constantly play catch-up with technological developments. The characteristics of the issues that the interactive legislative approach aims to address, can also be recognised in the intractability of decision-making on the cultivation of GM crops. We, therefore, consider this approach as a first step towards a potential coping strategy for addressing the issues concerning GM crop cultivation in Europe.

34 A Commission 'options paper' identifies four ideas, one of which excludes MS who are not represented or abstain from voting from the calculations for Qualified Majority (QM). Only taking into account yes/no votes should increase the chance of a QM.

35 Eriksson *et al.* (2018) suggest an opt-in mechanism that allows individual MS to authorise GM crops in their territory after the EFSA has published a positive opinion on the safety for humans and the environment. We note that this strategy seems an unlikely scenario as this would surpass the official European Comitology procedures that form the basis of European decision-making.

4.1 THE INTERACTIVE LEGISLATIVE APPROACH

The interactive approach (see Box 2) emphasises both horizontal decision-making (interaction) and the need for dynamics in norm-development (dynamics) (Poort 2013). By involving stakeholders in decision-making based on co-operative effort (interaction), stakeholders are more willing to accept the rules. After all, these stakeholders were involved in designing these rules. Furthermore, dynamics in norm-development are argued to improve responsiveness to developments in practice (Selznick 1992). Both interaction and dynamics are justified by a strong focus on reaching consensus in these processes of decision-making and norm-development. Consensus, here, means a quest for consensus, and is defined as a regulative ideal. In that sense, consensus is rather an orienting aim than being the ideal outcome. Van der Burg & Brom argue in the context of the ideal-typical model of the interactive approach, that it is enough if the various actors can deliberate freely together to come up with norms that are orientated to practice (Poort 2013, Chapter 9 and Van der Burg & Brom (2000). Furthermore, striving for consensus contributes to structuring these processes in such a way that stakeholders are willing to co-operate (Habermas 1996 and Gutmann & Thompson 1996).

Box 2. The Interactive legislative approach

The basic elements of the interactive legislative approach (interaction and dynamics) build on the ideas of Selznick and Fuller who both have had a major influence on the development of the theoretical model of the interactive legislative approach (Selznick 1992 and Fuller 2001).

Interaction can be related to both Selznick's and to Fuller's work. Selznick explains the need for a process of interaction between the legislature and society or relevant sectors within a society. Fuller points at the need for both horizontal and vertical structures of communications to guide interactive processes of law-making. According to Fuller, the vertical structures are embedded in the horizontal ones (Poort 2016).

The need for dynamics originates from Selznick's argument for responsiveness: an ongoing process of norm development ensures that legislation does not continually have to play catch-up with society. Dynamics can be stimulated by the use of open norms. Furthermore, the interplay between interaction and ongoing norm development contributes to concretisation of these norms and, thus, to dynamics.

The interactive approach identifies four functions of law: articulation, communication, interaction, and coordination. The first involves articulation of the issue at stake. The second function relates to the communication between government and the actors involved. The horizontal structure of this relationship ensures open and direct communication. The third function stimulates interaction between the legal framework and the field of application which leads to a dynamic interplay of norm development on various levels. The fourth function involves coordination of the interactive process by institutionalising this process and the framework for communication. This function ensures control and procedural fairness.[36]

Poort states that these incentives of willingness to co-operate and responsiveness to new developments can only be achieved if we no longer focus on consensus. She claims that, consensus striving even as a regulative ideal is counterproductive in the case of intractable disagreements as it risks premature closure of debate.[37] To that extent, despite the open structure of the legal framework, dynamics is not established. Furthermore, it also risks that for the sake of reaching consensus diverging viewpoints are excluded from the (legislative) process in an early stage. On the one hand, this can facilitate problem-definition and may stimulate smoothening of the regulatory process. On the other hand, only part of the problem is addressed and (some) stakeholders are excluded from the horizontal process of decision-making. Here, we can identify consensus-thinking as a taming strategy of governance which involves transforming wicked problems into more manageable ones (Daviter 2017). This, however, involves addressing only part of the problem, which may eventually backfire and result in a deadlock, as we see in the case of GM crops (see Poort (2013), Chapter 9 and Castle & Culver (2013).

With regard to the safety assessment of GM crops by EFSA and the decision-making process on an EU level, this is a recurrent complaint issued by several NGOs and scientists. Some safety arguments of NGO's and scientists are

36 The explanation of the four functions closely connects to the explanation Poort gives in Poort (2013) pp. 35-36.

37 Poort builds her argument on a threefold case study in which the regulation of animal biotechnology in three European countries (Switzerland, Denmark, and the Netherlands) was analysed; see Poort (2013) Chapters 5, 6 and 7.

declared invalid[38], and non-safety issues are excluded from legal decision-making.[39] As an alternative to consensus-thinking, Poort suggests an ethos of controversies which we will explain in the next Section.

4.2 AN ETHOS OF CONTROVERSIES

An ethos of controversies[40] can best be explained as a normative way of thinking in which, obviously, controversies have a more central role (Poort 2012). An ethos of controversies structures decision-making processes by exploring controversies and giving them an explicit role in the process.

The complex issues with a strong moral impact that the interactive legislative approach tends to cope with, are characterised by uncertainties and ambiguities on both facts and values. Poort argues that these uncertainties make it difficult or even impossible to arrive at concrete decisions, based on consensus. In this light, Castle & Culver (2013) refer to antecedent policy failures, meaning that failures in policy-making arise 'as a result of prior choices regarding the structure and starting point of a policy process' (p. 34). They argue that dissensus can better be used to structure these problems. Their argument coincides with the background of an ethos of controversies. This ethos can contribute to a comprehensive problem-definition as well as to avoid that problems will get out of control (antagonistic). Mouffe (1999) argues that the lack of resolvability that comes along with this conflicting nature has to be recognised. She claims that recognition of the conflict will do greater justice to the conflicting nature of pluralism. In Poort's view, acknowledgement of the conflict helps to establish a regulatory framework that manages intractable disagreements instead of trying to control them or impose consensus.

Hisschemöller & Hoppe (1995) argue for a coping governance strategy to deal with these kinds of issues and suggest a learning strategy. An ethos

38 See for example EFSA, 'Final review of the Séralini *et al.* (2012a) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology'(2012), EFSA journal 28 November 2012; and GMO free regions, 'Berlin declaration, 8 May 2015) <http://www.gmo-free-regions.org/fileadmin/files/gmo-free-europe/Berlin_declaration_final.pdf> Accessed 16 April 2018.

39 In delivering its scientific opinion, the EFSA GMO Panel took into account application (application no), additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications.

40 The explanation of the ethos of controversies and of three stages in which an ethos of controversies operates closely connects to its explanation in Poort (2012). However, the focus and goal of this paper differs fundamentally.

of controversies may structure such a learning process by acknowledging and confronting differing viewpoints, concerns and preferences, which stimulates further norm-development. The latter distinguishes the ethos of controversies from other coping strategies as it goes beyond reflecting upon and acknowledging intractability and diversity. By confrontation, the ethos of controversies seeks to stimulate further norm development. It, therefore, does not consider controversies as a known fact we have to cope with, but embraces its surplus value.

Of course, in the end decisions have to be made in regulatory frameworks. Decision-making would be a lot easier if all parties agreed. An ethos of controversies cannot offer an alternative to consensus-thinking in light of legitimacy of legal decisions. Waldron (1999) acknowledges that a decision has to be made, but at the same time he notices that a conflict can linger on. Acknowledgement of the conflicting nature may enable a constructive debate as awareness that disagreement still exists demonstrates greater respect for the views that have been excluded from the decision-making. It is, then, possible to have a reasonable and constructive debate while the core of intractable disagreements at first sight seems to go beyond reason.

4.2.1 THREE STAGES

The ethos of controversies functions in three stages: articulation, confrontation and awareness. In the first stage the problem is defined by articulating the various viewpoints, concerns and preferences. Different from other processes of norm-development, this stage involves taking stock of the *variety* of viewpoints, concerns and preferences instead of searching for commonalities. Poort argues that this approach will result in a more comprehensive definition of the problem. An ethos of controversies, here, avoids simplifying the conflict. Castle & Culver have developed a method of contested exchange to develop and exchange knowledge base and to prioritise core values. Within this method, the stage of articulation is designed as a stage in which different perspectives on several issues are identified and documented (Castle & Culver 2013, p. 39).

The second stage involves confrontation of the variety of viewpoints. Stakeholders in this stage acknowledge that differences in reasoning exist. They do so by a confrontation between the different viewpoints, concerns and preferences. Stakeholders are, then, forced to explain, to think through and perhaps even to reconsider their ideas. This process will result in reflected opinions instead of repeated statements. Consequently, confrontation

may result in a more comprehensive and thorough problem-definition and stimulate further development of norms. The aim of confrontation is to make the underlying issue and the diverging viewpoints explicit, not to judge these viewpoints. Following Castle & Culver's method of contested exchange, this stage can best be operated in an open session building on a systematic exchange of insights between the different perspectives. This exchange contributes to a better structuring of the issues, and to clearly identifying the core of emerging issues. Furthermore, participants are forced to reflect upon their deeply held convictions which may lead to new insights by stakeholders involved (Mouffe 1999). Following Stirling (2008), this stage involves broadening the input for decision-making, but it also opens up the output to alternative questions and framings (see also Leach *et al*. 2005). To that extent, the norm-development is reflexive and open-ended.

The third stage evolves around awareness and acknowledgement of the controversy. Eventually, decision-making will be easier if all stakeholders agree as we cannot legitimise decisions built on disagreements. It must be clear that an ethos of controversies cannot legitimise decisions. Nonetheless, the ethos of controversies can do justice to the diverging viewpoints and contribute to decision-making. This ethos can do so by ensuring that these viewpoints have had an explicit role in decision-making by facilitating awareness of the conflict that still exists after decisions are made. In other words, in this stage the ethos of controversies ensures acknowledgement of the temporary status of the compromise (political or otherwise) laid down in the legal decision or in the regulation.[41] A legal decision might not represent the end of the moral conflict and does not necessarily represent a consensus about underlying norms and values. This way, it does more justice to acknowledging and respecting different viewpoints. Smith & Stirling (2007) emphasise that 'social appraisal rarely closes down definitively upon a given socio-technical object'. This however, does not have to postpone or prevent legal-decision making.

41 Interactive approaches to law attract considerable criticism considering their tension between the traditional function of law to end conflict and the interactive approach's incentive to create dynamics. See for example John Griffiths, 'Do laws have symbolic effects?' in: Nicolle Zeegers, Willem Witteveen, Bart van Klink (eds.) *Social and symbolic effects of legislation under the rule of law,* (The Edwin Mellen Press, 2005) 147-161.We are aware of this criticism. Poort (2013) addresses this criticism by introducing a two-track approach in which legal and moral decision-making are distinct, but interplay. However, it exceeds the context of this paper to go into detail on this approach and the criticism. It is not relevant for the argument we intend to make here. For further information on this two-track approach, we refer to Poort (2013) Chapter 10.

5. THE NEW DIRECTIVE IN LIGHT OF AN ETHOS OF CONTROVERSIES

As became clear in the previous Sections, the new Directive is not generally conceived as an adequate solution to the struggle for decision-making on the cultivating of GM crops in the EU by all parties involved. Some argue that the new Directive symbolises a failure of the EP to come to a shared assessment framework: the EP has not come any closer to a solution after over twenty years of struggle. Others claim that this solution indicates a shift of the struggle from the EU-level to a national state-level in which an agreement on decision-making still needs to be found. National agencies struggle with the implementation of the Directive and the draft of an assessment framework. Furthermore, the recent voting makes clear that, so far, nothing has changed.

In Section 2, we have shown that the cultivation of GM-crops is a disagreement which is characterised by diverging viewpoints on the scientific, moral and social impact. Over the years, a consensus on the matter seemed to become more and more unlikely or even impossible. Despite this, the EC drafted and adopted the new Directive. As a result, this Directive was met with great pessimism and considered an empty box by several stakeholders. The first results of the Directive in practice seem to confirm this; a majority of the MS used the first step of the Directive to exclude their territory from the geographical scope of the GM crop application, but this did not change their voting behaviour on the safety of the European market application. Hence, a deadlock in decision-making on EU market authorisation applications remains. In this Section, we will first identify factors that might have caused the initial failure of the new Directive. These factors can be related to motivations of the proponents and the opponents of GM crops (user factors, Section 5.1) and to factors in the structural design of the Directive (design factors, Section 5.2).

Second, we think that a different approach could still unleash the potential of the new Directive and we argue that an ethos of controversies can potentially offer a first step in such an approach.

5.1 USER FACTORS LIMITING THE POTENTIAL SUCCESS OF THE DIRECTIVE

Let us go back to the motivation for the new Directive and those who initiated the process. The EC was confronted and burdened with taking a decision on the authorisation of GM crops because MS could not reach a qualified majority. Aware of the political sensitiveness of the subject, the EC has been hesitant to take a decision on, and to accept responsibility for, the legality of GM crop cultivation. Meanwhile, the intended procedure for market authorisation based

on an environmental safety assessment is hampered and those MS who do want to cultivate new GM crops cannot do so. Hence, the status quo is a very limited: cultivation of just one GM crop (MON810) in a few MS and an obstruction of the EU market authorisation procedure. The potential gain of the new Directive was to allow GM crops that are deemed safe for cultivation onto the European market, while acknowledging that some MS don't want GM crop cultivation for different reasons. Here, the EC, however, seems to simplify the problem.

First, we identify a lack of gains for the opponents of cultivation of GM crops. More particularly, the EC seems to have failed to take into account their gains within the status quo. For those MS who reject or abstain from voting on market authorisation of GM crops, the situation should be viewed from a different perspective. They reject GM crops or abstain from voting in order to represent national interests and to prevent these crops from entering the market. With currently only one GM crop authorised for cultivation and limited to no cultivation in most MS, one could argue that the 'naysayers' are supposedly quite satisfied with the status quo. And this may change with the new Directive that could, additionally, cause a shift of the debate on this topic from EU level to a national, regional or local level within MS.[42] From this perspective, the naysayers have a lot to lose compared to the status quo. Changing their formal position at an EU level regarding the market authorisation procedure based on environmental risks, can come at a (political) cost of being held accountable and reopening debate on a national or regional level (see also Tosun & Hartung (2018). This may not necessarily be a desirable option for opponents.

Second, proponents of cultivation, likely do not share the presumptions of the EC either. Proponents want to cultivate GM crops and are served with a smoothening of the market authorisation process by clear (scientific) rules on safety and risks. These rules were already available through the existing Directive 2001/18/EC and or Regulation (EC) No.1829/2003, resulting in positive opinions by EFSA on the safety of several GM crops. The new Directive obviously means more rules and more (political) decisions to be taken. Additionally, the implementation of the Directive on a national level seems to become a complex and time-consuming process, further delaying decision-making about pending applications. In summary, their gains from the new Directive are also limited.

42 This seems likely, as some MS already indicated 'no agreed national position' as a reason for the negative vote or abstention.

Third, the EC failed to recognise the underlying values within the environmental safety assessment and their role in driving MS to vote 'No'. After all, they argue, the GM crops that are presented for voting on market authorisation all have received a positive EFSA opinion and are thus considered safe. The new Directive offers the opportunity to address non-safety issues, but at the same time it indirectly denies the value-oriented discussion about safety and risks. It is assumed that safety (scientific) and non-safety (social) reasons can be strictly separated and that the latter are the (only) reason for MS to reject GM crops for cultivation. It presumes that MS agree on the topic of environmental risk assessment and risk management. Several reasons that were given during the last voting rounds in the Appeal Committee indicate that this is not the case.[43]

Fourth, the EC recognises differences in values on (GM) agriculture and offers the possibility to express these on a national level but it also denies the weight of more idealistic positions that encompass that no one in Europe (or even the world) should support GM crop cultivation. MS holding these idealistic positions have nothing to gain with the new Directive that may change the status quo of a negligible adoption of GM crop cultivation in their territory or even in neighbouring countries. The new Directive could more explicitly divide the MS when cultivation takes place in some MS and not others. Ideological factors are closely related to the last user factor: politics.

Fifth, the GM crop debate is also strongly intertwined with a political strategic view on agriculture (from the opponents' perspective: against industrial agriculture, use of pesticides and against technology ownership and control by large firms; from the proponents' perspective: hi-tech, biotechnology driven and large scale agriculture). From the opponents' perspective, any technology that facilitates industrial agriculture is seen as a threat. This indicates that from the opponents' side there is a strong political resistance against industrial agriculture overall. This could mean that the tables cannot be turned by adapting legal procedures for one particular aspect (GM crops), because it is part of a broader (political) strategy. This is in line with amongst others Head who criticises evidence based policy because political reality is not only driven by scientific facts but also by the messy reality of negotiations, commitments

43 Reasons for the negative vote or abstention during the last voting round (27th March 2017) on three GM crops also included: uncertainties in risk assessment, safety concerns for the environment, the precautionary principle and a lack of comprehensive data on long-term potential impact of GMOs. See European Commission (2017).

and other political interactions (Head 2010). Additionally, Daviter (2015) explains that the role of scientific facts is not inert and the political use of knowledge can differ from its scientific use in being used strategically.

We conclude that while drafting the new Directive, the EC seems to have followed a problem-definition that is not shared with all stakeholders involved.

5.2 DESIGN FACTORS AND THE DIRECTIVE AS A WINDOW OF OPPORTUNITY

Let us continue with our conclusion in the previous Section, namely that the problem-definition used to design the Directive is limited from a user perspective. From the perspective of the three stages of policy-making in which an ethos of controversies can operate, the EC moderated the stage of problem-definition by assuming all positions were clear and taken into account using a simplified categorisation of viewpoints in terms of safety and risks on the one hand and socio-economic values on the other. The EC failed to acknowledge the complexity of the positions in MS that cross these categorisations or that limits them to national territories. The question is how MS positions can be reflected more effectively in the design of the Directive.

As explained in Section 4, the first stage of an ethos of controversies inclines articulation of the viewpoints as well as of the motivations for a certain opinion. The new Directive is designed in such way that several motivations for prohibition or restriction can be used. As we explained in Section 3, the working mechanism of the Directive follows a two-step plan. In the first step however, no argumentation is needed for restricting the scope of an authorisation. A simple written request will do. In regulatory practice, the process thus far ends with step 1 without any debate, confrontation or explanation. We therefore argue that, from the perspective of an ethos of controversies, step 2 deserves more attention in order to arrive at adequate decision-making on GM crops. For, if an applicant denies the request for exclusion of the territory of the MS from the geographical scope, the MS can still take measures to restrict or prohibit cultivation based on step 2. Different from step 1, these measures must be reasoned and follow compelling grounds.[44]

44 The Directive states that the measures must be based on compelling grounds such as, but not limited to, those related to a) environmental policy objectives, b) town and country planning, c) land use, d) socioeconomic impacts, e) avoidance of GMO presence in other products without prejudice to Article 26a, f) agricultural policy objectives or g) public policy.

At first instance, this step thus creates room for an exchange of viewpoints and confrontation, reflecting the first stage in the ethos of controversies. In step 2 of the Directive other grounds than safety have to be made explicit by MS who want to restrict or prohibit cultivation on their territory. The requirement to motivate the decision forces the MS to articulate their viewpoints. This articulation is a first step towards further exploring the diverging viewpoints at stake, and to gaining a better understanding of the issue within MS itself. As discussed in Section 2.2, although the voting behaviour of MS suggests a national consensus, opinion polls, law suits[45] and literature indicate this is not necessarily the case. Therefore, step 2 of the new Directive offers an opportunity to reopen the debate on a national level as this step will force MS to reflect on their position regarding GM crop cultivation and express their motivations. The competence in step 2 thus gives room for further reflection on the considerations that play a role in the conflict about cultivation of GM crops. Viewpoints that were earlier excluded from national decision-making, either in favour or against GM crop cultivation, can be re-introduced in this procedure. A remark must be made on this point. Reopening the debate on a national level may not be desirable for some that are satisfied with the status quo and is at risk of having the same consensus-focused discussion on the safety or desirability of GM crops again. This would turn this Directive into window-dressing instead of a window of opportunity. It is therefore essential to focus on mapping diverging viewpoints. Confrontation of these diverging viewpoint may lead to better understanding and substantiating of the different viewpoints.

Step 2 of the Directive thus has a potential for articulation and confrontation of the issue, but there is a catch. When applying step 2 of the Directive, MS have to provide their motivation for a ban in writing to the applicant through the EC. Legally, the EC can but is not obliged to respond/comment on the argumentation of the MS. After deliberation on a national level, this could provide opportunity to continue and further develop viewpoints (confrontation and articulation) on an international EU level. Applying the Directive however, is the sole (legal) responsibility of the MS (or specific regions within a MS), not the EC. Any legal issues resulting from the national ban will be between the

45 Court of Justice of the European Union, Case C-111/16, 13 September 2017. In 2017, the European court ruled in favour of Italian farmer Giorgio Fidenato who was prosecuted by his country for planting genetically modified corn. Italy has upheld a ban on GM crop cultivation since 2006, the request for an emergency ban (safeguard clause) was turned down by the Commission. The court ruled that a MS does not have the right to ban GM crops without substantial evidence for human or environmental health hazards.

MS and the applicant. Therefore, one could say that the EC has no motive or incentive, to comment or deliberate on the argumentation of a MS to ban a GM crop on a national level. After all, one of the motives of the EC for the Directive was even to avoid being in a position of responsibility for national decision-making on cultivation of GM crops (Randour *et al.* 2014).

In summary; from the perspective of an ethos of controversies, there are two factors in the design of the Directive limiting its potential success: step 1 does not need articulation of viewpoints and step 2 does not require confrontation from other viewpoints.

To see the Directive as a window of opportunity we suggest, first of all, to give step 2 of the assessment framework a more prominent role (recommendation 1). And second, we suggest, to follow an ethos of controversies to improve problem structuring and to arrive at reflected opinions (recommendation 2). This will contribute to addressing and acknowledging the different viewpoints and motivations of the users of the Directive identified in Section 5.1.

That leaves us with the last factors, which concern the role of ideology and politics from a broader perspective on agriculture and food production. The political realities regarding GM crops are illustrated by amongst others the (non-)acting of the EC in taking measures against unjustified national bans or using its mandate to take authorisation decisions and in the different attitudes towards cultivation and importation. At first instance, the ethos of controversies does not offer an answer to the reality of the involved political aspects of such issues.

Political strategies seem to impede a comprehensive problem-definition (stage 1) and, moreover, seem to bring about avoidance of any form of confrontation (stage 2). As long as stage 1 and stage 2 of an ethos of controversies are not adequately followed and problem-definition is still ill-structured, decision-making is unsatisfactory and therefore deliberately hampered, as the actual voting exemplifies. MS have not changed their voting behaviour. Furthermore, the pessimistic attitude of both the industry and NGOs may cross this stage, as they represent part of the national interest. None of the stakeholders seems satisfied with the new assessment framework. Instead of acknowledging that the conflict remains unresolved, the EC initiated a similar proposal for

a Directive to restrict GM food and feed (import) on a national level[46] and mentioned plans for a change of the comitology procedure for smoothening the voting process.[47] Additionally, third parties have even suggested an opposite approach that focusses on an opt-in instead of an opt-out strategy (see Eriksson *et al.* 2018). These efforts illustrate both the frustration as well as the importance of this subject to stakeholders in Europe. The existing and proposed strategies seem to have something in common, which Daviter (2017) describes as a 'taming' strategy: aiming 'to transform an ill-structured or wicked problem into a more manageable and well-structured problem for the purpose of decision-making.' To accomplish this, the problem is framed in such a way 'to align it with existing administrative expertise and policy responsibilities' (p. 580). As an advantage of this strategy, amongst others limited participation and debate from public authorities are mentioned, as well as a reduced need for cross-sector coordination. According to Daviter, 'taming wicked problems accepts that competing problem perspectives are cast aside rather than explored'. Aside from solving and taming, he identifies a third strategy to deal with wicked problems: coping, which aims to reflect the fragmented, uncertain and ambiguous nature of wicked problems by relying on a more disjointed and tentative process of formulating policy responses.

We see possibilities of the ethos of controversies to contribute to the potential of the Directive already in place that are in line with a coping strategy. This is where the third stage ('awareness') comes into play.

We think that the basic idea of stage 3 of an ethos of controversies should be emphasised to deal with the identified political realities (recommendation 3). The third stage of an ethos of controversies involves awareness and ideally acknowledgement that the ideological, cultural or religious conflict continues to exist, even after decisions are made. Either cultivation of a GM crop or prohibition of it by MS does not signal the end of conflict or the end of a debate. Smith & Stirling (2007) argue that definitive closure around appraisal

46 The Commission proposed to amend Regulation (EC) No 1829/2003 by adding a new Article 34a, allowing Member States to restrict or prohibit the use of GM food and feed in part or all of their territory, complementing the possibilities they already have concerning GMOs for cultivation. The proposal was rejected in October 2015 on technical grounds by EU lawmakers and the process has since then been on a standstill. See <http://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2015/0177/COM_COM(2015)0177_EN.pdf > Accessed 16 April 2018.

47 A Commission 'options paper' identifies four ideas, one of which excludes MS who are not represented or abstain from voting from the calculations for QM. Only taking into account yes/no votes should increase the chance of a QM.

of a socio-technical object cannot be reached. Moreover, 'closure is not reached through objectification, but through negotiated commitment formation'. As such, it seems to make more sense to ensure commitment to the process and acknowledging fundamental differences than to chase objective knowledge to reach a consensus. As such, a decision or 'consensus' should be seen in a different light. Quoting Mouffe (2000):

> *'It is for that reason that the ideal of a pluralist democracy cannot be to reach a rational consensus in the public sphere. Such a consensus cannot exist. We have to accept that every consensus exists as a temporary result of a provisional hegemony, as a stabilization of power, and that it always entails some form of exclusion. The ideas that power could be dissolved through a rational debate and that legitimacy could be based on pure rationality are illusions, which can endanger democratic institutions.' (p.104)*

This means we also need to rethink the role and position of stakeholders in decision-making on GM crop cultivation. To create room for diverging value loaded viewpoints of the stakeholders and to create an area for confrontation of viewpoints, we need to view stakeholders as reflexive political agents (Biale & Liveriero (2017). Biale & Liveriero conclude, in an argument for grounding democratic legitimacy on the actual, non-idealised circumstances of deliberations, that 'disagreement is not only a factual circumstance of democratic decision-making systems, but the perfect expression of democratic ideals because only when citizens disagree and express their dissent can they properly exercise political agency.' (p.586) Citizens can only do so if they reciprocally acknowledge one another as epistemic peers (p.590). We intend to use a similar line of argument for stakeholders in GM crop regulation. The Directive can only function adequately if stakeholders as well as the EC and MS, in the context of step 2 of the assessment-framework, recognise their shared status as political agents with whom they might fundamentally disagree. Acknowledging the other as an equal peer, brings the reciprocal obligation to explain, challenge, compare and critically assess their claims, programs and values that shape their political proposals (p.586). These obligations correspond with the basic tenets of the ethos of controversies in the interactive legislative approach-though, within this approach, the reciprocal character of the relation between stakeholders being political agents has never been considered. This understanding of the relationship, however, suits one of the basic elements of the interactive legislative approach: interaction. In Section 4.1, interaction is explained in terms of responsiveness and co-operation.

These terms closely relate to an understanding of another as being an equal peer. We, therefore, consider this understanding a valuable contribution to Poort's model of the interactive approach. Although challenging[48], we think that this understanding, can help to overcome some of the difficulties caused by the actual circumstances of the political field in which the regulation of GM crop cultivation is debated.

6. CONCLUSION

By explaining the new GM crop cultivation Directive (EU) 2015/412 in light of an ethos of controversies, it can be seen as a window of opportunity for decision-making in Europe on the cultivation of GM crops. The twenty-year struggle resulted in a proposal in which EU MS can have their own considerations for prohibiting, restricting or allowing GM crops in their territory. In theory, this partial decentralisation step is in line with the concept of subsidiarity and could facilitate a form of multilevel governance in which more justice is done to local and regional factors while others, such as safety, remain centrally organised (see also Dobbs 2016).

By following this approach, broader grounds for prohibition or restriction of GM crop cultivation are acknowledged. In other words, the Directive aims to end a legal struggle on a European level, while at the same time, doing justice to diverging viewpoints that are deeply rooted and might never be overcome. This Directive provides a unique example of how those controversies are not only acknowledged, but non-safety considerations are also given an explicit legal status in the regulatory process. However, we have also shown that positioning controversies in law structures is not sufficient by itself, demonstrating a good example of the difference between 'law in books' and 'law in action'. As long as the Directive is used and implemented as a taming strategy instead of a coping one, competing problem perspectives are not explored and commitment from stakeholders not encouraged. Reciprocal acceptance of decentralised (MS level) decision-making and a continuous interaction, confrontation and exploration of the controversies is needed to arrive at effective decision-making.

We have argued that even when dealing with deep value-orientated disagreements, it is in theory possible to come to an adequate and reasonable regulation. The contribution of the theoretical lens of an ethos of controversies

48 Mampuys & Brom (2015) have shown that personal arguments (authority, ad hominem, conspiracy and tu quoque) play a recurring role in the GM debate, disqualifying the opponent as an equal peer. These arguments are contra-productive, increase polarisation and escalation of the debate.

lies in the explicit acknowledgement of different viewpoints, which can be a first step towards decision-making. Thereafter, several political and legal challenges remain still to be tackled. Decision-making will only be possible based on reciprocal acknowledgement of the remaining conflict and a willingness to loosen or let go of strategical political motivations.[49]

Finally, several legal challenges from a global perspective remain with the use of the new Directive, such as the question of what can legally and from an international perspective be considered a valid non-safety consideration and how to measure and evaluate these considerations (COGEM 2014, Tosun & Hartung (2018)). This has been thoroughly analysed by Punt & Wesseler (2016). Concerning the latter challenge, several bridges still have to be crossed. Considering the new Directive as a window of opportunity, however, is a first necessary step in unleashing its full potential.

49 We note that the Directive explicitly facilitates an opportunity for opponents to ban GM crop cultivation, in addition to obstructing decision-making in the previous procedures. It does not, for example, facilitate a similar opportunity for those in favour of GM crops. This could indicate that there is no demand for GM crops in Europe in general or that the specific characteristics of available GM crops do not benefit European agriculture because effective weed management is possible with existing measures or that pest insects targeted by insect resistant crops do not pose a problem (yet) in European agriculture.

CHAPTER 7

SOCIO-ECONOMIC CONSIDERATIONS IN REGULATORY DECISION-MAKING ON GM CROPS

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7

1. INTRODUCTION

Regulation has been fundamental to the debate on the use of agricultural biotechnology because of: (1) the possible safety implications for the environment and human health, and (2) non-safety implications including socio-economic considerations (SECs) on the other. Effective and useful regulation ensures an adequate level of safety while, at the same time, enables access to safe products that will benefit society in general, and local communities in particular. As such, regulation is concerned with obtaining a balance between costs and benefits. Cost can be economic costs, but can also include risks to humans and the environment. Benefits can be profit, but they also can include welfare, quality of life or environmental improvement. Apart from identifying and measuring costs and benefits, the distribution of each is of great importance; who bears the costs and who incurs the benefits? Many of these as classified as socio-economic aspects (SECs).

National and international regulations increasingly acknowledge the importance of formalising the inclusion of SECs in decision-making (CBD, 2010). Currently, most commercial applications in biotechnology relate to agricultural products (i.e. genetically modified [GM] crops), and as such, SECs in this field tend to focus on those aspects that have an influence on the food supply chain as a whole. SECs include economic as well as social effects at the farm-level, on the supply chain and on the end user (i.e. the consumer). The wide range of SECs covers everything considered socio-economically relevant; this can complicate their implementation and operationalisation in regulatory decision-making. It is therefore important to set out a clear framework indicating what is meant by SECs and how they can be measured. The assessment and inclusion of socio-economic impacts in regulatory decision-making for GM crops is complex, but the amount of research and data available on SECs s increasing (Smale *et al.*, 2009; Hall *et al.*, 2013; Brookes & Barfoot, 2017). Over the years, methodologies used for socio-economic impact assessments have improved with increasing experience of GM crops (Morris, 2011; Garcia-Yi *et al.*, 2014; Kathage *et al.*, 2016).

This article reviews of the use of SECs in regulatory decision-making, either in parallel to or as part of biosafety decision-making. First, a brief introduction to the international legal provisions for including SECs within regulatory decision-making will explore the most commonly used categories of SECs for GM crop cultivation. Next, the different aspects and challenges of measuring, implementing and using SECS in regulatory frameworks will be explored. Many

countries recognise the importance of SECs and have mentioned them in their biosafety regulations. However, relatively few have formally implemented them into the actual assessment of genetically modified organisms (GMOs). This review aims to provide greater insight into both the opportunities and challenges of integrating SECs into regulatory decision-making.

2. LEGAL BASIS. ARTICLE 26, CARTAGENA PROTOCOL ON BIOSAFETY

The legal basis for the inclusion of SECs in biosafety decision-making is primarily Article 26 of the Cartagena Protocol on Biosafety (CPB),[1] a legally-binding international agreement, negotiated, concluded and adopted in the framework of the Convention on Biological Diversity.[2] It was established to guide Parties in developing countries in the environmentally-sound management of modern biotechnology practices, specifically focusing on transboundary movements. Parties to the CPB are expected to establish functional regulatory systems that have both the capacity to access state-of-the-art research and development facilities along with a platform for exchanging scientific and technical information. Following the CPB, a number of capacity building initiatives have assisted (and continue to assist) developing countries to build functional regulatory systems. The CPB addresses all aspects of biosafety regulation, including the use of SECs (see **Box 1**).

According to Article 26 of the CPB, the inclusion of SECs in regulatory decision-making (1) can apply to import decisions; (2) can apply to issues included under domestic laws and regulations; and (3) is voluntary; and furthermore, (4) if countries chose to include them, then the assessment needs to be consistent with international obligations, for example the World Trade Organisation (see also Falck-Zepeda *et al.*, 2016). Finally, Article 26 of the CPB also suggests that SECs should have a specific focus: there should be direct causality from adopting GM crops to effects on biodiversity.

The importance of formalising the inclusion of SECs in national regulations is increasingly acknowledged, particularly in developing countries. There are, however, no standard provisions to include SECs in domestic legislation of Parties to the CPB: this creates possibilities and flexibility, as well as challenges, in implementing SECs at the national and international levels (Tung, 2014). Before addressing these challenges, SECs will be explored in more detail.

1 https://bch.cbd.int/protocol

2 The Convention on Biological Diversity (CBD; https://www.cbd.int) is a multilateral treaty with the objective to develop national strategies for the conservation and sustainable use of biological diversity.

Box 1. Article 26 of the Cartagena Protocol on Biosafety

Art. 26 states that:

1. *The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.*
2. *The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.*

3. SPECIFYING SOCIO-ECONOMIC CONSIDERATIONS

There is no strict definition of socio-economic considerations, nor is there an exhaustive list of factors that encompass SECs. SECs can be wide-ranging: they can relate to direct or indirect impacts, be technology-specific or relate to non-specific impacts. Moreover, the impacts can be positive or negative, and sometimes affect different groups of stakeholders at the same time in different ways. The specific impact and characteristics of SECs depend on the context in which they are used. The context of biotechnology applications can differ depending on the following variables: the type of application, as well as its geographical location and technology users (i.e. what, where and who).

- Type of application: this determines which SECs are relevant for analysis. Different types of GMOs are developed for a range of goals and contexts: for example, GM crops in an agricultural context and GM mosquitoes to eliminate vector-borne diseases in a human health-related context. GM crops are developed primarily to increase yield, farmers income and, further down the line, food security. The primary purpose of GM mosquitoes is to reduce disease incidences; they can have a direct (beneficial) effect on human health, but also a secondary (beneficial) effect on employment and income in local communities. Different SECs will be relevant for different situations; alternatively, the same SECs can have a different level of importance when assessing a specific GMO application. This review primarily focuses on the application of various types GM crops: insect-resistant, herbicide-tolerant, virus-resistant or bio-fortified.

- Geographical location: the location of release/use can influence the socio-economic impact of a GM crop. For example, the impact on food security is likely to be negligible in developed countries because agricultural inputs have already been optimised in many areas (such as irrigation, fertiliser, weed management and pest management). In developing countries, such as in Africa, 30 – 50 % of crops (and thus, harvests) can be lost because to insect pests (Deloitte & Touche, 2015). Introducing an insect-resistant GM crop can therefore have a big effect on food security in rural communities in these countries.

- Technology users (or stakeholders): SECs can have a varying impact on different users, known as 'the distribution of effects'. The socio-economic impact of a specific GM crop can vary amongst different groups of stakeholders (i.e. farmers, retailers and consumers) or within the same group of stakeholders (i.e. adopters and non-adopters of GM crops).

The following sections discuss the most commonly used SECS and their impacts on farming, on of coexistence measures, on environmental economy, along the supply chain and on food security and consumer.

3.1 FARM-LEVEL IMPACTS

GM crops can generate benefits for adopting farmers, including yield and profit increases, as well as less tangible benefits, such as less variability in yield and more flexibility in time management (for example, a wider time window for applying herbicides). However, not all farmers may profit equally from adopting GM crops. The extent of potential benefits will depend on characteristics of the specific agricultural plot and farm management, such as the previous incidence and severity of pest attacks, amongst others (Hall *et al*., 2013). To determine the underlying mechanisms of socio-economic effects, a socio-economic analysis should start by profiling the typology of farms, farmers and adoption rates in the area under research (Kathage *et al*., 2015). Adoption rates can be measured by (1) calculating the number of hectares planted with GM crop(s) divided by total hectares by crop or total hectares of arable land by country or region; (2) the number and proportion of farmers adopting GM crops (*ex post*); or (3) the number of farmers willing or unwilling to adopt a GM crop (*ex ante*). Farm typology relates to both farm characteristics (e.g. location [country/region], size, income by crop and livestock type, ownership and organic certification) and farmer characteristics (e.g. education, age, sex, household income, off-farm income and time dedicated to farming).

Socio-economic impacts at the farm-level include all direct and indirect effects (see Box 2) of a GM crop while it is being produced. The impacts can affect the farmer, farm workers or other farmers in the same region. The impacts can also be divided into income, health, social, and ethical or cultural aspects.

Box 2. Direct and Indirect Effects

Socio-economic impacts can be the direct or indirect consequences of technology use, as illustrated by the following examples.

Conventional (i.e. non-GM) crops such as maize need regular applications of pesticides. The incorrect or unprotected use of pesticides can poison field workers (Damalas & Eleftherohorinos, 2011). Insect-resistant GM crops produce a specific protein that functions as a pesticide. These GM cops will generally need fewer pesticide spraying applications than the comparable non-insect-resistant crop. Thus, insect-resistant GM crops can have the direct effect of reducing pesticide use. As an indirect effect, insect-resistant GM crops can decrease the number of cases of pesticide poisoning of field workers (Kouser & Qaim, 2011; Racovita 2015).

Herbicide-tolerant GM crops can facilitate a change in crop management system that requires a different herbicide to be applied and can result in a reduction in soil preparation (tilling). Such low or no-till agriculture can indirectly reduce soil erosion as well as fossil fuel use and greenhouse gas emissions due to less tractor use.

Virus-resistant GM crops can directly reduce local viral loads, which can indirectly cross-protect nearby non-GM crops sensitive to the same virus.

3.1.1 INCOME-RELATED ASPECTS

Income-related aspects of farm-level impacts contribute to the balance between inputs (expenses) and outputs (income). Farmers rely on different types of input, that is, expenses related to: seed and agrochemical (e.g. fertiliser, pesticides, herbicides) purchase; irrigation (depending on the climate); and fuel/machinery and labour. The output is the yield, which the farmer will sell for a certain price depending on crop quality and local market characteristics. Crop quality can be determined by seed quality and crop management efficiency, which also influences the overall input/output balance on a technical and allocative scale. For example, efficient management may result in more time to generate off-farm income from other activities.

There is no general formula for calculating the gain in income from adopting a GM crop. The potential increases in yield and economic return depend on a variety of factors (**Table 1**). The more heterogeneous these factors are, the more variable will be the resulting benefits and costs. The effect of a change or improvement in one factor may be mitigated by other factors. For example, the use of an insect-resistant GM crop may result in suboptimal yield if other factors are limiting.

Farmers who do not adopt GM crops may also be affected by the cultivation of GM crops by others. The availability of GM crops on the market can have an influence on the availability of non-GM seeds and output prices. Non-adopting farmers will probably face additional costs of segregation measures or damage (if cross-pollination or admixture occurs; see Section 3.2). However, they may also benefit from crop protection spill-overs (i.e. a local reduction in pest pressure caused by insect-resistant GM crop cultivation).

3.1.2 HEALTH ASPECTS

These relate to factors influencing the health of the farmer, farm workers and local community. For example, a change in pesticide management may influence not only income and yield, but also affect the health of workers, leading to longer, healthier and more productive working lives (Bennett *et al.*, 2006; Krishna & Qaim, 2012; Racovita *et al.* 2015). Increased yields or better-

Table 1: Factors determining changes in yield and economic returns

Factor	Variability
Current crop	Has the farmer already cultivated this crop?
Trait characteristics	What type of GM crop is introduced (e.g. herbicide-tolerant, insect-resistant, virus-resistant, biofortified)?
Incidence(s) of pest infestations	Low or high pest pressure? Single or multiple pests?
Agricultural practices	Low- or high-tech?
Climate conditions	Temperature, humidity, precipitation, etc.?
Soil conditions	Nutrient level, need for fertiliser etc.?
Seed costs	Price premium for GM seed?
Market characteristics	Are GM crops already on the market? What is the demand? Level of societal acceptance?

quality crops (with increased nutritional value) can benefit health. Finally, other less-quantifiable factors may influence people's health, such as a reduced need for physical labour or improved working conditions (Bennett *et al.*, 2006). Health aspects can be quantified economically using morbidity/mortality data associated with the use of pesticides and chemicals or with nutrition.

3.1.3 SOCIAL ASPECTS

The social, ethical and cultural aspects of farm-level impacts relate to factors influencing working conditions such as working hours and overtime, wages and health insurance, training and education, and the availability of machinery and safety equipment. All of these aspects influence the quality of life at the farm level. Additionally, there can be an impact on social interactions between farmers (i.e. between adopters/non-adopters or a shift/change in buyers and supplier). Impacts at the farm level can include ethical and cultural effects, such as a change in moral values (for example, concerning good agricultural practice and the exploitation of natural resources), the use of indigenous knowledge and cultural practices concerning farming (versus hi-tech agriculture) or the distribution of justice (accessibility of the technology and the influence on any inequality between adopting and non-adopting farmers). Social effects can be mapped qualitatively using interviews or questionnaires.

3.2 IMPACT OF COEXISTENCE MEASURES

Cultivating GM crops has implications for the organisation of agricultural production. GM crop-adopting farms might have an unintentional impact on non-GM adopting farms due to unwanted pollination between their fields or admixing of their products. Therefore, it is necessary to establish systems to enable the coexistence of GM and non-GM crops (conventional agriculture, including organic certified agricultural systems). Coexistence is defined as the ability to successfully produce and market products from both GM and non-GM crops within the same agricultural system. This enables farmers to choose a production system that helps meet demands for niche markets by maintaining crop integrity within a system and preserving the economic value of the harvest.

It should be noted that the issue of coexistence of GM crops with non-GM crops is not a safety issue as legal GM products on the market have passed health and environmental safety reviews and regulations. Rather, coexistence is an economic issue that is market-driven.

Socio-economic impacts of coexistence include all direct and indirect effects of measures to prevent unintentional presence of GMOs or admixture from GM crop farming to conventional and organic certified systems (see **Box 3**). Coexistence measures can influence farm-level costs and GM crop adoption dynamics.

Two strategies are generally used to implement coexistence: precautionary (*ex ante*) and damage control (*ex post*) strategies. The first strategy aims to

Box 3. Coexistence Measures to Minimise Adventitious Mixing

Coexistence systems aim to reduce the likelihood of admixing crops grown via GMO, conventional, organic or subsistence agriculture. Admixing can occur before, during and after crop production

Before crop production, admixing of seeds can occur. Ensuring seed purity is the first step in preventing GMO contamination. The risk of seed mixing depends on the type of seed system in use. Formal, well-organised seed systems are generally used by commercial farmers, whereas informal systems are used by smallholders or subsistence farmers. In an informal seed system, the seeds are saved by farmers, and then distributed by registered or unregistered traders and vendors. Therefore, seed mixing and adventitious presence of GMOs are more difficult to control in informal systems than in formal systems.

During crop cultivation, the unwanted presence of GMOs may result from gene flow due to cross-pollination between GM plants and non-GM plants of the same type. Whether cross-pollination actually occurs depends on several factors: the crop type, pollen and seed dispersal; and the distance between fields. Coexistence management measures are therefore crop-specific. The European Bureau on Coexistence has developed crop-specific guidance documents[1] for best practices in coexistence management.

Admixing can also occur after production; during harvest, transport and post-harvest crop handling (such as storage and drying). Therefore, GM and non-GM harvests must be handled separately to prevent co-mingling. A contributory factor is that (smallholder) farmers often share harvesting machinery, transport wagons and storage facilities. The difficulty and costs of separating production chains depends on many factors, for example, the adoption rate of GM crops and the availability of separate means of storage and transport.

1 https://ec.europa.eu/jrc/en/ecob/documents/best_practice

prevent admixture and gene flow; whereas the second provides measures to handle the situation after admixture has occurred. Ideally, both systems need to be in place because admixture is almost impossible to prevent. Examples of coexistence measures of both strategies are shown in **Table 2**.

Besides technical and practical measures to ensure effective coexistence, other measures include: careful record-keeping and administration and regular testing; training/education of farmers and farm workers; and good cooperation and communication between farmers and the operators of shared agricultural equipment. These measures provide transparency and may reduce or prevent disputes between neighbouring farmers.

Coexistence can increase farming costs such as operational costs, transaction costs, opportunity costs and testing and remediation costs. The type and scale

Table 2: Measures to promote coexistence (adapted from Czarnak-Kłos & Rodríguez-Cerezo, 2010; Devos *et al.*, 2009)

Pre-cautionary measures (*ex ante*)	**Damage control measures (*ex post*)**
Mandatory segregation: • Ensure seed purity • Provide rigid/flexible refuge areas • Have voluntary GM-free zones • Maintain isolation distances* • Adjust planting/flowering distance and/or timing • Keep machinery & equipment clean • Seal and label seed containers	Compensation funds
Identity preservation / traceability	Insurance schemes
Minimum GMO tolerance levels**	Marketplace liability

* Isolation distance is the distance maintained between fields of crop plants to help minimise cross-fertilisation by pollen flow. The minimum isolation distance depends on factors such as the fertilisation mechanism of the species (self- or cross-pollinated crop) and the pollination agent (wind or insect).

** Because zero admixing is not achievable in agricultural systems, a legal threshold for the products of adventitious mixing must be set. This varies, but for most countries the legal tolerance threshold for authorised GMOs in non-GM products is 0.9%.

of these costs can vary between GM crop adopters, conventional farmers and organic farmers.[3] The need for coexistence measures can influence GM crop adoption dynamics, such as the rate of adoption, spatial configuration of adoption, and the rate and stability of GM crop expansion. Finally, admixture can also have a social impact by damaging the level of trust between neighbours, leading to conflict or even lawsuits (Levidow & Boschert, 2011).

3.3 ENVIRONMENTAL IMPACTS

Besides farm-level impacts, GM crop cultivation can also have environmental impacts, both positive and negative (Raven, 2010; Mannion & Morse, 2012; Knox *et al.*, 2013; Garcia-Yi *et al.*, 2014). Environmental impacts related to SECs are limited to those with economic effect, such as pesticide use and carbon emissions. After all, an environmental risk assessment has already been conducted during the decision-making process. Environmental economic effects are crop-specific and relate to herbicide and insecticide use, crop yields and effects of unwanted gene flow. They can also have effects on soil, water and air conditions, biodiversity, the use of resources and fuel consumption. For example, drought- or salinity-tolerant GM crops can reduce the need for resources (water) and fuel use (reduced use of machineries), which can affect soil, water and air conditions in the area.

The use of GM crops may avoid the need for agricultural inputs and practices that might harm the environment, such as tilling. It can also change the type or quantity of herbicides/insecticides in use (Brookes & Barfoot, 2016), which may benefit soil and water conditions if the replacement herbicide/pesticide is less toxic. Apart from direct effects, the use of GM crops can have indirect effects due to changes in agricultural practices, such as less machinery and fossil fuel use resulting from fewer herbicide applications (e.g. CO_2 emission and carbon sequestration). Overall, improving crop yields without increasing the use of land and water resources could reduce total land use and help minimise impacts on biodiversity (Brookes & Barfoot 2017). GM crops approved for commercial cultivation have undergone a thorough environmental risk assessment and are considered safe. To date, no incidents of approved GM crops causing direct harm to the environment or human health have been

3 These differences are based on the relative costs compared to the consequences. Conventional farmers may lose part of the non-GM price premium for conventional crops and may be affected from not being able to sell the crop as non-GM. For organic farmers, the consequences can be more severe, as they can lose their organic certification which is based on the adherence to principles, such as not using pesticides or GMOs.

confirmed by governments or competent authorities (Nicolia *et al.,* 2014). Nevertheless, GM crops are associated with more general concerns related to industrial agriculture and pesticide use, both of which are considered unwanted or undesirable to the environment by certain stakeholders (Mampuys & Brom, 2015). Whether these should be considered as SECs remains under debate.

3.4 IMPACT ALONG THE SUPPLY CHAIN

Socio-economic impacts along the supply chain include all direct and indirect effects of the GM crop, from the technology provider and/or producer, to intermediaries (food industry, companies and retailers), and on to consumers. Changes resulting from the introduction of GM crops can affect the structure or performance of the supply chain or the distribution of costs and benefits within the supply chain (i.e. *shift*). The supply chain can be affected either upstream or downstream of the crop farming sector by various factors.

- Bidirectional effects. These include (inter)national GMO regulations, enforced local or national co-existence rules, voluntary and mandatory GMO certification schemes, and the protection of intellectual property rights (e.g. patents, licenses).

- Upstream effects. GM seed companies and manufacturers of complementary products (such as herbicides) may profit from GM crop-adopting farmers buying their products, while competitors selling non-GM seeds and other herbicides may lose market share. Similarly, GM insect-resistant crops: companies that sell insecticides might experience reduced sales because less pesticide is used compared with a non-GM crop. Further upstream, GM crop adoption can also affect innovation, for example by increasing or decreasing research investment in R&D.

- Downstream effects. These include all socio-economic effects on intermediaries between the farm level and consumer. GM crops can affect market access and (national) trade interests, logistics, governance mechanisms (coexistence). The market power of different actors (i.e. ability to influence the price of a commercial item), and the price elasticities of supply and demand for the crop can also be affected. The scale of these effects will depend upon whether the country is a large or small producer (i.e. price-setter or price-taker), whether the country trades the crop internationally (i.e. closed or open economy), adoption rates, and the nature and magnitude of the supply shift caused by GM crop adoption. The

cost of Identity preservation and traceability of GM crops affects the entire supply chain (Kalaitzandonakes *et al.*, 2009). In addition, the feed industry might benefit from lower prices for raw materials if an increased GM crop cultivation leads to higher yields combined with lower prices. Likewise, the organic industry might capitalise on the demand for non-GM feed. Although livestock producers may benefit from less expensive feed, those in the organic sector may have to pay a higher premium for GMO-free feed as it becomes scarcer as more GM crops are cultivated. The food industry depends on the acceptance of GM crops for food production and any related GMO labelling requirements.

The commercialisation of GM products under different enforced co-existence rules, labelling schemes, and intellectual property rights can impact the supply chain structure (both vertically and horizontally) and performance (e.g. efficiency, effectiveness, and innovation ability). This, in turn, can affect the distribution of costs and benefits amongst the different actors along the supply chain, as well as their market power (e.g. ability to influence the price of a commercialised item).

Worldwide, countries have different domestic regulations concerning the trade and labelling of GM products, which can affect the international trade patterns in agricultural products and the competiveness of partner countries and their corresponding sectors. The stringency of GMO regulations of large food importers such as Europe is reported to affect the strategies of developing countries (e.g. Argentina and selected African countries) concerning GMO production and regulations (Paarlberg, 2010; Adenle, 2011; Laursen, 2013).

The handling of GM materials and products along the supply chain can also have social or legal effects owing to political and trade differences regarding GMOs, such as disputes regarding market access and trade interests (World Trade Organisation; for an example, see Punt & Wesseler, 2016), shifts in market power of different actors and the response from retail sector based on (perceived) consumer acceptance (Tung, 2014).

3.5. FOOD SECURITY AND CONSUMER LEVEL IMPACTS

In countries with suboptimal agriculture and limited access to resources, GM crops can improve food security (Qaim & Kouser, 2013). Most of the world's hungry people live in developing countries, where one report estimated the prevalence of undernourishment as 14% (FAO, IFAD & WFP, 2013). The same report defined food security as:

> *"a situation that exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences, for an active and healthy life".*

It identified four dimensions of food security:

1. **Availability** of sufficient quantities of food of appropriate quality, supplied through domestic production or imports (including food aid);
2. **Access** by individuals to adequate resources for acquiring appropriate foods for a nutritious diet;
3. **Utilisation** of food through an adequate diet, clean water, sanitation and health care, to reach a state of nutritional well-being, where all physiological needs are met, and;
4. **Stability** in the availability of, and access to, food regardless of sudden shocks (e.g. an economic or climatic crisis) or cyclical events (e.g. seasonal food scarcity).

Thus, food security is a multi-dimensional concept that needs all four dimensions to be fulfilled simultaneously to be successful (Ruane & Sonnino, 2011). Therefore, GM crops alone are unlikely to provide an overall solution to food security problems. They can, however, contribute to a wider approach to food security (Dibden *et al.*, 2013). GM crops can improve food availability by utilising traits such as insect and/or herbicide resistance, as well as drought and/or salinity tolerance, to decreases yield losses from pest insects, weed infestations or adverse climate conditions. GM crops can also improve food access (e.g. by increasing income for farmers), and improve food utilisation (e.g. biofortified crops with increased nutritional value).

As indicated in Section 3.2., farmers can choose whether or not to cultivate GM crops or instead to adopt an organic farming system. This same range of choices extends to consumers, for whom a wide variety of food preferences that can be influenced by national, cultural and individual characteristics (age, gender, highest attained educational level) and values (cultural, religious and ethical influences). Consumer choice for GM or non-GM products is determined by availability, acceptance and pricing of GM versus non-GM products.

Several countries have either mandatory or voluntary GM-related labelling schemes (GMO or GMO-free), with different tolerance levels (i.e. the permitted threshold under which GMOs can be present in the final product without

impacting the products "non-GMO" status).[4] Most organic certification schemes require their products to be GMO-free, as this is one of the main principles of organic agriculture (USDA, 2013). Socio-economic impacts at the consumer level relate to the costs of labelling or banning products and the willingness to acquire or avoid specific products. The effect of price premiums for non-GM products have been evaluated in different GM-related labelling-schemes, including their effect on consumer welfare (Lusk *et al.*, 2005; Costa-Font *et al.*, 2010; Aerni *et al.*, 2011; Oh & Ezezika, 2014). As indicated by Garcia-Yi *et al.* (2014):

> *"Potential buyers can indicate their willingness to pay (WTP) for these products, and changes in social welfare can be calculated based on the differences between the WTP and actual or expected prices (price premiums). If there is a moratorium or ban on GM products, option values can be calculated based on a (hypothetical) WTP to preserve or maintain this situation. Social welfare can be estimated by the difference between the WTP and the opportunity costs of forgoing economic growth associated with the commercialization of GM products."*

4. USING SECS IN REGULATORY FRAMEWORKS

This section discusses the main aspects and challenges of using SECs within regulatory frameworks, beginning with methods to measure and compare SECs. SECs will then be discussed from a legal and regulatory perspective by identifying the challenges of implementing them and harmonising the different biosafety regulations.

4.1 MEASURING SOCIO-ECONOMIC IMPACTS

Numerous methods are available to calculate SECs (e.g. the list reported by Falck-Zepeda & Zambrano, 2011); however, there is no standard methodology for measuring socio-economic impacts. Every analysis is case-specific and each method has specific strengths and weaknesses.

SECs related to economic, social, environmental, cultural and health-related impacts can sometimes be expressed in monetary or other quantifiable terms (e.g. the number of employees, working hours, hourly pay rate, revenue in currency per tonne), but others, such as innovative ability or competitiveness

4 Tolerance levels for unintended adventitious or technically unavoidable low level presence of GMOs in food and feed are set because a zero tolerance level is almost impossible to achieve in an international trade setting. Most countries have a threshold value of 0.9 % per ingredient for authorised GMOs.

are more challenging to quantify. SECs can be quantitative and qualitative, absolute or relative. Social effects can be expressed quantitatively (e.g. the number of unemployed people, the number of people living in poverty or on social security benefits), but social exclusion or justice, for example, are more difficult to quantify.

Although there are many potential SECs, those used within a regulatory assessment framework should preferably have at least one measureable indicator (either quantitative or qualitative) and a plausible causal mechanism by which GM crop cultivation might affect the indicator (i.e. a direct relation or link between the indicator and GM crop cultivation). A scientifically sound method of assessing the impact of GM crop cultivation on the indicator is also needed to ensure transparency, traceability and reproducibility (Kathage *et al.*, 2015). The following sub-sections discuss the most significant aspects of measuring SECs.

4.1.1 *EX POST* OR *EX ANTE*?

Socio-economic assessments can be done *ex post* or *ex ante:*

- *Ex post* assessment. This is done to evaluate a technology after it has been introduced, based on data from the actual case, within a specific country/region and over a specified time period. Information gathering is based on production input and output data and information from surveys. One example is a study of Bt cotton in South Africa that highlighted the impact that institutions can have on the type and level of benefits that technology may bring to farmers (Gouse *et al.*, 2005; Gouse, 2009). The study found that the successful introduction and adoption of Bt cotton by smallholder cotton farmers on the Makhathini flats in South Africa came to a halt due to institutional failure.

- *Ex ante* assessment. This is done by countries when there is a need to evaluate a technology before deciding whether it can be authorised for introduction. As no data is already available specific to the SECs of the technology in the country, data has to be identified from identical or comparable cases and/or assumptions based on baseline data and extrapolation. One example is a series of studies by Kikulwe and colleagues (cited by Falck-Zepeda & Grouse, 2017) on GM banana in Uganda, where low adoption levels due to negative perceptions about GM technology in general was identified as a potential risk, and was addressed by increased communication efforts by the developer.

- In general, an *ex ante* assessment has more uncertainties and limitations compared to an an *ex post* study; therefore it is even more important that the assessment is clearly defined in terms of scope, methods and assumptions made.

4.1.2 DATA AVAILABILITY AND QUALITY

It is important to first define the scope of the socio-economic analysis: What exactly is to be investigated? For instance, is it an investigation of the impact of a GM crop on farm gross income, or on local food security, or on farm workers health? Once the research question has been defined, the type of data to challenge the hypothesis can be quickly identified. This can be primary data (input/output, crop specific) or secondary data (welfare economics). It is important to remember that data sets may not always be available or accessible, and might need to be collected or generated by the researchers.

Next, it is important to evaluate the data quality (Falck-Zepeda & Gouse, 2017). This is influenced by factors such as specificity, significance, sample size, accuracy and reliability, experimental design and randomisation, and statistical analysis. Data on GM crop adoption and distribution should preferably be distinguished by typology of farms and farming systems to overcome potential biases (see **Table 3**).

In measuring farm-level effects (such as adoption rates), obtaining accurate and sufficient data on the adoption and distribution of GM seed by type/size of farmers (large-scale, small-scale, commercial or subsidence) may be challenging if accurate records of seed sales and users are unavailable. Similar issues concern the accuracy of farmer survey recall data and the administration of on-farm activities, which may be impaired because of illiteracy, for example. Although it may not be possible to solve these issues or to adjust for them, it is important to acknowledge and make explicit potential uncertainties and limitations of the data set.

When investigating socio-economic impacts over a specified period, the data continuity is important. Single-year and single-location studies have limited value, because climatic conditions and the production practices of individual farmers may unduly influence pest pressure or weed persistence and thus the assessment. Multi-year / multi-location studies are preferable to increase the representativeness and accuracy of the results. However, data continuity may also pose a challenge. Inevitably, climate conditions and pest pressure over

Table 3: Potential biases in socio-economic assessments of GM crops (adapted from Falck-Zepeda & Gouse, 2017).

Source of bias	Description
Selection	Can occur when individuals, groups or data are selected for analysis such that proper randomisation is not achieved: the obtained sample is therefore not representative of the intended population. For example is when adopters and non-adopters have different characteristics (other than adopting/not adopting the technology) that affect the indicator and are not controlled for. Another example is when adopters within government programmes or programmes initiated by seed companies are not 'real adopters' because the decision to adopt was not made by them.
Measurement	Can occur when the act of sampling influences the measurement. This can result from factors such as too small sample size or too few samples taken from a population.
Estimation	Can occur when the impact is over- or underestimated, for example in farmer surveys.
Simultaneity	Can occur when the explanatory variable is determined jointly with the dependent variable. An example is when input decisions may be related but their connectivity is not addressed (i.e. the use of specific herbicides with herbicide-tolerant crops).
Sampling	Can occur when samples are collected in such a way that some members of the intended population are less likely to be included than others, such as sampling only higher profit-generating or larger farms.

the years may vary (within a certain range). Other, less predictable factors can also hamper data continuity, such as extreme erratic weather or damage from animals, farmers discontinuing GM crops because of external conditions such as off-farm employment, changes in government support or subsidies, and seed availability. Finally, gradual climate change may lead to the loss of a group of farmers (e.g. GM crop adopters) after a number of seasons. These factors are not directly associated with the effect of the crop itself, but they may influence the data continuity and the results of the assessment.

4.1.3 UNCERTAINTIES AND LIMITATIONS

SEC measurements inevitably suffer from uncertainties and limitations. Uncertainties can relate to the objectivity and accuracy of data, for example, how independent are the data, who collected or provided them, and how objective and accurate are data from farmer surveys or interviews (e.g. when

asking about (perceived) drawbacks or benefits of adopting GM crops or the motivations for certain decisions in farm management)? Uncertainties relate not only to the data but also to the method chose for quantification.

It is theoretically possible to quantify almost every SEC by scoring the responses related to experiences with GM crops. However, quantification should never be a target in itself because quantitative analysis is often partial and does not present a complete picture. In addition, quantitative assessment is only as good as the input data. Therefore, the risk of quantifying qualitative data is that it gives the illusion of hard data.

For these reasons, uncertainty and sensitivity analysis are extremely important, along with an explicit analysis of the limitations, when assessing SECs. The use of averages in multi-year, multi-location studies can easily mask effects on individual stakeholders, whereas specific effects might overestimated or underestimated in smaller studies. Hence, the limitations of all studies should be made explicit when drawing up conclusions.

Once effects have been identified and measured, their position within the overall context of the study must be determined. To arrive at a conclusion, the measured effects need to be compared with a baseline (see **Box 4**). In an analysis of GM crops, the impact is usually calculated as the value indicator under the impact scenario (i.e. with GM cultivation) minus the value indicator under the baseline scenario (i.e. without GM cultivation) (Kathage *et al.*, 2015).

In conclusion, measuring and comparing SECs can be challenging due to a lack of (accessible) data and the effort needed to transform data into a form that is useful for analysis. There may also be information asymmetries: data on benefits (health/environmental impacts) are often scarcer (and more uncertain) than data on costs. Finally, the use of both qualitative and quantitative information may cause difficulty in comparing impacts.

Box 4. Baseline

A baseline (or reference) is a minimum or starting point used for comparative analysis, usually comprising an initial set of critical observations or data used for comparison or as a control. It is therefore critical for assessing the impact of an intervention. A comparable alternative (counterfactual) rather than a baseline (actual) approach can also be used for comparisons.

4.2 IMPLEMENTING SECS IN REGULATORY FRAMEWORKS

An effective regulatory system should: (1) have adequate legal authority and clear safety standards for decision-making procedures; and (2) operate in a cost- and time-efficient manner (Jaffe, 2004). As discussed in Section 2, Article 26 of the Cartagena Protocol on Biosafety (see Box 1) allows for the inclusion of socio-economic considerations in biosafety approval processes. Moreover, the openness of the CPB to different interpretations provides possibilities and flexibility, as well as challenges, in implementing SECs at the national and international level. These relate to the meaning of SECs and how they can be used in an overall assessment framework of GM crop applications.

The importance of clearly defining the questions "when", "how" and "under what decision-making-rules" that developers or decision-makers will consider in assessing the socio-economic issues for products undergoing regulatory review is widely recognised, not only for companies and other stakeholders but also from an international perspective (Jaffe, 2005; COGEM, 2009, Falck-Zepeda, 2009; Binimelis & Myhr, 2016; Racovita, 2017). Two types of challenges using SECs in regulatory decision-making can be identified: procedural and technical challenges (see **Tables 4** and **5**).

From a procedural perspective, the CPB does not indicate the rationale for including SECs in Parties reaching a decision on specific GMOs. Therefore, depending upon interpretation by individual Parties, this can lead to the question of whether SECs can constitute a legitimate reason to object or ban GM crops that are deemed safe.[5]

Several technical challenges relate to the inclusion of SECs in biosafety decision-making. This review, describes several categories of SECs that can be split into numerous sub-categories and indicators. A clear definition of scope, method and data requirements is needed to effectively include SECs in regulatory decision-making (see **Table 5**).

For the purposes of regulatory decision-making, the assessment of SECs requires a mechanism for identifying positive and negative socio-economic impacts. This, in turn, requires a workable framework to ensure that socio-

5 Biosafety regulations predominantly require an assessment of risk, or safety, to underpin decision-making. The inclusion of SECs into this procedure is highly debated because it not only brings up the question of whether SECs might be used to ban GM crops, but also how this relates to comparable conventional crops that are not subject to such a safety assessment nor a socio-economic analysis.

Table 4: Procedural challenges with the inclusion of SECs in biosafety decision-making (adapted from Falck-Zepeda & Zambrano, 2011; Falck-Zepeda et al., 2016)

Attribute	Procedural Choices
Goal	• Provide insight OR • Support decision-making
Status	• Voluntary OR • Mandatory OR • Absent
Applications	• All applications OR • (Confined) field trials ONLY OR • Market applications ONLY
When	• Concurrent but separate to the ERA* OR • Sequential (after the ERA) OR • Embedded within the ERA
How	• Case-by-case OR • Per crop trait (herbicide tolerant, insect/virus resistant or biofortified crops)
Who	• Policy makers OR • Experts OR • Applicants

* ERA: environmental risk assessment

economic impact assessments add valuable insights and arguments to decision-making and do not constitute an obstacle to the safe development and transfer of biotechnology products to end users. Therefore, it is important that socio-economic assessment frameworks are conducted within a regulatory framework that is accessible, transparent, reproducible, flexible, predictable and science-based.

4.3 HARMONISATION OF REGULATORY FRAMEWORKS

There is no universal agreement or consensus on which factors constitute SECs, or on the way that they should be used in regulatory decision-making. As Article 26 of the CPB is open to interpretation, its implementation has resulted in the use of various terminologies and in different combinations of associated non-safety concerns. An overview of the status of national implementations of Art. 26 of the CPB can be found in the working documents of the Ad Hoc Technical Expert Group on Socio-Economic Considerations of the Convention on Biological Diversity.[6]

6 www.cbd.int/doc/meetings/bs/bs-ahteg-sec-01/official/bs-ahteg-sec-01-02-en.pdf

Table 5: Technical challenges with the inclusion of SECs in biosafety decision-making (adapted from Falck-Zepeda & Zambrano, 2011; Falck-Zepeda et al., 2016)

Attribute	Technical Challenges
Scope	• What questions are relevant for SECs in GM crop applications?
Method	• Which methodology is best suited for the purpose of the analysis?
Data	• Availability • Accessibility • Quality • Objectivity

4.3.1 INTERNATIONAL DIFFERENCES

Article 26 of the CPB limits the scope of SECS to those impacts on biodiversity that are valued by indigenous and local communities, while national legislation in several countries has an expanded scope that includes a broader set of socio-economic issues. Some national laws simply include only the term 'socio-economic' with an indication of its type or role, while others link them to other aspects, such as culture, ethics, religion or even to esthetical norms (Falck-Zepeda, 2009).

Measuring, objectifying or weighing several of these aspects in the overall decision-making process for GM crops will obviously be difficult. This may, in turn, lead to uncertainty for applicants and stakeholders (such as farmers) about whether new GM crops will be approved for market release. Eventually, this may justify avoiding certain markets and investment climates, potentially leading to opportunity costs.

International differences in procedural aspects of the implementation are also observed. For example, some countries have proposed that SECs should be included in all stages of the decision-making process and for all applications, whereas other countries have proposed their inclusion only in specific stages or for only some types of applications (Falck-Zepeda & Zambrano, 2011). With respect to how SECs, risk assessment, and decision-making should interrelate or interact with one another, some jurisdictions require SECs to be incorporated into the risk assessment process, whereas others instead have a process that separates SECs from risk assessment but within decision-making. Other differences relate to which actors should assess SECs within the regulatory system, potentially leading to overlapping mandates between Ministries or expert committees.

4.3.2 ONGOING EFFORTS TO HARMONISE SEC IMPLEMENTATION

Several of the Parties of the CPB have already begun to experience difficulties in defining and identifying SECs for their national context, as well as in how to integrate SECs into decisions in a manner consistent with international obligations such as the World Trade Organisation Law. Faced with these implementation challenges, they have identified a need for further guidance when choosing to include SECs in their legislation.

International differences can also impair ongoing R&D and the introduction of new GM crops to the market. Otherwise, a well-structured harmonised regulatory system confers benefits such as: cost efficiency; effectively shared technical capacity; harmonised compliance procedures; the creation of more competitive markets; a facilitation of cross-border trade; and standardised and transparent processes for predictability in international trade. These benefits are of socio-economic importance to countries and regional economic communities. Owing to regional and national agroecological differences and concomitant regional and national regulations, international harmonisation of the inclusion of SECs in regulatory decision-making of GM crops requires insight, understanding and a willingness to cooperate from all involved Parties. Regulatory harmonisation requires a platform for consultation and a clear understanding of the benefits of an efficiently functioning system. Such a platform calls for peer-level (country-to-country) dialogues for confidence building and for partnerships that promote resource-sharing and exchange of experiences, data and best practices.

To develop a global overview, several activities and mechanisms were undertaken to compile, take stock of and review information on SECs. A scoping exercise on SECs was carried out by United Nations Environment (UNEP) – Global Environment Facility (GEF) and included a survey that was conducted in late 2009 in three UN languages; English, French and Spanish (Secretariat of the CBD, 2010). The survey highlighted a need for further work. Therefore, an Ad Hoc Technical Expert Group on SECs (overseen by the Secretariat of the Convention on Biological Diversity) was created which has since examined the outcomes of online discussion groups and regional online conference in an attempt to provide conceptual clarity on SECs. These efforts, amongst others, have resulted in a descriptive approach to SECs (AHTEG-SEC, 2014). Continuing dialogue is aimed at agreement on identifying those SECs that can be included in regulatory decision-making in a standardised and structured way.

5. CONCLUSIONS & DISCUSSION

Worldwide, there is a growing global adoption of GM crops; as a consequence, several socio-economic benefits for society and farmers have been reported, including farm profitability, decreases in crop losses, increased income stability, ease of operation, savings on labour and pesticide use, time savings, and less exposure to toxic chemicals. Many SECs are not specific to GM crops and are applicable to other agricultural developments and changes. These include: access and affordability of planting materials and accompanying technologies; suitability of hi-tech crop systems to smallholder farm operations and resource-poor farmers; intellectual property rights; the influence of large seed companies; balancing food distribution infrastructure vs production output; commercialisation of relevant products versus profit considerations; and a possible negative impact on trade with traditional trading partners.

Inherently, new market introduction has concomitant microeconomic and competitive benefits and drawbacks. Distribution of the benefits and costs between growers, consumers, food manufacturers, retailers, and technology developers can make an assessment rather complex. Socio-economic impacts can be advantageous or disadvantageous, and sometimes both, so it is important to note that in most cases, both effects will occur and are not necessarily specific to GM crops. Socio-economic analyses focus on the resources used or gained by a specific GMO introduction compared with alternatives to determine the better option. However, it should be noted that not introducing (or even delaying) a technology or application can also have a socio-economic (Zimmerman & Qaim, 2004; Stein *et al.*, 2006; Wesseler, 2017). SECs are dependent on the type of GM crop, geographical location and type of user. Therefore, data and conclusions for a socio-economic assessment of a certain type of crop in one country cannot simply apply to the crop in another country.

Worldwide, modern biotechnology and its regulation are subject to public and political debate. In addition to environmental risk assessments, socio-economic assessments can contribute to balanced decision-making regarding the market approval of GMOs and future investments in R&D and technology deployment. This calls for systematic and clearly outlined procedures and data/information gathering, to guide policy formulation and decision-making on biotechnology applications.

To include all possible SECs in biosafety decision-making would take a tremendous effort and significant funding, which does not seem either feasible

or practical within GMO regulatory decision-making. However, the importance of SECs in agricultural development is internationally acknowledged and becomes increasingly important when assessing at not only the risks but also at the potential benefits of GM crops.

Until countries have agreed on why and how SECs should be included in their decision-making processes for biotechnology applications, Binimelis & Myhr (2016) suggest taking a learning process approach as a starting point in order to establish a more solid knowledge basis. In a co-creative process, a pool of data can be established that provides better insight into the socio-economic impact of GM crops. Over time, this could result in a more structured approach for the inclusion of specific SECs in regulatory decision-making.

CHAPTER 8

EMERGING CROSSOVER TECHNOLOGIES; HOW TO ORGANISE A BIOTECHNOLOGY THAT BECOMES MAINSTREAM?

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1. INTRODUCTION

Biotechnology is an important driver for innovation in multiple fields and sectors. After years of continuous research and selected applications entering the market, developments in this field have started to accelerate (Booth 2016). Biotechnological techniques are broadly taken up across the field of agricultural, environmental, medical and industrial innovation. Furthermore, modern biotechnology is increasingly used in combination with other emerging technologies such as nanotechnology or 3D printing, leading to novel applications, but also to potentially new or uncertain risks (Oye *et al*. 2014).

From an innovation perspective, the integration of biotechnology can be viewed as a regular development of a technology reaching adulthood and becoming mainstream (Mampuys & Brom 2010). From a societal and safety perspective, however, a strong debate is ongoing on the potentially far-reaching implications of this powerful technology. On an international and individual level, there are diverging views on what role we want biotechnology to play in our world and lives.

Given the turbulent political and societal history of biotechnology and particularly the application of genetic modification, the process of integration will therefore inevitably be confronted with both regulatory and societal challenges. However, as biotechnology vanishes from its original position as a demarcated technology, this also means that it can no longer be regulated or discussed from a unique and separate position. Thus, the central question is: how can we properly organise and regulate a socially contested technology that technically becomes mainstream? In this paper we will illustrate the merging of biotechnology into other areas and identify governmental and societal issues that arise because of this process. We will argue that the fundamentals of current biotechnology regulatory frameworks no longer suffice to provide suitable governance of scientific developments. Instead, we suggest to move from a technology specific risk regime to a general balanced framework from the perspective of both innovation and safety that, within reason, takes into account different perspectives on the role of technology in our daily lives.

2. EXPANSION AND REFINEMENT OF BIOTECHNOLOGICAL TECHNIQUES

Biotechnology merges into two directions, 1) fields of application and 2) sectors. From a scientific technological perspective, this means that biotechnological tools and techniques become less application specific. The

newest biotechnological techniques such as CRISPR–Cas are extremely versatile and used as a one–size–fits–all tool in agricultural, environmental, medical and industrial biotechnology. We propose to call this horizontal integration. From a technological–innovation perspective, biotechnology converges with other technologies such as nanotechnology, computer science, neuroscience, modeling and engineering. Different technologies converge into innovation platforms. We suggest calling this vertical integration. We will illustrate the merging of biotechnology with two developments that exemplify horizontal and vertical integration of biotechnology; CRISPR–Cas (see **Box 1**) and synthetic biology (see **Box 2**).

Box 1. CRISPR horizontally integrates biotech working fields

The recent discovery of the gene editing precision tool CRISPR was taken up horizontally across all working fields of biotechnology. The CRISPR-Cas system provides a new tool to edit (remove, change or add) genetic information (DNA and RNA) (Jinek *et al.* 2012). The technique, originating from a bacterial defense system, is highly specific and efficient and can theoretically be used in every cell type and in any living organism (microorganisms, plants, animals and humans) (Barrangou & Doudna 2016). Additionally, the tool is easy to design and use and at low costs. More interestingly, the tool does not necessarily result in a genetically modified organism or GMO (e.g. if no foreign or vector DNA is introduced). This strategy can – amongst others – be used to speed up the breeding process.

The simplicity and efficiency of CRISPR technology were embraced by all biotechnology fields. In **agriculture**, CRISPR has been proved to work in a wide variety of crops such as maize, wheat, rice, soybeans, potatoes, sorghum, oranges and tomatoes (Schiml & Puchta 2016). The technique is also being explored for trait improvement in livestock such as cattle, chickens and pigs (Nature 2016a,b). In the **industrial** production of cheese and yoghurt manufacturers have been using the natural CRISPR-encoded resistance to fend off phage infections in their production process to avoid food waste (Grens 2015). Potential applications in food and industrial biotechnology are engineering probiotic cultures and the manufacturing of green chemicals such as biofuels and biomaterials (Selle & Barrangou 2015). In **medical** research, the technique is used for fundamental research into the gene function, to create custom disease models (germline modification) and new therapies. In 2016 the first two CRISPR based gene therapy trials in humans were approved (somatic cell gene therapy) (Nature 2016a, b).

Box 2. Synthetic biology integrates beyond biotech

Synthetic biology can be described as the rational design and construction of new biological parts, devices and systems with predictable and reliable functional behaviour that do not exist as such in nature, and the redesign of existing natural biological systems, for basic research and targeted purposes (Pauwels *et al.* 2013). The applications make use of diverse skills from different scientific disciplines that go beyond biology, including engineering, chemistry, physics, computer science and bioinformatics. The vertical integration of this part of biotechnology is illustrated best by the wide variety of applications that have been developed with metabolic pathway engineering, a subfield of synthetic biology. Synthetic biology is well known for its application in the production of semi-synthetic artemisinin, a precursor for anti-malaria medicine (Paddon & Keasling 2014). Other pharmaceutical products and vaccines are in the pipeline (Jones 2015). Micro-organisms have been engineered to convert corn sugar to biopolymers that are used in commercial carpets and apparel such as sports clothing (COGEM and Gezondheidsraad 2016). Last but not least industrial applications such as the production of lubricants and biofuels are put into commerce (Chubukov *et al.* 2016).

Synthetic biology has been on the horizon a little longer and has, after an initial hype (Mampuys & Brom 2010), diversified into specialized subfields such as metabolic pathway engineering, synthetic cells (protocells) and xenobiology. Synthetic biology became an umbrella term for a wide variety of applications that have been vertically taken up in divergent sectors and industries (see **Box 2**).

CRISPR and synthetic biology are typical examples that illustrate the horizontal and vertical merging of biotechnology. There are a number of other developments that confirm this trend of refining and expanding tools within and beyond the field of biotechnology.

Besides CRISPR, a set of other new techniques has been developed over the years providing a comprehensive toolbox for (plant) biotechnology. Within plant biotechnology, these techniques are horizontally integrating in and fading the boundaries between conventional and 'modern' plant breeding (Sprink *et al.* 2016). Several of these techniques such as zinc fingers and TALENs are also used in medical applications, and as mentioned earlier, CRISPR has been taken up in all three main sectors of biotechnology. Additionally, a patent analysis in

The Netherlands showed that applications of biotechnology no longer strictly adhere to a single use purpose (e.g. medical, agricultural or industrial), but are increasingly a blend of food and medical use or agricultural and industrial use (COGEM & Octrooicentrum 2014).

Besides synthetic biology, other cross-sector applications of biotechnology have surfaced, such as bioprinting and data storage. 3D bioprinting uses different technologies (engineering, cell biology, chemistry, modelling and math) to print living structures that can be used in medical applications such as tissue, skin, bone or partial organs (Mandrycky *et al*. 2016). The use of DNA for data storage as archiving technology is gaining an increasing interest from research and business (Extance 2016). Fields such as optogenetics - the use of light and genetics to manipulate and monitor the activities of defined cell populations - and bionanotechnology are moving towards application as well (Song & Knöpfel 2016, Nagamune 2017).

3. BIOTECHNOLOGICAL DEVELOPMENTS ACCOMPANIED BY A MULTITUDE OF CHALLENGES

The expansion and refinement of biotechnology and its horizontal and vertical merging into other sectors diminishes its visibility as a separate entity; this means it can also hardly be regulated and discussed as a separate and unique technology anymore. And this could lead to governance issues because biotechnological developments bring a wide array of challenges to the table ranging from political to legal, ethical and risk issues.

It is already debated in the EU whether new plant breeding techniques (NPBTs) and applications result in genetically modified organisms (GMOs), as the end products do not necessarily differ from products from conventional breeding techniques, not using genetic modification (SAM 2017). The agricultural context of this debate – which is ongoing for more than a decade now – becomes increasingly problematic as any regulatory decisions will also affect other fields of biotechnology. The horizontal integration of gene editing techniques such as CRISPR means that either restrictive or permissive regulatory decisions based on the techniques used, not only affect one working field (such as agriculture) but also have consequences for other fields of application (e.g. medical applications). On the other hand, the same tools, treated differently depending on their application (for example in animals vs. plants) also leads to incomprehension and debate (Nature 2017). Additionally, tools such as CRISPR can induce both subtle to comprehensive genomic changes with similar ranges

in uncertainties and risks - not necessarily related to the size of the DNA changed. Therefore, from this perspective, regulating a tool or technique in itself does not seem to match the purpose of regulations in view of managing risks.

The widespread adoption of CRISPR illustrates that the stakes are high while at the same time the speed and uptake of the technique across the entire biotechnology field pressurizes the discussion about the regulatory status of these applications (GMO or not? (Europe), novel or not? (Canada), plant pest or medicinal product? (United States)).

The uptake of synthetic biology into everyday consumer products seems successful and has largely gone unnoticed (Hayden 2014). However, the potential to spark public debate remains present, as illustrated by a case of an eco-friendly firm that got into trouble after going public about its shift from palm oil to the use of oil made by (synthetically) genetically engineered algae. The discussion on products made by new biotechnology (either GMOs or not) is unpredictable and irregular but emphasizes the societally contested status of biotechnology (Stemerding & Asveld 2016). Moreover, other biotechnological trends, such as 3D bioprinting, RNAi technology, personalised medicine, GM insects, gene therapy and next generation sequencing all represent a multitude of challenges for governments, scientist and society (COGEM & Gezondheidsraad 2016).

It can be concluded that several challenges resulting from biotechnological trends await political decision-making. However, a problem arises as we realise that the current regulatory and legal frameworks might no longer apply to the merged biotechnological applications and their consequences. Resulting products from techniques such as CRISPR and synthetic biology can't always strictly be defined or distinguished into legal categories and their implications are not specific to biotechnology but relate to broader issues relating to our view on agriculture, health and food production. Societal debates about agriculture and food production differ significantly from discussions about medical applications. They are viewed through different lenses and usually either conceived as a chance or a threat. These debates have influenced regulatory decision making over the years, specifically in Europe that has a reputation of being restrictive and in indecisive with regard to plant biotechnology (Malyska *et al*. 2016). We emphasize that regulatory decisions on techniques such as CRISPR extend to other fields (both new and existing) where these issues are

not relevant or relevant from a different perspective. For example; discussing the use of gene editing (i.e. CRISPR) in food production in a regulatory context as a form of GM because it raises the same food-identity issues as GM food, can also have consequences for framing the use of CRISPR in health care where the relevant medical issues differ from GMO-related questions (Stemerding 2017).

4. STIMULATING, REGULATING AND DEBATING BIOTECH

The focus of regulating biotechnology is and from the start has been specifically on the risk and safety of GMOs (i.e. Berg *et al*. 1975). A comprehensive risk assessment is required before GMOs can be used in research, field trials or brought onto the market. The trigger for (GMO or biotechnology) regulation varies internationally, depending on whether one looks mainly at the process (EU), the product (US) or the novelty of the characteristics introduced (CA). Internationally, different approaches are in place, each with their own benefits and issues (Sprink *et al*. 2016).

Besides the GMO/non-GMO distinction, the atmosphere of the societal debate also differentiates between fields of application. Society overall has different attitudes towards green (agriculture), red (medical) and white (industrial) biotechnology. In general, the most intense debate focusses on biotech in the food/agricultural sector and at medical applications directed at human enhancement. Medical applications directed at restoring or maintaining health are mostly accepted and industrial applications thus far hardly generate any attention, although this is expected to change (Hayden 2014). However, as a consequence of the horizontal and vertical integration, the regulatory frameworks (based on GMO/non-GMO) and the societal frame (based on red/green/white biotech) no longer fit. In response, several countries are looking into a reform of the regulations, but this is easier said than done (Barbero, Boling *et al*. 2016, Kuzma 2016, Parliament 2016).

For years, regulators have tried to 'domesticate' new biotechnological developments to make them fit into the existing frameworks. The predominantly process-based EU regulations strictly define a GMO, lists which techniques lead to the production of a GMO and which ones are exempted. A thorough legal debate is ongoing for many years now to discuss the applicability of the GMO definition to NPBTs (SAM 2017). But even if they fall within the definition, the products resulting from NPBTs cannot always be distinguished from conventional products, significantly impeding enforcement of regulations

(Sprink, Eriksson *et al*. 2016). The USA basically has a voluntary GMO regulation and regulates some applications and not others, resulting in questions from producers and consumers (Nature 2016c). International ad hoc adaptations (within the EU and outside) to deal with new developments can – unseen and unintended – enlarge international differences (Abbott 2015). In the absence of regulatory decision-making in Europe, several individual countries (Sweden, Germany, UK, Finland) have concluded on their own that some applications of new techniques (CRISPR, Oligonucleotide Directed Mutagenesis (ODM)), do not result in a GMO as defined in the EU regulations (Eklöf 2015, Fladung 2016).

EU regulations, or more specifically, their implementation and use, also have additional issues. The European position towards GMO crops has a reputation for being inconsistent with regards to its different attitudes towards importation and cultivation (Tagliabue 2016). This issue has been moreover identified and emphasized in international literature. Because of strict regulations that are not adapted to the scientific state of the art, Europe is lagging behind from an innovation perspective while in the USA new developments can go unnoticed and disregard potential ethical and societal issues such as admissibility, ownership and privacy.

This calls into question whether new developments should be regulated eventually but also calls to question whether techniques that do not legally result in a GMO are inherently safe and do not need to be regulated. Both questions are difficult to answer and there is much at stake. Postponing answering these questions could lead to a regulatory limbo and innovation standstill, as currently in the EU (Podevin *et al*. 2012, Kuzma 2013). And in the meantime, technological innovations continue to develop rapidly.

5. PREPARING POLICY: FROM REACTION TO FORESIGHT

From a governance perspective, the biotechnological developments can no longer be dealt with by force-fitting them into the existing regulatory frameworks. Besides legislation that is lagging, the developments call for a broader discussion on non-safety issues. If this debate is not picked up actively, technical developments will move ahead and choices are made regardless of public support. This has been illustrated recently in the medical field. While the world is discussing the ethical and safety implications of human genome editing and mitochondrial replacement therapy (MRT), the birth of the first 'three parent baby' was announced by a Chinese doctor working in a US hospital who initiated the procedure in Mexico to circumvent legal issues. The

announcement was quickly followed by news from other countries claiming similar developments (Coghlan 2016). International differences in regulations are a fact and there will always be ways found around legal restrictions. However, these events also illustrate that the lack of international governance and coordination can (unintentionally) facilitate a race to the bottom where scientific fame or commercial benefit prevail. If individual countries do not actively take up the regulatory and ethical discussion, the lowest denominator in the international context can become leading. According to König (2017), the focus should not be to control, but to manage different approaches to deal with new technological developments

Policy makers should rapidly start preparing for these developments and they can do so by identifying the issues that ask for stimulating, regulating and debating biotechnology and making them explicit from a policy perspective. A suitable instrument for this identification is the compiling of a trend analysis, as illustrated in the Netherlands with the Biotechnology trend analysis 2016 that provides an overview of eight trends typical of modern biotechnology: next generation sequencing (NGS), CRISPR-Cas, personalized medicine, gene therapy, new techniques (RNAi), GM insects, 3D bioprinting and synthetic biology. For each trend, the major societal, regulatory and legal dilemmas and questions have been identified (COGEM & Gezondheidsraad 2016). The issues and challenges in this report are not only applicable to the Dutch or European context but also have international ramifications.

Besides a positioning towards these issues on a national level, an international dialogue is urgent: firstly because international regulatory frameworks interact in both politics and policy development (Brom 2015), secondly because both scientific-technological and technical-innovative perspectives are evolving in a global perspective and thirdly because regulations and societal acceptance are of major influence on global trade systems. This dialogue should be held in an international context and should focus on how to shift from a biotechnology / GMO framed debate to a debate about the normalisation of biotechnology from three perspectives:

A debate about **innovation** should focus on biotechnology as one of the (many) instruments to contribute to global challenges with regard to food supply and distribution, climate change, sustainability, infectious diseases etc.

A debate about **safety** should focus on making safety regulations less technology specific. This means a reform of the (global) (GMO) regulations is urgent. The current EU approach based on a GMO/non-GMO distinction with either process or product as a regulatory trigger is no longer manageable, nor does it properly safeguard the potential risks of new products from integrating emerging technologies or does it do justice to societal concern and freedom of choice. The integration of biotechnology asks for a context related safety assessment. What is needed is to zoom out from the perspective of specific GMO biosafety to a more general view on biosafety, regardless of what types of technologies are involved or combined. In relation to the recently initiated US regulatory reform, it was suggested that a global coordinated framework should be novelty- and risk based (Straus & Sax 2016). Given the current difficulties in international trade it seems that a global consensus on regulating biotechnology is unlikely. Therefore, a system needs to be developed that facilitates and manages transparency and national autonomy.

A debate about **societal embedding** should shift from a technology-specific (GMO) discussion to a debate about which role we want technology to play in our lives. Technology is not value-free and can bring about societal and ethical issues and challenges such as human enhancement, equal access, privacy, sustainability and bio-piracy (Schmidt *et al*. 2009). It is up to society to take up an active role in shaping technology and deliberate about the conditions and terms for (bio)technology to be used. Over the years, it has become clear that many arguments in the GMO debate relate to wider issues than safety. Specifically, the role and importance of non-risk-related arguments in agriculture have been recognised for some time (Devos *et al*. 2014). After a long period of deadlock in the decision-making process with regard to GM crop approvals in Europe, the EU installed a new directive in 2015 (Dir (EU) 2015/412) that, separately from the safety assessment, enables individual member states to refuse GM crop cultivation based on non-safety arguments. Although a brave move towards a more inclusive debate in a pluralistic society, this has – thus far - not changed the overall voting behaviour on the safety assessment for market applications for GM crop cultivation. This shows the resilience of normative frames, agent-relative expectations and the fundamental views on the world, future & nature. It seems that moving away from a technical scientific perspective is impossible in the context of GMO-regulation. If the notion of GMO is tainted beyond depuration, we might need to develop a perspective in which new technologies can be regulated outside

the distinction of GMO/non-GMO. Confining the definition of GMO strictly and discussing the new technologies (gene editing, bionanotechnology etc) in a broader discussion on the role of technology in general in food production and medical treatments, might be a fruitful step. Additionally, this may enable a reframing of the discussion and provide an opportunity to shift ideologies without losing face and focus on the role of technology in general in food production and medical treatments.

6. CONCLUSION

Recent developments in biotechnology have a major impact on society, policy and legislation while we lose sight of their impact on our everyday lives at the same time as a consequence of refinement and merging of the techniques. This brings about the question how to organize a biotechnology that becomes a tool instead of a strictly defined working field in a world where both regulations and societal debate is focused on the distinction between GMO and non-GMO. As the current focus on event and GMO based regulations is surpassed by technological developments, other approaches should be investigated that are future-proof and workable in an international context. These approaches do not necessarily have to be drawn up from scratch. With technological tools integrating, a starting point could be a learning process between the different risk regimes to identify and manage uncertainties, risks and benefits. One of the hurdles is the presence of not one, but several problem-owners with different goals and agenda's. A coordinated action is needed from policy makers and scientists to start a dialogue, with a shared responsibility for prioritizing the issue. As well in the past, as more recently there have been several initiatives that explore ideas for a multi-agency and multi-criteria approach to facilitate adaptive governance on emerging technologies and their accompanying risks and benefits (Cummings & Kuzma 2017, Oye 2012, Trump *et al*. 2017).

There are and will always be diverging views on what kind of world 'we' want to live in and what kind of technologies 'we' want to adopt into our daily lives (the problem of 'we'). Therefore, there is a need for a plural and robust style of governance that does not solely focus on safety and absence of risks, but balances these with the potential gains, as with any other technology. To facilitate the societal embedding of biotechnology becoming mainstream, an international dialogue and agenda setting is urgently needed from the perspective of innovation, safety and public opinion.

CHAPTER 9

EUROPEAN DECISION-MAKING ON GM CROP AUTHORISATIONS: REPOLITICISATION IS EVADED BUT NEEDED

R. Mampuys

1. INTRODUCTION

The authorisation of GM crops in Europe is seen as a prime example of a wicked problem (e.g. Jelsma 2001, Durant & Legge 2006b, Bovenkerk 2010, Inghelbrecht *et al.* 2014, Newman & Head 2017, Daviter 2017 and Weimer 2014). Wicked problems (Rittel & Webber 1973) involve conflicting facts and values, they lack a shared problem definition and show significant resilience to being resolved. The authorisation of GM crops in Europe fits these characteristics which have led to a situation in which decision-making is stalling because (1) the final step in formal decision-making (e.g. comitology) systematically results in 'no opinion' (Smart *et al.* 2015) and (2) the European Commission (EC), who is mandated (but not obliged) to take a decision in these situations, is reluctant to do so. With significant delays (Smart *et al.* 2017), decisions on importation are taken eventually (driven by amongst others economic reasons and the threat of international trade conflicts),[1] while decisions on GM crop cultivation are completely deadlocked since 1998. Only one GM crop has been authorised for cultivation and its renewal process has been in legal limbo for over a decade.[2] In addition, several European Member States (MS) have installed bans on GM crops, some of which are being upheld despite being declared invalid by European authorities (e.g. EFSA 2004, 2005, 2006, 2008, 2012f, 2013 and 2014).

In Chapter 2 I argued that so far, attempts to resolve the deadlock in decision-making have had limited success (see also Chapter 4, 5 and 6). I have discussed three strategies that have been used to, either directly or indirectly, mitigate the GM crop conflict by focusing on improving the input into the decision-making process, and the process itself: more scientific research and expertise to reduce uncertainties, public and stakeholder participation processes for consensus building and adapting regulations to be more evidence-based, precautionary and inclusive. I have argued that these strategies, alone or together, are and will be insufficient to arrive at a yes/no decision about GM crop authorisations because their outcomes do not compel (a singular course of) action.

1 See Tagliabue (2017) and Lieberman & Gray (2006) for more details on the dependency of Europe on (GM) soy imports. In addition, see WTO dispute DS291 for an example of a trade conflict about GM crop authorisations.

2 Maize MON810 was authorised in 1998 for a period of 10 years. A renewal application was submitted in 2008 and received a positive EFSA opinion in 2009. Voting under comitology took place in 2017 and 2018 with an outcome of 'no opinion'. The EC has taken no further action. The old application remains valid until a decision has been made.

The current situation where applications for GM crop authorisation are systematically neither approved nor rejected (the outcome of the voting process is 'no opinion'), does not engage with the variety of opinions that are present in society about GM crops and GM food. Not engaging reaffirms the conflict about GM crops which has led to a strongly polarized arena with little room for dialogue or transforming positions. Instead it seems that the breathing room within the existing regulatory framework is used by both national and European actors responsible for political decision-making, to obstruct the decision-making process about the authorisation of GM crops. They do so by delegating responsibility for decision-making to science and/or society or by postponing decision-making awaiting a change of regulations.

In this concluding chapter I will focus on the role of politics in the decision-making process. I will argue that political conflict is, deliberately or not, evaded and why political decision-making is important and needed. This substantiates my hypothesis that repoliticisation of the decision-making process about GM crop authorisations in Europe is an underexposed or ignored factor in the problematisation of the issue.

In Section 2, I will reflect on the contribution of scientific input, participatory activities and the regulatory framework to the decision-making process. In Chapter 2 I concluded that these factors will not by themselves add up to a final decision. This however, does not render them useless. Therefore, this section reflects on what we can and cannot expect from them.

Section 3 discusses the importance of political decision-making in situations of conflict. While I have described indicators of political conflict in Chapter 3 of this thesis (Section 3.2), I will now take my argument a step further and defend the position that engaging with political conflict is strategically evaded in the authorisation of GM crops. In addition, I will illustrate that political decision-making is possible about controversial technology (applications), even without scientific certainty or societal consensus. I will do this through a brief discussion of the authorisation process of glyphosate (a broad spectrum pesticide) in Europe. The debate about this case shows strong similarities to the GM crop discussion; potential harm, scientific uncertainties and strongly divided interests and values in society and amongst stakeholders. The authorisation of pesticides in Europe also follows roughly the same procedures as GM crops. Remarkably though, a decision about the glyphosate authorisation was forced through exercising politics (negotiating, bargaining, arguing). This

begs the question what then withholds political decision-making in case of GM crops? I will discuss possible answers and argue a difference between high and low level politics is a probable one. It seems that authorisation decisions on GM crops lack political priority and that in the absence of priority, evading decision-making on complex issues could be justified from a strategic political perspective. However, in view of the normative nature of the conflict about GM crops and the role and responsibility of the political decision-making actors from a democratic perspective, I will argue that avoiding decision-making on GM crops does not do justice to either GM crop opponents or proponents. Finally, I will reflect on the implications of repoliticisation of decision-making about GM crop authorisations.

In Section 4, I will revisit and answer my research questions and formulate recommendations on future research. I conclude that GM crop authorisation in Europe is a wicked problem by design in which decision-making is evaded through delegating responsibilities to scientific, societal and legal actors. Whilst science, participatory activities and a regulatory framework each contribute to the input in the decision-making process, political judgement and decision-making are needed now. Evading explicit decision-making and upholding the illusion of a working system, does not do justice from a democratic perspective to both proponents and opponents of GM crops.

2. ADJUSTING EXPECTATIONS FROM AND WITHIN SCIENCE, PARTICIPATORY ACTIVITIES AND REGULATIONS

In chapter 2 and 3 I have critically analysed and discussed three common strategies in the field of regulatory science to mitigate the conflict over GM crop authorisations in Europe: they focus on science, public and stakeholder participation and the regulatory framework. I argued that alone or together they are unlikely to result in the singular course of action that is needed for decision-making on GM crop authorisations: either a yes or a no. However, their limitations in the overall decision-making on GM crop authorisations do not render them useless. Before zooming in on the role of politics in the decision-making process, I recapitulate on what I think we can expect of these factors in the overall process.

2.1 SCIENCE INFORMS EXPECTATIONS

Science informs expectations about choices and their possible outcomes. Technical and scientific expertise are essential to 'navigate causal complexity and reduce uncertainty' (Daviter 2018, p.161). However, science is in a certain

way always provisional; it cannot produce everlasting facts about the world, because scientific uncertainty is endemic and irreducible. More importantly, science in itself does not compel action: it does not tell us what to do, let alone tell us what the 'right' choice is in a certain situation. It provides knowledge that has a validity within a specific research context and methodology, and until other research might prove otherwise. This implicates science is not well-suited to deal with challenges that play a role in policy making such as 'shifting problem boundaries, incompatible and competing problem perceptions and unclear or evolving evaluative criteria' (Daviter 2018, p.161).

In situations of uncertainty, a common strategy is the involvement of experts in the decision-making process (i.e. post-normal science, see Funtowicz & Ravetz 1993). Interdisciplinary scientific and expert knowledge can be valuable to help determine the most desirable, least risky or most precautionary way forward. However, scientific or expert knowledge on complex issues usually cannot feed directly into the policy process (i.e. the science-policy gap, see Cairney *et al.* 2017, Wellstead *et al.* 2018), but has to be translated and evaluated in order to be used in argumentation for a specific policy action. Sarewitz (2004) called this 'an excess of objectivity' that is produced by science. And as he – and others – argue, this excess can be used to substantiate a variety of political decisions (e.g Daviter 2015, Klika 2013, Robert 2019). This means advocates of particular viewpoints can select, contextualize or reframe information to substantiate their preferred action. This is a part of the political process, and as a consequence this also means that scientists have to accept that their input may be used strategically outside the scientific discourse. In addition, the excess of objectivity and the science-policy gap also exemplify the limits of policymakers and politicians to take knowledge into account. It is impossible for one agent to take into account all possible evidence relating to a certain issue (i.e. 'bounded rationality' see Cairney 2017). Therefore, choices have to be made on the use, prioritization and translation of knowledge.

Just as scientific knowledge can provide new insights, technologies resulting from scientific insights can create new options for policy problems. They can provide a window of opportunity, which can bridge conflicting values and 'allow them to co-exist in a shared sense of practical benefits' instead of forcing a choice between them (Sarewitz 2011). Although contested, the attempt to resolve the 'naturalness' conflict about GMOs through technical innovations could be seen in this light. It has been argued that small genetic changes (gene editing, see Chapter 1) that could also occur in nature or that do not cross a species barrier may be perceived as more 'natural' and thus

acceptable (Matveeva & Otten 2019, Custers *et al.* 2019, Ricroch *et al.* 2016). This new 'fork in the road' would not necessarily bridge the value conflict about genetic modification, but it could facilitate a partial agreement on the legal acceptability of some types of GM crops. However, with regard to the example of the 'naturalness' conflict about GMOs, the issue for opponents is not (only) the species-barrier but also manmade intentional and targeted genetic change or broader impacts besides risks (Van Hove & Gillund 2017, GMWatch 2019a). From this perspective, gene editing is labeled as a technological fix.

Scientists are increasingly expected to interact and cooperate with society, the private sector, policy makers and politicians in both their role as scientists as in their role as expert (e.g. Poort & Bovenkerk 2016, Saltelli & Giampietro 2017). While this is encouraged from perspectives of, for example, robust science or responsible innovation, it inevitably has consequences for the role scientists have. It will become difficult or even impossible to be the 'pure scientist' or the 'honest broker' of knowledge (Pielke 2007). Pielke identified four idealised roles of science in policy and politics,[3] and pointed out these are not always explicitly or willingly chosen (i.e. scientists can hide value commitments behind science or can be pressurised into value judgements) and emphasised the importance of being aware and transparent about the role of science. A conflict or tension can arise when science is considered as value free and objective on the one hand, and as justified and accountable from the perspective of democratic politics and society on the other hand. This tension is not new and has already been mentioned by Daniels (1967) who stated that 'The pure science ideal demands that science be as thoroughly separated from the political, as it is from the religious or the utilitarian. Democratic politics demands that no expenditure of public funds be separated from political control' (p.1704). The discourse analysis of alarming studies has shown that the objectivity and independence (or the lack thereof) of scientists is a recurring argument in the discussions (see Chapter 4).

Even in their role as scientist, they are engaged in normative judgements. The scientific 'true or false' distinction is based on what has been agreed on to be 'good science' or 'good scientific practice'. As we have seen in the case of alarming studies, there are scientific disagreements on how 'good science' should be done in the context of environmental and food safety research. On

3 Pielke (2007) identifies the following four idealised roles for scientists: the pure scientist (a resource of general factual information), the science arbiter (resource of information about specific questions), the issue advocate (requested to provide information to substantiate a specific decision) and the honest broker (has a guiding role that provides information but leaves the choice open for the decision-maker).

the bright side, these conflicts provide opportunity to improve the scientific method, but at the same time it is a continuous source of conflict about the value of scientific results. Moreover, science is not immune to value-related criticism about decisions based on scientific input. Montpetit (2011) has shown that scientific disagreement is more likely to occur on highly politicised topics, because of the perceived high costs of scientific error in these cases. This has also been pointed out by Jasanoff (2003), who asserted that 'science invoked to support policy tends to unravel under the stresses of politics: those wishing to question a given scientific interpretation can generally find errors, hidden biases or subjective judgements that undercut their opponents' claims to truth and objectivity' (p.160).

For these reasons, science cannot provide an unambiguous objective answer to determine political decision-making on GM crops. However, it can help identify potential risks and provide estimates of how a GM crop will interact with the environment. Whether a GM crop is safe enough and an acceptable option for agriculture and food production, is a political choice and requires political argumentation. This is also the case for other types of knowledge that are included or considered in the decision-making process. Chapter 7 discussed the opportunities and challenges of socio-economic considerations in regulatory frameworks on GM crops. The overview illustrated that data and numbers can be put on almost every aspect of life, but their value and weight in the overall balance are even so subject to political judgement.

2.2 PARTICIPATION HIGHLIGHTS VALUES, HOPES AND THREATS OF TECHNOLOGIES

Participatory and deliberative activities can contribute to the identification of values and of perceived hopes and threats of a technology that can inform the political decision-making process. The broader and more inclusive, the more likely these processes are to capture the variety of perspectives that may need to be taken into account in policy- and decision-making. In turn, participatory activities and the inclusion of societal actors and stakeholders may contribute to trust in the eventual decision-making process.

However, participatory activities are unlikely to result in societal agreement or consensus about wicked problems. The general public and stakeholders can't make decisions as an entity, because it is a pluralistic collective of individuals with a broad spectrum of different and sometimes conflicting views on 'the good life', 'goods' and 'a good society'. While individual views on 'a good life' may be facilitated by regulations, a conflict between a view on 'a good society'

and a view that is seen as a compromise reflected in the regulations may be irreconcilable (e.g. when GM food labelling facilitates individual consumers' choice, while in the view of some consumers 'a good society' should be GM free). Christiansen *et al.* (2017) even argued that public participation activities about controversial science cannot be justified from a democratic perspective, because how can we expect general public to form an opinion on an issue based on knowledge that even scientists cannot agree about?

According to Biale & Liveriero (2017), the different views in society inform deliberative democracy, even calling dissent the 'raison d'être of democracy' (p.585). They argue for robustness as a criterion for political decision-making, in the sense that it does not refer to an external standard of rightness but evaluates whether decisions are responsive to the agents involved in the deliberation. In other words: it is not solely about the process (i.e. including all stakeholders as a primary criterion) or the outcome (i.e. a 'good' or 'right' decision), but a combination of the two that can justify a decision from a democratic perspective. In the light of Sarewitz (2004) notion of 'excess of objectivity', the input from participatory and deliberative activities with societal actors could be seen as providing an 'excess of subjectivity' as input into the political decision-making process.

Nonetheless, the aim of societal consensus on controversial technologies before moving ahead towards decision-making seems unfeasible.

2.3 REGULATIONS ASSIGN RESPONSIBILITIES

Regulations, amongst others, assign responsibilities and define rules on who needs to decide about what based on which criteria. EU regulations are designed and implemented though a co-decision procedure of the European Commission, The Council (representing the MS) and the European Parliament (representing EU citizens). Their decisions are supposed to reflect views of 'goods' and 'the good society', and determine both liberties and rights of the general public and stakeholders in society. In view of GM crops, the regulatory framework reflects what needs to be protected (human health, the environment, freedom of choice) and what is acceptable within the realm of (individual or collective) freedom (biotechnological research and innovation). As such, the regulations for GM crops facilitate the freedom of industry to develop and commercialise GM crops, and the right of individuals in society to safe products and to avoid GMOs in food products if they want to. If the criteria and prerequisites defined in the regulations are fulfilled, the resulting decisions can be seen as justified and from a legal perspective 'good'.

The view of the 'good society' reflected in the regulations cannot (fully) overlap with all different conflicting individual views on 'a good life'. In addition, the GMO regulations have been be criticized from a scientific (Amman 2014), risk (Edvardsson Björnberg *et al.* 2018), and legal (Christiansen 2019) perspective, but they may still be justified from a societal perspective. Justified, because the regulations reflect the plurality of views on 'goods' or visions on 'the good society' by promulgating a perspective in which fundamental moral disagreements are acknowledged. At the same time, conflicting views on a 'good society' or on 'goods' are not resolved through regulatory strategies alone, as has been illustrated in this thesis.

Aiming to address conflicting values on GM crops has resulted in an interactive regulatory framework that has characteristics of being both science-based as well as precautionary (see Chapter 2). The inclusion of different views and perspectives in the regulations inevitably leaves room for different interpretations, and facilitates the use of arguments from the principle of precaution as ammunition against the principle of being evidence- or science-based. At the same time this may be inherent to a dynamic system that reflects the existing gap between expectations of different stakeholders and the general public. I have argued in Chapter 3 that regulations may determine the rules and requirements based on a reflection of what has been democratically decided to represent a common perspective on 'a good society'. However, these rules and requirements do not determine the outcome of a decision. Regulations cannot resolve conflict by themselves and they inevitably have a certain distance from actual societal values because of the legal context in which regulations have to function. This legal context also has another consequence, namely that it always has a degree of interpretative space, i.e. that different courses of action can be justified in view of the same regulations based on different views on the intended outcome. Regulations need to be fit for purpose but not too rigid, specifically when applied to a scientific context that may change in the future. Necessarily, a tradeoff has to be made with regard to flexibility and being future-proof and the legal room for diversion (i.e. the more specific and comprehensive definitions are formulated, the more robust a framework, however, less future proof when it comes to scientific developments that do not fit within the narrow definitions). This tradeoff is part of the (political) process of designing and implementing new regulations. In Chapter 8, Brom and I have argued that given the scientific developments, the current regulatory framework on GMOs in Europe has reached the limits of its flexibility and that horizontal and vertical integration of biotechnology developments calls for a multi-agency and multi-criteria approach to facilitate adaptive governance of

emerging technologies and their accompanying risks and benefits. In this final chapter however, I will firstly emphasise the importance of decision-making itself, whether under the current regulatory framework or a future one.

3. POLITICAL RESPONSIBILITIES, MOTIVATIONS AND DECISION-MAKING AT EU LEVEL

I have argued that while scientific, participatory and regulatory factors are essential and contribute to the overall decision-making process, they will not compel action. They don't automatically point towards the singular course of action that is needed for a digital yes/no decision on GM crop authorisations. And this is, in my view, where acknowledgement of the political nature is needed to balance the input from science and society/stakeholders and take decisions in situations of uncertainty and conflicting views.

However, political behavior and actions such as deliberation, argumentation, bargaining and compromising have shown to be very limited or even absent in the case of GM crop authorisations. The decisive step has been reduced to a voting process by MS representatives with a predetermined national voting mandate under EU comitology procedures (see also Weimer 2010, p.646). As a consequence, the only way to express underlying disagreements about the issue of GM crops, is to use the breathing room within the existing regulatory framework to obstruct the decision-making (e.g. negative votes or abstaining from voting, national or regional bans on GM crops).

In Chapter 2 I mentioned that the technocratic, participatory and regulatory strategies I would discuss are not necessarily deliberately and purposefully thought out strategies designed by a specific actor. In this final chapter I will take a less neutral and more normative approach to these strategies. One of the reasons for discussing these particular strategies is that political actors, policy-makers and stakeholders in the GM crop conflict repeatedly refer to these approaches as they emphasize the need for (more) scientific certainty and societal consensus. What if political actors are the implicit agent of these strategies and what if their purpose is not resolving but avoiding political deliberation and decision-making? With this in mind, in the next section I will have another look at some of the indicators of political conflict I have identified in Chapter 3.

3.1 INDICATORS OF EVASION OF POLITICAL CONFLICT

Here I will take a normative view on the previously identified indicators of political conflict about GM crop decision-making. Firstly, I will argue that the regulations themselves as well as the procedures defined in them, are used

strategically to avoid decision-making. Secondly, I will discuss an example of another contested technology application that shows many similarities to the GM crop debate and that is subject to the same procedures and decision-making under comitology. In this case however, decisions have been taken despite scientific uncertainty and stakeholder disagreement, substantiating the crucial role of politics.

The regulations provide room for the evasion of political debate by being broad and to varying degrees either very specific and mandatory or vague and optional. The draft decisions on GM crop authorisation of the EC are predominantly based on a scientific risk assessment from the EFSA. Socio-economic and ethical issues are part of the regulations,[4] but they are not mandatory and do not play an explicit role in the current reality of decision-making. Instead, non-safety issues have to a certain extent been delegated to the national and individual realm, which avoids having to discuss them at EU level. They are put in the category of views on 'the good life' through mandatory labelling of GM ingredients in food for individual consumers (Regulation (EC) No 1830/2003) and the option to ban GM crops on a national level (Directive (EU) 2015/412). The optional character of the latest Directive can also be seen as to serve another purpose, namely that of international accountability towards the World Trade Organisation (WTO) and trade partners. Europe is seen as having one of the strictest GMO regulations worldwide and has been accused of protectionism (e.g. Tagliabue 2017, WTO dispute DS291). In this light, the regulatory changes that have been made over the years can be seen as a strategic way of managing accountability[5] on several levels. This argument can be illustrated by two examples: the *de facto* moratorium (1998–2004) and the 2015 Directive.

Lieberman & Gray (2006) discussed three different interpretations of the *de facto* moratorium (1998 – 2004, see also Chapter 1): there was an effective moratorium (1), there was no effective moratorium (2) and: there was no formal moratorium (3). The *de facto* moratorium facilitated the MS who are opposing GM crops to maintain to their electorates and the environmental movement that a moratorium on approvals of new GM crops for cultivation is effectively in place. The MS who are in favor or have no objections against GM

4 See for example Directive 2001/18/EC, consideration 62 and Art. 29, and Regulation No 1829/2003/EC, consideration 42 and Art. 33, see also Chapter 2.

5 Skogstad (2011, p.898) identified different notions of accountability: accountability through participation or delegation, horizontal (between MS) and vertical accountability (between EU and MS) or internal (within EU) and external accountability (EU to non-EU countries).

crops can maintain to the agri-biotech sector that there is no formal ban on either previously-licensed GM crops and foods, or newly-licensed GM foods. Towards the WTO and international trade partners it could be argued that no official moratorium was or is in place. In conclusion, from the perspective of protecting it's the European Commission's accountability on different levels, the fact that this was never a 'formal' moratorium, can be seen as politically strategic.

In my view, a similar argument can be made for Directive (EU) 2015/412 which provides MS with the option to ban a GM crop from cultivation on their national territory. Since this Directive is optional (in addition to and separately from Directive 2001/18/EC and Regulation (EC) No 1829/2003), the main criterion for GM crop authorisations remains safety. From a legal perspective, it can be argued that Directive (EC) 2015/412 does not play a role in the overall EU decision-making process, hence avoiding issues of the EC with the WTO based on accusations of protectionism.

Towards MS, it is argued that disagreements on GM crops are acknowledged,[6] but the EC may also have chosen the option of a new Directive strategically over another option, namely an overhaul of the entire GMO legislation. Randour (2014) discussed the Directive (EC) 2015/412 as a compromise given the complex situation in Europe. He argued that there is no grand overhaul of the entire GMO legislation because 'individual Member States have an interest not to get too involved in substantial discussions on GMOs that are politically sensitive at the domestic level, although the 2010 proposal might also be seen as an attempt by the Commission to force Member States to make clear choices on GMO policies so that the latter can no longer shift the blame for unpopular GMO policies to the Commission' (p.1319).

However, the Directive has thus far not resulted in a political debate within MS themselves. A majority of the MS used the Directive to ban GM crops, but have taken no further action to implement the Directive. As explained in Chapter 6, the first step of the Directive only requires a simple opt out request to the applicant. Unless the applicant denies the request, it is granted. Here too, political deliberation is avoided. Or, as Poort and I have argued in Chapter 6, objections and controversies on GM crops are not confronted. If the applicant would object to the request, the MS has to provide a written argumentation on why / which grounds it wants to ban the GM crop. For this step, the Directive

6 e.g. Directive (EU) 2015/412, Considerations 6 & 7

has to be implemented in national legislation and procedures need to be in place to act in such a situation. Given the controversy of the issue not only between but also within MS, the implementation of the Directive would likely initiate a political debate on how to do this. Despite the fact that a majority of the MS have used the Directive to ban GM crops that were pending for cultivation authorisation in 2018, most of them have not taken further action to implement it in national regulations (see Dobbs 2017). Given the very limited amount of cultivation applications in Europe that are still in the regulatory system and given that applicants have not objected to the national bans, there seems to be no urgency to implement the Directive on a national level. That also means there is no (legal) urgency to organize political debate on a national level.

Finally, EU regulations for GM crop authorisation that reflect both precaution and the importance of scientific evidence, provide leeway to avoid decision-making because arguments based on these principles can endlessly feed into each other: we need to be precautious because there are scientific uncertainties, therefore we need more science to reduce uncertainties, but science will always be uncertain, so we need to be precautious… and so on. In academic literature, the avoidance of political responsibility has been noted by several authors such as Van Asselt & Vos (2010, p.282) who labelled it as 'organised irresponsibility' (a concept from Beck 1986) and Weimer (2015, p.624) who argues that political responsibility gets lost through the accelerating trends of politicisation and scientification.

Evading political deliberation is also facilitated in the final decision-making procedures. GM crop authorisations have been put in the legal category of implementing acts, which are subject to a voting procedure that leaves ample room for political deliberation. MS representatives can, if they wish, make a statement about their reasons to abstain from voting or a negative vote, but this is not mandatory and not intended to trigger a discussion or change MS positions. The representatives have a mandate from their national authorities and lack the political power to make adjustments.

The last reform[7] of the comitology procedures in 2011, after the Lisbon Treaty, resulted in several changes that further depoliticised the decision-making on GM crops: firstly, a 'no opinion' in the first voting is no longer referred to the Council of ministers of the MS, but to an 'appeal committee'. The appeal

7 Regulation (EU) No 182/2011.

committee was intended to represent a higher political level (see Christiansen & Dobbels 2012), but there are no strict requirements on the (political) status of the MS representatives in this committee.[8] In practice, the composition of the Appeal committee changed over time to represent representatives of an equal level as the standing committee (Christiansen & Dobbels 2012, note 2). Secondly, the EP (representing EU citizens) has less power to intervene in the process, as it can only object through a non-binding resolution (Stratulat & Molino 2011). As pointed out in Chapter 1, resolutions on draft decisions about GM crop authorisations are systematically submitted objecting both the decision itself as well as the 'undemocratic' process of decision-making. The EC is not obliged to act or respond to these resolutions and in practice goes ahead with decisions when concerning GM crop importation.

In addition, the voting procedures themselves have been systematically delayed and postponed (e.g. Smart *et al* 2015, 2017, Punt & Wesseler 2016). Officially, the EC has to schedule a voting in the standing committee within three months after the EFSA opinion has been published. In practice, there may be years in between, and even so between the first and the second voting. If the second voting also results in 'no opinion', the EC is mandated but not obliged to take a decision, providing it with a strategic and flexible position where she can instantly adopt the decision in case a complaint is filed with the WTO by non-EU countries and trade partners, or postpone decision-making indefinitely should MS or the EP complain about undemocratic decision-making.

Besides the EC, also the MS themselves seem to evade political debate. Several MS have used the safeguard clause or emergency measures to ban GM crops based on safety reasons.[9] But even when these bans have been considered unjustified by EFSA (see Chapter 1), they are not lifted and the Council has rejected proposals from the EC to enforce this process (MS don't want to impose measures onto each other with regard to their own territory on this controversial topic). It seems that it is not only the EC avoiding political debate but also the Council and the MS themselves.

Finally, by requesting more scientific data or calling for additional research, the EC can postpone decision-making while it awaits the results. This may

8 Regulation 281/2011, consideration 7: 'Where appropriate, the control mechanism should include referral to an appeal committee *which should meet at the appropriate level*' (emphasis added)

9 Based on regulatory safeguard clauses (Directive 2001/18/EC, Art. 23) or emergency measures (Regulation (EC) No 1829/2003, Art. 34)

be technical scientific research (such as the GRACE and G-Twyst project), legal research (such as the expert working groups on NPBTs) or the upcoming stakeholder consultations on NPBTs. Through these actions, the EC is seemingly and temporarily delegating part of the responsibility for decision-making to science, society and legal experts. Interestingly, while political actors seem to evade politics, other actors have become more politicised and they fuel the above processes of evading decision-making. The debates about alarming studies can be seen in this light, where both the instigators of the alarming study as the ones involved in reviewing or repeating the research become politicised (see Chapter 4).

3.2 GLYPHOSATE AUTHORISATION: SIMILAR CASE, DIFFERENT OUTCOME

In Chapter 1, I have discussed academic insights on wicked problems, most of which concluded that solving this type of problem is not possible. Instead, the focus has been on so called partial and imperfect solutions that do not aim to be comprehensive and exhaustive, but in the best case form an accumulation of small wins that eventually lead to steps forward (e.g. Termeer *et al.* 2019). The 'strategies' of evading decision-making can be seen as examples of 'coping' (e.g. Daviter 2017) or 'muddling through' (a concept from Lindblom 1959) ways of dealing with wicked problems, where decisions are made based on partial knowledge and the prioritisation of certain values over others. However, in my view these coping strategies should be seen as unsuccessful because they freeze the status quo, increase the level of discontent amongst stakeholders and translocate the debate to areas that are unsuitable arenas for political conflict (science regulation).

In the last part of this section, I will argue that better strategies are in theory possible, because the GM crop conflict is not 'wicked by nature' but 'wicked by design' (a distinction made by Nie 2003, see Chapter 1). I will substantiate this through a comparison with a similar case of a controversial technology application. If the GM crop conflict would be wicked by nature (i.e. controversial because of its scientific and societal implications), it suggests that other controversial technologies that go through similar procedures in Europe, are likely to suffer the same fate of undecideability. Interestingly, this is not necessarily the case. I will briefly discuss the case of the European authorisation of glyphosate, a broad spectrum herbicide. This case too, is controversial with regard to divided perspectives on human and environmental risks and its societal benefits. Its controversy however, did not result in undecidedness, because the EC actively engaged in political behavior through

arguing, bargaining and compromising with the MS until a (temporarily) decision was made on the authorisation of glyphosate.

The case of the market authorisation of the herbicide glyphosate has been more extensively discussed by Tosun *et al.* (2018), Bazzan & Migliorati (2020) and Arcuri & Hendlin (2020). In brief, glyphosate is the active ingredient of several broad-spectrum herbicides that are used in Europe and worldwide for agricultural and non-agricultural purposes (such as weed control and gardening) since the mid-70s. The compound also has a direct link with GM crops, since a major part of the GM crops that are commercialised worldwide are tolerant to glyphosate.[10] The first European authorisation of glyphosate in 2002 was unproblematic and had a validity of 10 years. The renewal authorisation process of glyphosate however, turned out to be challenging and initially resulted in a deadlock after several 'no opinion' outcomes under comitology voting. Finally, the EC changed its strategy from a 'static technocratic' position to a 'responsive' one (see Bazzan & Migliorati 2020) resulting in an explicit political process where the EC argued and bargained with the MS to find circumstances that would result in a qualified majority vote of the MS. Eventually, it was a (coincidental) shift of political powers in Germany that led to a qualified majority for the renewal of the glyphosate authorisation, but the explicit political process differs substantially from the situation with GM crops.

Similar to GM crops, science played an essential role in the debate about glyphosate. At the time of renewal, scientific studies indicated two risks: a contamination of drinking water sources and soil and the World Health Organization's International Agency for Research on Cancer (IARC) classified glyphosate as a probable human carcinogen (IARC 2015). This resulted in a discussion in the scientific field and beyond that is very similar to the dynamics around the 'alarming studies' described in Chapter 4. Starting out as a scientific debate with a focus on uncertainty and precaution, shifted towards a broader debate about human health, food production and sustainable agriculture and finally resulting in accusations of non-neutrality and conflicts of interests on those involved in the assessment and reassessment of glyphosate (e.g. Myers *et al.* 2016, Unterweger (2017).

10 Herbicide tolerant plants are unaffected by the use of certain herbicides, facilitating weed management for producers, since they do not have to avoid their crop when applying herbicides. The use of herbicide tolerant GM crops is integrally connected to the use of the specific herbicide that crop is tolerant for.

The EFSA was asked by the EC to review the IARC findings and came to the conclusion that glyphosate was unlikely to pose a carcinogenic hazard to humans (EFSA 2015). The report was heavily criticised and accused of being influenced by industry (i.e. Monsanto).[11] Nevertheless, the EC prepared a draft proposal to renew the authorisation for 15 years. A first voting under comitology procedures resulted in 'no opinion' (European Commission 2017d). Next, more science was added to the table when the EC asked the European Chemicals Agency (ECHA) to also assess the hazard from their expertise. ECHA supported the conclusion of EFSA (ECHA 2017). This was followed by another EFSA study, several rounds of discussions of the EC with the MS (indicating the urgency for political deliberation),[12] a citizen's initiative calling for a ban on glyphosate (heightening the political visibility of the conflict) and resolutions from the EP opposing the renewal for authorisation (European Parliament 2016, 2017). Finally, a 4th revision of the EC proposal, in which the authorisation period had been shortened from 15 to 5 years and MS were encouraged to take measures to minimize the use of the herbicide, was adopted by qualified majority in the Appeal Committee in 2017. It should be noted that the reason for this breakthrough was more coincidental than specifically related to the glyphosate case. A qualified majority was reached because Germany changed its position from abstaining to voting in favor of the draft proposal.[13] Tosun (2018) points out that the political conflict is likely to be reignited within five years when the next decision on renewal needs to be taken. She concludes that 'in the end, all member states will have to determine how best to address the substance in the future, and what levels of uncertainty they are willing to accept concerning its potential hazards—both to humans and the environment' (p.14), followed by referring to the need for stakeholder engagement within the MS. While I agree with the need for deliberation on a MS level, I argue in this thesis that

11 EUWeed-Killer Evidence 'Written by Monsanto'. Available online: https://euobserver.com/environment/137741

12 Different from GM crops, the legal authorisation of herbicides/pesticides in Europe is subject to expiration, meaning that if the authorisation expires without a decision on its renewal, its use would become illegal.

13 Germany usually abstains in GMO votings because of a rule that requires agreement between the minister of environment and agriculture to voting in favour or against. This was never the case. In 2017 however, because of delays in forming a new coalition government, the cabinet of Chancellor Angela Merkel had to act as a caretaker government. Under these circumstances, the German delegates were asked to vote in favour of the Commission's proposal, against the will of the minister of environment (see Tosun 2019, p.10). It should be noted that the minister of agriculture was under both internal and external pressure, as Germany was also the European Rapporteur for the glyphosate assessment that had a big influence on the EC's proposal. Ignoring their conclusion would indicate the minister did not trust the German Federal Institute for Risk Assessment.

the process requires more than a 'broader debate' and an 'open dialogue' with stakeholders. It requires the acknowledgement of the political nature of the conflict to balance the input from science and society/stakeholders and take decisions in situations of uncertainty and conflicting views.

The glyphosate case illustrates a similarly controversial case as GM crops where the decision-making is under threat of ending in a deadlock. The decision on glyphosate was initially strategically blocked through the comitology procedures (resulting in 'no opinion'), and the weight of the discussion shifted to science and scientific experts. With regard to science and risk assessment, Arcuri & Hendlin (2020) note that the regulations on pesticides are theoretically very stringent, but nevertheless omit vulnerable groups in the actual assessments (p. 245). In addition, they argue that legal frameworks determining risk in environmental toxicology tend to minimise risks and overestimate the certainty and accuracy of assessments. As a consequence, important concerns are systematically excluded from the decision-making process. Interestingly, for glyphosate the uncertainties and concerns seem to be no reason to delay and postpone decision-making, while for GM crop authorisations it is. This strengthens the view that decisions on what or whom should be protected are political decisions, and that therefore, both science and regulations themselves are insufficient to inform the exact course of decision-making on this level.

There is at least one important difference between the two cases. It seems that the political priority of the subject of glyphosate is significantly higher than GM crops. According to Tosun (2018) this has to do with the fact that glyphosate is widely used in Europe, and critical for agri-food production in Europe as a whole. Glyphosate is related to economic and agricultural benefits that have to be weighed against environmental and health costs. Interest groups from both sides are strongly involved in lobbying activities, indicating there is also something to win from a political perspective. The increase of issue visibility was also pointed out by Bazzan & Migliorati (2020) as an important urgency factor to resolve this issue. Being unable to decide could result in reputation damage for the EC as well. Finally, the EC engaged in political behavior through organising discussions with the MS to bargain and negotiate under what circumstances a decision could be made.

The glyphosate case illustrates that priorities, urgency and potential political wins can put dynamics back into discussions on controversial technologies, even in situations that seem wicked at first. Like other wicked problems, the

glyphosate issue is also characterised by a variety of problem definitions and solutions and widely diverging views on facts and values towards agriculture, environment and human health. More importantly, the glyphosate case illustrates that scientific certainty on the risks, nor a consensus amongst the general public or stakeholders involved are prerequisites for political decision-making.

An even more striking example emerged more recently: in June 2020, the EC presented a draft proposal to dismiss the environmental risk assessment for clinical research with GMOs intended to treat or prevent COVID-19[14] (such as GM-vaccines), arguing that human health, or even individual patients' health overrides other considerations such as the environment (European Commission 2020). Despite concerns from MS scientific advisory bodies (e.g. COGEM 2020, personal communication), the proposal was adopted by the Council and the EP and entered into force on July 17 (see Regulation (EU) No 2020/1043).

These examples substantiate my claim that technocratic or participatory strategies with the aim of (scientific) certainty or consensus are not only unfeasible but also not necessary for decision-making on a political level. The current regulatory system for GM crop authorisations provides political actors leeway to be accountable internally (to the MS) and externally (to the WTO and international trade partners) without having to take a decision that will cause political debate. This could be a valid strategy from a political perspective, but, in the next section I will argue that this strategy is not justified from a democratic perspective because proponents and opponents of GM crops need and deserve explicit political decision-making. While evasion of decision-making can provide strategic political breathing room, but damages democratic legitimacy when postponed indefinitely.

3.3 THE NEED FOR POLITICAL DECISION-MAKING ON GM CROPS

In this section I will use the views of amongst others Bovenkerk (2012) and Poort (2013) on deliberative democracy with regard to biotechnology to defend that whilst deliberation outside of the formal political realm is important to inform decision-making, it is a responsibility of political actors to (1)

14 At the end of 2019, the first human infections were reported of what turned into a pandemic in 2020. A – seemingly bat derived – coronavirus was transferred to humans and quickly spread across the globe. The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) leads to Coronavirus disease 2019 (COVID-19), and has resulted in 14,3 million infections, 602,000 deaths (as of 19 July 2020) and severe economic and societal disruption because of national and regional lockdowns.

decide when public deliberation has (temporarily) reached its transformative potential and (2) to move forward to deliberation on a political level with the explicit aim of decision-making. In Chapter 3 I briefly characterised political decision-making which, apart from input of different sources of information and a predefined process to arrive at a legitimate decision, requires a sense of direction and argumentation. The last two are, in my view, aspects that fall typically within the responsibility of politics. In addition, I will argue that the timing for this step is now or even overdue, since upholding the current decision-making framework can be seen as an illusion of a working system that is not justified from a democratic perspective towards both opponents and proponents of GM crops.

Deliberative democracy is a political model in which political decisions are legitimate when they are reached through free and uncoerced debate between equals in the absence of power structures. In other words, political decision-making should not (only) be arrived at through voting, bargaining and compromising (the dominant approach in most liberal democratic views), but in essence should be informed by deliberation based on quality of argument. These deliberative actions can have a different audience, goal and aim, depending on what view on deliberative democracy one holds. They may focus on (ideal) consensus (e.g. Habermas 1989, Cohen 1997) broadening participation and inclusion (e.g. Einsiedel 2001, Bovenkerk 2012), or structuring and deepening the debate (e.g. Gutmann & Thompson 1990, Poort 2013).

While I agree with the importance of the previously mentioned deliberative approaches (focusing on inclusion, broadening and deepening the discussion and if possible even with the aim of consensus), I conclude that they are insufficient to result in decision-making. I will provide three arguments that illustrate the application of theoretical perspectives on deliberative democracy is complicated in reality and one argument illustrating why these strategies will both in theory and in practice not lead to a closure of the debate. Firstly, given the long history of debate, entrenched positions of strong opponents and proponents and powerful (commercial and political) actors, it seems impossible to have an open and inclusive debate about GM crops free of power-structures. Secondly, the call for an inclusive dialogue with citizens presupposes that there are clear criteria and boundaries on how to organise such a dialogue. Thirdly, it presupposes there is a clear view on with whom and by whom this dialogue should be organised (e.g. all citizens? Stakeholders? A representative part or a majority?). Fourth and in my opinion most importantly, neither of the

deliberative strategies addresses the question when this step of the process is (sufficiently) fulfilled or how this can be determined.

Several authors have argued that striving for consensus risks premature closure of the debate and results in the exclusion of certain viewpoints (e.g. Poort 2013, Chapter 9, Castle & Culver 2013). They take an agonistic approach where the acknowledgement of disagreement deepens the discussion. The question of when the disagreement has been deepened sufficiently and how to take a next step towards decision-making remains unanswered. Bovenkerk (2012) argued that 'In order to respect the views of their citizens [...] governments need to participate as a non-party to the conflict as long as possible' (p.4). Hisschemöller & Hoppe (1995), who promote a learning strategy for unstructured problems, conclude that a decision on problem choice should not be taken before problem structuring has produced 'new insights on the problem and its potential solutions' (p.66). Each of these strategies aim for an inclusive and broad public deliberation to deepen the discussion and/or reveal the real sources of disagreement. This, in turn, could enable opinion transformation (Bovenkerk 2010). Neither of these authors claim that these strategies will result in consensus or decision-making, but they also refrain from going into the matter of when a controversy has been sufficiently acknowledged, deepened or addressed to take a justified decision and how this should be done.

In other words, when is a closure of the debate and a move towards decision-making no longer premature? Whose responsibility is it to decide when the 'real' sources of disagreement are revealed and when there has been sufficient opportunity for opinion transformation? When has the potential for opinion transformation reached its limits? Is this a matter of time? And if so, is five or ten or twenty or more years enough? (I note that the conflict over GM crops is ongoing since the 90s). And if no (partially) shared perspectives can be achieved: when, at what percentage, is there sufficient support or rejection of the general public to vote in favor or against a GM crop authorisation? The same holds for questions about scientific certainty or other sources of knowledge: at what point is there sufficient certainty? How safe is safe enough? Which socio-economic considerations should be taken into account? These are not questions for science or the general public, but depend on 'a wider judgement of the relative merits of a particular technology compared with its alternatives' (Mayer & Stirling 2004, p.1023). I argue that the answers to these questions will not present themselves and decisions on when to move ahead are an essential

part of politics. In my view there are no predetermined or 'right' answers to be found on these questions, which is exactly why they require political decision-making. In addition, I argue that the repetitive character of the discussion about alarming studies and GM crop authorisations provides strong indications that these discussions have reached the limits of their transformation potential and require political decision-making as a next step.

Political decision-making is not (solely) the outcome of scientific research or societal perspectives, nor is it a static reflection of 'reality' or the end of moral disagreement. Carpentier (2016, p.99) identified views on decisions either as a 'consensus', reflecting 'social makeability' or as 'universality' as 'fantasies' that do not reflect the reality of political decision-making. Presenting them this way may even further obstruct the decision-making process. By accepting the regulations and acting according to them, there is an implicit acceptance of underlying assumptions in the system that suggest being rationally comprehensive (all factors have been taken into account, as illustrated amongst others by the inclusion of broad non-mandatory terms such as ethics and socio-economic considerations). This may suggest that by playing according to these rules, one in principle, accepts GM crops, which does not reflect the views of individuals or collectives with fundamental objections against GM crops. Here I will follow Mouffe (1999) who argues that political decisions should not be seen as the end of moral conflict, but as a temporarily compromise between different (or even agonistic) views. It is 'a stabilisation of power that always involves some form of exclusion' (p.756). While Mouffe also doesn't go into the timing of decision-making itself, in theory this could be at any point where a compromise or simply a well substantiated decision can be reached. In view of the central case of this thesis, GM crop authorisations, I want to add urgency to the step towards decision-making and I will do this by reflecting on the consequences of not taking a decision and keeping a 'neutral' position.

While the importance of a neutral position of the government towards some issues is widely recognised (e.g. matters that relate to individual choices based on views on 'a good life'), amongst others Van der Burg & Brom (2010), have argued that political inaction on moral issues is not always as neutral as it seems. It risks removing topics off the agenda because no agreement can be reached. In that sense, Gutmann & Thompson (1990) propose to deal with intractable moral disagreement through a so-called 'economy of moral disagreement', where one tries to avoid moral conflict with one another while at the same time

not compromising their own moral views and principles (p.85-94). Based on the analysis in this thesis I argue that (1) scientific, participatory and regulatory strategies are (close to) being exhausted in attempts to bring proponents and opponents closer together and (2) that the (fundamental) disagreements about GM crops are unlikely to be solved. With regard to GM crop authorisations, the question then is what kind of decision can be justified based on the current positions in the debate about GM crops? The EU is prolonging the deliberative space on this fundamental disagreement by avoiding decision-making, which raises the question of when refraining from a decision can be justified from the perspective of neutrality and when it becomes unfair towards those who (urgently) need or deserve an explicit political decision.

Several authors have pointed out that taking a decision or staying neutral both have consequences. Bovenkerk (2012) argued that 'a government could avoid conflict by simply declaring one view to be correct or by remaining neutral between its citizen's views. In the first case it would not accord its citizens the equal respect they deserve and would fail to be democratic; in the second case it would fail to acknowledge the nonneutral consequences of doing nothing.' (p.235). Bovenkerk illustrates the last point by pointing at the normative choice to allow GM crops on the market in the first place (instead of banning them), which (potentially) penalizes farmers who want to stay GM-free. In my view however, this does not accurately reflect the situation. Inghelbrecht (2016) described the European situation as one 'where moving forward in trying to implement GM crops has been systematically blocked, while at the same time attempts to fully exclude GM crops from EU agriculture have been systematically prevented' (p.12). I want to take this claim a step further and argue that the EC disregards both GM proponents and opponents whilst upholding the 'illusion' of a working system. According to the official website of the European Union, the EC is supposed to promote the general interest of the EU by proposing and enforcing legislation as well as by implementing policies. It is also supposed to protect the interests of the EU and its citizens on issues that can't be dealt with effectively at national level. However, the EC decides not to interfere with the deadlock in the decision-making process on GM crops while upholding a system that can hardly be challenged by either proponents or opponents, because theoretically the system 'works'.

Firstly, people with fundamental objections against GM crops are disregarded in the current system. Despite the lack of decision-making, there are GM crop products on the (consumer) market. They are present indirectly through

importation of livestock feed containing GM crops and ingredients, but also in other food ingredients (such as vitamins) produced by GM micro-organisms. In addition, for practical reasons, there are threshold levels for labelling, meaning that some unlabelled products may still contain small amounts of GM ingredients. Inghelbrecht *et al.* (2014) argue that 'the current EU non-GM crop regime is in fact a 'fictitious' or 'virtual' non-GM crop regime that has developed into a wicked problem (p.67). With the rise of NPBTs it will become even more problematic if not impossible to trace GMO's in the food system (ENGL 2019, see also Chapter 8). By upholding the current traceability and labelling regime, the EC promises something that is not realistic or feasible.

Secondly, the current system also disregards GM proponents. There is a legal framework that aims to facilitate, amongst others, agricultural innovation and a functioning internal market, but in practice, decisions are not made and the feasibility of commercial applications is limited to agricultural staple crops (maize, soybean, rapeseed and cotton) with a very limited set of GM traits (herbicide tolerance and insect resistance). Effectively, there are no authorisations for GM crop cultivation and GM crops are only and after significant delays authorised for importation for feed purposes. This disregards principles such as legal certainty and proportionality towards companies and developers of GM crops.

In summary, I agree that in cases of conflict, moving too early towards decision-making based on consensus striving or by dismissing certain values, conceptions, types of knowledge, arguments or controversies, risks premature closure of the debate that can backfire. In a democratic society, complex and wicked problems that involve disagreement on both facts and values should have an opportunity to be discussed and explored to enable a learning process and opinion transformation. However, political judgement is needed to arrive at decision-making too.

I have argued that a decision on when technocratic and deliberative strategies have been sufficiently applied, also belongs to the responsibility of political actors. In my view the timing of this step is now or even overdue because the current system does not do justice to either proponents or opponents. I argue that (1) if facilitating individual decisions based on conceptions of a 'good life' are insufficient (the political liberal strategy) and if at the same time, (2) conflicting views on a 'good life' obstruct or hijack decision-making based on democratically determined conceptions of 'goods' and a 'good society',

this puts the topic in the realm of views of a good society, and thus within the responsibility of political judgement and decision-making. Upholding the illusion of a working regulatory system to both proponents and opponents, in my view, makes it difficult from a democratic perspective to justify avoiding decision-making on a political level and delegating the issue back to science, stakeholders and the general public. Instead, there is a need for repoliticisation of the political level in the decision-making process about GM crop authorisations, both at a MS and EU level.

3.4 FACTORS AFFECTING THE LIKELIHOOD OF REPOLITICISATION

Politicisation can be seen as a means to add political power; to act and decide from a non-neutral point of interest. In academic literature there are various views on the meaning of depoliticisation and repoliticisation in different contexts, as have been discussed by amongst others Hisschemöller & Hoppe (1995), Bovenkerk (2012) and Poort *et al.* (2013). These authors have mainly focused on the need and function of de- and repoliticisation through technical expertise, delegated bodies (such as ethics committees) and the general public, where the first two can be viewed as processes of depoliticisation while the involvement of the general public is seen as a way of repoliticisation that brings the issue at hand out in the open to be debated and to facilitate opinion transformation. In my view repoliticisation of the decision-making procedures of GM crop authorisations means acknowledging the political nature of the decision-making process and actively initiating political deliberation with the aim of arriving at a decision. In other words, repoliticisation means explicit political decision-making in situations of (scientific) uncertainty and controversy. Moreover, it implicates marking a point in time with a decision (that expresses intentionality through an explicit standpoint) that excludes alternatives for the time being.

In this thesis I have emphasised and substantiated the need of repoliticisation from a theoretical perspective. However, in the real world additional factors play a role that influence the likelihood of repoliticisation. In this last section I will switch my perspective once more from theory to practice and briefly reflect on two factors that may either facilitate or impede repoliticisation: problem ownership and urgency.

Mühlböck & Tosun (2017) have shown that MS voting behavior on GM crops is driven by different national interests such as public opinion, the ideological

background of the Ministers[15], and sectoral and structural interests. The reason for MS to abstain from voting is usually because they also diverge on these aspects within their borders, as is also illustrated by the network of GMO free regions in the EU (Tosun & Shikano 2015). Therefore, the EC has argued that a MS level would be a more suitable arena for political discussions about the authorisation of GM crops.[16] This view has been endorsed by several authors supporting decentralised competences in multi-level systems (e.g. Tosun & Hartung 2017) and subsidiarity-based multi-level governance (Dobbs 2016). In my view this could be a first step towards political deliberation about GM crop authorisations.

However, it has been noted that renationalisation of part of the decision-making may strategically shift the discussion and responsibility to another level (and is successfully avoided by the EC) where it may also be ignored or avoided for the same reasons of being contentious (e.g. Tosun & Hartung 2017 and Hartung & Hörisch 2017). This is illustrated by the fact that most MS have not taken active steps in implementing Directive (EU) 2015/412 in their national legislation (Dobbs 2017). Dobbs (2016) recognises the potential of subsidiarity-based multilevel governance within the GM cultivation regime, but also identifies opportunities for further improvement with regard to agenda setting, decision-making power and coordination. She particularly highlights the underlying question of authority. 'In the long run, a more proactive approach may be required - one that considers specifically where relevant powers ought to rest.' (p.246). I support this view because the question is not only whether GM crops should be authorised, but also who has the political power to decide about this. Here a difference can be found with the notion of deliberative democracy as described in Section 3.3 that aims to be free of power-relations. Deliberative democracy at a political level should in my view explicitly address first and foremost where the decision-making power lies.

This requires coordination, since at this point there seems to be a lack of incentive for MS to initiate these discussions as no GM crops are authorised and the status quo remains unchanged. Since the authorisation of GM crops is ultimately an EU decision, one could argue that the EC is the issue owner and should take (political steps) to engage the debate with the MS, who in turn also

15 Mühlböck & Tosun (2017) analyse voting data from before the Lisbon Treaty, where Ministers of the MS were voting. After the Lisbon Treaty, the voting has been downscaled to a lower political level and is being exercised by MS representatives.

16 Resulting in Directive (EU) 2015/412

have to initiate dialogue on a national level. In the absence of an active issue owner, I think steps are unlikely to be taken.

The glyphosate case (Section 3.2) illustrated that the EC is capable of organising political discussions with MS about controversial topics, but apparently only does so for some cases (i.e. glyphosate, COVID-19) and not others (i.e. GM crops). Similarly, Tosun (2019) noted that 'the application of the precautionary principle is determined by the dynamics of the relevant political process. Sometimes its application is accepted by the European Commission, and in other instances it is challenged' (p.4). In addition, in the past, the EC has engaged in political behaviour with the MS about GM crops. Skogstad (2003) describes the early days of the GM conflict (late 90s) as a process of aggregated politics including power politics and brokerage politics (p.332). It seems that there was a process of political bargaining between 1998 and 2004 resulting in the current hybrid regulatory system that takes into account both scientific and broader aspects. Once settled however, the failure of the execution of this framework seems either insufficient or not urgent enough to reopen political debate with the MS. In this view, Princen & Rhinard (2006) made a relevant distinction between high and low level politics. High level politics are topics that are characterised by a high-level of controversy or intense public debate and are sensitive to media attention. Decisions on these issues are the responsibility of high level politicians. In low-level politics, the key actors are state bureaucracy (scientific) experts and interest groups. Whether low-level politics results in policy outputs or not depends on the relationship between bureaucracy and politicians as well as the politicians' assessment of the topic in terms of electoral benefits. When reflecting once more on the case of glyphosate and COVID-19, these topics can be seen as moving from low-level politics to high-level politics because of the urgency of a decision. Even fundamental viewpoints that have been static for a long time seem to be dynamic again because of the high stakes (e.g. generally dismissing the environmental risk analysis for COVID-19 research versus referring to uncertainties about the food safety of GM crops after extensive research and upholding data requirements that are deemed unnecessary by a large part of the scientific community, see Chapter 1, Section 5). Several authors have pointed out that GM crops have a low political urgency in Europe, putting hardly any weight in the scale (for the moment) with regard to reigniting political deliberation. Skogstad (2011) said 'the majority view in every EU MS is that GM foods are not useful, not morally acceptable, and a risk for society' (p.906). More recently, the low political priority of GM crops has also been mentioned by Smart *et al.* (2015): 'We suggest

that further research test the hypothesis that in the EU the political-economic benefit-cost ratio is too low for politicians to vote in favour of approving GE crops.'(p.258).

In conclusion, in my view unless an issue owner with sufficient political power steps out, or if political urgency with regard to GM crops moves the issue from low- to high-level politics, repoliticisation of the authorisation of GM crops seems unlikely compared to the 'comfort' of the status quo that has been around for at least two decades. However, I have argued that this undeciciveness cannot be justified from a democratic perspective.

4. CONCLUSIONS & RECOMMENDATIONS

My main research question was: **Why is there a deadlock in decision-making on the authorisation of GM crops in Europe and how can it be addressed?**

In this thesis I have argued that it is the lack of political judgement and decision-making that is an underexposed and avoided factor in the conflict over GM crops. Underexposed because stakeholders, policy-makers, politicians and academics keep pointing at scientific, regulatory and societal factors as the cause of the conflict and focus their mitigation strategies on those. Avoided because these factors seem to be used strategically to postpone, delay or stall decision-making. Decision-making on GM crop authorisations in Europe is deadlocked because the voting procedures under comitology regulations systematically result in 'no-opinion', and the EC is reluctant to decide on the MS behalf about such a contentious issue. In this chapter, I have argued that strategies to evade decision-making might be justified from the perspective of internal and external accountability, but they cannot be justified from the perspective of democratic accountability towards both GMO proponents and opponents amongst stakeholders and the general public.

Therefore, a repoliticisation of decision-making about GM crop authorisations is needed to resolve, not solve, the conflict over GM crop authorisations. Questions about how safe is safe enough and when have societal discussions been deepened sufficiently do not have 'right' answers, and therefore they ultimately require political decision-making. In my view the repetitive character of the discussion about GM crops provides an important indication that the transformation potential of opinions has been reached. Political decision-making is needed, despite scientific uncertainties and in the presence of diverging viewpoints. This implicates decision-making should take place

in an environment, either at the subnational, national or EU level, that allows for political deliberation to be taken into account and decisions to be made. It also has implications for the meaning of decisions that are made. Finally, I have identified problem ownership and political urgency as two factors which co-determine the circumstances under which repoliticisation of GM crop decision-making can be facilitated.

I. What kind of problem is the deadlock in decision-making about GM crops and why?

In Chapter 1 I have argued that the GM crop conflict has the characteristics of a wicked problem, because it involves disagreement on both (scientific) facts and (normative) values. This has been illustrated in depth in Chapter 4 providing a discourse analysis of the debate about alarming studies. The wickedness of the GM crop issue can also be found in its resilience to problem solving, as illustrated by the attempts of resolving the disagreement about alarming studies through technocratic strategies in Chapter 5 (standard governance responses to alarming studies fail). In Chapter 2 I have analysed and evaluated the technocratic, participatory and regulatory strategies that have been used over the years to mitigate the issue and concluded that their success has not been overwhelming. After analysing why these strategies did not work (chapter 3) I have argued that they cannot resolve the situation in the absence of political decision-making. After identifying several indicators of political conflict in chapter 3, in this final chapter I have also provided argumentation to substantiate that the avoidance of political decision-making could be deliberate. From this perspective, I argue that the GM crop conflict is not just 'wicked' but 'wicked by design', and there seems to be a situation of strategic political undecideablity.

II. Why is the deadlock in decision-making a problem?

In this chapter I have argued that the deadlock in decision-making about GM crops may be justified from a political perspective of internal and external accountability towards MS and non-EU parties. Nevertheless, I have defended that decision-making is needed from a democratic perspective with respect to stakeholders and the general public, representing both proponents and opponents of GM crops. In addition, the current situation of non-decision-making disregards basic legal principles such as legal certainty and accountability in a national and international setting. Furthermore, Chapter 7 has illustrated that GM crops have potential impacts on both innovation and other socio-economic considerations and finally, the undecideability in the

EU will not stop developments in an international setting (Chapter 8). In this light, not deciding also resembles the decision not to take part in what future governance frameworks should look like when biotechnology integrates both horizontally and vertically into other fields.

III. Has the issue been addressed and how?

The deadlock in decision-making has been addressed through technocratic, participatory and regulatory strategies (Chapter 2, 4 and 5). Some of these strategies have been addressed in more depth in Chapter 6 with regard to the inclusion of non-safety arguments on a national level as a legal argument to ban GM crops on a national level. The opportunities and challenges of the inclusion of non-safety (e.g. socio-economic) considerations have been reviewed in Chapter 7.

IV. Did this resolve the issue and why (not)?

In Chapter 2 and 3 I have argued that these strategies have proven insufficient to resolve the deadlock in decision-making about GM crop authorisations because they are alone or together insufficient to result in the single course of action that is needed for a yes/no decision on authorisation of GM crops. These strategies did not resolve the deadlock, but instead are used strategically to evade decision-making. In addition, the positioning of contentious issues as implementing acts in the EU decision-making process facilitates evading political judgement and postponement and delays hiding behind a complex regulatory framework that has a focus on technocratic factors on safety and risk. This problem is not specific for GM crops, but also in other policy areas such as pesticides (glyphosate). The latter issue has been (temporarily resolved) amongst others because of urgency and political prioritisation.

V. How can the issue be addressed to improve the situation?

My hypothesis was that technocratic, participatory and regulatory input in the decision-making process are insufficient if political actors renounce or are unable to take up their own role in the decision-making process; which is to decide in case of conflict. An explicit repoliticisation of the decision-making process about GM crops is needed.

In this final chapter I have substantiated this hypothesis by looking into the contributions and limitations of science, participatory activities and regulatory frameworks and identifying and describing the specific role of politics that is needed in addition to these processes. It is a task and responsibility of political

actors to argue and defend when there has been sufficient room for scientific and societal deliberation, confrontation and discussion. These answers will not present themselves but require political judgement and decision-making. Repoliticisation of the decision-making process is needed. In my view, repoliticisation in the context of this thesis means explicit decision-making in situations of scientific uncertainty and controversy. Finally, I argue that repoliticisation is only likely to take place if there is a shared motivation or urgency to resolve the deadlock. In my view, unless an issue owner with sufficient political power steps out or the urgency of a decision is increased that moves the issue from low- to high-level politics, repoliticisation of the authorisation of GM crops seems unlikely compared to the 'comfort' of the status quo of non-decision-making that has been around for at least two decades. Nevertheless, I argue that the strategic political undecisiveness cannot be justified from a democratic perspective.

Finally, some recommendations or focus points for future research on wicked problems can be made based on the research presented in this thesis. In my view, research on decision-making about controversial technologies should not only focus on gaining insights into why decision-making is problematic, but also into what is needed to arrive at decision-making. It would be valuable for future research to look into the question when the preceding (deliberative) steps towards political decision-making are (sufficiently) fulfilled and how this can be determined? In other words, when is a closure of the debate and a move towards decision-making no longer premature? How can be decided when the 'real' sources of disagreement are revealed and when there has been sufficient opportunity for opinion transformation?

SUMMARY

Altering the DNA of living organisms, also genetic modification, genetic engineering or genetic manipulation, triggers a wide variety of views and standpoints related to moral values, perceptions of risks and benefits and broader issues such as socio-economic aspects. To address these diverging perspectives, a regulatory framework for Genetically Modified Organisms (GMOs) has been developed in Europe that aims to guarantee safety for humans and the environment, facilitates innovation for research and commercial applications and leaves room for individual decision-making regarding the consumption of genetically modified (GM-) food. However, this system doesn't work as intended in **Europe**. This is particularly the case for **market authorisations of GM crops** for importation and cultivation. The European conflict over GM crops is ongoing since the late 90s and has shown to be remarkably resilient to being solved or mitigated.

Under the current regulatory system, GM crops are neither explicitly approved nor rejected by the Member States (MS). European regulatory decision-making procedures on the authorisation of GM crops are systematically delayed or stalling. After a positive opinion from the European Food Safety Authority (EFSA) on the risks to humans and the environment, the European Commission (EC) presents a draft proposal for authorisation to the MS. However, the voting procedure (part of EU comitology) with the MS nearly always result in 'no opinion' because no qualified majority can be reached either in favor or against the proposal. Consequently, most GM crop authorisation applications for importation have been authorised through a unilateral decision from the EC and without the support of the MS. Authorisations of GM crop cultivation have completely halted since the late 90s.

Discussions over the safety and acceptability of GM crops amongst political and policy actors, stakeholders, scientists, NGOs and the general public have shown a repetitive pattern of exchanging the same arguments over and over without moving in any direction. These discussions are regularly reignited by **'alarming studies'**, a concept that was introduced by the author of this thesis. These are scientific or other studies claiming that a technological innovation (e.g. a GM crop) poses a threat to human health or the environment which has not been acknowledged by the existing governance system. These studies trigger a technocratic response from governments, which has proven insufficient to reach an agreement about the scientific value of these studies because, amongst others, perspectives on 'good science' diverge. In addition, involving stakeholders or adapting regulations have also proven unable to move towards

a common ground for decision-making about GM crops. Alarming studies continue to be cited by those opposing GM crops as proof that they are unsafe. Legislative opportunities and interpretative leeway are used by MS to divert from a multilateral European decision on GM crop authorisations.

These characteristics of the GM crop conflict, such as a lack of a shared problem definition and disagreement on both facts and values, classify the issue as a **wicked problem**, a concept from Rittel & Webber. They used it initially to distinguish technical from societal problems in engineering, but the concept has taken its own turn in academic literature over the years, where it became used to describe problems that are wicked in themselves. Framing GM crops as a wicked problem suggests that a) it is biotechnology itself that is a problem and b) the issue is impossible to solve because of its wickedness. Nevertheless, strategies have been developed and applied to deal with the issue of GM crops in Europe. After two decades however, these strategies seem to have had limited success.

This thesis provides an empirically informed analysis of the decision-making process on European GM crop authorisations and the factors contributing to this decision. It aims to analyse why there is a deadlock in decision-making on the authorisation of GM crops in Europe and how it can be addressed.

Besides an empirical analysis of the discourse used in discussions on alarming studies, I use academic literature from the field of sociology, political science, philosophy of law, and science & technology studies (STS) to reflect on the common mitigation strategies which are proposed in the field of regulatory science to deal with GM crop authorisations, alarming studies and new scientific developments. This approach of combined methodologies provides a toolbox that enables a multidimensional view on the problem at hand. In addition, working for a scientific advisory body (The Netherlands Commission on Genetic Modification (COGEM)) provided me with firsthand experience of how 'messy' reality can be compared to theory. Together, the interaction, overlap and differences of these empirical, academic and anecdotal insights have resulted in a dissertation that aims to provide a step forward in the controversy over GM crops.

The dissertation can be divided in three parts.[1] The first part (**Chapters 1 - 3**) introduce the subject of this thesis (GM crop authorisations) and provide

1 For a chronological overview of the chapters in this thesis see Chapter 2, Section 4

the problem analysis that results in my research question and hypothesis. The second part (**Chapters 4 – 8**) consists of a series of published articles that deepen the problem analysis as well as provide partial answers to the question why mitigation strategies for the GM crop conflict thus far have had limited success. Finally, I wrap up my findings in **Chapter 9** and substantiate my **hypothesis** that the GM crop issue is wicked by design and in urgent need of acknowledgement of the political nature of the conflict, followed by explicit decision-making.

Several strategies have been developed to mitigate the deadlock in GM crop authorisations in Europe. These strategies predominantly focus on three areas: science, (public) participation and regulation: increase scientific knowledge, involve the general public and stakeholders and add or change regulations to be fit for purpose. The potential and contributions of each of these strategies are evaluated in **Chapter 2** of this thesis, while their limitations are discussed in **Chapter 3**.

Technocratic strategies seem to be based on the assumption that better science and more knowledge will lead to better decision-making. Three examples of commonly used technocratic strategies are discussed: 1) reducing uncertainties, 2) adding scientific expertise and 3) technological solutions. These strategies seem to be a standard response to situations of conflict about GM crops, whether they be about alarming studies, authorisation processes or the regulation of new plant breeding techniques (NPBTs). But although broadly applied, their success has been limited. Besides practical insights, I used critical theoretical views on technocratic strategies from amongst others Sarewitz and Jasanoff to substantiate this conclusion.

The debates about existing alarming studies remain and reignite when new ones are published. This is analysed in more depth in **Chapter 4** which consists of a discourse analysis that illustrates the repetitive pattern of arguments being brought forward after publication of a series of alarming studies. **Chapter 5** discusses the standard governance responses that focus on the scientific debate while omitting the normative aspects of science as well as the broader underlying debate about GM crops that relate to fundamentally different views on agriculture and food production. Scientific expertise has not resulted in decisions about the regulatory status of NPBTs, nor has it convinced MS to lift their national bans on GM crops or did it resolve the debate about the scientific value of alarming studies. Finally, technological solutions, such

as the possibility to create small DNA changes that can also occur in nature, have not changed the debate on GM crops. These solutions have not provided generally accepted answers to questions about naturalness or benefits of GM crops.

In **Chapter 9** I revisited these findings on technocratic strategies and I argue that science and scientific expertise are on the one hand essential to navigate complexity and reduce uncertainties. On the other hand science is always provisional with an endemic and irreducible level of uncertainty. Science does not compel action or tells us what to do. Whether a GM crop is safe enough and an acceptable option for agriculture and food production, is a political choice and requires political argumentation. This is also the case for other types of knowledge that are included or considered in the decision-making process, such as a broader assessment that includes socio-economic considerations. Socio-economic considerations are, perhaps even more than environmental risk, subject to normative judgements and choices providing a number of challenges, which are reviewed in **Chapter 7**. Finally, the input of science in the decision-making process is challenging: it needs translation (the **'science-policy gap'**) and provides an **'excess of objectivity'** that can be used to substantiate a variety of viewpoints. At the same time, policy-makers and politicians face **'bounded rationality'** that makes it impossible to take all existing evidence into account. A strong focus on adding science can even have an adverse effect, leading to discussions about reproducibility, integrity and legitimacy of science and scientific experts.

Participatory strategies can contribute to the identification of values and of perceived hopes and threats of a technology that can inform the political decision-making process. The broader and more inclusive, the more likely these processes are to capture the variety of perspectives that may need to be taken into account to legitimise policy- and decision-making from a democratic perspective. In addition, participatory activities and the inclusion of societal actors and stakeholders may contribute to trust in the eventual decision-making process. Calls for public and stakeholder participation seem to suggest that taking stakeholders into account ideally results in a collective vision on the way forward, or at least a shared or common ground on which decisions can be built. In **Chapter 2** and **3** I discuss and evaluate three types of participatory strategies, focusing on 1) inclusion and engagement, 2) consensus building and 3) acknowledging controversies. I use insights from amongst others Bovenkerk and Poort whose work has also been directed at biotechnology and genetic

modification as a case study. In **Chapter 9** I further reflected on and criticised their work and finally added my own perspective to it. Numerous initiatives, global observatories, dialogues etc. have been set up over the years about GM crops, GM animals and GM in humans, but viewpoints remain diverged and the (intended) use of the outcome of participatory strategies in decision-making on regulations and authorisations is often implicit, providing difficulty to identify or measure the results of participatory strategies. Revisiting these reflections in **Chapter 9**, I argue that the general public and stakeholders can't make decisions as an entity, because these groups are a pluralistic collective of individuals with a broad spectrum of different and conflicting views on 'the good life', 'goods' and 'a good society'. While participation and deliberation are valuable and necessary in debates about controversial technologies, they are in themselves insufficient to inform the direction of the decision-making on GM crop authorisations.

Regulatory strategies to mitigate the conflict on GM crops focus on evaluating and (re)defining rules and boundaries on who decides about what and based on which grounds. These strategies seem to be based on the assumption that that 'better' rules and regulations will facilitate better decision-making.

The regulations have been criticised and adapted moreover throughout the years to improve the conflict over GM crop authorisations in Europe and within MS. Interestingly, these strategies generally follow two opposite directions; they focus on a more science or **evidence-based** regulatory framework and on a more **precautionary** & broader regulatory framework that includes non-safety aspects. There has been an increase of (legally binding) requirements for the environmental and food safety assessments on the one hand. On the other hand regulations have been implemented facilitating consumers freedom of choice through food labelling (Regulation (EC) No 1830-2003) and acknowledging non-safety arguments as a reason to ban cultivation of GM crops on a national level (Directive (EU) 2015/412).

I used critical reflections from academic literature from amongst others Cairney, Tosun and Stirling to point out that both strategies encounter practical challenges on implementation. Science-focused regulatory frameworks are based on the assumption that 1) there is sufficient scientific evidence and 2) there is agreement about this evidence. Differences in national risk assessments on GM crop authorisations and the discussion over alarming studies illustrate this is not the case. In addition, the scientific developments

discussed in **Chapter 8** illustrate that the scientific status quo reflected in the regulations will continuously be challenged by new findings, which calls for a more dynamic instead of a more detailed science-based regulatory framework. Broader and more inclusive regulatory frameworks tend to lead to a complex regulatory framework that takes into account an almost endless amount of factors that are difficult or even impossible to compare and balance due to normative differences. The current EU framework for GMOs has both characteristics of precautionary and evidence-based systems. As a result, a tension arises between those that see science as the only legitimate source of knowledge for a regulatory framework and those that promote the inclusion of other perspectives (such as political, cultural, and socio-economic factors). Instead of complementing each other, the concepts of evidence-based and precaution seem to be used as ammunition against each other, contributing to a deadlock in decision-making.

A third proposed regulatory strategy aims to change the rules of the voting procedures to dismiss the option of 'no opinion'. This will force MS to take a position in favor or against GM crops. This strategy could work, in theory, but reality has proven to be more complex. **Chapter 6** provides an in depth normative analysis of Directive (EU) 2015/412, illustrating that adjusting the regulations does not necessarily provide a solution for the conflict and disagreement on biotechnology, even if the regulation in itself seems fit and reasonable. As with every regulation or directive, there is always a certain amount of leeway for alternative use, facilitating differences between **'law in books'** and **'law in action'**. Therefore, it seems unlikely that a change of comitology rules would mitigate the issue on GM crop authorisations as long as underlying issues are not explicitly addressed.

Revisiting these insights in **Chapter 9**, I argued that regulations may determine the rules and requirements based on a reflection of what has been democratically decided to represent a common perspective on 'a good society' but, these rules and requirements do not determine the outcome of a decision. Regulations cannot resolve conflict by themselves and inevitably include a degree of interpretative space, i.e. different courses of action can be justified in view of the same regulations based on different views on the intended outcome. In addition, the views on a 'good society' reflected in the regulations can impossibly (fully) overlap with all different conflicting individual views on 'a good life'.

The insights from the discussion and evaluation of technocratic, participatory and regulatory strategies substantiate the proposition that no matter how much science, regulatory measures or public participation you throw at it, these will not automatically result or add up to political decision-making. And this is, in my view, where acknowledgement of the political nature of the conflict is needed to balance the input from science and society/stakeholders and **take decisions in situations of uncertainty and conflicting views.**

Political behavior and actions such as deliberation, argumentation, bargaining and compromising have been very limited or even absent in the case of GM crop authorisations. The decisive step has been reduced to a voting process by MS representatives with a predetermined national voting mandate under EU comitology procedures. As a consequence, the only way to express underlying disagreements about the issue of GM crops, is to use the breathing room within the existing regulatory framework to obstruct the decision-making (e.g. negative votes or abstaining from voting and installing national or regional bans on GM crops). In **Chapter 9** I argued that decision-making on GM crops is strategically evaded by the EC and the MS by using the leeway in the regulations and delegating responsibilities back to science (to provide more certainty) and society (to build a consensus or shared perspective) or by postponing decision-making awaiting a change of regulations.

This strategy of evasion can be seen as a strategic way of managing accountability on different levels (i.e. towards MS and non-European countries) to avoid economic, political or legal consequences. The hybrid regulatory system that is both detailed and science-based as well as broad and optional on non-safety issues, combined with decision-making rules (comitology) that provide room for non-decision-making (i.e. 'no opinion'), leaves the EC with a strategic and flexible position where she can instantly adopt decisions in case a complaint is filed with the WTO by non-EU countries and trade partners, or postpone decision-making should MS or the European Parliament (EP) complain about undemocratic decision-making. This classifies the conflict on GM crop authorisations not just as a wicked problem, but as a **wicked problem by design** (a concept from Nie). This claim can be substantiated with a comparison of a similar case of a wicked problem: the authorisation of the broad spectrum herbicide glyphosate in Europe. Despite its wicked character, a lack of scientific certainty and societal consensus, an authorisation decision was reached, because the EC engaged in political behavior and argued, bargained and negotiated with the MS until a compromise had been reached. The glyphosate case illustrates

that priorities, urgency and potential political wins can put dynamics back into discussions on controversial technologies, even in situations that seem wicked at first.

Based on the analysis in this thesis I argue that (1) scientific, participatory and regulatory strategies are (close to) being exhausted in attempts to bring proponents and opponents closer together in the conflict over GM crops and (2) that the (fundamental) disagreements about GM crops are unlikely to be resolved. With regard to GM crop authorisations, the question then is what kind of decision can be justified based on the current positions in the debate? The EU is prolonging the deliberative space on this fundamental disagreement by avoiding decision-making, which in addition raises the question of when refraining from a decision can be justified from the perspective of neutrality and when it becomes unfair towards those who (urgently) need or deserve an explicit political decision.

In academic literature on deliberative democracy, the importance of a neutral position of the government is emphasised in cases of controversy. Government should stay neutral to allow for deliberation amongst stakeholders and the general public to voice their concerns and optionally transform their viewpoints. This view has also been criticised, since staying neutral also has consequences. Authors such as Bovenkerk and Poort have endorsed a view on deliberative democracy that focusses on inclusion of all stakeholders and deepening disagreements, while also acknowledging that these approaches will not automatically lead to decision-making. However, they refrain from going into the matter of when a controversy has been sufficiently acknowledged, deepened or addressed and moving forward to decision-making is no longer premature. After this critical note, I added to their work and argued that a decision on when technocratic and deliberative strategies have been sufficiently applied, also belong to the responsibility of political actors. In addition, in my view the timing of this step is now or even overdue because the current system does not do justice to either proponents or opponents of GM crops. The current situation of non-decision-making disregards basic legal principles such as legal certainty and accountability in a national and international setting. **Chapter 7** has illustrated that GM crops have potential impacts on both innovation and other socio-economic considerations and the undecideability in the EU will not stop developments in an international setting (**Chapter 8**). In this light, not deciding also resembles the decision not to take part in what future governance frameworks should look like when biotechnology integrates both horizontally and vertically into other fields.

Upholding the illusion of a working regulatory system to both proponents and opponents, in my view, makes it difficult from a democratic perspective to justify non-decision-making on a political level and delegate the issue back to science, stakeholders and the general public. Instead, there is **a need for repoliticisation** on the political level in the decision-making process about GM crop authorisations, both at a MS and EU level. In my view, repoliticisation in the context of this thesis means **explicit decision-making in situations of scientific uncertainty and controversy.** However, as democratic accountability is not the only determinant for political decision-making, I note that, similar to the glyphosate case, **political urgency** as well as **issue ownership** are important factors that determine the likelihood of decision-making in the real world.

SAMENVATTING

Het wijzigen van het DNA van levende organismen, ook wel genetische modificatie of genetische manipulatie genoemd, roept een grote diversiteit aan perspectieven en standpunten op die gerelateerd kunnen worden aan morele waarden, risicopercepties en aspecten zoals sociaal-economische factoren. Om deze uiteenlopende perspectieven recht te doen, is wet- en regelgeving ontwikkeld voor Genetisch Gemodificeerde Organismen (GGO's) die beoogt de veiligheid voor mens en milieu te waarborgen, onderzoek en innovatie te faciliteren en ruimte te bieden voor individuele keuzevrijheid op het gebied van genetisch gemodificeerd (gg-) voedsel. Dit systeem werkt in **Europa** echter niet zoals bedoeld. Dit is in het bijzonder het geval voor **markttoelatingen van genetisch gemodificeerde (gg-) gewassen** voor import en teelt. Het Europese conflict over gg-gewassen loopt al sinds eind jaren 90 en toont zich bijzonder weerbarstig tegen aangedragen oplossingen en compromissen.

In de huidige situatie worden marktaanvragen voor gg-gewassen niet expliciet goedgekeurd noch afgewezen door de Europese lidstaten. De Europese besluitvormingsprocedures voor de autorisatie van gg-gewassen zitten in een **impasse** en worden systematisch vertraagd of lopen volledig vast. Na een positieve opinie van de Europese autoriteit voor Voedselveiligheid (European Food Safety Authority, EFSA) over de risico's voor mens en milieu, presenteert de Europese Commissie (EC) een voorstel voor een besluit tot toelating aan de lidstaten. De stemmingsronde die hierop volgt (als onderdeel van de Europese comitologie of besluitvormingsprocedures) resulteert vrijwel altijd in 'geen mening' omdat er geen gekwalificeerde meerderheid voor danwel tegen het conceptbesluit wordt behaald. Als gevolg hiervan, worden de meeste besluiten voor import uiteindelijk unilateraal genomen door de EC, zonder de steun van de lidstaten. De markttoelating van gg-gewassen voor teelt is volledig tot stilstand gekomen sinds eind jaren 90.

Discussies over de veiligheid en aanvaardbaarheid van gg-gewassen onder politieke en beleidsactoren, stakeholders, wetenschappers, NGO's en het algemene publiek laten een patroon zien waarbij dezelfde argumenten steeds opnieuw worden uitgewisseld zonder dat de uitkomst van de discussie in enige richting beweegt. Deze discussies worden regelmatig aangewakkerd door zogeheten '**alarmerende studies**', een concept dat werd geïntroduceerd door de auteur van dit proefschrift. Dit zijn wetenschappelijke of andere studies die claimen dat een technologische innovatie (bijvoorbeeld een gg-gewas) een risico vormt voor de humane gezondheid of het milieu dat (nog) niet erkend is door de autoriteiten. Deze studies leiden in eerste instantie tot een

technocratische respons van overheden om de wetenschappelijke validiteit van het onderzoek te onderzoeken. Deze aanpak is echter onvoldoende gebleken om overeenstemming te bereiken over de wetenschappelijke waarde van alarmerende studies, onder meer omdat ook de meningen over wat 'goede wetenschap' is, blijken te verschillen. Het breed betrekken van stakeholders bij dergelijke evaluaties evenals het aanpassen van de regelgeving zijn eveneens onvoldoende gebleken om een gezamenlijk draagvlak te bereiken voor besluitvorming over de veiligheid van gg-gewassen. Hoewel formeel afgewezen om hun gebrek aan wetenschappelijke validiteit, worden alarmerende studies nog steeds aangehaald door tegenstanders van gg-gewassen als bewijs dat deze gevaarlijk zijn. De juridische mogelijkheden en interpretatieve ruimte binnen de regelgeving wordt daarnaast volop gebruikt door lidstaten om af te wijken van een multilaterale besluitvorming over de markttoelating van gg-gewassen.

Deze kenmerken van het conflict over gg-gewassen, zoals een gebrek aan een gezamenlijke probleemdefinitie en onenigheid over zowel 'feiten' als 'waarden', classificeren het conflict als een **'wicked probleem'**, een concept van Rittel & Webber. Zij gebruikten het om een onderscheid te maken tussen technische en sociale problemen in de bouwkunde, maar het concept is in de loop der jaren vooral gebruikt om problemen te beschrijven die 'wicked' in zichzelf zijn. Het classificeren van gg-gewassen als een wicked probleem suggereert dat a) biotechnologie zelf een probleem is en b) het probleem onoplosbaar is door zijn intrinsieke 'wickedness'. Desondanks zijn in de loop der jaren verschillende strategieën ontwikkeld en toegepast om een oplossing te vinden voor het conflict over gg-gewassen in Europa. Na ruim twee decennia lijken deze strategieën echter beperkt succesvol.

Dit proefschrift presenteert een empirisch geïnformeerde analyse van het besluitvormingsproces over Europese markttoelatingen voor gg-gewassen en van de factoren die bijdragen aan deze besluiten. De vraag die ik hiermee wil beantwoorden is waarom er een impasse is in de besluitvorming over markttoelatingen van gg-gewassen in Europa en hoe deze kan worden geadresseerd. Naast een empirische analyse van het discours dat gebruikt wordt in discussies over alarmerende studies, gebruik ik inzichten uit de academische literatuur van verschillende vakgebieden waaronder sociologie, politieke wetenschappen, rechtsfilosofie en science & technology studies (STS) om te reflecteren op de bijdragen en beperkingen van veelgebruikte strategieën om een oplossing te bieden voor het conflict. Deze 'gecombineerde methode'

benadering levert een gereedschapskist op die een multidimensionaal perspectief op het probleem faciliteert. Mijn werk voor het wetenschappelijke adviesorgaan de Commissie Genetische Modificatie (COGEM) heeft mij bovendien uit de eerste hand laten ervaren hoe 'rommelig' de realiteit kan zijn ten opzichte van de theorie. Samen hebben de interactie, overlap en verschillen van deze empirische, academische en anekdotische inzichten geresulteerd in een proefschrift dat beoogd een stap voorwaarts te bieden in de controverse over gg-gewassen.

Het proefschrift bestaat uit drie delen.[1] Het eerste deel (**Hoofdstukken 1-3**) introduceert het object van het onderzoek (markttoelatingen van gg-gewassen) en vormt de probleemanalyse die leidt tot de onderzoeksvraag en hypothese. Het tweede deel (**Hoofdstukken 4 – 8**) bestaat uit een serie gepubliceerde artikelen die de probleemanalyse verder verdiepen en deelantwoorden geeft op de vraag waarom strategieën om het conflict over gg-gewassen op te lossen vooralsnog weinig succes hebben gehad. Het derde deel betreft het afsluitende **Hoofdstuk 9** waarin ik reflecteer op mijn bevindingen en mijn **hypothese** onderbouw dat het conflict over de besluitvorming over gg-gewassen niet wicked in zichzelf is maar een **ontworpen wicked probleem** (**'wicked problem by design'**). Dit vraagt om erkenning van de politieke aard van het conflict gevolgd door expliciete politieke oordeelsvorming en een besluit: **repolitisering** van de besluitvorming.

Er zijn verschillende strategieën ontwikkeld om de vastgelopen besluitvorming over gg-gewassen vlot te trekken. Deze strategieën hebben voornamelijk een focus op drie gebieden: wetenschap, stakeholderbetrokkenheid en regelgeving: meer wetenschappelijke kennis, het betrekken van een breder publiek en meer stakeholders en het aanpassen van de regelgeving zodat deze beter aansluit bij de wetenschappelijke en maatschappelijke ontwikkelingen. De (potentiele) bijdragen van deze **technocratische, participatieve en juridische strategieën** zijn geëvalueerd in **Hoofdstuk 2**, en hun beperkingen worden besproken in **Hoofdstuk 3**.

Technocratische strategieën lijken gebaseerd op de aanname dat betere wetenschap en meer kennis tot betere besluitvorming leiden. Ik bespreek drie voorbeelden van veelgebruikte technocratische strategieën: 1) reduceren van onzekerheden, 2) inzetten van wetenschappelijke expertise en 3) technische oplossingen. Deze strategieën lijken een standaard reactie te zijn op discussies

1 Voor een chronologisch overzicht van de hoofdstukken in dit proefschrift zie Hoofdstuk 2, Sectie 4 (Outline).

over gg-gewassen, of het nu gaat om alarmerende studies, markttoelatingen of de regulering van nieuwe plantenveredelingstechnieken (NPBTs). Maar hoewel breed toegepast is het succes van deze strategieën beperkt. Naast bevindingen uit de praktijk, gebruik ik kritische perspectieven uit de academische literatuur van onder andere Sarewitz en Jasanoff om te beargumenteren dat technocratische strategieën beperkingen hebben voor het oplossen van het probleem.

Discussies over bestaande alarmerende studies gaan onverminderd door en worden aangewakkerd wanneer nieuwe alarmerende studies gepubliceerd worden. In **Hoofdstuk 4** worden deze discussies geanalyseerd aan de hand van een discoursanalyse die het patroon van de verschillende argumenten laat zien. In **Hoofdstuk 5** wordt de standaard reactie van overheden op dit soort discussies besproken die vooral gericht is op de wetenschappelijke discussie, terwijl de normatieve aspecten van wetenschap evenals de onderliggende discussie over fundamenteel verschillende visies op landbouw en voedselproductie genegeerd worden.

De inzet van wetenschappelijke experts heeft niet geresulteerd in besluitvorming over de juridische status van nieuwe plantenveredelingstechnieken, het opheffen van nationale verboden voor gg-gewassen of consensus over de wetenschappelijke waarde van alarmerende studies. Ook technologische oplossingen, zoals de mogelijkheid om met nieuwe technieken alleen wijzigingen in het DNA aan te brengen die ook in de natuur voor (kunnen) komen, hebben geen brug kunnen slaan tussen voor- en tegenstanders van gg-gewassen. Deze technische oplossingen worden bestempeld als een **'technologische fix'** en leveren geen generiek aanvaardbare antwoorden op ten aanzien van het (moreel geladen) natuurlijkheidsvraagstuk of perspectieven op de voor- danwel nadelen van gg-gewassen.

In **Hoofdstuk 9** reflecteer ik op deze bevindingen en beargumenteer ik dat wetenschap en wetenschappelijke expertise enerzijds essentieel zijn om te navigeren binnen complexe vraagstukken en om onzekerheden te verminderen. Anderzijds heeft wetenschappelijke kennis inherent een tijdelijk karakter en een endemische onzekerheid. Wetenschap dwingt bovendien niet tot specifieke acties; het vertelt ons niet wat te doen. Of een gg-gewas veilig genoeg is en een aanvaardbare optie voor landbouw en voedselproductie, is uiteindelijk een politieke keuze en vraagt om politieke argumentatie. Dit geldt ook voor andere soorten kennis die worden meegenomen in het besluitvormingsproces, zoals

sociaaleconomische overwegingen. Deze overwegingen zijn, mogelijk nog meer dan veiligheidsrisico's, onderhevig aan normatieve oordelen en keuzes. Het betrekken van sociaaleconomische overwegingen in de regulering van gg-gewassen leidt tot een breed scala aan uitdagingen, die besproken worden in **Hoofdstuk 7**. Wetenschappelijke kennis kan bovendien niet zomaar worden toegevoegd aan het besluitvormingsproces. Het moet vertaald worden om de **'kloof tussen wetenschap en beleid'** ('the science-policy gap') te overbruggen en levert vaak een **'overschot aan objectiviteit'** ('excess of objectivity') dat gebruikt kan worden om verschillende standpunten te onderbouwen. Tenslotte hebben beleidsmakers en politici te maken met **'gebonden rationaliteit'** ('bounded rationality'). Het is onmogelijk voor één actor om al het beschikbare bewijsmateriaal ten aanzien van een complex vraagstuk in ogenschouw te nemen. Een te sterke focus op wetenschappelijk bewijs kan zelfs een nadelig effect hebben, wanneer het leidt tot discussies over de wetenschap zelf ten aanzien van reproduceerbaarheid, integriteit en legitimiteit van wetenschap en wetenschappelijke experts.

Participatieve strategieën kunnen bijdragen aan de identificatie van waarden, verwachtingen en angsten die het politieke besluitvormingsproces kunnen informeren. Hoe breder en meer inclusief, hoe groter de kans dat dit soort activiteiten de variëteit aan perspectieven in kaart kunnen brengen waar mogelijk rekening mee gehouden moet worden om de democratische legitimiteit van politieke en beleidsmatige besluiten te waarborgen. Daarnaast kan het betrekken van stakeholders en algemeen publiek bijdragen aan vertrouwen in het besluitvormingsproces. De oproep om stakeholders te betrekken lijkt te suggereren dat dit soort activiteiten idealiter resulteren in een collectieve visie of een gedeelde basis voor besluitvorming. In **Hoofdstuk 2 en 3** evalueer ik drie soorten participatieve strategieën die gericht zijn op 1) inclusie en betrokkenheid, 2) consensus en 3) erkenning van controverse. Ik gebruik inzichten van onder meer Bovenkerk en Poort wiens werk eveneens gericht was op biotechnologie en genetische modificatie als casus. In **Hoofdstuk 9** plaats ik enkele kritische noten bij hun werk waarna ik mijn eigen perspectief daaraan toevoeg met een suggestie voor een volgende stap.

Door de jaren heen zijn vele initiatieven ontplooid om stakeholders en algemeen publiek te betrekken bij de discussie over gg-gewassen, gg-dieren en genetische modificatie bij mensen. De afstand tussen de uiteenlopende perspectieven blijft echter bestaan en het gebruik van de (beoogde) uitkomsten van participatie-activiteiten blijft vaak impliciet, waardoor het lastig is om de

resultaten hiervan te meten of identificeren. In **Hoofdstuk 9** beargumenteer ik dat participatieve strategieën geen oplossing kunnen bieden voor het conflict over gg-gewassen. Algemeen publiek en stakeholders kunnen geen besluit nemen als entiteit omdat deze groepen bestaan uit een pluralistisch collectief van individuen met een breed scala aan verschillende en conflicterende visies op 'het goede leven', 'het goede' en 'een goede samenleving'. Hoewel participatie en deliberatie waardevol en nodig zijn in discussies over controversiële technologieën, zijn ze op zichzelf onvoldoende om de richting te bepalen van de besluitvorming over gg-gewassen.

Juridische strategieën om het conflict over gg-gewassen op te lossen zijn gericht op het evalueren en (her)definiëren van de regels voor, en grenzen van wie waarover besluit en op basis van welke gronden. Deze strategieën lijken er vanuit te gaan dat betere regelgeving betere besluitvorming faciliteert. De ggo-regelgeving is door de jaren heen bekritiseerd en meermaals aangepast om de besluitvorming over gg-gewassen te verbeteren. Opmerkelijk genoeg volgen de verschillende wijzigingen van de regelgeving een tegenovergestelde richting; ze zijn enerzijds gericht op een systeem dat gebaseerd is op meer **'wetenschappelijke feiten'** ('science based') en anderzijds op een bredere regelgeving die ook **niet-veiligheidsaspecten** meeneemt en sterk leunt op het **voorzorgsbeginsel**. Hierdoor zijn in de loop der jaren aan de ene kant de (juridisch bindende) datavereisten voor de milieu- en voedselveiligheidsbeoordeling toegenomen. Aan de andere kant is aanvullende regelgeving geïmplementeerd om keuzevrijheid van de consument te faciliteren door middel van labeling (Verordening (EC) Nr. 1830/2003), en om niet-veiligheidsaspecten te erkennen als formele reden voor een nationaal verbod op de teelt van gg-gewassen (Richtlijn (EU) 2015/412). Ik gebruik kritische reflecties uit de academische literatuur van onder andere Cairney, Tosun en Stirling om te onderbouwen dat deze strategieën verschillende praktische beperkingen en uitdagingen kennen. Zo gaat regelgeving die sterk gebaseerd is op wetenschappelijke feiten er vanuit dat er 1) voldoende wetenschappelijk bewijs beschikbaar is en 2) dat er overeenstemming bestaat over de waarde van dit bewijs. De verschillen in de uitkomsten van de risicobeoordeling door de Europese lidstaten en de discussies over het wetenschappelijke bewijs van alarmerende studies laat zien dat dit vaak niet het geval is. Daarnaast laat ik in **Hoofdstuk 8** zien dat de wetenschappelijke status quo die is neergeslagen in de regelgeving continu op de proef zal worden gesteld door nieuwe ontwikkelingen die juist vragen om een dynamisch en open in plaats van een meer gedetailleerde wetenschappelijk gerichte regelgeving. Ook breder georiënteerde regelgeving kent verschillende

praktische uitdagingen. Meer inclusieve regelgeving waarbij ook niet-veiligheidsaspecten worden meegenomen, hebben de neiging om uit te monden in een complex systeem dat een bijna oneindig aantal factoren in overweging neemt die ook nog eens moeilijk of zelfs onmogelijk onderling met elkaar vergelijkbaar zijn door normatieve verschillen.

De huidige regelgeving voor gg-gewassen heeft kenmerken van beide systemen (gericht op inclusiviteit en voorzorg EN gericht op wetenschappelijk bewijs). Hierdoor ontstaat een spanning tussen actoren die wetenschappelijke data zien als enige legitieme bron van kennis voor de regelgeving en actoren die voorstander zijn van het betrekken van bredere kennisbronnen zoals contextuele, culturele en sociaaleconomische factoren. In plaats van elkaar aan te vullen, worden de concepten van wetenschappelijk bewijs en voorzorg tegen elkaar gebruikt, hetgeen bijdraagt aan een impasse in de besluitvorming.

Een derde juridische strategie die ik bespreek is niet gericht op het inhoudelijk oplossen van het conflict over gg-gewassen, maar op het veranderen van de regels voor de stemmingsronde waarbij de optie voor 'geen mening' komt te vervallen. Dit zou lidstaten ertoe dwingen om een expliciete positie in te nemen voor of tegen gg-gewassen. Deze strategie zou in theorie kunnen werken om een besluit af te dwingen, maar de realiteit blijkt vaak meer complex. Zo bevat **Hoofdstuk 6** een normatieve analyse van Richtlijn (EU) 2015/412 die laat zien dat het aanpassen van de regelgeving niet noodzakelijkerwijs een oplossing biedt voor onenigheid over biotechnologie, zelfs niet als de regelgeving op papier een uitstekend passend en redelijke oplossing lijkt. Elke richtlijn of verordening heeft bovendien een zekere mate van 'interpretatieve ruimte' voor alternatief gebruik die kan leiden tot verschillen tussen **'law in books'** en **'law in action'**, oftewel een verschil tussen theorie en praktijk. Daarom lijkt het onwaarschijnlijk dat een verandering van de regels voor comitologie het conflict over gg-gewassen op zal lossen zolang onderliggende issues niet expliciet geadresseerd worden. In **Hoofdstuk 9** bekijk ik deze juridische oplossingen opnieuw en beargumenteer ik dat regelgeving weliswaar de regels en vereisten kan bepalen op basis van een democratische reflectie van een visie op 'een goede samenleving', maar dat het niet de uitkomsten van een besluit kan bepalen. Regelgeving alleen kan het conflict over gg-gewassen daarom niet oplossen en zal altijd een zekere interpretatieve ruimte laten, dat wil zeggen dat verschillende acties gelegitimeerd kunnen worden op basis van dezelfde regelgeving op basis van verschillende visies op de beoogde uitkomsten. Daarnaast kan het perspectief op 'een goede samenleving' dat ingebed is

in de regelgeving onmogelijk volledig overlappen met alle verschillende en conflicterende individuele visies op ‘een goed leven’ in de maatschappij.

De inzichten uit de evaluatie van technocratische, participatieve en juridische strategieën onderbouwen de stelling dat hoeveel wetenschap, regelgeving of publieke betrokkenheid men er ook bij haalt, dit niet vanzelfsprekend en automatisch zal resulteren in politieke besluitvorming. Dit is, naar mijn mening, waar erkenning van het politieke karakter van besluitvorming nodig is om de input uit wetenschap en maatschappij te wegen en besluiten te nemen in situaties van onzekerheid en controverse.

Kenmerken van politiek gedrag zoals deliberatie, argumentatie, onderhandelen en compromissen sluiten zijn zeer beperkt of zelfs afwezig bij het proces voor markttoelatingen van gg-gewassen. De uiteindelijke besluitvorming is gereduceerd tot een stemmingsronde met vertegenwoordigers van de lidstaten die een vooraf vastgesteld mandaat hebben. De enige manier om onderliggende onenigheid over gg-gewassen te uiten, is de juridische ruimte te gebruiken in de regelgeving om besluitvorming te voorkomen (zoals tegenstemmen of onthouden van stemmen of het instellen van nationale of regionale verboden voor gg-gewassen). In **Hoofdstuk 9** heb ik beargumenteerd dat besluitvorming over gg-gewassen strategisch lijkt te worden vermeden door zowel de Europese Commissie als de lidstaten door gebruik te maken van de interpretatieve ruimte in de regelgeving en door verantwoordelijkheden tijdelijk terug te delegeren naar de wetenschap (om onzekerheden weg te nemen) en de maatschappij (om tot een consensus of gedeeld perspectief te komen) of door het uitstellen van besluitvorming in afwachting van een wijziging van de regelgeving.

Het vermijden van besluitvorming kan gezien worden als een strategische manier om verantwoordelijkheid te managen op verschillende niveaus (zowel naar de lidstaten als naar niet-Europese landen) om economische of juridische consequenties op internationaal niveau te voorkomen. De Europese hybride regelgeving die zowel zeer gedetailleerd en wetenschappelijk gericht is, evenals breed en optioneel aangaande niet-veiligheidsaspecten, gecombineerd met besluitvormingsregels (comitologie) die ruimte laten voor niet-besluiten (‘geen mening’) faciliteert een flexibele positie voor de Europese Commissie. Zij kan een knoop doorhakken als een juridisch conflict dreigt met de Wereldhandelsorganisatie (World Trade Organisation, WTO) of kan besluitvorming uitstellen als lidstaten of het Europees Parlement hun beklag doen over niet-democratische beslissingen. Op basis hiervan kan het

conflict over gg-gewassen niet alleen geclassificeerd worden als een 'wicked' probleem, maar als een ontworpen wicked probleem (**'wicked problem by design'**, een concept van Nie). Dit kan verder onderbouwd worden door een vergelijking met een andere casus van een wicked probleem: de autorisatie van het herbicide Glyfosaat in Europa. Ondanks het 'wicked' karakter van dit probleem, gekenmerkt door een gebrek aan wetenschappelijke zekerheid en maatschappelijke consensus, werd hierover toch een besluit genomen, omdat de Europese Commissie politiek inzette en onderhandelde met de lidstaten totdat een akkoord was bereikt. De Glyfosaat casus laat zien dat prioriteit, urgentie en mogelijk politiek gewin de dynamiek terug kunnen brengen in discussies over controversiële technologieën, ook in situaties die in eerste instantie 'wicked' lijken.

Gebaseerd op de analyse in dit proefschrift heb ik beargumenteerd dat 1) wetenschappelijke, participatieve en juridische strategieën uitgeput worden in een poging om voor- en tegenstanders dichter bij elkaar te brengen in het conflict over gg-gewassen en 2) dat het onwaarschijnlijk is dat de (fundamentele) onenigheid over gg-gewassen hiermee wordt opgelost. Met het oog op markttoelatingen van gg-gewassen is de vraag enerzijds welk besluit gerechtvaardigd kan worden gebaseerd op de huidige posities in het debat. De Europese Commissie prolongeert de deliberatieve ruimte over dit fundamentele conflict door besluitvorming te mijden, wat anderzijds de vraag oproept wanneer het ontwijken van een besluit gerechtvaardigd kan worden vanuit het perspectief van neutraliteit en wanneer dit als onrechtvaardig kan worden gezien naar diegenen die een expliciet politiek besluit nodig hebben of verdienen. In academische literatuur over deliberatieve democratie wordt het belang van een neutrale positie van de overheid benadrukt in gevallen van controverse. Overheden moeten neutraal blijven om deliberatie tussen stakeholders te faciliteren en de ruimte te creëren voor transformaties van standpunten. Deze positie is echter ook bekritiseerd omdat een neutrale positie ook niet vrij van consequenties is. Auteurs zoals Bovenkerk en Poort promoten een perspectief op deliberatieve democratie dat de nadruk legt op inclusie van betrokkenen en het uitdiepen van de controverse. Zij erkennen echter ook dat deze benaderingen niet direct resulteren in besluitvorming. De vraag die hiermee niet beantwoord wordt, is echter hoe bepaald kan worden wanneer een controverse voldoende is erkend, uitgediept en geadresseerd en wanneer een besluit niet langer prematuur is. Na deze kritische noot, beargumenteer ik dat een dergelijk besluit eveneens onder de verantwoordelijkheid van politieke actoren valt. Wat betreft de discussie over gg-gewassen is het naar

mijn mening de hoogste tijd dat een dergelijk politiek besluit genomen wordt omdat het huidige systeem vanuit democratisch perspectief geen recht doet aan zowel voor- als tegenstanders. De huidige situatie van 'niet-besluiten' veronachtzaamt principes zoals juridische zekerheid en aansprakelijkheid in een nationale en internationale setting. In **Hoofdstuk 7** heb ik laten zien dat gg-gewassen impact kunnen hebben op zowel innovatie als andere sociaaleconomische aspecten en uit **Hoofdstuk 8** komt naar voren dat het niet nemen van besluiten internationale ontwikkelingen niet zal stoppen. Dit betekent, dat niet-besluiten tegelijkertijd een besluit is om niet deel te nemen aan de discussie over hoe toekomstig beleid eruit zou moeten zien als biotechnologie zowel horizontaal als verticaal integreert in andere kennis- en toepassingsgebieden en daardoor steeds minder zichtbaar wordt.

Het vasthouden aan de illusie van een functionerend systeem en uitstellen van besluitvorming is vanuit democratisch perspectief moeilijk te verantwoorden naar zowel voor- als tegenstanders. In plaats van het terug delegeren van het vraagstuk naar wetenschap en maatschappij is **repolitisering** van de besluitvorming over gg-gewassen nodig op het niveau van zowel lidstaten als de EU. Repolitisering in de context van dit proefschrift betekent **expliciete besluitvorming in situaties van wetenschappelijke onzekerheid en controverse.** Ik erken echter ook dat democratische aansprakelijkheid niet de enige determinant is voor politieke besluitvorming en voeg daaraan toe dat **politieke urgentie** evenals **probleemeigenaarschap** belangrijke factoren zijn die de waarschijnlijkheid van besluitvorming in de echte wereld mede bepalen.

PORTFOLIO

SHORT ACADEMIC BIOGRAPHY

Ruth Mampuys has a bachelor degree in medical biochemistry (2003) and a master degree in 'Philosophy of Science, Technology and Society' (PSTS) (cum laude) from the University of Twente (2006). Since 2007 Ruth has been working at the Netherlands Commission on Genetic Modification (COGEM). COGEM is an independent scientific advisory body of the Dutch government that advises on the risks of GMOs to human health and the environment, and informs the relevant ministries of ethical and societal issues linked to genetic modification. During her career at COGEM, Ruth has written policy reports about a broad variety of topics related to GMOs, ranging from sustainability of GM crops, GMOs and art, socio-economic aspects of GM crops, ethical and legal aspects of human germline modification and international differences in GMO legislation. She also attended and presented at a variety of international conferences and workshops.

In 2017 her PhD research proposal on 'governance of contested technologies: from controversies to decision-making' was accepted by the Erasmus School of Law. Her academic work has been published in amongst others the Journal of Agricultural and Environmental Ethics, the Journal of Responsible Innovation and the Journal of Law, Innovation and Technology.

PUBLICATIONS

Articles & book chapters

1. Trump BD, Galaitsi SE, Appleton E, Bleijs DA, Florin M, Gollihar JD, Hamilton RA, Kuiken T, Lentzos F, MampuysR, Merad M, Novossioloiva T, Oye K, Perkins E, Garcia-Reyero N, Rhodes C and Linkov I (2020). Building biosecurity for synthetic biology. Molecular Systems Biology 16(7): e9723
2. Mampuys R & Poort L (2019). Controversy first: factors limiting the success of EU Dir 2015/412 for national decision-making on the cultivation of GM crops. Journal of Law, Innovation and Technology 11(2): 175-202 doi.org/10.1080/17579961.2019.1665794
3. Mampuys R & Te Molder FHTM (2019). Van debat naar dialoog: omgaan met internationale ontwikkelingen kiembaanmodificatie. Podium voor bioethiek 2019-01.
4. Mampuys R & Van der Wilk F (2018). Balanceren tussen technologie en beleid; 'Trendanalyse biotechnologie' van de cogem als toekomstverkenning. In 'Met de Kennis van Morgen; toekomstverkenningen voor de Nederlandse overheid. Van der Duijn P en Snijders D. Red. Amsterdam University Press.

5. Mampuys R (2018). Socio-economic considerations in regulatory decision-making on genetically modified crops. International Centre for Genetic Engineering and Biotechnology (ICGEB). Collection of Biosafety Reviews Vol. 10 (2018): 8-34
6. Mampuys R & Brom FWA (2017). Emerging crossover technologies: how to organize a biotechnology that becomes mainstream. Environment Systems and Decisions. doi.org/10.1007/s10669-017-9666-1
7. Mampuys R & Brom FWA (2015). Ethics of dissent: a plea for restraint in the scientific debate about the safety of GM crops. J. Agr. Environ. Ethics 28(5): 903-924
8. Mampuys R & Brom FWA (2015). Governance strategies for responding to alarming studies on the safety of GM crops. Journal of Responsible Innovation 2(2): 201-219
9. Pauwels K, Mampuys R, Golstein C *et al.* (2013). Event report: SynBio Workshop (Paris 2012) – Risk assessment challenges of Synthetic Biology. Journal für Verbraucherschutz und Lebensmittelsicherheit 8(3): 215-226
10. Mampuys R & Roeser S (2011). Replicating GM Viruses in Cancer Therapy; a Conflict of Emotions? Journal of Disaster Research 6(5): 514-521
11. Mampuys R & Brom FWA (2010). The quiet before the storm: anticipating developments in synthetic biology. Poiesis & Praxis: International Journal of Technology Assessment and Ethics of Science 7(3): 151-168

Policy reports written at COGEM

1. No rose without thorns: implications of a product based regulatory system for GM crops in the European Union. (CGM/191010-01)
2. CRISPR & Animals: implications of genome editing for policy and society. (CGM/180501-01)
3. Editing human DNA: moral and social implications of germline genetic modification. (CGM/170328-01) - With the Health Council of the Netherlands
4. Gentechdebat op scherp. Invalshoeken voor een vruchtbare dialoog (2016). Boek. Eds. Ruth Mampuys, Frank van der Wilk
5. Trend analysis Biotechnology 2016. A regulatory disconnect (CGM/160614-01) - With the Health Council of The Netherlands and supported by the Scientific Council for Government Policy (WRR)
6. Recurrent themes in GMO authorisation. The position of genetic modification in a departmental assessment framework for safety (CGM/151215-02)
7. GMOs on Display. The use of genetically modified organisms in exhibitions (CGM/141219-01)

8. Building blocks for an assessment framework for the cultivation of GM crops (CGM/141222-01)
9. Synthetic Biology – Update 2013. Anticipating developments in synthetic biology (CGM/130117-01)
10. Where there is smoke, is there fire? Responding to the results of alarming studies on the safety of GM crops (CGM/131031-01)
11. Genetically modified animals: a wanted and unwanted reality (CGM/12011-01)
12. Geboeid door keuzevrijheid. Een verkenning van de ontwikkeling en rol van keuzevrijheid rondom ggo's in Europa (CGM/101230-01)
13. Global motivation or European character? Four scenarios for GMOs in European Agriculture. (CGM/110224-01) - With The Rathenau Institute
14. Socio-economic aspects of GMOs. Building blocks for an EU sustainability assessment of genetically modified crops. (CGM/090929-01)

Selected presentations at conferences and workshops

1. 'Implications of a product based regulatory framework for GM crops in Europe' Presentation at COGEM international symposium Gene edited crops; global perspectives and regulation. The Hague, The Netherlands, 10 October 2019
2. 'Critical governance challenges in ~~biotechnology~~ / ~~GMOs~~ / synthetic biology' Presentation and panel discussion on critical governance challenges at the NATO workshop Security for emerging synthetic biology and biotechnology threats. Lausanne, Switzerland 7-10 July 2019
3. 'Biotechnology: the need for acknowledging disagreement' Presentation at The Sixth Annual Conference on Governance of Emerging Technologies & Science (GETS): Law, Policy and Ethics, ASU Sandra Day O'Connor College of Law, Phoenix, AZ, USA, 16-18 May 2018
4. 'Ethical and legal aspects of human genome editing in The Netherlands' Presentation and panel at workshop on human genome editing in the EU, French Academy of Medicine, Paris, France, 28 April 2016
5. 'Regulating Deep Disagreements: the European Struggle for an Assessment Framework for Cultivating GM-crops as an example' Presentation at conference on Deep Disagreements; philosophical and legal perspectives, Humboldt University Berlin, Germany, 11-13 June 2015

BIBLIOGRAPHY

A

Abbott A (2015). Europe's genetically edited plants stuck in legal limbo. Nature 528(7582): 319–320

Adenle AA (2011). Response to issues on GM agriculture in Africa: Are transgenic crops safe? BMC Research Notes 4, Article 388

Aerni P, Scholderer J and Ermen D (2011). How would Swiss consumers decide if they had freedom of choice? Evidence from a field study with organic, conventional and GM corn bread. Food Policy 36(6): 830–838

AFBV (2018). Trois expertises française et européennes invalident les résultats et conclusions de l'étude de GE Séralini sur les maïs OGM. Association Francaise des biotechnologies Vegetales, press release, 11 June 2018

AHTEG-SEC (2014). Report of the Ad Hoc Technical Expert Group on socioeconomic considerations. Ad Hoc Technical Expert Group on Socioeconomic Considerations (AHTEG-SEC), Secretariat of the Convention on Biological Diversity, Montreal, Canada. UNEP/CBD/BS/AHTEG-SEC/1/3

Aklin M & Urperlainen J (2013). Perceptions of scientific dissent undermine public support for environmental policy. Environmental Science & Policy 38: 173–177

Alliance for Science (2018). European studies disprove Seralini's GMO maize tumor claims. Joan Conrow for Alliance for Science, 7 June 7 2018

Alliance for Science (2019). Many plants are naturally GMO, research finds. Joan Conrow for Alliance for Science, 9 October 2019

Amman K (2014). Genomic misconception: a fresh look at the biosafety of transgenic and conventional crops. A plea for a process agnostic regulation. New biotechnology 31(1): 1–17

Ando AW & Khanna M (2000). Environmental costs and benefits of genetically modified crops. American Behavioral Scientist 44(3): 435–463

Arcuri A & Hendlin YH (2020). The chemical Anthropocene: glyphosate as a case study of pesticide exposures. Kings Law Journal 30(2): 234–253

Arjó G, Portero M, Pinol C *et al*. (2013). Plurality of opinion, scientific discourse and pseudoscience: an in depth analysis of the Seralini *et al*. study claiming that Roundup Ready corn or the herbicide Roundup cause cancer in rats. Transgenic Res, 22(2): 255-267

Atkinson R & Flint J (2004). Snowball Sampling. In: Lewis-Beck MS, Bryman A, & Liao TF (Eds.), The SAGE Encyclopedia of Social Science Research Methods: SAGE Publications, Inc.

B

BAC (2012). Advice of the Belgian Biosafety Advisory Council on the article by Séralini *et al*., 2012 on toxicity of GM Maize NK603. Belgian Biosafety Advisory Council. Ref: WIV-ISP/41/BAC/2012_0898

Ballmann A, Epstein D and O'halloran S (2003). Delegation, comitology, and the separation of powers in the European Union. International Organization 56(03): 551-574

Barbero R, Doherty J, Goldstein M *et al*. (2016). Building on 30 years of experience to prepare for the future of biotechnology. The White House. Available from: https://bit.ly/3g19l6C (Accessed 24 July 2020)

Bardocz S, Clark A, Ewen SW, Hansen M, *et al*. (2012). Seralini and Science: an open letter. Correspondence (pp. Comment by user 'Richard Lasker' on October 14, 2012 at 5:34 pm): Independent Science News

Barrangou R & Doudna JA (2016). Applications of CRISPR technologies in research and beyond. Nature Biotechnology 34(9): 933-941

Batie SS, & Schweikhardt DB (2009). Societal concerns as wicked problems: the case of trade liberalization. Proceedings of an OECD workshop. In: Policy responses to societal concerns in food and agriculture, Paris, France, 2 - 3 November 2009

Bauer-Panskus A & Then C (2014). Comments regarding the GRACE publication 'Ninety-day oral toxicity studies on two genetically modified maize Mon810 varieties in Wistar Han Rcc Rats' (Eu 7th Framework Programme Project Grace). Available from: https://bit.ly/2ZWTj8e (Accessed 24 July 2020)

Bazzan G & Migliorati M (2020). Expertise, politics and public opinion at the crossroads of the European Commission's decision-making: The case of Glyphosate. International review of public policy 2(1): 68-89

Beck U (1986). Risk society: towards a new modernity. London: Sage

Benessia AS, Funtowicz M, Giampietro A *et al.* (2016). The rightful place of science: Science on the verge. The consortium for science, policy and outcomes, Arizona State University

Bennett R, Morse S and Ismael Y (2006). The economic impact of genetically modified cotton on South African smallholders: yield, profit and health effects. The Journal of Development Studies 42(4):662-677

Berg P (2008). Meetings that changed the world: Asilomar 1975: DNA modification secured Nature 455(7211): 290–291

Berg P, Baltimore D, Brenner S *et al.* (1975). Summary statement of the Asilomar conference on recombinant DNA molecules. Proc Natl Acad Sci USA 72(6): 1981–1984

Bergmans H, Kleinjans R, Poort L *et al.* (2020). Uitspraak van het Europese Hof over gene editing en de ggo-regelgeving. Reikwijdte en consequenties. COGEM research report CGM/2020-03 (in Dutch)

Bergmans H, Poort L and Kleinjans R (2016). Analyse van de Europese wet- en regelgeving over genetisch gemodificeerde organismen' COGEM research report CGM/2016-05 (in Dutch)

Bevir M (2012). Governance; s very short introduction. Oxford, UK: Oxford university press

Beyond GM (2016). Gene editing – A gmo by another name. Article by Janet Cotter, 26 February 2016. Available from: https://bit.ly/39uPU3m (Accessed 24 July 2020)

Biale E & Federica Liveriero (2017) A multidimensional account of democratic legitimacy: how to make robust decisions in a non-idealized deliberative context. Critical review of international social and political philosophy 20(5): 580-600

Biddle JB (2017). Genetically engineered crops and responsible innovation. Journal of responsible innovation 4(1): 24-42

Biesbroek GR, Termeer CJAM, Klostermann JEM *et al*. (2014). Analytical lenses on barriers in the governance of climate change adaptation. Mitigation and Adaptation Strategies for global change 19: 1011-1032

Biesbroek R, Dupuis J, Jordan A *et al*. (2015). Opening up the black box of adaptation decision-making. Nature Climate Change 5(5): 493-494

Bijker WE, Bal R and Hendriks R (2009). The paradox of scientific authority: the role of scientific advice in democracies. The MIT Press, Cambridge, MA

Binimelis R, Myhr AI (2016). Inclusion and implementation of socio-economic considerations: needs and recommendations. Sustainability 8(1): 1-24

Black J (1998). Regulation as facilitation: negotiating the genetic revolution. The modern law review limited

Blankesteijn M, Munnichs G and Drooge van L (2014). Contested science – public controversies about science and policy. The Hague: Rathenau Institute

Blom-Hansen J (2008). The origins of the EU comitology system: a case of informal agenda setting by the commission. Journal of European Public Policy 15(2): 208-226

Bohannon J (2013). Who's afraid of peer review? Science 342(6154): 60-65

Böhling K (2009). Symbolic knowledge at work: comitology and learning from experts in European Technology policy. WZB discussion paper No.SP IV 2009-301

Bohman J (1996). Public deliberation: pluralism, complexity, and democracy. Cambridge, MA: MIT Press

Booth BL (2016). This time may be different. Nature Biotechnology 34(1): 25-30

Böschen S, Kastenhofer K, Rust I *et al*. (2010). Scientific nonknowledge and its political dynamics: the cases of Agri-biotechnology and Mobile phoning. Science, technology & Human Values 35(6): 783-811

Bovenkerk B & Poort LM (2008). The role of ethics committees in public debate. International journal of applied Philosophy 22(1): 19-35

Bovenkerk B (2012). The biotechnology debate: democracy in the face of intractable disagreement. (Vol. 29, Library of Ethics and Applied Philosophy). Dordrecht: Springer

Bradshaw GA & Borchers JG (2000). Uncertainty as information: narrowing the science-policy gap. Conservation Ecology 4(1): 7
Brom FWA (2019). Institutionalizing applied humanities. Humanities in interdisciplinary research for public policy. Palgrave communications 72

Brom FWA, Chaturvedi S, Ladikas M *et al*. (2015). Institutionalizing ethical debates in science, technology and innovation policy: a comparison of Europe, India and China. In: Ladikas M, Chaturvedi S. Zao Y and Stemerding D (Eds.), Science and technology governance and ethics: Springer Open

Brookes G & Barfoot P (2016). Environmental impacts of genetically modified (GM) crop use 1996–2014: Impacts on pesticide use and carbon emissions. GM Crops Food 7(2): 84–116

Brookes G & Barfoot P (2017). Environmental impacts of genetically modified (GM) crop use 1996–2015: Impacts on pesticide use and carbon emissions. GM Crops & Food 8(2): 117-147

Brooks H (1964). The scientific advisor. In: Robert Gilpin and Christopher Wright (eds). Scientists and national policy-making. New York: Columbia University Press

Brown W (2002). Inclusive governance practices in nonprofit organizations and implications for practice. Nonprofit Management and Leadership 12(4): 369-85

Budge I (2015). Issue emphases, saliency theory and issue ownership: A historical and conceptual analysis. West European Politics 38 (4): 761–777

C

Cairney P & Oliver K (2017). Evidence-based policymaking is not like evidence based medicine, so how far should you go to bridge the divide between evidence and policy. Policy and Systems 15:35

Cairney P & Weible CM (2017).The new policy sciences: combining the cognitive science of choice, multiple theories of context, and basic and applied analysis. Policy Sciences 50(4): 619-627

Cairney P (2012). Complexity theory in political science and public policy. Political studies review 10(3): 346-358

Cairney P (2016). The politics of evidence-based policy making. London: Palgrave.

Cairney P (2018). Evidence-based policymaking: political strategies for scientists living in the real world. Available from: https://bit.ly/3jDiWCI (Accessed 24 July 2020)

Cairney P, Oliver K and Wellstead A (2016). To bridge the divide between evidence and policy: reduce ambiguity as much as uncertainty. Evidence in Public Administration 76(3): 399-402

Callaway E (2016). Dolly at 20: the inside story of the world's most famous sheep. Nature 534 (7609): 604-608.

Carlin RE and Love GJ (2013). The politics of interpersonal trust and reciprocity: an experimental approach. Political Behavior. 35(4): 43-63

Carman JA, Vlieger HR, Versteeg LJ *et al.* (2013). A long-term toxicology study on pigs fed a combined Genetically modified (Gm) soy and GM maize diet. Journal of Organic Systems 8: 38-54

Carpentier N (2011). Policy's hubris: Power, fantasy, and the limits of (global) media policy interventions. In: Mansell R & Raboy M (Eds.) Handbook of global media and communication policy. London: Blackwell

Carpentier N (2016). What is a decision? A post-structuralis exploration of the trinity of decidedness, undecidedness and undecideability. In: Politics,

Civil Society and Participation: Media and Communications in a transforming environment Edition: Bremen

Castle D & Culver K (2013). Getting to 'No': The method of contested exchange. Science and Public Policy 40(1): 34–42

CBD (2010). Summary report on the survey on the application of and experience in the use of socio-economic considerations in decision-making on living modified organisms. UNEP/CBD/BS/COP-MOP/5/INF/10. Secretariat of the Convention on Biological Diversity (CBD), Montreal, Canada

CBSNews (2012). Study says genetically modified corn causes tumors, but other scientists skeptical about research. Michelle Castillo M CBS News, 21 September 2012

Choi BCK, Gupta A, Ward B (2009). Good thinking: six ways to bridge the gap between scientists and policy makers. Journal of Epidemiology & Community Health 63(3): 179–180

Choi J, Rui Y, Kim J *et al*. (2020). Nonviral polymeric nanoparticles for gene therapy in pediatric CNS malignancies. Nanomedicine: Nanotechnology, Biology and Medicine 23(1): 102115

Christiansen A & Gunnar Hallsson B (2017). Democratic decision making and the psychology of risk. Les ateliers de l'éthique 12(1): 51–83

Christiansen A, Joncho-Clausen and Kappel K (2017). Does controversial science call for public participation? The Case of GMO scepticism. Les ateliers de l'éthique 12(1): 26–50

Christiansen AT, Marchman Andersen M and Kappel K (2019). Are current EU policies on GMOs justified? Transgenic research 28(1): 267–286

Christiansen T & Dobbels M (2012). Comitology and delegated acts after Lisbon: how the European Parliament lost the implementation game. European Integration Online Papers 16, Article 13

Christiansen T & Polak J (2009). Comitology between political decision-making and technocratic governance. Regulating GMOs in the European Union. EIPAScope 2009(1): 7

Chubukov V, Mukhopadhyay A, Petzold CJ *et al*. (2016). Synthetic and systems biology for microbial production of commodity chemicals. npj Systems Biology and Applications 2, Article 16009

COGEM & Gezondheidsraad (2016). Trend analysis biotechnology 2016: A regulatory disconnect. CGM/160614-01, The Netherlands Commission on Genetic Modification, Bilthoven

COGEM & Octrooicentrum (2014). Biotechnologie: informatie uit octrooien. Research report CGM/2014-07, Netherlands Commission on Genetic Modification, Bilthoven (in Dutch)

COGEM (2005). The farm scale evaluations evaluated. Policy report CGM/050408-04, The Netherlands Commission on Genetic Modification, Bilthoven

COGEM (2009). Socio-eonomic aspects of GMOs. Building blocks for an EU sustainability assessment of genetically modified crops. Policy report CGM/090929-01, The Netherlands Commission on Genetic Modification, Bilthoven

COGEM (2013). Where there is smoke, is there fire? Responding to the results of alarming studies on the safety of GMOs. Policy report CGM131031-01, The Netherlands Commission on Genetic Modification, Bilthoven

COGEM (2014). Building blocks for an assessment framework for cultivation of genetically modified crops. Policy report CGM/141222-01, The Netherlands Commission on Genetic Modification, Bilthoven

COGEM (2017). Gentechdebat op scherp: invalshoeken voor een vruchtbare dialoog. Eds. Mampuys R & Van der Wilk F. COGEM; Bilthoven ISBN/EAN: 978-90-809753-4-7 (in Dutch)

COGEM (2019). No rose without thorns; implications of a product based regulatory framework for genetically modified crops in Europe (2019). Policy report CGM/191010-01, The Netherlands Commission on Genetic Modification, Bilthoven

COGEM (2020). COGEM advice concerning the proposal by the EC to suspend the environmental risk assessment of clinical trials for the treatment or

prevention of COVID-19. Advisory report CGM200624-01, The Netherlands Commission on Genetic Modification, Bilthoven

Coghlan A (2015). More than half of EU officially bans genetically modified crops. NewScientist, 5 October 2015

Coghlan A (2016). Exclusive: '3-parent' baby method already used for infertility. New Scientist, 10 October 2016

Cohen J (1997). Deliberation and democratic legitimacy. In: Bohman J & Regh W(eds.), Deliberative Democracy. Essays on reason and politics. Cambridge, Mass.: The MIT Press

Collingridge D and Reeve C (1986). Science speaks to power: The role of experts in policy making. Frances Pinter, London

Cornel MC, Howard HC, Lim D *et al.* (2019). Moving towards a cure in genetics: what is needed to bring somatic gene therapy to the clinic? European Journal of Human Genetics 27(12): 484-487

Costa-Font M, Tranter R, Gil J *et al.* (2010). Do defaults matter? Willingness to pay to avoid GM food vis-à-vis organic and conventional food in Denmark, Great Britain and Spain. Paper presented at the 84th Conference of Agricultural Economics, 29-31 March 2010, Edinburgh, Scotland

Coumoul X, Servien R, Juricek L *et al.* (2018). The GMO90+ Project: absence of evidence for biologically meaningful effects of genetically modified maize-based diets on Wistar rats after 6-months feeding comparative trial. Toxicological Sciences 168(2): 315-338

Council of the European Union (2019). Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study. Official Journal of the European Union L 293/103-104

CRIIGEN (2013). Complaints of defamation filed against critics, Raw data released to a notary. Comité de recherche et d'information indépendantes sur le génie génétique, press release 11 January 2013

Crowley K & Head BW (2017). Expert advisory bodies in the policy system. In: Brans M, Iris G and Howlett M (Eds.), Routledge Handbook of Comparative Policy Analysis (pp. 181-198) Abingdon, Oxon, United Kingdom: Taylor and Francis

Cummings CL & Kuzma J (2017). Societal Risk Evaluation Scheme (SRES): scenario-based multi-criteria evaluation of synthetic biology application. PLOS one 12(1): e0168564

Custers R, Casacuberta JM, Eriksson D *et al*. (2019). Genetic alterations that do or do not occur naturally; consequences for genome edited organisms in the context of regulatory oversight. Frontiers in Bioengineering and Biotechnology, research topic Plant Genome Editing – Policies and Governance

Czarnak-Kłos M & Rodríguez-Cerezo E (2010). Best practice documents for coexistence of genetically modified crops with conventional and organic farming: maize crop production. European Coexistence Bureau, Institute for Prospective Technological Studies, Joint Research Centre, European Commission, Seville, Spain

D

Damalas CA & Eleftherohorinos IG (2011). Pesticide exposure, safety issues, and risk assessment indicators. International Journal of Environmental Research and Public Health 8(5): 1402–1419

Daniels GH (1967). The pure science ideal and democratic culture. Science 156(3783): 1699-1706

Davison J & Amman K (2017). New GMO regulations for old: determining a new future for Europe. GM crops & Food 8(1): 13-34

Daviter F (2015). The political use of knowledge in the policy process. Policy Science 48(3): 491-505

Daviter F (2017). Coping, taming or solving: alternative approaches to the governance of wicked problems. Policy studies 38(6): 571-588

Daviter F (2017). Policy analysis in the face of complexity: What kind of knowledge to tackle wicked problems? Public policy and administration 34(1): 62-83

Daviter F (2018). The rise and demise of epistemic policy learning: the Case of EU biotechnology regulation. In: Dunlop CA *et al*. Learning in public policy

DeFrancesco L (2013). How safe does transgenic food need to be? Nature Biotechnology 31(9): 794-802

Deloitte & Touche (2015). Reducing food loss along African agricultural value chains. Member of Deloitte Touche Tohmatsu Limited

Devos Y, Demont M, Dillen K *et al*. (2009). Coexistence of genetically modified (GM) and non-GM crops in the European Union. A review. Agronomy for Sustainable Development 29(1): 11-30

Devos Y, Naegeli H, Perry JN *et al*. (2016). 90-day rodent feeding studies on whole GM food/feed. Is he mandatory EU requirement for 90-day rodent feeding studies on whole GM food/feed fit for purpose and consistent with animal welfare ethics? EMBO reports, Science & Society 17: 942-945

Devos, Y, Sanvido O, Tait J *et al*. (2014). Towards a more open debate about values in decision-making on agricultural biotechnology. Transgenic Research 23(6): 933-943

Dibden J, Gibbs D and Cocklin C (2013). Framing GM crops as a food security solution. Journal of Rural Studies 29(1): 59-70

Dobbs M (2016). Attaining subsidiarity-based multilevel governance of genetically modified cultivation. Journal of Environmental Law 28(2): 245-273

Dobbs M (2017). Genetically modified crops, agricultural sustainability and national opt-outs: enclosure as the loophole? Common market law review 54(4): 1093-1122

Dryzek JS (2010). Foundations and frontiers of deliberative governance. Oxford Scholarship Online

Dryzek, J (1990). Discursive democracy: Politics, policy, and political science. Cambridge, UK: Cambridge University Press

Dunwell JM (2014). Genetically Modified (Gm) Crops: European and Transatlantic Divisions. Molecular Plant Pathology 15(2): 119-121

Durant RF & Legge JS (2006). Public opinion, risk perceptions and genetically modified food regulatory policy. Reassessing the calculus of dissent among European Citizens. European Union Politics 6(2): 181–200

Durant RF & Legge JS (2006). Wicked problems, public policy and administrative theory: lessons from the GM food regulatory arena. Administration & Society 38(3): 309–334

E

EASAC (2013). Planting the future: opportunities and challenges for using crop genetic improvement technologies for sustainable agriculture. European Academies Science Advisory Council report, June 2013

Eckley N & Selin H (2004). All talk, little action: precaution and its effects on European chemicals regulation. Journal of European Public Policy 11(1): 78–105

Economist (2013). Trouble at the lab. Scientists like to think of science as self-correcting. To an alarming degree, it is not. The Economist, Blog 18 October 2013

Edvardsson Björnberg K, Zetterberg C, Ove Hansson S *et al*. (2018). Consistent risk regulation? Differences in the European regulation of food crops. Journal of risk research 22(12): 1561–1570

EFSA (2004). Opinion of the Scientific Panel on genetically modified organisms [GMO] on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC. EFSA journal 2(7): 1–13

EFSA (2005). Opinion of the Scientific Panel on genetically modified organisms [GMO] related to the safeguard clause invoked by Hungary according to Article 23 of Directive 2001/18/EC. EFSA journal 3(7): 1–14

EFSA (2006). Opinion of the Scientific Panel on genetically modified organisms [GMO] related to the safeguard clause invoked by Greece according to Article 23 of Directive 2001/18/EC and to Article 18 of Directive 2002/53/EC. EFSA journal 4(11): 1–26

EFSA (2008). Request from the European Commission related to the safeguard clause invoked by France on maize MON810 according to Article 23 of

Directive 2001/18/EC and the emergency measure according to Article 34 of Regulation(EC) No 1829/2003 Scientific opinion of the Panel on Genetically Modified Organisms. EFSA journal 6(10): 1-45

EFSA (2009). Applications (EFSA-GMO-RX-MON810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto' Scientific opinion, 31 July 2009.

EFSA (2010). Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal, 8(11): 1879-1990

EFSA (2012a). EFSA provides Séralini *et al* with data on GM maize NK603. European Food Safety Authority, press release 22 October 2012, Parma, Italy

EFSA (2012b). EFSA to issue statement on potential glyphosate toxicity as used in herbicides and GM maize NK603. European Food Safety Authority, press release 19 september 2012, Parma, Italy

EFSA (2012c). Final review of the Séralini *et al*. (2012a) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology. EFSA journal 10(11): 2986-2996

EFSA (2012d). Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. EFSA Journal 10(2): 2561

EFSA (2012e). Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA Journal 10(10): 2943

EFSA (2012f). Scientific opinion on a request from the European Commission for the assessment of the scientific elements put forward by Luxembourg to support the prohibition for the placing on the market of GM potato EH92x527x1 for cultivation purposes in Luxembourg. EFSA journal 10(9): 2874

EFSA (2013). Scientific opinion on a request from the European Commission related to the emergency measure notified by Italy on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003. EFSA journal 11(9): 3371

EFSA (2014). Statement on a request from the European Commission related to the emergency measure notified by Bulgaria on genetically modified maize MON 810 according to Article 34 of Regulation (EC) 1829/2003. EFSA journal 12(12): 3962

EFSA (2015). Conclusion on the peer review of the pesticide risk assessment of the active substance Glyphosate; EFSA: Parma, Italy, 2015.

EFSA (2018). Guidance on uncertainty analysis in scientific assessments. EFSA journal 16(1): 1-39

EFSA (2019). Guidance on communication of uncertainty in scientific assessments. EFSA journal 17(1)

EFSA (2019b). Opinion on oilseed Rape. Annex G Member States comments. Available from: https://bit.ly/3f4inOF (Accessed 24 July 2020)

Einsiedel E & Eastlick DL (2000). Consensus conferences as deliberative democracy: a communications perspective. Science communication 21(4): 323-343

Einsiedel E, Jelsøe E and Breck T (2001). Publics at the technology table: The consensus conference in Denmark, Canada and Australia', Public Understanding of Science, 10(1): 83-98

Eklöf S (2015). Information on interpretation of CRISPR Cas9 Mutated plants, Plant and Environment Department, Swedish Board of Agriculture. Available from: https://bit.ly/2OXoBW0 (Accessed 24 July 2020)

Elowitz MB & Leibler S (2000). A synthetic oscillatory network of transcriptional regulators. Nature 403(1): 335-338

Elsevier (2013). Elsevier announces article retraction from Journal Food and Chemical Toxicology. Elsevier Press release 28 November 2013, Cambridge, MA

El-Shamayleh Y & Horwitz GD (2019). Primate optogenetics: Progress and prognosis. PNAS 116(52): 26195-26203

Elster J (1998). Deliberative Democracy. Cambridge: Cambridge University Press

Engdahl FW (2012). Cancer of corruption, seeds of destruction: The Monsanto GMO whitewash. Global Reseach Canada. Avalable from: https://bit.ly/3i09Tdm (Accessed 24 July 2020)

ENGL (2019). Detection of food and feed plant products obtained by new mutagenesis techniques. European Network of GMO laboratories, report 26 March 2019

ENSSER (2013). Statement: No scientific consensus on GMO safety. European Network of Scientists for social and environmental responsibility. Available from: https://bit.ly/2WXqGpr (Accessed 24 July 2020)

Entine J (2012). Does the Seralini corn study fiasco mark a turning point in the debate over GM Food? (pp. Comment by user 'John Bying' on November 14, 2012 at 8:48 am). Forbes magazine, 30 September 2012

EPEC (2011). Evaluation of the EU legislative framework in the field of cultivation of GMOs under directive 2001/18/EC and regulation (EC) No 1829/2003, and the placing on the market of GMOs as or in products under directive 2001/18/EC, European Policy Evaluation Consortium, final report. Brussels

EPRS (2014). Changed rules for qualified majority voting in the Council of the EU' (2014), European Parliamentary Research Service. At a Glance, December 2014

Ercan SA & Dryzek JS (2015) Conclusion: the reach of deliberative democracy. Policy studies 36(3): 359-361

Erikkson D (2018). The Swedish policy approach to directed mutagenesis in a European context. Physiologica Plantarum 164 (4): 385-395

Eriksson D *et al*. (2018) 'Why the European Union needs a national GMO opt-in mechanism' Nature biotech 36: 18-19.

Ernst & Young & EuropaBio (2014). Biotechnology in Europe, the tax, finance and regulatory framework and global policy comparison.

ETC group (2007). Extreme genetic engineering: an introduction to synthetic biology. Action Group on Erosion, Technology and Concentration.

ETC group (2014). Why genetically modified crops pose a threat to peasants, food sovereignty, health, and biodiversity on the planet. A summary of scientific arguments. Action Group on Erosion, Technology and Concentration. 14 August 2014

Etzkowitz H (1996). Conflicts of interest and commitment in academic science in the United States. Minerva, 34(3): 259–277

Euractiv (2014). Evidence-based union? A new alliance for science advice in Europe. James Wilson for Euractiv news, 23 June 2014

Euractiv (2019a). Commission in search of 'robust response' to gene editing challenge. Gerardo Fortuna for Euractiv news, 21 May 2019

Euractiv (2019b). EU study to clarify gene editing court ruling further muddies waters. Natasha Foote for Euractiv news, 5 December 2019

Euractiv (2019c). Senselessly shunning science: the EU parliament's GMO dilemma. Beat Späth of Europabio for Euractiv Opinion, 17 December 2019
Euractiv (2019d). The EU must not de-regulate gene-edited crops and foods. Michael Antoniou for Euractiv Opinion, 9 July 2019

EuropaBio (2015). How long does it take for a GM crop for import to be approved and how much does this cost? EuropaBio FAQ. Available from: https://bit.ly/2CPxEG5 (Accessed 24 July 2020)

EuropaBio (2016). GMO risk assessment timelines: is the EU losing the innovation game? Infographic. Available from: https://bit.ly/3fZHPWV (Accessed 24 July 2020)

EuropaBio (2018a). EU must reinstate science in GMO safety assessment and eliminate unnecessary animal testing. Press release 17 April 2018

EuropaBio (2018b). Mandatory feeding studies for GM crops should be abolished because they contradict EU science and ethical principles. Position paper, 15 November 2018

EuropaBio (2019). Achieving the potential of genome editing. The Perspective of the European Biotech Industry. Position paper, June 2019

European Commission (2000a). White paper on food safety, COM (1999), 719, 12 January, Brussels

European Commission (2000b). Communication from the Commission on the precautionary principle, COM (2000), 2 February, Brussels

European commission (2008). Attitudes of European citizens towards the environment. Special Eurobarometer 295/ Wave 68.2

European Commission (2009). Proposal for a Council Decision concerning the provisional prohibition of the use and sale in Austria of genetically modified maize (Zea mays L. Line MON810) pursuant to Directive 2001/18/EC of the European Parliament and of the Council. COM (2009) 56

European Commission (2010a). GMOs: Member States to be given full responsibility on cultivation in their territories. European Commission press release 14 July 2010

European Commission (2010b). A decade of EU-funded GMO research (2001-2010). EUR 24473 EN

European commission (2010c). Communicating research for evidence-based policymaking. A practical guide for researchers in socio-economic sciences and humanities. Luxembourg: European Commission Directorate-General for research

European Commission (2010d). Biotechnology. Special Eurobarometer 341 / Wave 73.1

European Commission (2010e). Commission Recommendation of 13 July 2010 on guidelines for the development of national coexistence measures to avoid the unintended presence of GMOs in conventional and organic crops. 2010/C 200/01, 13 July

European Commission (2015a). Review of the decision-making process on GMOs in the EU: questions and answers. Memo 15-4779_EN, Brussels, 22 April

European Commission (2015b). Annex to the communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions. Reviewing the decision-making process on genetically modified organisms (GMOs). COM (2015) 176 final, Brussels, 22 April

European Commission (2017a). Summary report of the Joint meeting of the standing committee on plants, animals, food and feed and regulatory committee under directive 2001/18/EC, held in Brussels on 27 January 2017. Reference: sante.ddg2.g.5 (2017) 637128

European Commission (2017b). Summary report of the appeal committee genetically modified food and feed. Regulatory Committee 2001/18/EC held on 27 March 2017

European Commission (2017c). Proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. COM/2017/085 final – 2017/035 (COD)

European Commission (2019). Food safety in the EU. Special Eurobarometer Wave EB91.3

European Commission (2020). Proposal for a regulation of the European Parliament and of the Council on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease. COM(2020) 261, 17 June, Brussels

European Parliament (2016). Resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (D044281/01 – 2016/2624(RSP)

European Parliament (2017). Resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (D053565-01 – 2017/2904(RSP)

European Parliament (2020). Resolution of 2 March 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87708 × MON 89788 × A5547-127 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D065067/03 2020/2535(RSP)

Ewen SW & Pusztai A. (1999). Effect of diets containing genetically modified potatoes expressing galanthus nivalis lectin on rat small intestine. Lancet, 354(9187): 1353–1354

Extance A (2016). How DNA could store all the worlds data. Nature 537(7518): 22-24

F

Falck-Zepeda J & Gouse M (2017). Regulation of GMOs in developing countries: Why socio-economic considerations matter for decision-making. In: Genetically Modified Organisms in Developing Countries. Risk Analysis and Governance. AA Adenle, EJ Morris & DJ Murphy (eds.), Cambridge University Press, Cambridge, UK. pp. 91-102

Falck-Zepeda J (2009). Socio-Economic Considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake? AgBioForum 12(1): 90-107

Falck-Zepeda JB & Zambrano P (2011). Socio-economic considerations in biosafety and biotechnology decision making: The Cartagena Protocol and National Biosafety Frameworks. Review of Policy Research 28(2):171-195

Falck-Zepeda JB, Smyth SJ and Ludlow K (2016). Zen and the art of attaining conceptual and implementation clarity: socio-economic considerations, biosafety and decision-making. The Estey Journal of International Law and Trade Policy 17(2):117-136

FAO, IFAD and WFP (2013). The state of food insecurity in the World. The multiple dimensions of food security. Food and Agriculture Organization of the United Nations (FAO), Rome, Italy. Available from: https://bit.ly/32RxKru (Accessed 24 July 2020)

Faulkner A & Poort L (2017). Stretching and challenging the boundaries of law: varieties of knowledge in biotechnologies regulation. Minerva 55(2): 209-228
FDA (2019). First FDA-approved vaccine for the prevention of Ebola virus disease, marking a critical milestone in public health preparedness and response. FDA news release, 19 december 2019

Ferretti MP (2007). Why public participation in risk regulation? The case of authorizing GMO products in the European Union. Science as Culture 16(4): 377-395

Finkel E (2012). GM corn and cancer: the Séralini affair. Cosmos Magazine, 9 October

Fitzsimons J (2009). Genetic modification reAccessed. In: Speech to the NZ Institute of Agricultural and Horticultural Science Inc - forum, 1 July 2009 Website Green Party of Aotearoa New Zealand

Fladung M (2016). Cibus' herbicide-resistant canola in European limbo. Nature 34(5): 473-474

Frewer LJ, Miles S, Brennan M *et al.* (2002). Public preferences for informed choice under conditions of risk uncertainty. Public understanding of Science 11(4): 363-372

Friends of the Earth (2011). The socio-economic effects of GMOs. Briefing 1 April 2011

Friends of the Earth (2013). Synthetic biology Vanilla: 'natural' and 'sustainable'. Issue Brief October 2013.

Friends of the Earth, CTA and ETC group (2012). The principles for the oversight of synthetic biology, report 1 December 2012

FSANZ (2013) Detailed Comment on Carman *et al.* (2013): Study design and conduct. Australia New Zealand Food Standards Available from https://bit.ly/2ZXfXgw (Accessed 24 July 2020)

Fuller LL (2001). The principles of social order, selected essays of Lon L. Fuller, edited, with an introduction by Kenneth I. Winston. Hart Publishing, 2001

Funtowicz SO & Ravetz JR (1990). Uncertainty and quality in science for policy. Kluwer Academic Publishers, Dordrecht

Funtowicz SO & Ravetz JR (1993). Science for the post-normal age. Futures 25(7): 739-755

G

Garcia-Yi J, Lapikanonth T, Vionita H *et al*. (2014). What are the socio-economic impacts of genetically modified crops worldwide? A systematic map protocol. Environmental Evidence 3, Article 24

Gardner TS, Cantor CR and Collins JJ (2000). Construction of a genetic toggle switch in Escherichia coli. Nature 403(1): 339-342

Gaskell G, Stares S, Allansdottir A *et al*. (2006). Europeans and biotechnology in 2005: Patterns and Trends. Final report on Eurobarometer 64.3, July 2006

Gaskell G, Stares S, Allansdottir A *et al*. (2010). Europeans and biotechnology in 2010 - Winds of change? Report to the European Commission's Directorate-General for Research, October 2010

Georgiev V (2013). Too much executive power? Delegated law-making and comitology in perspective. Journal of European Public Policy 20(4): 535-551

Gieryn TF (1983). Boundary-work and the demarcation of science from non-science: strains and interests in professional ideologies of scientists. American Sociological Review 48(6): 781-785

GM-FreeCymru (2012). Revealed: How EFSA Staff orchestrated "official" rebuttals of Seralini research. GM-Free Cymru press release, 8 October 2012

GMOSeralini (2012). Frequently asked questions. Why this study now? Available from: www.gmoseralini.org/faq-items/why-this-study-now (Accessed 24 July 2020)

GMOSeralini (2013a). Republication of the Séralini Study: Science speaks for itself. Available from: https://bit.ly/3hC1EnH (Accessed 24 July 2020)

GMOSeralini (2013b). Ten things you need to know about the Séralini study. www.gmoseralini.org/ten-things-you-need-to-know-about-the-seralini-study (Accessed 24 July 2020)

GMOSeralini (2014). Republication of the Séralini study: Science speaks for itself. Available from: www.gmoseralini.org/republication-seralini-study-science-speaks (Accessed 24 July 2020)

GMWatch (2012a). Pusztai hitman oversaw EFSA's demolition of Seralini. GMWatch news, 10 October 2012

GMWatch (2012b). Shock as EFSA Says "no problem" with GM Maize it claimed was safe. GMWatch news, 4 October 2012

GMWatch (2016). Comments on National Academy of Sciences' report on GM crops. GMWatch news, 19 May 2016

GMWatch (2018a). EU-funded rat feeding studies do not refute the Séralini study. GMWatch news, 12 June 2018

GMWatch (2018b). Old lobby, new language. GMWatch news, 31 December 2018

GMWatch (2018c). The Bayer-Monsanto merger just got a major green light — but farmers are terrified. GMWatch news, 13 April 2018

GMWatch (2019a). Natural GMOs' hype debunked. GM Watch News, 22 October 2019

GMWatch (2019b). Deceptive reporting of GMO90+ EU-funded feeding study on GM maize. GM Watch News, 24 January 2019

Goemine G (2011). Has science ever been normal. On the need and impossibility of a sustainability science. Futures 43(6): 627-636

Gómez-Tatay L & Hernández-Andreu JM (2019). Biosafety and biosecurity in Synthetic Biology: A review. Critical Reviews in Environmental Science and Technology. Volume 49(17): 1587-1621

Gornitzka, A & Sverdrup U (2008). Who consults? The configuration of expert groups in the European Union, West European Politics, 31 (4): 725-750

Gorski D (2013). More bad science in the service of Anti-Gmo activism. pp. Comment by user 'Alia' posted June 17, 2013 at 2011:2014 pm. In: Science-Based Medicine, 17 June 2013

Goulart E (2019). 3D bioprinting of liver spheroids derived from human induced pluripotent stem cells sustain liver function and viability in vitro. Biofabrication, 12(1), 015010

Gouse M (2009). Ten Years of Bt cotton in South Africa: putting the smallholder experience into context. In: Biotechnology and Agricultural Development. Transgenic Cotton, Rural Institutions and Resource-Poor Farmers. R Tripp (ed.), Routledge, London, UK

Gouse M, Kirsten J, Shankar B *et al.* (2005). Bt cotton in KwaZulu Natal: Technological triumph but institutional failure? AgBiotechNet 7(1): 1-7
GRACE (2015). Final report summary – GRACE (GMO risk assessment and communication of evidence. Available from: https://bit.ly/2ZWiwj4 (Accessed 24 July 2020)

Grens K (2015). There's CRISPR in your yoghurt. The Scientist, 31 December 2014

Guéguen D (2017). The new comitology reform. Overhauling the balance of powers or institutional tinkering? Personal Blog, 10 April 2017. Available from: https://bit.ly/39pKfMe (Accessed 24 July 2020)

Gutmann A & Thompson D (1996). Democracy and Disagreement. Harvard University Press, 1996

Gutmann A and Thompson D (1990). Moral conflict and political consensus. Ethics 101(1): 64-88

H

Habermas J (1989). Structural transformation of the public sphere: An inquiry into a category of bourgeois society, trans. Thomas Burger and Frederick Lawrence. Cambridge, MA: MIT Press, 1989

Habermas J (1996) Three normative models of democracy. In: Sheila Benhabib (ed), Democracy and Difference. Contesting the Boundaries of the Political. Princeton University Press, 1996: 21-30

Hagemann S, Hobolt S, and Wratil C (2016). Government Rresponsiveness in the European Union: Evidence from Council Voting'. Comparative Political Studies 50(6): 850-876

Hall C, Knight B, Ringrose S *et al*. (2013). What have been the farm-level economic impacts of the global ltivation of GM crops? Systematic Review. CEE Review 11-002. Collaboration for Environmental Evidence

Haniotis T (2000). Regulating agri-food production in the US and the EU. AgBioForum 3(2&3): 84-86

Hansson SO (2004). Philosophical perspectives on risk. Techné: Research in Philosophy and Technology 8, Fall 2004

Hartley S (2016). Policy masquerading as science: an examination of non-state actor involvement in European risk assessment policy for genetically modified animals. Journal of European Public Policy 23(2): 276–295

Hartung U & Hörisch F (2017). Regulation vs symbolic policy-making: genetically modified organisms in the german states. German Politics 27(3): 380-400

Hayden EC (2014). Synthetic-biology firms shift focus. Nature 505(7485): 598

Hayes AW (2013). Food and Chemical Toxicology Editor-in-Chief, A. Wallace Hayes, publishes response to letters to the Editors. In: Cambridge: Elsevier

Head BW & Alford J (2015). Wicked problems: Implications for public policy and management. Administration & Society 47(6): 711–739

Head BW (2008). Wicked problems in public policy. Public Policy 3(2): 101–118

Head BW (2010). Reconsidering evidence-based policy: key issues and challenges. Policy and society 29(2): 77-94

Head BW (2018). Forty years of wicked problems literature: forging closer links to policy studies. Policy and society 38(2): 180-197

Heather JM & Chain B (2016). The sequence of sequencers: The history of sequencing DNA. Genomics 107(1): 1-8

Helliwell R, Hartley S, Pearce W *et al*. (2017). Why are NGOs sceptical of genome editing? EMBO reports, Science & Society 18(12): 2090-2093

Herman RA & Raybould A (2014). Expert opinion vs empirical evidence. GM crops & Food 5(1): 8-10

Hess S, Lagerkvist CJ, Redekop W *et al*. (2013). Consumers' evaluation of biotechnology in food products: New evidence from a Meta-Survey. Proceedings of the Agricultural & Applied Economics Association's 2013 AAEA & CAES Joint Annual Meeting; 2013 August 4-6, 2013
Heveran CM, Williams SL, Qiu J *et al*. (2020). Biomineralization and successive regeneration of engineered living building materials. Matter 2(2): 481-494

Hilbeck A, Binimelis R, Defarge N *et al*. (2015). No scientific consensus on GMO safety. Environmental Sciences Europe, 27(4): 1-6

Hisschemöller M & Hoppe R (1995). Coping with intractable controversies: The case for problem structuring in policy design and analysis. Knowledge and policy 4 (8): 40-60

Hisschemöller M (1993). De democratie van problemen: de relatie tussen de inhoud van beleidsproblemen en methoden van politieke besluitvorming (The Democracy of Problems: Exploring the Relationship Between Policy Content and Method of Political Decision Making). PhD diss., VU, Amsterdam (in Dutch)

Hoffman B (2013). Golden Rice and GMOs: The best solutions to world hunger. Forbes Magazine, 31 august 2013

Holbrook JB & Briggle A (2014). Knowledge kills action – Why principles should play a limited role in policy making. Journal of responsible innovation 1(1):51-66

Hoppe R (2018). Rules of thumb for problem-structuring policy design. Policy design and practice 1(1): 12-29

Horst M & Irwin A (2010). Nations at ease with radical knowledge: On consensus, consensusing and false consensusness. Social studies of Science 40(1): 105-126

Huber D. (2011). Roundup may be causing animal miscarriages and infertility. Personal communication to US Secretary of Agriculture Vilsack ed.

Hurlbut B, Jasanoff S (2018). A Global observatory for gene editing. Nature 555(7697): 435-437

I

IARC (2015). IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides. International Agency for Research on Cancer, 20 March 2015

Inf'OGM (2015). Understanding labelling of GMOs in food: the current situation of French and European legislation. Inf'OGM news, 19 January 2015

Inghelbrecht L (2016). GM crops in the EU as a wicked problem. On technology, morality and a polarized debate. Thesis, University of Gent

Inghelbrecht L, Dessein J and Van Huylenbroeck G *et al*. (2014). The 'Wickedness' of GM crop applications in the European Union. International journal of agricultural management 3(2): 2047-3710

Insites Consulting (2017). De burger aan het woord: publieksopvattingen over moderne biotechnologie. Onderzoeksrapport InSites Consulting November 2017 (In Dutch)

Irwin A, Rothstein H, Yearley S *et al*. (1997). Regulatory science – towards a sociological framework. Futures 29(1): 17-31

ISAAA (2018). Brief 54: Global Status of commercialized Biotech/GM crops: 2018

J

Jaffe G (2004). Regulating transgenic crops: A comparative analysis of different regulatory processes. Transgenic Research 13(1): 5-19

Jaffe G (2005). Implementing the Cartagena Biosafety Protocol through national biosafety regulatory systems: An analysis of key unresolved issues. Journal of Public Affairs 5(3-4): 299-311

Jasanoff S (2003). (No?) Accounting for expertise. Science and public policy 30(3): 157-162

Jasanoff S (2005). Designs on nature: Science and democracy in Europe and the United States. Princeton, NJ: Princeton University Press

Jasanoff S. (1990). The fifth branche: Science advisers as policymakers. Harvard University Press

Jelsma J (2001). Frame-Reflextive Policy Analysis in Practice: Co-evaluation of a policy regime and intractable controversy in biotechnology. In: Hisschemoller M, Hoppe R, Dunn WN, & Ravetz JR (Eds.), Knowledge, Power, and Participation in Environmental Policy Analysis (pp. 201-228). (Policy Review Annual; No. Vol. 12). New Brunswick and London: Transaction Publishers.

Jennings CG (2006). What you can't measure, you can't manage: the need for quantitative indicators in peer review. Nature, Peer Review: Debate Quality and value: The true purpose of peer review

Jinek M, Chylinski K, Fonfara I *et al*. (2012). A programmable dual-RNA–Guided DNA Endonuclease in adaptive bacterial immunity. Science 337(6096): 816-821

Jones LH (2015). Recent advances in the molecular design of synthetic vaccine. Nature Chemistry 7(12): 952-960

Joss S & Durant J (1995). Public participation in Science: the role of consensus conferences in Europe. NMSI Trading Ltd

K

Kahan DM (2002). The logic of reciprocity: trust, collective action and law. Available at SSRN: https://ssrn.com/abstract=361400

Kahan DM, Jenkins-Smith H and Braman D *et al*. (2010). Cultural cognition of scientific consensus. Journal of risk research 14(2): 147-174

Kalaitzandonakes N, Alston JM and Bradford KJ (2007). Compliance costs for regulatory approval of new biotech crops. Nature biotechnology 25(5): 509-511

Kalaitzandonakes N, Matsbarger R and Barnes J (2009). Global identity preservation costs in agricultural supply chains. Canadian Journal of Agricultural Economics 49(4):605–615

Kathage J, Gómez-Barbero M, Rodríguez-Cerezo E (2015). Framework for the socio-economic analysis of the cultivation of genetically modified crops. European GMO Socio-Economics Bureau, 1st Reference Document. Science and Policy Reports, Institute for Prospective Technological Studies, Joint Research Centre (JRC), European Commission, Seville, Spain

Kathage J, Gómez-Barbero M, Rodríguez-Cerezo E (2016). Framework for assessing the socio-economic impacts of Bt Maize cultivation. European GMO Socio-Economics Bureau, 2nd Reference Document. Science and Policy Reports, Institute for Prospective Technological Studies, Joint Research Centre (JRC), European Commission, Seville, Spain

Kelly SE (2003). Public bioethics and publics: Consensus, boundaries, and participation in biomedical science policy. Science, Technology & Human Values 28(3): 339-364

Kettenburg AJ, Hanspach J, Abson Dj *et al*. (2018). From disagreements to dialogue: unpacking the golden rice debate. Sustainability Science 13(1): 1469-1482

Klika C, Kim J and Versluis E (2013). Why science cannot tame politics: The new EU comitology rules and the centralised authorisation procedure of GMOs. European Journal of Risk Regulation 4(3): 327-334

Knox O, Hall C, McVittie A *et al*. (2013). A systematic review of the environmental impacts of GM crop cultivation as reported from 2006 to 2011. Food and Nutrition Sciences 4(6A): 28-44.

Koch J Gantebein S, Masania K *et al*. (2019). A DNA-of-things storage architecture to create materials with embedded memory. Nature Biotechnology 38(12): 39-43

König H (2017). The illusion of control in germline-engineering policy. Nature Biotechnology 35(6): 502-506

Konig N, Børsen T and Emmeche C (2017). The ethos of post-normal science. Futures 91: 12-24

Koppejan J & Klijn Eh (2004). Managing uncertainties in networks; a network to problem solving and decision-making. Routledge, London

Kouser S, Qaim M (2011). Impact of Bt cotton on pesticide poisoning in smallholder agriculture: a panel data analysis. Ecological Economics 70(11): 2105–2113

Kreutzberg GW (2004). The rules of good science. EMBO reports 5(4): 330–332
Kriegman S, Blackiston D, Levin M *et al*. (2019). A scalable pipeline for designing reconfigurable organisms. PNAS 117(4): 1853–1859

Krishna VV, Qaim M (2012). Bt cotton and sustainability of pesticide reductions in India. Agricultural Systems 107: 47–55

Kuntz M (2012) Destruction of public and governmental experiments of GMO in Europe. GM Crops & Food Biotechnology in Agriculture and the Food Chain 3(4): 258–264

Kurzer P & Cooper A (2007). Consumer activism, EU institutions and global markets: the struggle over biotech foods. Journal of public policy 27(1): 103–128

Kuzma J (2013). Properly paced? Examining the past and present governance of GMOs in the United States. Innovative governance models for emerging technologies. E. Elgar. Cheltenham, UK: 176–197

Kuzma, J. (2016). A missed opportunity for US biotechnology regulation. Science 353(6305): 1211–1213

L

Laclau E (1996) Emancipation(s). London: Verso

Lasswell H & Kaplan A (1950). Power and society; a framework for political enquiry. New York: Yale University

Lasswell HD (1956). The decision process: Seven categories of functional analysis, Harold D. Lasswell, (College Park, Maryland: University of Maryland Press, 1956)

Laursen L (2013). Argentina cuts GM red tape. Nature Biotechnology 31(7):579

Leach M, Scoones I and Wynne B (2005). Science and citizens: globalization and the challenge of engagement. London: Zed Books, 2005 218–231

Leib E (2005). Deliberative democracy in America: A proposal for a popular branch of government. University Park, PA: Pennsylvania State University Press

Lempert RJ & Schlesinger ME (2000). Robust strategies for abating climate change. Climatic change 45(3-4): 387-401

Levidow L (2001). Precautionary uncertainty: Regulating GM crops in Europe. Social Studies of Science 31(6): 842–874

Levidow L, Boschert K (2011). Segregating GM crops: Why a contentious 'risk' issue in Europe? Science as culture 20(2): 255-279.

Levidow L, Carr S and Wield D (2005). European Union regulation of agri-biotechnology: precautionary links between science, expertise and policy. Sci. Public Policy 32 (4): 261–276.

Levidow L, Carr S, von Schomberg R *et al*. (1996). Regulating agricultural biotechnology in Europe: harmonisation difficulties, opportunities, dilemmas. Science and Public Policy 23(3): 135–157

Levin KB, Cashore B, Bernstein S *et al*. (2012). Overcoming the tragedy of super wicked problems: constraining our future selves to ameliorate Global Climate Change. Policy Sciences 45(2): 123–152

Lieberman S & Gray ST (2006). The so-called 'moratorium' on the licencing of new genetically modified (GM) products by the European Union 1998-2004: a study in ambiguity. Environmental politics 15(4): 592-609

Lindblom CE (1959). The science of 'muddling through'. Public Administration review 19(2): 79-88

Löfstedt R (2004). The swing of the regulatory pendulum in Europe: from precautionary principle to (regulatory) impact analysis. Journal of Risk and Uncertainty 28(3): 237–60

Lusk J, House L, Valli C *et al*. (2005). Consumer welfare effects of introducing and labeling genetically modified foods. Economics Letters 88(3): 382–388

M

Mackenzie D & Cremers HC (1992). Europe wrangles over Herman's sex life. Newscientists, 28 November 1992

Maeseele P, Allgaier J, Martinelli L (2013). Bio-objects and the media: the role of communication in bioobjectification processes. Croatian Medical Journal 54: 301-305

Malyska A, Bolla RI, Twardowski T (2016). The role of public opinion in shaping trajectories of agricultural biotechnology. Trends in Biotechnology 34(7): 530-534

Mampuys R & Brom FWA (2010). The quiet before the storm: anticipating developments in synthetic biology. Poiesis & Praxis: International Journal of Technology Assessment and Ethics of Science 7(3): 151-168

Mampuys R & Brom FWA (2015a). Ethics of dissent: a plea for restraint in the scientific debate about the safety of GM crops. Journal of Agricultural and Environmental Ethics 28(5): 903-924

Mampuys R. & Brom FWA (2015b). Governance strategies for responding to alarming studies on the safety of GM crops. Journal of Responsible Innovation 2(2): 201-219

Mandrycky c, Wang Z, Kim K *et al*. (2016). 3D bioprinting for engineering complex tissues. Biotechnology Advances 34(4): 422-434

Mannion A & Morse S (2012). Biotechnology in agriculture: Agronomic and environmental considerations and reflections based on 15 years of GM crops. Progress in Physical Geography: Earth and Environment 36(6): 747–763

Marris C (2001). Public Views on GMOs: Deconstructing the Myths. EMBO Reports, Science & Society 2(7): 545-548

Masip G, Sabalza M, Perez-Massot E (2013). Paradoxical EU agricultural policies on genetically engineered crops. Trends in Plant Science 18(6): 312-324

Matveeva TV & Otten L (2019). Widespread occurrence of natural genetic transformation of plants by Agrobacterium. Plant molecular Biology 101 (1-2): 415-437

Mayer S & Stirling A (2004). GM crops good or bad? EMBO reports, Science & Society 5(11): 1021-1024

McDougall P (2011). The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait. Croplife Canada report, 7 November 2011

Mchughen A & Wager R (2010). Popular misconceptions: agricultural biotechnology. New biotechnology 27(6): 724-728

McHughen A (2013). Who's afraid of the big bad GMO? C2C journal, 7(1): 13-17

McLeod C & Nerlich B (2017). Synthetic biology, metaphors and responsibility. Life sciences, society and policy 13:13

McNaughten P (2016). Responsible innovation and the reshaping of existing technological trajectories. The hard case of genetically modified crops. Journal of Responsible Innovation 3(3): 282-289
McNaughton SJ (1999). What is good science? Natural Resources & Environment 13(4): 513-518

Meester G, Berkhout P and Dries L (2013). Eu beleid voor landbouw, voedsel en groen: van Politiek naar Praktijk. Eu Policy for Agriculture, Food and Rural Areas: From Politics to Practice: Wageningen Academic Publishers.

Meijer AJ & Brom FWA (2009). Biotechnology and social learning: an empirical analysis of the Dutch Animal Biotechnology Act. Technology in Society, 31(1): 117 –124

Midgley M (2000). Biotechnology and monstrosity: Why we should pay attention to the "yuk Factor". Hastings Center Report 20(5): 7-15

Mielby H, Sandøe P and Lassen J (2012). The role of scientific knowledge in shaping public attitudes to GM technologies. Public Understanding of Science 22(2): 155-168

Miles S & Frewer LJ (2011). Public perception of scientific uncertainty in relation to food hazards. Journal of risk research 6(3): 267-283

Millstone E, Stirling A and Glover D (2015). Regulating genetic engineering, the limits and politics of knowledge. Issues in science and technology. Stirling A, Glover D and Millstone E (2015). Regulating Genetic Engineering: The Limits and Politics of Knowledge. Issues in science & technology xxxi(4), Summer 2015

Montpetit E (2011). Scientific credibility, disagreement, and error costs in 17 biotechnology policy subsystems. The policy studies journal 39(3): 513-533

Moravcsik A (1998). The Cchoice for Europe: Social purpose and State power from Messina to Maastricht. Ithaca, NY: Cornell University Press

Morris EJ (2011). A semi-quantitative approach to GMO risk-benefit analysis. Transgenic Research 20(5): 1055-1071

Morris SH & Spillane C (2010). EU GM crop regulation: A road to resolution or a regulatory roundabout? European Journal of Risk Regulation 1(4): 359–369

Moses V & Brookes G (2013). The world of 'GM-free'. GM crops & food. Biotechnology in agriculture and the food chain 4(3): 135-142

Mouffe C (1999). Deliberative Democracy or Agonistic Pluralism? Social Research 66(2): 745-759

Mouffe C (2000). For an agonistic model of democracy. In: Chantal Mouffe, The Democratic Paradox (London, Verso, 2000

Mühlböck M & Tosun J (2015). Deciding over controversial issues: Voting behavior in the Council and the European Parliament on genetically modified organisms. 22nd International Conference of Europeanists, 8.- 10.07.2015, Paris

Mühlböck M & Tosun J (2017). Responsiveness to different national interests: Voting behaviour on genetically modified organisms in the Council of the European Union. Journal of Common Market Studies 56(2): 385-402

Myers JP, Antoniou MN, Blumberg B *et al*. (2016). Concerns over use of glyphosate-based herbicides and risks associated with exposures: A consensus statement. Environmental Health 15, Article 19

Myhr AI & Traavik T (2002). The precautionary principle: scientific uncertainty and omitted research in the context of GMO use and release. Journal of agricultural and environmental ethics 15(1): 73-86

Myhr AI (2010). A precautionary approach to genetically modified organisms, challenges and implications for policy and science. Journal of agricultural and environmental ethics 23(1): 501-525

N

Nagamune T (2017). Biomolecular engineering for nanobio/bionanotechnology. Nano Convergence 4(1): 1-56

NASEM (2015). On Human Gene Editing: International Summit Statement. National Academies of Sciences, Engineering and Medicine. News release 3 December 2015

NASEM (2016). Genetically Engineered Crops: experiences and prospects. National Academies of Sciences, Engineering, and Medicine. Washington, DC: The National Academies Press

Natarajan AT (2005). Chemical mutagenesis: From plants to human. Current science 89(2): 312-317

Nature (2006). Despite enthusiasm for the concept, open peer review was not widely popular, either among authors or by scientists invited to comment. Nature, Overview: Nature's peer review trial

Nature (2006). Overview: Nature's Peer Review Trial. Nature, December 2006

Nature (2016a). First CRISPR clinical trial gets green light from US panel. Sara Reardon for Nature news, 22 June 2016

Nature (2016b). Welcome to the CRISPR zoo. Reardon for Nature news 531(7593): 160-163

Nature (2016c). Gene-editing surges US rethinks regulations. Nature 532(7598): 158-159

Nature (2017). First genetically engineered salmon sold in Canada. Emily Waltz for Nature news, 4 August 2017

Nature (2017). Harmonize conflicting regulations for genetically engineered plants and animals. Editorial Nature 546(7658): 327-328

Nature (2018). Genome-edited baby claim provokes international outcry. David Cyranoski & Heidi Ledford for Nature news, 26 November 2018

Nature (2019). Self-destructing mosquitoes and sterilized rodents: the promise of gene drives. Megan Scudellari for Nature news, 9 July 2019

Nature biotechnology (2019). Meat-free outsells beef. Nature biotechnology 37, 1250

Naurin D (2009). Most common when least important: deliberation in the European Union of ministers. British journal of political science 40(1): 31-50

New Scientist (2015). More than half of EU officially bans genetically modified crops. News, 5 October 2015

Newman J & Head BW (2017). Wicked tendencies in policy problems: rethinking the distinction between social and technical problems. Policy and Society 36(3): 414-429

Nicolia A, Manzo A, Veronesi F *et al*. (2014). An overview of the last 10 years of genetically engineered crop safety Research. Critical Review of Biotechnology 34(1): 77-88.

Nie MA (2003). Drivers of natural resource-based political conflict. Policy Sciences 36(3): 307-341

Nielsen KM & Myhr *et al*. (2013). Understanding the uncertainties arising from technological interventions in complex biological systems. The case of GMOs. In: Biosafety First (2007) Traavik T & Lim LC (eds.), Tapir Academic Publishers

Nowotny H (2003). Democratising expertise and socially robust knowledge. Science & Public Policy 30(3): 151–156

NVWA (2012). Teleconference with Efsa and Member States on Séralini *et al*. Study (2012) (Personal Notes). In: The Netherlands Food and Consumer Product Safety Authority

O

O'Keefe (2015). Editing' genes: a case study about how language matters in bioethics. The American journal of bioethics 15(12): 3-10

OECD (2005). A Framework for Biotechnology Statistics, OECD, Paris

OECD (2018). Revised proposal for the revision of the statistical definitions of biotechnology and nanotechnology, OECD Science, Technology and Industry Working Papers, 2018/01, OECD Publishing, Paris. Friedrichs S & van Beuzekom B

Oh J & Ezezika OC (2014). To label or not to label: balancing the risks, benefits and costs of mandatory labelling of GM food in Africa. Agriculture & Food Security 3, Article 8

Oliver MJ (2014). Why we need GMO crops in agriculture. Missour Medicine 111(6): 492-507

Oreskes N (2004). Science and public policy: What's proof got to do with it? Environmental Science & Policy, 7(5): 369-383

Oye KA (2012). Proactive and adaptive governance of emerging risks: The case of DNA synthesis and synthetic biology. International Risk Governance Council (IRGC), June 2012

Oye KA, Esvelt K, Appleton E *et al*. (2014). Regulating gene drives, regulatory gaps must be filled before gene drives could be used in the wild. Science 345(6197): 626-628.

P

Paarlberg R (2010). GMO foods and crops: Africa's choice. New Biotechnology 27(5): 609-613

Paddon CJ & Keasling JD (2014). Semi-synthetic artemisinin: a model for the use of synthetic biology in pharmaceutical development. Nature reviews Microbiology 12(5): 355-367

Parfitt C & Dunn B (2013). Golden Rice is no Silver Bullet: hunger needs a political solution. The Conversation., 20 February 2013

Parliament (2016). EU regulation of the life sciences. First report of the session 2016-17 Science and Technology Commitee, House of Commons, UK. Available from: https://bit.ly/2WW6x2X (Accessed 24 July 2020)

Pauwels K, Mampuys R, Golstein C *et al*. (2013). Event report: SynBio Workshop (Paris 2012) – Risk assessment challenges of Synthetic Biology. Journal für Verbraucherschutz und Lebensmittelsicherheit 8(3): 215-226

Pellizzoni L (2001). The myth of the best argument: Power deliberation and reason. British Journal of Sociology 52 (1): 59-86

Pielke RA (2004). When scientists politicize science: making sense of controversy over The Skeptical Environmentalist. Environmental science & Policy 7(5): 405-417

Pielke RA (2007). The Honest Broker: Making sense of science in policy and politics. Cambridge University Press, Cambridge, UK

Podevin N, Devos Y, Davies H *et al*. (2012). Transgenic or not? No simple answer! New biotechnology-based plant breeding techniques and the regulatory landscape. EMBO Reports, Science and Society 13(12): 1057-1061

Podevin N, Davies H, Hartung F *et al*. (2013). Site-directed nucleases: A paradigm shift in predictable, knowledge-based plant breeding. Trends in Biotechnology 31 (6): 375-83

Poort L & Bovenkerk B (2016). Changing expectations of experts: The symbolic role of Ethics Committees. In: Symbolic legislation Theory and developments in Biolaw, Van Klink B, van Beers B and Poort L (eds), Springer, 2016

Poort L (2013). Consensus and controversies in animal biotechnology: An interactive legislative approach to animal biotechnology in Denmark, Switzerland, and the Netherlands. Eleven International Publishing, 2013

Poort L (2016). The tension between the functions of law: ending conflict vs dynamics' in Bart van Klink, Britta Van Beers, Lonneke Poort (eds), Symbolic Legislation Theory and New Developments in Biolaw, Springer, 2016

Poort L, Holmberg T and Ideland M (2013). Bringing in the controversy: re-politicizing the de-politicized strategy of ethics committees. Life science, society and policy 9(11): 1-13

Princen S & Rhinard M (2006). Crashing and creeping: agenda-setting dynamics in the European UnionJournal of European Public Policy 13(7): 1119-1132

Princen S (2011). Agenda-setting strategies in EU policy processes, Journal of European Public Policy 18(7). 927-943

Punt M & Wesseler J (2015). Legal but costly: An analysis of the EU GM regulation in the light of the WTO Trade dispute between the EU and the USA. The World Economy 39(1): 158-169

Q

Qaim M, & Kouser S (2013). Genetically Modified Crops and food security. PLoS ONE 8(6): e64879

Quist D & Chapela IN (2001). Transgenic DNA introgressed into tradiational Maize ;andraces in Oaxaca, Mexico. Nature 414(5): 541-543

R

Racovita M (2017). Being scientific about Socio-Economics in GMO decision-making in developing countries. In: Genetically Modified Organisms in Developing Countries. Risk Analysis and Governance. AA Adenle, EJ Morris & DJ Murphy (eds.), Cambridge University Press, Cambridge, UK, pp. 115-127

Ramessar K, Capell T, Twyman RM *et al*. (2010). Going to ridiculous lengths – European coexistence regulations for GM crops. Nature biotechnology 28(2): 133-136

Randour F, Janssens C and Delreux T (2014). The cultivation of genetically modified organisms in the European Union: a necessary trade-off? Journal of Common Market Studies 52(6): 1307-1323

Raven P (2010). Does the use of transgenic plants diminish or promote biodiversity? New Biotechnology 27(5): 528–533

Ravetz JR (2006). Post normal science and the complexity of transitions towards sustainability. Econological complexity 3(4): 275-284

Rayner S & Malone EL (1998). Ten suggestions for policymakers. In: human choice and climate change vol. 4 what have we learned

Rees HA & Liu DR (2018). Base editing: precision chemistry on the genome and transcriptome of living cells. Nature Reviews Genetics 19(12): 770-788

RetractionWatch (2014). Retracted Seralini GMO-rat study republished. Available from: https://bit.ly/33mIZZ9 (Accessed 25 July 2020)

Reuters (2012). Science journal urged to retract Monsanto GM study. Reuters News, 30 November 2012
Ricroch AE, Amman K and Kuntz M (2016). Editing EU legislation to fit plant genome editing. EMBO Reports, science & society 17(10): 1365-1369

Rittel HWJ & Webber MM (1973). Dilemmas in a general theory of planning. Policy Sciences 4(2): 155-169
Robert C (2019). The political use of expertise in EU decision-making: the case of comitology. A report of the Greens, EP. Available from: https://bit.ly/39Eg4RH (Accessed 24 July 2020)

Roberts NC (2000). Wicked problems and networks approaches to resolution. International Public Management Review 1(1): 1–19

Robinson C (2013). Don't look, don't find: Health hazards of Genetically Modified Food. [Newsletter]. Journal of the Canadian Association of Naturopathic Doctors

Robinson C, Fagan J and Antoniou M (2016). GMO Myths and Truths. An evidence-based examination of the claims made for the safety and efficacy of genetically modified crops and foods. 3rd edition

Roco MC (2007). Possibilities for global governance of converging technologies. Journal of Nanoparticle Research 10(1): 11-29

Rodrigues JL & Rodrigues LR (2017). Synthetic biology: perspectives in industrial biotechnology. Current developments in biotechnology and bioengineering. Foundations of biotechnology and bioengineering 2017: Chapter 8: 239-269

Roeser S (2002). Ethical intuitions and rmotions: A philosophical study. [PhD diss.]. Amsterdam: Free University
Romeis J, Meissle M, Brunner S *et al*. (2013). Plant biotechnology: research behind fences. Trends in Biotechnology 31(4): 222-224

Rosi-Marshall EJ, Tank JL, Royer TV *et al*. (2007). Toxins in transgenic crop byproducts may affect headwater stream ecosystems. Proceedings of the National Academy of Sciences of the United States of America 9(104): 16204-16208

Rosner L (2004). The technological fix, how people use technology to create and solve social problems. New York: Routledge

Ruane J & Sonnino A (2011). Agricultural biotechnologies in developing countries and their possible contribution to food security. Journal of Biotechnology 156 (4): 356–363

Ruivenkamp G & Jongerden J (2010). Politiek in Convergerende Technologieën: Sociale Denkplaatsen Als Beleidsperspectief [Politics in Converging Technologies; Thinking Laboratories as Policy Option]. Bilthoven. Research report; no. CGM/2010-04 (in Dutch)

Rushefsky ME (1986). Making cancer policy. SUNY, Albany, NY

S

Saltelli A & Giampietro M (2017). What is wrong with evidence based policy, and how can it be improved? Futures, special issue on post-normal science in practice 91: 62-71

Saltelli A (2017). What is science crisis really about? Futures, special issue on post-normal science in practice 91: 5-11

Salter L (1988). Introduction to mandated science. In: Mandated Science. Environmental Ethics and Science Policy, vol 1. Springer, Dordrecht

SAM (2016). Scoping paper: new techniques in agricultural biotechnology. Scientific Advice Mechanism High Level Group of Scientific Advisors, 25 November, 2016

SAM (2017). New techniques in Agricultural biotechnology, Science Advice Mechanism, Directorate-General for Research and Innovation, European Commission

SAM (2017). New techniques in agricultural biotechnology. Explanatory note Scientific Scientific Advice Mechanism High Level Group of Scientific Advisors, March 2017

SAM (2018). A scientific perspective on the regulatory status of products derived from gene editing and the implications for the GMO Directive. Statement Scientific Advice Mechanism High Level Group of Scientific Advisors, November 2018

Sarewitz D & Pielke RA (2000). Breaking the global warming gridlock. Atlantic Monthly, July 2000

Sarewitz D (2004). How science makes environmental controversies worse. Environmental Science & Policy, 7(5): 385-403

Sarewitz D (2006). Liberating science from politics. American Scientist 94(2): 104

Sarewitz D (2011). Political effectiveness in science & technology. In: Science in the Context of Acpplication. Pp: 301-315

Sarewitz DR. & Frodemen (Ed.) (2000). Science and environmental policy: An excess of objectivity, earth matters: The earth sciences, philosophy, and the claims of community, Prentice Hall (2000), pp. 79-98

SCENIHR, SCCS, SCHER (2014) Synthetic Biology I Definition, Opinion. Scientific Committee on Emerging and Newly Identified Health Risks, Scientific Committee on Consumer Safety and Scientific Committee on Health and Environmental Risks, September 2014

SCENIHR, SCCS, SCHER (2015a) Synthetic Biology II - Risk assessment methodologies and safety aspects, Opinion. Scientific Committee on Emerging and Newly Identified Health Risks, Scientific Committee on Consumer Safety and Scientific Committee on Health and Environmental Risks, May 2015

SCENIHR, SCCS, SCHER (2015b) Synthetic Biology III – Research priorities, Opinion. Scientific Committee on Emerging and Newly Identified Health Risks, Scientific Committee on Consumer Safety and Scientific Committee on Health and Environmental Risks, December 2015

Scharpf FW (1996). Negative and positive integration in the political economy of European Welfare States. In: Marks G, Scharpf FW, Schmitter PC and Streeck W (eds) Governance in the European Union (London: Sage), pp. 15–39.Sharpf F (1999). Governing in Europe: effective and democratic? New York: oxford University Press

Schiemann J, Steinberg P and Salles B (2014). Facilitating a transparent and tailored scientific discussion about the added value of animal feeding trials as well as in vitro and in silico approaches with whole food/feed for the risk assessment of genetically modified plants. Archives of Toxicology 88(12): 2067-2069

Schiemann, J (2014). Open Letter to Testbiotech in Response to Its Report and Press Release. In: GRACE Consortium, 7 November 2014

Schiml S & Puchta H (2016). Revolutionizing plant biology: multiple ways of genome engineering by CRISPR/Cas. Plant Methods 12(8): 1–9

Schmidt M, Kella A, Ganguli-Mitra A *et al*. (2009). Synthetic biology, the technoscience and its societal consequences. Springer Science & Business media

Schön DA & Rein M (1994). Frame reflection: toward the resolution of intractable policy controversies. New York. Basic Books

Schön DA & Rein M (1996). Frame-critical policy analysis and frame-reflective policy practice. Knowledge and Policy 9(1): 85-104
Schwartz JP (2018). Political judgement confronts ideology: Hannah Arendt's contribution. Polity 50(3): 485-511

Science Magazine (2013). Switzerland creates secure test site for GM crops. Jop de Vrieze for Science Magazine, 28 February 2013

Scott D (2011). The technological fix criticism and the agricultural biotechnology debate. Journal of Agricultural and Environmental Ethics 24(2): 207-226

Selle K & Barrangou R (2015). CRISPR-Based technologies and the future of food science. Journal of Food science 80(11): 2367-2372

Selznick P (1992). The moral commonwealth: social theory and the promise of community. University of California Press
Seralini GE (2020). Update on long-term toxicity of agricultural GMOs tolerant to roundup. Environmental Sciences Europe 32(18): 1-7

Séralini GE, Claira E, Mesnage R *et al*. (2012). Long term toxicity of a Roundup Herbicide and a Roundup-Tolerant Genetically Modified Maize. Food and Chemical Toxicology 50(11): 4221-4231

Séralini GE, Mesnage R, Defarge N *et al*. (2013). Answers to critics: Why there is a long term toxicity due to a Roundup-tolerant genetically modified maize and to a Roundup herbicide. [Reply to letters to the editor]. Food Chem Toxicol 53: 476-483

Simon, HA (1973). The structure of ill-structured problems. Artificial Intelligence, 4(3–4), 181–201

Simon, HA (1977). Models of discovery and other topics in the methods of science. Dordrecht: Springer.

Skogstad G (2003). Legitimacy and/or policy effectiveness? network governance and GMO regulation in the European Union. Journal of European public policy 10(3): 321-338

Slob M (2006). Interview with Maarten Haier. In Zeker weten: in gesprek met politici, bestuurders en wetenschappers over omgaan met onzekerheid (Being certain: conversations with politicians, board members and scientists about handeling uncertainty). The Hague: Rathenau Institute (in Dutch)

Slovic P (2000). The perception of risk (Risk, society, and policy series). Michigan: Earthscan Publications

Smale M, Zambrano P, Gruère G *et al*. (2009). Measuring the economic impacts of transgenic crops in developing agriculture during the first decade: Approaches, findings, and future directions. Food Policy Review 10. International Food Policy Research Institute, Washington, D.C., USA

Smart RD, Blum M and Wesseler J (2015). EU member states' voting for authorizing genetically engineered crops: a regulatory gridlock. German Journal of Agricultural Economics 64(4): 244-262

Smart RD, Blum M and Wesseler J (2017). Trends in approval times for genetically engineered crops in the United States and the European Union. Journal of Agricultural Economics 68(1): 182-198

Smith A & Stirling A (2007). Moving oOutside or inside? Objectification and reflexivity in the governance of Socio-Technical systems. Journal of Environmental Policy & Planning 9(3-4): 351-373

Song C & Knöpfel T (2016). Optogenetics enlightens neuroscience drug discovery. Nature reviews drug discovery 15(2): 97-109

Sprink T, Eriksson D, Schiemann J *et al*. (2016). Regulatory hurdles for genome editing: process- vs. product-based approaches in different regulatory contexts. Plant Cell Reports 35(7): 1493-1506

Spruijt P (2014). Roles of scientists as policy advisers on complex issues: a literature review. Environmental science & Policy 40: 16-25

Spruijt P (2015). Differences in views of experts about their role in particular matter policy advice: Empirical evidence from an international expert consultation. Environmental Science & Policy 59: 44-52

Steele KS (2006). The precautionary principle: a new approach to public decision-making. Law probability and risk 5(1): 19-31

Stein AJ, Sachdev HPS and Qaim M (2006). Potential impact and cost-effectiveness of Golden Rice. Nature Biotechnology 24(10): 1200-1201

Steinberg P, Van der Voet H and Wilhelm R (2019). Lack of adverse effects in subchronic and chronic toxicity/carcinogenicity studies on the glyphosate-resistant genetically modified maize NK603 in Wistar Han RCC rats. Archives of toxicology 93(1): 1095-1139

Stemerding D & Asveld L (2016). Industrial biotechnology under the spotlights, Rathenau Institute, The Hague

Stemerding D (2017). NBIC convergence as a challenge for bioethics and biopolitics. Convergence of New Emerging Technologies. Ethical challenges and new responsibilities. Caenazzo L, Mariani L and Pegoraro P. Padova, Italy, Piccin Nuova Libraria: 23-62

Stephan HR (2012). Revisiting the transatlantic divergence over GMO's: toward a cultural-political Analysis. Global Environmental Politics 12(4): 104-124

Stirling A (2008). Opening up or closing down: analysis, participation and power in the social appraisal of technology. Science, Technology and Human Values 33(2): 262-294

Stirling A (2008). Science, precaution and the politics of technological risk. Converging implications in evolutionary and social scientific perspectives. Annals of the New York Academy of Sciences 1128(1): 95-110

Stirling A (2012). Opening up the politics of knowledge and power in bioscience. PLOS biology 10(1)

Stoker G & Evans M (2016). Connecting social science and policy. In: G. Stoker & M. Evans (Eds.), Evidence-based policy making in the social sciences: Methods that matter (pp.263-270). Bristol: Policy Press

Stone D (1988). Policy paradox, the art of political decision-making. Ww Norton & Co

Stoye E (2020). Coronavirusvaccine ready for human clinical trials, says US biotech company. Nature briefing, 25 February 2020

Stratulat C & Molino E (2011). Implementing Lisbon: what's new in comitology. European Policy Centre, 15 April 2011

Straus SH & Sax JK (2016). Ending event-based regulation of GMO crops. Nature 34(5): 474-477

Sustein CR (2005). Laws of fear: Beyond the Precautionary Principle. Cambridge university press

Sustein CRV (2009). Symposium of conspiracy theories. Conspiracy theories: causes and cures. Journal of political philosophy 17(2): 202-227

Swierstra T & Te Molder HFM (2012). Risk and soft impacts. In Roeser S, Sandin P, Peterson M (Ed.), Handbook of Risk Theory. pp. 1050 – 1066

T

Tagliabue G & Amman K (2018). Some basis for a renewed regulation of agri-food biotechnology in the EU. Journal of Agricultural and Environmental Ethics 31(1): 39-53

Tagliabue G (2016). European incoherence on GMO cultivation versus importation. Nature Biotechnology 34(7): 294-295

Tagliabue G (2017). The EU legislation on "GMOs" between nonsense and protectionism: An ongoing Schumpeterian chain of public choices. GM crops & Food 8(1): 57-73

Te Molder HFM (2011). Beyond happy science and grim technology: Science Communication in an Interactional Perspective. Publisher: Enschede: Universiteit Twente. Inaugurele rede bij de aanvaarding van het ambt van hoogleraar, 15 september 2011

Teich AH (1993). Technology and the future (6th ed.). New York: St. Martin's Press

Tepfer M, Racovita M and Craig W (2012). Putting problem formulation at the forefront of GMO risk analysis. GM crops and food 4(1): 10–15

Termeer CJAM, DeWulf ARPJ and Biesbroek R (2019). A critical assessment of the wicked problem concept: relevance and usefulness for policy science and practice. Policy and society 38(2): 167–179

Termeer CJAM, Dewulf ARPJ, Breeman GE *et al*. (2013). Governance capabilities for dealing wisely with wicked problems. Administration & Society 47(6): 680–710

Testbiotech (2015a). GRACE – The EU risk research project sold out to industry. Background document. Available from: https://bit.ly/3eZvBfP (Accessed 25 July 2020)

Testbiotech (2015b). Testbiotech files complaint about GRACE project. Ombudsman asked to investigate maladministration at the EU commission.

Testbiotech press release, 12 March 2015
Testbiotech (2019). Risk assessment of genetically engineered plants deemed insufficient. Press release 30 October 2019

The Economist (2013) Trouble at the lab. Scientists like to think of science as self-correcting. To an alarming degree, it is not. The Economist, Blog 19 October 2013

The Guardian (2015). Tens of thousands march worldwide against Monsanto and GM crops. The Guardian news, 24 May 2015

Then C & Bauer-Panskus A (2017). Possible health impacts of Bt toxins and residues from spraying with complementary herbicides in genetically engineered soybeans and risk assessment as performed by the European Food Safety Authority EFSA. Environmental Sciences Europe 29(1): 1

Thompson PB (1997). Food biotechnology in ethical perspective (Techniques and perspectives in Food Biotechnology 1). London: IFIS Publishing

Thompson PB (2015). How we got to now: why the US and Europe went different ways on GMOs. The Conversation, 6 November 2015

Tiberghien Y (2009). Competitive governance and the quest for Llegitimacy in the EU: The Battle over the Regulation of GMOs since the Mid-1990s. European Integration 31(3): 389–407

Tosun J & Hartung U (2018). Decentralising competences in multi-level systems. Insights from the regulation of genetically modified organisms. West European Politics 41(3): 803–823

Tosun J & Schaub S (2017). Mobilisation in the European public sphere: the struggle over genetically modified organisms. Review of policy research 34(3): 310–330

Tosun J & Shikano S (2015). GMO-free regions in Europe: an analysis of diffusion patterns. Journal of risk research 19(6): 743–759

Tosun J (2013). How the EU handles uncertain risks: understanding the role of the precautionary principle. Journal of European public policy 20(10): 1517–1528

Tosun J, Lelieveldt H and Wing TS (2018). A case of 'muddling through'. The politics of renewing glyphosate authorisation in the European Union. Sustainability 11(2): 1–18

Traavik T & Ching LL (2007). Biosafety First: Holistic approaches to risk and uncertainty in Genetic Engineering and Genetically Modified Organisms. Tapir Academic Press

Treib O (2010). Party politics, national interests and government – Opposition dynamics cleavage structures in the Convention Negotiations on EU social policy. European Union Politics 11(1): 119–42

Trump B, Cummings C, Kuzma J *et al*. (2017). A decision analytic model to guide early-stage government regulatory action: Applications for synthetic biology. Regulation & Governance 12(1): 88–100

Tung OJ (2014). Transboundary movements of genetically modified organisms and the Cartagena Protocol: Key issues and concerns. Potchefstroom Electronic Law Journal 17(5): 1739–1787

Turnbull N & Hoppe R (2018). Problematizing 'wickedness': a critique of the wicked problems concept, from philosophy to practice. Policy and society 28(2):315–337

U

Unterweger J (2017). Ethics and pesticides: The precautionary principle as illustrated by Glyphosate. In: The Role of Integrity in the Governance of the Commons; Westra L, Gray J, Gottwald F, Eds.; Springer: Cham, Switzerland, 2017; pp. 215–223

USDA (2013). Organic 101: Can GMOs be used in organic products? USDA Blog, United States of America Department of Agriculture (USDA), Washington, D.C., USA. Available from: https://bit.ly/2WYcCw1 (Accessed 25 July 2020)

V

Van Asselt MBA & Vos E (2006). The precautionary principle and the uncertainty paradox. Journal of Risk Research 9(4): 313–336

Van Asselt MBA & Vos E (2010). Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox. Journal of Risk Research 11(1–2): 281–300

Van der Burg W & Brom FWA (2000). Legislation on ethical issues: towards an interactive paradigm. Ethical theory and moral practice 3(1): 57–75

Van der Burg W (2014). The dynamics of law and morality: A pluralist account of legal interactionism Ashgate, 2014

Van der Burg W (2016). The emerging interactionist paradigm and the ideals of democracy and rule of law. In: Bart van Klink, Britta van Beers, Lonneke Poort (eds), Symbolic Legislation Theory and New Developments in Biolaw (Springer, 2016) Chapter 3, 37–53

Van der Linden S (2013). Moon landing faked!!! - Why people believe in conspiracy theories. Scientific American, 30 April 2013

Van Haperen PF, Gemmen B and Jacobs J (2012). Reconstruction of the ethical debate on naturalness in discussions about plant-biotechnology. Journal of Agricultural and Environmental Ethics 25(6): 797–812

Van Hove L & Gillund F (2017). Is it only the regulation? Broadening the debate on cisgenic plants. Environmental Sciences Europe 29(1): 22-31

Van Oudheusden M (2014). Where are the politics in responsible innovation? European Governance, Technology Assessments, and Beyond. Journal of responsible innovation 1(1): 67-86

Vidal J (2012a). Study linking GM maize to cancer must be taken seriously by regulators. Environment Blog (pp. Comment by user 'Shoe' on September 28, 2012 at 7:53pm): The Guardian, 28 September 2012

Vidal J (2012b). Study linking GM maize to cancer must be taken seriously by regulators. Environment Blog (pp. Comment by user 'SouT' on September 28, 2012 at 7:30 pm): The Guadian, 28 September 2012

Vidal J (2012c). Study linking GM maize to cancer must be taken seriously by regulators Environment blog (pp. Comment by user 'dusha100' on September 28, 2012 at 7:32 pm): The Guardian, 28 September 2012

Vidal J (2012d). Study linking GM maize to cancer must be taken seriously by regulators. Environment blog: The Guardian, 28 September 2012

Vives-Vallés JA & Collonnier C (2020). The judgment of the CJEU of 25 July 2018 on Mutagenesis: Interpretation and interim legislative proposal. Research topic Leeway to operate with plant genetic resources, Frontiers in Plant Science

Voß J, Bauknecht D and Kemp R, eds. (2006). Reflexive governance for sustainable development. Cheltenham, UK: Edward Elgar

W

Wager R & McHughen A (2010). Zero sense in European Approach to GM. EMBO reports 11(4): 258-262

Waigmann E, Gomes A, Lanzoni A *et al*. (2013). Editorial: New Commission implementing regulation on risk assessment of GM plant applications: novel elements and challenges. EFSA journal 11(12): e11121

Waldron J (1999). Law and Disagreement Oxford: Oxford University Press

Wardekker JA, Van der Sluijs JP, Janssen PHM *et al*. (2008). Uncertainty communication in environmental assessments: Views from the Dutch Science-Policy Interface. Environmental Science & Policy 11(7): 627-641

Warner M. (2002). Publics and counterpublics (abbreviated version). Quarterly Journal of Speech 88(4): 413-425

Weible CM & Cairney P (2018). Practical lessons from policy theories. Policy & Politics 46(2): 183-197

Weimer M (2010). Applying precaution in EU authorisation of genetically modified products – challenges and suggestions for reform. European Law Journal 16(5): 624-657

Weimer M (2015) Risk regulation and deliberation in EU administrative governance – GMO regulation and its reform. European Law Journal 21(5): 622-640

Weimer M (2019). Regulation of agricultural biotechnology as a wicked problem. In Risk regulation in the internal market: lessons from Agricultural biotechnology. Oxford University Press

Weinberg AM (1969). Reflections on big science. Cambridge, MA: MIT Press

Weingart P (1997). From finalization to mode 2: old wine in new bottles? Social Science Information 36 (4): 591–613

Weingart P (1999). Scientific expertise and political accountability: paradoxes of science in politics. Science Public Policy 26(3): 151–161

Weingart P (2008). How robust is socially robust knowledge? In: The Challenge of the Social and the Pressure of Practice: Science and Values ReAccessed. Carrier M, Howard D, Kourany J (Eds); Pittsburgh: University of Pittsburgh Press: pp 131–145

Weiss C (2003). Scientific uncertainty and science-based precaution. International Environmental Agreements 3(2): 137–166

Weiss C (2006). Precaution: the willingness to accept costs to avert uncertain danger. In: Marti K, Ermoliev Y, Makowski M, Pflug G (Eds.), Coping With Uncertainty; Modeling and Policy Issues, 581. Springer-Verlag, Berlin Heidelberg, pp. 315–330

Wellstead A, Cairney P and Oliver K (2018). Reducing ambiguity to close the science-policy gap. Policy design and Practice 1(2): 115-125

Wesseler J, Smart RD, Thomson J *et al*. (2017). Foregone benefits of important food crop improvements in Sub-Saharan Africa. PLoS One 12(7): e0181353

Wesselink A & Hoppe R (2011). If post normal science is the solution, what is the problem? The politics of activist environmental science. Science technology & human values 36(3): 389-412

Williams AW (1999). Examination of Witnesses (Questions 240 - 259). In: Committee on Science and Technology Testimony of Professor Philip James and Dr. Andrew Chesson ed. UK Parliament Homepage

Woegerbauer M, Stepanek W and Brueller W (2016). GRACE: no place for doubts? An endorsement for communicating uncertainty in scientific assessments. Archives of Toxicology 90(12): 3139-3141

Wolt JD, Kan W and Bing Y (2016). The regulatory status of genome-edited crops. Journal of Plant Biotechnology 14(2): 510-518

Wolt J, Keese P, Raybould A et al. (2010). Problem formulation in the environmental risk assessment for genetically modified plants. Transgenic Research 19(3):425-436

World Politics Review (2019). Why African countries maintain tight restrictions on genetically modified food. Avaliable from: https://bit.ly/32RMneo (Accessed 25 July 2020)

Worstall T (2012). Monsanto's GM corn and cancer in rats: real scientists deeply unimpressed. Politics not science perhaps? (pp. comment by user 'Memsomerville' on September 20, 2012 at 9:35 pm): Forbes Magazine tech blog

Wynne B (1989). Sheepfarming after Chernobyl: A case study in communicating scientific information. Environment. Science and Policy for Sustainable Development 31(2): 10-39

Wynne B (1991). Knowledges in context. Science, Technology & Human Values 16(1): 111-121

X

Xiang WN (2013). Working with wicked problems in socio-ecological systems: Awareness, acceptance, and adaptation. Landscape and Urban Planning, 110(1): 1–4

Z

Zaidi SS, Vanderschuren H, Qaim M *et al*. (2019). New plant breeding technologies for food security. Science 363(6434): 1390-1391

Zander J (2010). The Aapplication of the precautionary principle in practice. Comparative Dimensions. Cambridge: Cambridge University Press

Zdjelar G & Nikolic Z (2013). Genetically modified crops – A potential risk for sustainable agriculture. Environmental Science

Zettenberg C & Edvardsson Björnberg K (2017). Time for a new EU regulatory framework for GM crops? Journal of Agricultural and Environmental Ethics 30(3): 325–347

Zimmerman R & Qaim M (2004). Potential health benefits of Golden Rice: A Philippine case study. Food Policy 29(2): 147-168