



Genetically Modified Organisms and the Precautionary Principle

Insights from Bulgarian Parliamentary Debates since 2003



The RECIPES project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824665

Authors

Ventseslav Kozarev, Applied Research and Communications Fund

Zoya Damianova, Applied Research and Communications Fund

Desislava Asenova, Applied Research and Communications Fund

Manuscript completed in April 2020

Document title	Genetically Modified Organisms and the Precautionary Principle: Insights from the Bulgarian Regulatory Experience since 2003
Work Package	WP2
Document Type	Internal Document
Date	April 2020
Document Status	Final

Acknowledgments & Disclaimer

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 824665.

Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the following information. The views expressed in this publication are the sole responsibility of the author and do not necessarily reflect the views of the European Commission.

Reproduction and translation for non-commercial purposes are authorised, provided the source is acknowledged and the publisher is given prior notice and sent a copy.

Abstract

Genetically modified organisms (GMOs) are the product of advanced biotechnology and are non-naturally occurring plants, animals and microorganisms whose genomes have been altered intentionally and artificially. The modification is typically achieved by inserting a gene from another, often unrelated, organism into the DNA of the host, with the intention of introducing a new trait. Despite their numerous applications, commonly GMOs are most frequently associated with crops and foods.

This case study looks into the evolution of the Bulgarian regulatory context around GMOs and the ensuing policy discourse, with the intention to investigate and demonstrate the relevance of the precautionary principle and its integration within legislative and broader debates in the country. It recounts the legislative experience in the adoption of the Law on Genetically Modified Organisms (LGMO), and on key amendments in the period 2003-2017.

While derived from EU law, the Bulgarian LGMO is considered to be rather conservative and restrictive, and is discussed in this study as an example of a strong precautionary principle - adopting explicitly cautious approach to risk management. The case also demonstrates how scientific uncertainty can translate into legislative uncertainty, due to different interpretations and perceptions of the scope, severity and impact of risks. It concludes with a short discussion of the repercussions on innovation, narratives on which were entirely absent from the Bulgarian parliamentary debate on the LGMO.

Table of Contents

Abstract	ii
1 Introduction	1
1.1 Introduction	1
1.2 Key timeline	3
2 Potential benefits	4
3 Scientific uncertainty about risks	7
3.1 Risk/threat	7
3.2 Scientific analysis	9
3.3 Scientific uncertainty, complexity and ambiguity	11
3.4 Relevance of the PP to the case	14
4 Risk governance and the precautionary principle	15
5 The precautionary principle and its future	21
5.1 Reflection on the PP in the literature	21
5.2 Effect of the PP on innovation pathways	23
5.3 Innovation principle	23
6 Synthesis	25
7 Conclusion	26
8 References	26

List of abbreviations

- HGT** Horizontal transfer of recombinant genes
- GA** Grant Agreement
- GM** Genetic modification
- GMO** Genetically modified organism
- LGMO** [Bulgarian] Law on the genetically modified organism

1 Introduction

1.1 Introduction

The advances in biotechnology and the ever increasing knowledge in the fields of genomics over the last quarter of the 20th century have enabled the emergence of science-based industries with allegedly huge transformational and innovation potential. Genetically modified organisms (GMOs) have gained public attention at the end of the 20th century¹ and have since been the subject of controversies and disagreements – both within the community of scientists and experts, among politicians, and within the general public. The scope of these disagreements has typically remained focused on three main concerns: the effect that GM-derived foods have on human health; the impact that GM crops have on the environment and biodiversity; and the overall socio-economic impacts of GM-focused agriculture.¹

The “term” GMO is widely and popularly understood to refer to any plants, animals and micro-organisms whose genomes have been altered through biotechnology resulting in a non-naturally occurring species. In the EU, they are subject to strict regulation with a common regulatory framework, supplemented by a range of national solutions in the different member states that build upon, extend or restrict the EU regulations. To the general public, however, GMOs are commonly associated with certain foods and crops, while other applications, such as drug-producing bacteria, farm animals, soil bacteria or even more novel approaches such as plant-derived vaccination², are largely unknown.

This case study looks into the evolution of the Bulgarian regulatory context around GMOs and the ensuing policy discourse, with the intention to investigate and demonstrate the relevance of the precautionary principle and its integration within legislative and broader debates in the country. It recounts the legislative experience in the adoption of the Law on Genetically Modified Organisms (LGMO), and on key amendments in the period 2003-2017. It attempts to explain how legislative decisions are influenced, or not, by arguments of precaution and science, and how very often these arguments were challenged by a great degree of uncertainty and socially constructed perception of risks. The study does not offer any assessment or normative conclusions regarding the alleged or potential benefits, harms, safety or threats of GMOs or related technologies.

The case starts by presenting some general aspects that are not country specific, around GMOs and establishes the main issues that make this a contentious subject. Therefore, the intention of the authors is to make the case study interesting to a broader audience, while using the specificity of the Bulgarian experience to contribute to the wider understanding of the GMO debate.

In Bulgaria the regulatory framework on GMOs is defined mostly in the Law on Genetically Modified Organisms (LGMO). It was submitted to the Parliament in July 2003, and was enacted into law almost two full years later – in March 2005, entering into effect on June 1st 2005. Effectively, parliamentary debates on this initial draft took around a year, with 6 months passing from the draft’s submission to the first plenary debate on February 12th 2004.³

¹ Jennings, R.C. (2015). “Conflicting Values in the GM Food Crop Debate”, *Journal of Clinical Research and Bioethics*, vol.6(5)

² Phillips, T. (2008). “Genetically modified organisms (GMOs): Transgenic crops and recombinant DNA technology”. In *Nature Education*, vol.1(1).

³ Details of the debate can be seen in Bulgarian language at <https://parliament.bg/bg/plenaryst/ns/1/ID/1278>.

Since its initial adoption the LGMO has been amended 17 times, the last time in 2017, or about once every year on average. The most significant changes were made in 2010 when amendments or additions were made to more than 220 of the law's articles. Between 2011 and 2016, in comparison, less than a total of 30 changes have been made, with most of them editorial, reflecting changes in names of different regulatory bodies concerned. The amendment adopted in 2017 (last one at the time of writing this case) introduced further 70 changes, with most providing greater detail on various administrative procedures.⁴ Thus, the most significant overhaul of the LGMO was done in 2010, which also coincided with heightened public attention to the law itself, lengthy debates in parliamentary committees and in the plenary, as well as by a spike in the number of media publications on the topic.⁵ As Bulgaria is an EU Member State, the regulatory framework is based closely on the relevant EU directives and regulations.

The LGMO refers directly to the precautionary principle, and explicitly states as its primary objective the need to ensure protection of the human health and the environment from any hazards resulting from the activities it sought to regulate. These are explicitly specified to include any work with GMOs in contained environment, deliberate release of GMOs in the environment, release to the market of GMOs or combination of GMOs as single products or product ingredients, the relocation, transportation, import and export of GMOs, and further specifies the scope of management and control of these activities.

In early 2010 the national GMO debate suddenly expanded to the general public, as the proposed amendments were effectively ending some of the restrictions on GMOs and would allow the deliberate release of GMOs into the environment. This triggered serious public outcry, resulting in heightened pressure on the Government and the Parliament. MPs from the governing party proposed a draft for a resolution to ban any GMO-related activities, contained use, deliberate release within Bulgarian territory – at the very same time as the Government had proposed amendments to the LGMO. Following a series of public protests heated parliamentary debate, and heightened media attention, the final redaction of the proposed amendments to the LGMO effectively made it impossible for any GMO release into the environment, including field trials, and imposed stricter regulation and control on contained use, as well as stricter risk management procedures.

To prepare this case study, the authors have reviewed scientific articles, popular (science) blogs and web sources, a number of EU policy regulations, several Bulgarian laws that provide the regulatory framework on GMOs, transcripts of debates in plenary and in parliamentary standing committees, particularly in the period 2003-2005 when the law was first adopted, and in early 2010 when the largest and most significant changes were introduced. Several interviews with scientists (plant biologists, molecular biologists and geneticists) from Bulgaria and France were carried out to help frame the scope of the case and improve our own understanding of the scientific discourse on GMOs. Unfortunately, several scientists and former Members of Parliament, all of whom had taken part in the legislative debates on the LGMO since 2003, either declined or did not respond to our invitations for an interview, so their insights could not be included. Therefore, the case takes into account only their official positions at the time, as recorded in parliamentary transcripts.

⁴ Numbers are based counting the number of changes per each amendment to the law, as reported in the digital version of the LGMO available at <https://www.lex.bg/laws/ldoc/2135501153>.

⁵ That spike is clearly visible through a simple browsing through and counting media publications containing references to GMOs in the title, and is further evidenced through Google Trends analysis, indicating peak popularity of the search term "GMO" (in Bulgarian) of 100 (the maximum score, indicating the most popular search term over a given period) for February 2010, as shown at <https://trends.google.com/trends/explore?date=all&geo=BG&q=%D0%93%D0%9C%D0%9E>.

The case attempts to demonstrate the relevance of the precautionary principle to GMOs, with a particular reference to their use as food and feed, which is where the majority of current controversies are. We chose to look more closely at the Bulgarian regulatory experience as a specific example of how GMO regulations are being impacted by precautionary reasoning, public sentiments, and compatibility requirements with the EU regulatory framework.

1.2 Key timeline

The following table presents a summary of relevant developments that contributed to the development of the regulatory framework and the overall perception of GMOs. As it is not possible to include all relevant historic milestones, a priority for inclusion was given to events and facts referred to in the case study.

	<i>Political</i>	<i>Science/risk assessment</i>	<i>Public debate</i>
Year	Event	Relevance to case study	
1973	Scientists Herbert Boyer and Stanley Cohen develop a method to transfer a gene from one strain of bacteria into another	This achievement is considered the first example of a GMOs and spurs the development of the field	
1987	First time genetic modification is used in crops for food	This opens up the discussions on risks to human health and gives rise to controversies within society	
1992	The UN adopts the Rio Declaration of Environment and Development	The declaration provides the classic definition of a precautionary approach that later gives shape to the legal Precautionary Principle used by the European Commission	
2000	The Bulgarian Parliament ratifies the Cartagena Protocol on Biosafety to the Convention of Biological Diversity	The protocol is a key international agreement which aims to ensure the safe handling, transport and use of living modified organisms resulting from modern biotechnology (including GMOs) that may have adverse effects on biological diversity, taking also into account risks to human health. The Cartagena Protocol recognises that biological diversity can be faced with risks from GMOs. It embodies the Precautionary Principle to allow signatory states to take protective measures against possible threats and damages from GM foods and crops.	
2003	The Cartagena Protocol on Biosafety enters into force The draft of the first Bulgarian Law on Genetically Modified Organisms is submitted to the Parliament	The LGMO is the principle legislative document regulating GMOs, specifically contained use, deliberate release, release to the market, risk assessment and control procedures. It refers to the Precautionary Principle.	
2005	The Bulgarian LGMO enters into force.	Bulgaria has a dedicated law regulating contained use, deliberate release to the environment and release to the market of GMOs, which embodies the precautionary principle and provides measures to ensure safety, risk assessment and management, as well as administrative sanctions.	
2010	Public protests and heightened media attention to GMOs, in response to proposed amendments to the LGMO Most significant amendments adopted to the LGMO	The beginning of 2010 saw the most significant changes to the LGMO, but due to public pressure, the Law remained restrictive, effectively banning experiments in the field, deliberate release and release to the market of GMOs.	

2 Potential benefits

Discussing benefits – real or claimed – of GMOs is still a subject of controversy and disagreement. This study does not make an attempt to advocate for, to endorse, or in any other way to argue for the value of any claimed benefits. That would require a different method, or at least a far broader scope. Any of the benefits claimed by the authors cited are perhaps the subject of denial from others, but here benefits are listed from an exploratory perspective – to provide the reader with the list of the typical benefits associated to GMOs.

Genetically modified organisms are “plants, animals or microorganisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination”.⁶ A major premise behind GMOs is that through the underlying techniques used to produce them it has become possible to change certain plants and organisms and have them obtain a new trait or property – resistance to disease, insects, weather impacts, tolerance to particular herbicides, improving nutritional values or yields.⁷ In principle, a GMO is the product of the so-called recombinant DNA, which enables the transfer of genes from one organism to another, including from an unrelated one.⁸ Hence, GMOs are also seen as products that “do not occur naturally by mating and/or natural recombination.”⁹ Other authors additionally emphasise that GMOs are necessarily the product of biotechnological modification.¹⁰ The first successful genetically modified organism is attributed to scientists Herbert Boyer and Stanley Cohen in 1973, who developed a method allowing them to transfer a gene from one strain of bacteria into another, making the latter resistant to antibiotics.¹¹ This was followed by several other successful applications of the technology in the delivery of commercially viable products with clear and undisputed benefits (such as insulin producing bacteria or bacteria for oil spill mitigation). It also sparked ongoing debate within and outside science on the potential ramifications and consequences on human health, ecosystems and the environment. Most subjected to controversy was the use of genetic modification in crops and food, once the latter became a reality in the late 1980s.

GM technology enables the transfer of (useful) characteristics among unrelated species, by taking genetic material from one species and transferring it to the genome of another, resulting, in theory, in an allegedly improved product. Each organism (and particularly plants and crops) is modified for a different purpose – herbicide tolerance, insect resistance, altered nutritional value being the most typical. Thus, benefits of GMOs (and in many cases – also the risks) can as well be viewed on a micro-level – down to the specific organism and desired trait.

On a more general level, Zhang et al (2016)⁸ outline three key reasons why GMOs have received so much attention and why the technology is often being seen as an opportunity for innovation. These arguments have been the cornerstone of GMO proponents, and are

⁶ Definition by the World Health Organisation, available at https://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/.

⁷ See https://ec.europa.eu/food/plant/gmo_en.

⁸ Zhang, C., Wohlhueter, R. & Zhang, H. (2016). “Genetically modified foods: A critical review of their promise and problems”. In *Food Science and Human Wellness*, vol. 5(3), pp.116-123.

⁹ Food and Agriculture Organization of the United Nations (2016). <http://www.fao.org/docrep/005/y2772e/y2772e04.htm>

¹⁰ See for example Oliver, M. J. (2014). “Why we need GMO crops in agriculture”, In *Missouri medicine*, vol. 111(6).

¹¹ Rangel, G. (2015). “From Corgis to Corn: A Brief Look at the Long History of GMO Technology”. In *Science in the News*. Harvard University. Available at <http://sitn.hms.harvard.edu/flash/2015/from-corgis-to-corn-a-brief-look-at-the-long-history-of-gmo-technology/>.

widely accepted as truthful and legitimate narratives by GMO scientists and commercial producers.

The first such reason is the rapid growth of the global human population, with expectations for growth surpassing 2 billion more people by 2050. Population growth is seen as the direct cause for the growth in undernourished people and is the source for concern regarding future food security and supply. This is seen as an acute challenge for developing countries where malnourishment is a chronic problem. This argument in particular has come under criticism, however, since for the period that GMOs have been in existence, little has changed globally to solve food shortages.¹² On the other hand, a particular kind of modified rice – the so-called *Golden Rice* – is frequently provided as an example (though not without dispute) how GMOs might improve nutritious values – by enhancing rice to produce vitamin A, which is of critical shortage in diets across countries in Africa and South-East Asia.¹³

A second reason to give rise to GMOs, as outlined by Zhang (2016), is the decrease in arable land globally. According to the FAO, it is expected that by 2050, the amount of arable land available for food production will dwindle down by 25% compared to today.¹⁴ This poses a very serious challenge that further compounds the effect of the population increase and potential food shortages, and requires innovative ways to ensure food production can still satisfy global demand. The goal would be to attain greater yield by unit of land, which would require either changes in agricultural practices – such as increased use of fertilisers and water, or genetic modifications to enable higher yields, or both. Either scenario entails further challenges – i.e. continuing urbanisation, increasing demand for biofuels, soil erosion and pollution, climate change and water scarcities.

The third reason has to do with the long-time horizons and limited scalability of conventional breeding, if it is to be relied upon for the expression of certain desired property or trait. Selecting such traits requires years-long process of identifying and selecting the best progeny, and even more years to confirm the new trait and have it commercially available. Biologically, however, such strategies depend on the availability of rich genetic variety, and this is frequently found to be decreasing, turning the attention to other technological solutions – such as utilising chemicals or radiation to induce genetic mutations. None of these, however, have any guarantee to deliver the desired outcome, but depend mostly on random chance, which increases the uncertainty of the outcomes. GMOs on the other hand, are the product of an allegedly more precise and more targeted intervention – down to a particular gene responsible for the desired trait. The technology thus supposedly eliminates the reliance on chance, but the time needed from the lab to the market typically is also considerable and takes several years in order to perform all required assessments of safety and environmental impacts.

The above reasons are frequently used to demonstrate the comparative attractiveness, and alleged economic viability of resorting to biotechnology in order to (comparatively quickly) develop new traits and characteristics of food plants. Thus it is more common to argue for the benefits of GMOs in terms of adding opportunity – to reduce costs in agriculture, to increase the nutritional value of certain crops, to help conserve national habitats, to eliminate or at least put under control plant disease. Many of these alleged benefits however are commonly linked to commercial interests, and sometimes to specific

¹² ____ (2012). "Are Genetically Altered Foods the Answer to World Hunger?". In *Earth Island Journal*. Published online at https://www.earthisland.org/journal/index.php/magazine/entry/are_genetically_altered_foods_the_answer_to_world_hunger/.

¹³ Jamil, Kaiser (no date). "Biotechnology – A Solution to Hunger?". In *UN Chronicle*. Published online at <https://www.un.org/en/chronicle/article/biotechnology-solution-hunger>.

¹⁴ Alexandratos, N. & Bruinsma, J. (2012). World agriculture towards 2030/2050: the 2012 revision.

corporations hosting and sponsoring the research, marketisation and commercialisation of GM crops. This makes it particularly challenging to provide an unbiased and credible assessment of the extent to which benefits can be transferred onto end consumers. Following is a brief attempt to group the most commonly cited (macro) *benefits* in the body of literature reviewed by the authors of the case. These alleged benefits are not undisputed either, clearly exemplifying the scope of disagreement underlying the GMO narratives.

- *Agricultural benefits.* It is estimated that since the adoption of GM technology in agriculture, globally GMO crops have accounted for additional “138 million tons of soybeans, 274 million tons of corn, 21.7 million tons of cotton lint, and 8 million tons of canola.”¹⁵ Without the added yields of the GMO crops, authors argue, between 11% and 23% more arable land would have been needed to produce an equivalent amount. As crops are frequently modified to become resistant to weather influences or tolerant to herbicides and pesticides, however, GMOs result in changing agronomic practices – alleged reductions in quantities used or a preference towards a particular brand, novel chemicals used as herbicides and pesticides, with consequences to the surrounding ecosystems.
- *Economic benefits.* Increased yields of production result in increased income for the producing farms. According to some authors, 42% of the income gain was due to the increased yield resulting from genetic modification and resistance to pests and weeds, while the decreased costs of production due to reduced usage of pesticides and herbicides accounted for the other 58%.^{15,16}
- *Nutritional benefits.* Certain genetic modifications enable the enriching of certain nutrients or substances with proven therapeutic effects or highly regarded health value, such as vitamins or unsaturated fatty acids. Other examples include alterations in the amino acid composition of proteins or the content of carbohydrates, or changes in enzyme presence.¹⁷
- *Enhanced food qualities.* Certain modifications have aimed at improving the appearance of the products or to delay ripening (i.e. in tomatoes) in order to allow longer shelf life. There are further examples where genetic modification has been carried out on animal species, such as salmon, to accelerate growth by modifying the production of growth hormones or increase body mass. It is argued that such fish would significantly reduce the negative pressure from overfishing in wild populations.¹⁸
- *Enabling therapeutics.* There is ongoing research into altering specific plants (rice, soybeans, maize and potatoes) so that they can produce specific antigens as vaccine to certain diseases.¹⁹

A differently targeted look into benefits of GMOs carried out by Klümper and Qaim (2014)²⁰ further argues for agronomic and economic benefits, but highlights that impacts vary both

¹⁵ Brookes, G. & Barfoot, P. (2014). “Economic impact of GM crops: the global income and production effects 1996–2012”. In *GM crops & food*, vol. 5(1), pp. 65-75.

¹⁶ James, C. (2013). Global Status of Commercialized Biotech/GM Crops: 2013. *ISAAA Brief No. 46*.

¹⁷ Kramkowska, M., Grzelak, T. & Czyzewska, K. (2013). “Benefits and risks associated with genetically modified food products”. In *Annals of Agricultural and Environmental Medicine*, vol. 20(3).

¹⁸ Chandler, S. & Dunwell, J. M. (2008). “Gene flow, risk assessment and the environmental release of transgenic plants”. In *Critical reviews in plant sciences*, vol. 27(1), pp. 25-49.

¹⁹ Abeyundara, A.T., Aponso, M. & De Silva, G.O. (2017). “A review on edible vaccines: A novel approach to oral immunization as a replacement of conventional vaccines”. In *International Journal of Food Science and Nutrition*, vol. 2(4).

²⁰ Klümper, W. & Qaim, M. (2014). “A meta-analysis of the impacts of genetically modified crops”. In *PloS one*, vol. 9(11).

by trait and by region, with yields from GM crops being higher in developing countries than in developed ones. The authors further claim that NGO reports and non-scientifically reviewed publications were found to be more likely to report lower estimates of positive impacts of GM crop benefits than ones published in peer-reviewed journals. These differences are found to be evidence of the continuing disagreement (although without delving into the causes thereof) on the positive effects of GM crops.

3 Scientific uncertainty about risks

3.1 Risk/threat

If benefits of GMOs, particularly crops and food, are contested, so are their risks. Even though a genetic modification is deliberately introduced in the host organism to enable the transfer of a beneficial trait from the origin species, it also poses a risk, whose scope may not be immediately clear. The consequences of the transfer may not be known and may not be predictable.²¹

A detailed and thorough summary of risks and threats of GMOs are provided by Prakash et al (2011), and is displayed as Table 1 below:²⁹

Table 1 Summary of risks of GMO and their impacts (source Prakash et al, 2011)

Risk	Impact
<i>Genetic Contamination/Interbreeding</i>	<i>Introduced GMOs may interbreed with the wild-type or sexually compatible relatives. The novel trait may disappear in wild types unless it confers a selective advantage to the recipient. However, tolerance abilities of wild types may also develop, thus altering the native species' ecological relationship and behaviour.</i>
<i>Competition with Natural Species</i>	<i>Faster growth of GMOs can enable them to have a competitive advantage over the native organisms. This may allow them to become invasive, to spread into new habitats, and cause ecological and economic damage.</i>
<i>Increased Selection Pressure on Target and Nontarget Organisms</i>	<i>Pressure may increase on target and nontarget species to adapt to the introduced changes as if to a geological change or a natural selection pressure causing them to evolve distinct resistant populations.</i>
<i>Ecosystem Impacts</i>	<i>The effects of changes in a single species may extend well beyond the ecosystem. Single impacts are always joined by the risk of ecosystem damage and destruction.</i>

²¹ Ellstrand, N. C., Prentice, H. C., & Hancock, J. F. (1999). "Gene flow and introgression from domesticated plants into their wild relatives". In *Annual review of Ecology and Systematics*, vol. 30(1), pp. 539-563.

Risk**Impact**

<i>Impossibility of Follow-up</i>	<i>Once the GMOs have been introduced into the environment and some problems arise, it is impossible to eliminate them. Many of these risks are identical to those incurred with regards to the introduction of naturally or conventionally bred species. But still this does not suggest that GMOs are safe or beneficial, nor that they should be less scrutinised.</i>
<i>Horizontal Transfer of Recombinant Genes (HGT) to Other Microorganisms</i>	<p>HGT is the acquisition of foreign genes (via transformation, transduction, and conjugation) by organisms in a variety of environmental situations. It occurs especially in response to changing environments and provides organisms, especially prokaryotes, with access to genes other than those that can be inherited.</p> <p>HGT of an introduced gene from a GMO may confer a novel trait in another organism, which could be a source of potential harm to the health of people or the environment. For example, the transfer of antibiotic resistance genes to a pathogen has the potential to compromise human or animal therapy. HGT has been observed for many different bacteria, for many genes, and in many different environments. It would therefore be a mistake to suppose that recombinant genes would not spread to other bacteria, unless precautions are taken. Recent evidence from the HGT technology confirms that transgenic DNA in GM crops and products can spread by being taken up directly by viruses and bacteria as well as plant and animals cells.</p>
<i>Adverse Effects on the Health of People or the Environment</i>	These include enhanced pathogenicity, emergence of a new disease, pest or weed, increased disease burden if the recipient organism is a pathogenic microorganism or virus, increased weed or pest burden if the recipient organism is a plant or invertebrate, and adverse effects on species, communities, or ecosystems.
<i>Unpredictable and Unintended Effects</i>	HGT may transfer the introduced genes from a GMO to potential pests or pathogens and many yet to be identified organisms. This may alter the ecological niche or ecological potential of the recipient organism and even bring about unexpected changes in structure or function. Furthermore, the gene transferred may insert at variable sites of the recipient gene, not only introducing a novel gene but also disrupting an endogenous gene, causing unpredictable and unintended effects.

Risk

Impact

<i>Loss of Management Control Measures</i>	Regulatory approvals for field trials of GMOs often require measures to limit and control the release in space and time. With the spread of the introduced gene(s) to another species by HGT, a new GMO is created. This new GMO may give rise to adverse effects which are not controlled by management measures imposed by the original license or permit.
<i>Long-Term Effects</i>	Sometimes the impact of HGT may be more severe in the long term. Even under relatively strong selection pressure, it may take thousands of generations for a recipient organism to become the dominant form in the population. In addition, other factors such as timing of appropriate biotic or abiotic environmental conditions and additional changes in the recipient organism could delay adverse effects.
<i>Ethical Concerns</i>	Various ethical issues associated with HGT from GMOs have been raised including perceived threats to the integrity and intrinsic value of the organisms involved, to the concept of natural order and integrity of species, and to the integrity of the ecosystems in which the genetically modified organism occurs.

3.2 Scientific analysis

Although GMOs are understood as products of novel biotechnology and have received wider public attention over the past 30 to 40 years, attempting the promotion of certain desirable traits has been practiced for thousands of years through artificial selection and selective breeding, which involves careful selection of parental organisms exhibiting those traits and breeding them to propagate these traits in subsequent generations.²² Genetic modification through biotechnology became possible after decades of research into genetics in the 20th century, but the real breakthrough came in 1973 when scientists Boyer and Cohen successfully engineered the first transgenic organism. That gave rise to GMO research, to commercialisation of the technology and its products, as well as to a fast growth of industrial agriculture, especially in North America.

But not all scientist share a positive narrative of GMOs' safety. Safety is understood not just in terms of food safety and human health, but also in terms of environmental safety and sustainability. The state of doubt is further reiterated by observations that scientific conclusions are strongly correlated to the source of funding, as well as by the disciplinary training of the authors.²³ Industry-funded scientific studies, as well as those authored by molecular biologists, tend to be more likely to express positive attitudes to GM crops and argue against serious inherent risks. Publicly funded scientists, and those trained in ecology, are more likely to purport negative attitudes, emphasising the involved

²² Raman, R. (2018). "The impact of genetically modified (GM) crops in modern agriculture: A review". In *Biotechnology in Agriculture and the Food Chain*, vol. 8(4), pp. 195-208.

²³ Hilbeck, A., Binimelis, R., Defarge, N. et al. (2015). "No scientific consensus on GMO safety". In *Environmental Sciences Europe*, vol. 27(4).

uncertainties and ignorance. The result, as aptly summarised by Hilbeck et al (2015), is this:

"[T]he the totality of scientific research outcomes in the field of GM crop safety is nuanced; complex; often contradictory or inconclusive; confounded by researchers' choices, assumptions, and funding sources; and, in general, has raised more questions than it has currently answered."

Even though the scientific methods and procedures underpinning genetic modification are well understood by scientists, regardless of their own attitudes and conviction, GMOs are still not unanimously accepted by the general public across the globe. Both disagreements in science, as well as public distrust, prompted the development of regulations to ensure safety and proper awareness of risks and impacts – especially when it comes to GM foods. Since at least the 2000s serious concerns have been raised about potential irreversible impacts of GMOs when released into the environment.²⁴ A lot of research has been carried out into both the risks and the benefits of GMO, and numerous safety narratives are in circulation. Thus, even after decades of experience, GMOs are still a source of controversy – not just in science, but also among consumers and the general public. The fact that different jurisdictions favour different approaches to regulatory oversight as a response to differences in the perception of risk and threat, is a further proof that the controversy affects policy making as well.

In addition to the above, the perceptions of risks also differ across countries and cultures. For example, in a meta-review of more than 70 articles, Frewer et al (2013) demonstrate that people in the EU tend to see more and greater risks than people in the EU and in Asia, but at the same time ethical and moral objections tend to be higher in the US than in the EU. This is also reflected in the different regulatory approaches to GMO on both sides of the Atlantic.

Another line of research looks into not only in the controversies themselves, but rather into the scale of polarisation that underlies these controversies.²⁵ The division is not merely between pro and anti-GMO, but goes deeper in both directions, because it is, in fact, rooted into differences of values. In the words of Biddle (2018), conclusions put forward in the GMO debate are not always based on evidence, so he argues that the "debate includes much space for rational disagreement—that the evidence alone might not settle the question of whether one should be supportive or critical of a particular GM crop, or even how we should characterize the risks of that crop." Thus, underlying values also affect the perception and definition of *safety*, as well as on the scope of evidence required to determine such safety.

GMOs provide a clear case of scientific uncertainty, regardless of their (relatively) long history of use. Despite a large body of research into their risks, there is still little to no consensus across scientific disciplines on their safety, nor within policy communities, and even less among the general public. Even scientists within the same disciplinary domain continue arguing, and others have noted inconsistencies in data availability, data interpretation, cases of poor methodological rigour or questionable commercial interests casting doubt on the impartiality of the research results and/or their interpretation. Across disciplinary domains, there is even less agreement. Thus, although as a technology, genetic modification is already considered mature and well understood, it is the use of GM products that is considered to pose the most serious concerns or even threats, typically on a product-by-product basis. Differences in regulatory approaches – i.e. between the EU

²⁴ Wolfenbarger, L. & Phifer, P. (2000). "The Ecological Risks and Benefits of Genetically Engineered Plants". In *Science*, vol. 290(5499), pp.2088-2093.

²⁵ Biddle, J. B. (2018). "Antiscience Zealotry"? Values, Epistemic Risk, and the GMO Debate". In *Philosophy of Science*, vol. 85(3), pp. 360-379.

and the US, but also among EU member states, only add to the complexity, as the different approaches to regulating GMOs are frequently rooted in the consideration and interpretation of scientific evidence. These discrepancies are additionally fuelled by strong public opinion in some jurisdictions, which are not based on science, but seek to actively refute even well-established evidence, contributing to a heightened and at times heated public debates, where science does not participate on an equal footing.

The extent of the controversies in the GMO narratives also translate into the perception of which risks are relevant within the GMO discourse. Most typically, the risks in question when it comes to GM food are those to health and safety, which some authors consider to be the only relevant risks of GMOs.²⁶ Saletan (2015), for example, argues against the inclusion of socio-economic risks in the debate on GMO since they are not a product of the technology itself, nor are they specific to the processes of genetic engineering. To the extent that socio-economic risks would be considered as probabilities of harm, then such harm would not and cannot be causally linked to the underlying technology since there is nothing inherent in it that increases the probability of that harm. To this, Biddle (2018) responds that it would, however, be completely legitimate to assess a given technology on its intended use. Therefore, as long as the intended uses for which a GMO is designed raise the probability of harm, there is no need to search for causality. Therefore, socio-economic implications can legitimately be considered an integrative part of the risk narrative. Hence, how regulatory frameworks consider the range of risks and weigh their importance is to a great extent a reflection on (public) values.

3.3 Scientific uncertainty, complexity and ambiguity

GMO debates produce their own narratives out of uncertainty and do not help with either advancing or accepting scientific evidence, which further contributes to continuing uncertainty within science itself. In part, this can be attributed to the fast development of the underlying technology that is not adequately matched by objective science communication efforts, leading to the continuous “recycling” of arguments without proper scientific reference or rooting. On the other hand, there is commercial push in some jurisdictions to bring GMO products to the market, and partly due to how knowledge of risk is developed through scientific research. In the latter case, there have been multiple instances when current studies refute prior ones as they employ, for example, different and more rigorous methodologies that add up to the understandings of risks and impacts.²⁷

GMOs represent a clear case of complex interdependencies within food supply chains and throughout food systems owing to the fact that once released into the environment, modified crops tend to have an impact not just in the way they were originally designed – i.e. increased yields, herbicide tolerance or insect resistance, but also exhibit a number of spill-over effects (externalities), some of which more obvious than others.

Genetic modifications involve the deliberate transfer of genes from one organism to another, often an unrelated one, with the most common, and most popularly contested, targets being plants used for food. Even though the technological process itself might be well-developed and understood (at least in terms of process), there is frequently inherent uncertainty in the final result of the modification. Gene insertion can have different outcomes. Thus, even though the role and function of the gene in the “source” organism

²⁶ Saletan, W. (2015). “Unhealthy Fixation: The war against genetically modified organisms is full of fearmongering, errors, and fraud. Labeling them will not make you safer.” In *Slate*. Available online at https://www.slate.com/articles/health_and_science/science/2015/07/are_gmos_safe_yes_the_case_against_them_is_full_of_fraud_lies_and_errors.html?via=gdpr-consent

²⁷ Kvakkestad V, Gillund F, Kjolberg KA, Vatn A. (2007). “Scientists perspectives on the deliberate release of GM crops.” In *Environmental Values*, vol. 16(1), pp. 79–104.

may well be understood, the full range of consequences of the transfer are not always known or may not always be adequately predicted.²¹ The rearrangement of genetic sequences may impact functional operation, cause genetic instability or interference, and ultimately increase the likelihood of unforeseen negative outcomes or risks.²⁸

Scientific uncertainty translates easily into public misunderstanding and into regulatory uncertainty, and the Bulgarian experience with GMO regulatory developments since at least 2003 is a clear example of that. Legislators' decisions aim to regulate the technology, but science and their understanding thereof is not the only component in regulatory decision-making. Besides taking account of the range of possible risks, the conditions that make them more likely, and designing a framework that controls and mitigates those risks, legislators are often pressured by public and private interests, stretching the span of their accountability.

Uncertainty has at least two complementary dimensions, when it comes to regulatory decision-making on GMOs (although it is not exclusively specific to GMOs). On the one hand, decision-makers are faced with the lack of confirmed information on, or knowledge of, the subject they need to regulate due to sometimes conflicting evidence that precludes the attainment of undisputed knowledge. On the other hand – decisions still need to be made, and when that is done on the basis of incomplete or missing information, this leads to uncertainty, especially with regards to the future implications.²⁹

It is highly unlikely that there will ever be the same level of understanding of GM technology, processes, risks and benefits between scientists, on the one hand, and consumers, or the general public, on the other. Hayes et al. (2004) argue that the balance of expertise will always be skewed towards the side of the GMO proponents, which are often the companies developing the GMOs and the scientists behind them.³⁰ This creates a significant challenge to establishing a strong and independent scientific base and to building public understanding and awareness, and results in continuous perpetuation of ambiguity among scientists, policy-makers and society at large.

The Bulgarian experience with the legislation of GMOs provides a strong example to the above. A significant part of the national debate on GMOs, particularly GMO foods, as seen in the transcripts of deliberations in the parliamentary committees and in the plenary, rests on an implicit assumption of GMOs as a significant source of risk to human health and the environment. Regardless of how exhaustive such concerns are, and the degree to which scientific evidence is available and comprehensible, they have strong impacts on policy-making and regulatory developments on national and international level. The Bulgarian legislative debates on GMOs are a vivid example of this since implicit harm from GMOs is put forward in parliamentary deliberations as the core of deliberation. The majority of the narratives used are rarely based on scientific proof or disproof. Instead statements are often found to assign blame to the opponent of being negligent of the risks. That is largely the situation across the EU too, particularly with regards to the import and cultivation of GM crops³¹, and some authors have even raised a concern that the EU has been

²⁸ Dennis, C. (2002). "The brave new world of RNA". In *Nature*, vol.418, pp. 122-124.

²⁹ Prakash, D., Verma, S., Bhatija, R. & Tiwary, B.N. (2011). "Risks and Precautions of Genetically Modified Organisms". In *ISRN Ecology*, vol. 2011

³⁰ Hayes, K. R., Gregg, P. C., Gupta, V. V. S. R. et al. (2004). "Identifying hazards in complex ecological systems. Part 3: Hierarchical Holographic Model for herbicide tolerant oilseed rape". In *Environmental Biosafety Research*, vol.3(2), pp. 109-128.

³¹ Devos, Y., Reheul, D., De Waele, D., & Van Speybroeck, L. (2006). "The interplay between societal concerns and the regulatory frame on GM crops in the European Union". In *Environmental Biosafety Research*, vol. 5(3), pp. 127-149.

experiencing an increasingly politicised perception of risk, which in turn might increase the risk that consumers would, in the end, consume unsafe products.³²

Furthermore, in the case of GMOs there is clear divergence between how risks are objectively assessed via scientifically agreed methods and protocols, and what is being referred to as socially constructed risks, or what and how society perceives as a risk.³² This can be observed in the national debates on the LGMO, as it has had significant impact on how *risk* is being framed and interpreted for regulatory purposes. It represents an evolution in the understanding of risk – not as the product of just hazard and exposure to it, but also to include a third component – termed by Sandman (1994) *outrage*, which refers to the public's response to and perception of risk.³³ In Sandman's (1994) terminology, hazard and outrage "refer, respectively, to technical and nontechnical (a composite of such factors as control, fairness, familiarity, trust, dread and responsiveness) seriousness of a risk." Smyth and Phillips (2014) refer to outrage as the consumers' and citizens' response to risk, and propose that a sound risk analysis framework should take into account the hazard identification and characterization, exposure assessment, and outrage. The added significance of the *outrage* factor is in that it expands on the scientifically derived measure or risk. From such a perspective, then one could more easily understand how public pressure, albeit entirely unscientific, can influence the legislators' assumption on the likelihood and severity of potential risks, and their use of precaution in defining measures for mitigation, control and avoidance.

From a social science perspective, anti-GMO sentiments appear to be intuitively appealing to the majority of people for quite some time.³¹ Most people without a scientific background or training in biotechnology appear to perceive DNA as a product's identity, so they refuse to accept transgenic plants (i.e. fish DNA inserted into a tomato) as having an "identity" of their own, but rather think of them as the confluence of the "identities" of the original species.³⁴ With years of data from locations where GMOs were cultivated, others further conclude that there is little evidence of increased yield of GMO crops compared to non-GMO counterparts, coupled with evidence of increased use and concentrations of pesticides.³⁵ Thus concerns are validly being raised not only on the safety aspects of GMOs themselves, but also on systemic risks resulting from GMO use.

Another line of argument is linked to the fact that GMOs, when used as food and feed, come from and benefit high-tech agricultural industry, and are thus a constituent part of business processes (with little attention to the science itself). On the one hand, this means that GMOs are part of energy intensive (due to scale) agricultural production, which is perceived as a threat to sustainability objectives and is also resource intensive. On the other hand, GMOs enable higher usage of pesticides (as they are intentionally modified to make them resistant to specific pesticides), thus causing potential additional harm to the soil, other plants and animals in the ecosystem, and the environment in general.³⁶

³² Smyth, S. J., & Phillips, P. W. (2014). "Risk, regulation and biotechnology: the case of GM crops". In *GM crops & food*, vol. 5(3), pp. 170–177.

³³ Sandman P. (1994). "Mass media and environmental risk: Seven principles.". In *Risk*, vol. 5, pp. 251-60.

³⁴ Gelman S.A., Rhodes M. (2012) "Two-thousand years of stasis: how psychological essentialism impedes evolutionary understanding". In: Rosengren K.S. (2012). *Evolution Challenges. Integrating Research and Practice in Teaching and Learning about Evolution*. Oxford University Press, pp. 3-21.

³⁵ See for example reporting on <https://www.nytimes.com/2016/10/30/business/gmo-promise-falls-short.html>.

³⁶ Odum, Mary (2015). "Arguments against GMOs". Published online at <http://prosperouswaydown.com/arguments-gmos/>.

3.4 Relevance of the PP to the case

Although risks of GMOs have been identified and studied from multiple perspectives, there are still inherent uncertainties and complexities that preclude a unanimous and categorical judgement on their consequences, particularly when used as food and food ingredients. The scientific uncertainty remains in part because it is not entirely possible to determine the full extent and likelihood of possible harms, especially when the exact source or reason for such potential harm may not be clear.

The precautionary principle, at least with regards to biosafety, was first put forward in the United Nation's Rio Declaration on Environment and Development from 1992³⁷. It gained further significance and through the international Cartagena Protocol on Biosafety to the Convention of Biological Diversity.³⁸

The pursuit of technological regulation through law has always been a response to the recognition of existing or possible risks to human health, as well as to the environment, and GMOs provide a suitable example. The science behind the technology of gene modification outpaces significantly the science necessary to identify and quantify the associated risks, resulting in a distinct "lag" and in a period when the true scope of risks – especially to human health – remains unproven or simply unknown.³⁹ Therefore, regulations that are at least partially premised on insufficient and evolving knowledge of their subject, should recognise this state of scientific ignorance (scientists do not know what they do not know) and follow a precautionary approach. Otherwise scientific ignorance may easily translate into legislative ignorance whereby decision-makers fail to recognise the likelihood of unknown risks and unanticipated consequence.

In the EU, the precautionary principle is a basic tenet in Directive 2001/18/EC, and in the Bulgarian regulatory context – a foundational framing for the LGMO. The Principle is explicitly mentioned at its very beginning. The LGMO provides a short definition of the precautionary principle as "prioritising the protection to human health and the environment in the face of probable potential adverse impacts regardless of existing economic interests or the absence of scientific proof."⁴⁰ The LGMO requires that the Ministry of Environment and Waters maintains a registry of all sites where there contained use of GMOs is authorised (i.e. research labs). Such sites require prior authorisation to begin their work, and interested parties are required to submit a detailed application, which includes a thorough risk assessment, identification of any potential adverse effects on the environment and human health, an assessment of the likelihood of such effects, and an impact assessment. Before contained use is authorised, the applicant is asked to provide an Emergency Response Plan, which is subject to review and update. These plans, and updates thereof, should be provided to the public by the applicant. The final authorisation decision is made by the Minister. The Ministry is further expected to organise public hearings before granting authorisation for the deliberate release of a GMO in the environment. The Ministry's regulatory oversight is further supported by a Scientific Committee, which advises the Minister on each application for authorisation. However, protocols or transcripts from the deliberations of this Committee are not publicly available. Records of Committee meetings' agendas and decisions made are available as a list, but only until 2015, without any clarity for the lack of more recent data. At the same time, the

³⁷ Full text of the Declaration is available at

<https://sustainabledevelopment.un.org/content/documents/1709riodeclarationeng.pdf>

³⁸ The Protocol was agreed upon in 2000, and entered into force in the signatory states in 2003. See <https://bch.cbd.int/protocol> for details.

³⁹ Van Tassel, K. (2009). "Genetically Modified Plants Used for Food, Risk Assessment and Uncertainty Principles: Does the Transition from Ignorance to Indeterminacy Trigger the Need for Post-market Surveillance?". In *Boston University Journal of Science and Technology Law*, vol.15.

⁴⁰ Law on genetically modified organisms, art. 1(2). In force since June 2003. Last amended in June 2017. Available in the Bulgarian language at <https://www.lex.bg/laws/ldoc/2135501153>.

most current data on the website of the Ministry reveal there are currently five locations (research labs) where contained use is authorised, but not a single authorisation for either specific research on any GMO or deliberate release, has been granted (since at least 2010).⁴¹

The realisation of the precautionary principle through legislative and regulatory texts reflects normative⁴² and value-driven assumptions underpinning the principle itself. To this end, the differences in the scope of regulatory measures put forward in the relevant legal texts reflect differences in the interpretation of the precautionary principle, particularly in regards to the scope of discretion allowed in managing risks due to scientific uncertainty (or the apparent lack of scientific certainty). Some authors, however, argue that legal texts, particularly on GMOs, that rest on interpretations of the precautionary principle can become quickly outdated due to the rapid advances in science (i.e. gene editing), as well as the accumulation of newer evidence.⁴³

4 Risk governance and the precautionary principle

Risk assessment is a common regulatory tool typically used in the decision-making process, for example – for a proposed commercial release of a GMO into the environment or for GMOs in contained use.⁴⁴ Risk assessments are mandated by law, and are meant to ensure the study into possible adverse effects of GMOs on human health and the environment, to details on contained use of GMOs, the probability that an adverse effect does occur, and the severity of the impact should that does happen.

In the EU, risk assessment on GMOs is based on a case-by-case approach, whereby separate risk assessment procedures are carried out for each product or trait as long as there is sufficient scientific information and experience. Risk assessment guidelines are most detailed by the European Food Safety Authority. The regulatory framework has been criticised by some scientists as being “increasingly static up to a point that it has become too cumbersome to cope with technological and scientific developments.”⁴⁵

In the EU risk assessment and product approval were decoupled with the establishment of EFSA.³² EFSA carries out risk assessments based on science-based protocols and procedures, but it does not make the decision – it only provides a report to the European Commission, which has the final say on product approval. Member States can also conduct their own risk assessment, which is then shared with EFSA for an opinion. Typically, EFSA can carry out two types of risk assessments under the same Regulation 1829/2003.⁴⁶ One is for the cultivation of GMOs and the other is for GMOs when proposed for use as food and

⁴¹ Data available at <https://www.moew.government.bg/bg/priroda/gmo/registri-gmo/>.

⁴² Vos, E. & De Smedt, K. (2020). Taking stock as a basis for the effect of the precautionary principle since 2000. RECIPES Project Deliverable WP1.

⁴³ Davidson, J. & Ammann, K. (2017). “New GMO regulations for old: Determining a new future for EU crop biotechnology”. In *GM Crops & Food: Biotechnology in Agriculture and the Food Chain*, vol. 8(1), pp. 13-34.

⁴⁴ Hill, R.A. (2005). “Conceptualizing risk assessment methodology for genetically modified organisms”. In *Environmental Biosafety Research*, vol. 4(2), pp. 67–70.

⁴⁵ Erikson, D., Custers, R., Björnberg, K.E. & al. (2020, forthcoming). “Options to Reform the European Union Legislation on GMOs: Risk Governance”. In *Trends in Biotechnology*, vol. 38(4), pp. 349-351.

⁴⁶ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Accessible at <https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32003R1829>.

feed. As new scientific information becomes available, it is possible that the concerned Member State can adopt new emergency measures based on the newly identified risk.

The EU has adopted its own legal framework that defines the regulatory scope on GMOs. On the Union level, as well as in Member States, regulatory oversight is process-based – it is the technology of genetic engineering around which regulations are designed.⁴⁷ The following directives and regulations are the main pieces of legislation⁴⁸:

- Directive **2001/18/EC** on the deliberate release of GMOs into the environment. This directive establishes in legal terms that genetically engineered crops are fundamentally different to crops improved by any other type of breeding technology. It is further based on the precautionary principle seen as a set of general principles of risk management, including: proportionality between the chosen level of protection and the measures taken; nondiscrimination in the application of the measures; consistency of the measures with measures already executed in similar circumstances; cost-benefit analysis of action or inaction; revisiting of the measures upon new scientific developments.⁴⁹
- Directive (EU) **2015/412** amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory
- Regulation (EC) **1829/2003** on genetically modified food and feed
- Regulation (EC) **1830/2003** concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs
- Directive **2009/41/EC** on contained use of genetically modified micro-organisms
- Regulation (EC) **1946/2003** on transboundary movements of GMOs.

Several Bulgarian laws contain regulations addressing GMOs:

- **Law on genetically modified organisms**, in effect since 2005. It transposes Directives 2001/18/EC and 2009/41/EC of the EU into the national legal system, and regulates: 1. the contained use of GMOs; 2. the release of the GMOs in the environment; 3. the placing on the market of GMOs or combination of them as products or ingredient of products; 4. the transfer of GMOs; 5. the import, export and transit of GMOs; 6. the control over the activities under items 1-5. The Law explicitly refers to the precautionary principle as its foundation.
- **Law on foodstuffs**, in effect since 1999. It contains specific provisions addressing GMOs in food, including packaging, labelling and consumer awareness.
- **Law on veterinary practice**, in effect since 2006. Includes administrative regulations addressing release to the market of GM feed for animal feeding.
- **Law on feed**, in effect since 2006. This law treats GMOs when in use as animal feed. It regulates the transportation, marketing, labelling and use of GM feed. It is focused on feed in general, not specifically on GM feed. The law contains substantial number of direct references to Regulation (EC) 1829/2003.

Until 2005 Bulgaria did not have a dedicated law to regulate any aspect of development, experimentation, transportation, release of GMOs. There was a government decree in effect, whose sole focus was on the deliberate release of GM plants obtained through recombinant DNA (so-called transgenic plants). As a regulatory instrument, it was

⁴⁷ Zetterberg, C. & Björnberg, K.E. (2017). "Time for a New EU Regulatory Framework for GM Crops?". In *Journal of Agricultural and Environmental Ethics*, vol.30, pp. 325-347.

⁴⁸ See https://ec.europa.eu/food/plant/gmo/legislation_en.

⁴⁹ Aerni, P. (2019). "Politicizing the Precautionary Principle: why disregarding facts should not pass for farsightedness". In *Frontiers in plant science*, vol. 10.

regarded as highly inefficient, not least because MPs could recognise the rapid development of the science and technology behind genetic modification, as well as the ensuing complexity, especially when the draft of the LGMO was submitted to the Parliament in 2003 and the debates started, many of the MPs saw the LGMO as a significant and needed upgrade to the regulatory framework.

A review of the parliamentary debates on the Bulgarian LGMO (and by reference of several other debates where GMOs appear as subject) suggests that the Bulgarian regulators have not been engaged with detailed (public) discussions on the actual risks from GMOs. GMOs were perceived as inherently risky, but risk was seen more as an expression of generally persisting (scientific) uncertainty (“we don’t know what could go wrong”). The legislators routinely referred to the EU frameworks and relevant directives as foundational in the definition of risks and risk management procedures. In much of the debates, the attention was on strict monitoring and control as a form of prevention rather than on risk mitigation. The LGMO, which is the principal legal text on GMO regulation, has a detailed section on risk management, and provides for a regime of authorisation and close monitoring for every single GMO and every single site (lab or planting location). Over time, there have been more references to notions of socially constructed risks (referring to public perceptions and mainstream narratives, not necessarily in line with science) to a much larger extent than to scientific evidence or uncertainty of risks. This, to a degree, precluded wider public discussions on understanding the risks, communicating effectively among stakeholders on the scientific evidence of threats, and instead focused the legislative attention on the management and containment of risks seen from a restrictive lens. Moreover, despite the frequently cited concern for ensuring the viability of particular economic sectors (such as bioagriculture), no economic analyses were quoted or provided. Thus it is impossible to infer from the available transcripts of there had been any cost-benefit analysis to inform and support the line of argument that presents GMOs as an economic threat.

The initial adoption of the LGMO took a little over a year between the time the draft was submitted to the Parliament and the time it was enacted into law. The LGMO entered into force on June 1st 2005. Before that date, Bulgaria had no dedicated law, only a government decree with a sole focus on the deliberate release of GM plants obtained through recombinant DNA technology. No regulation was in existence on contained use of GMOs.

The draft LGMO was introduced to the plenary by the then-Minister of the Environment and Waters on February 12th 2004.⁵⁰ The minister explained that the law was necessary for two main reasons: “[1] to ensure complete legal regulation of GMO-related activities and [2] to respond to the commitments made by the Government during the negotiations for accession to the European Union.”⁵¹ The draft preparation was prepared by a mixed group of experts from relevant ministries, scientists and civil society organisations, under the coordination of the Ministry of the Environment.

A key point in the debate in 2004 concerns the possibility to use the LGMO as an opportunity to promote a policy approach that is unique to Bulgaria, while also complying with the EU directives. One of the MPs openly advocates for that stating the distinct difference in the regulatory approaches used by the United States (key role for the market and multinational companies) and by the EU (key role for governance institutions). While arguing for the necessity of the law, he asked: “Can Bulgaria choose a third kind of policy? One that prohibits the agricultural production of GMOs?”, and further promotes stricter control procedures. The key supporting argument used was that GMOs represent a threat to Bulgarian bioagricultural sector, and the LGMO should ensure the restriction of

⁵⁰ Transcript of the plenary session is available in the Bulgarian language at <https://parliament.bg/bg/plenaryst/ns/1/ID/1278>.

⁵¹ Bulgaria acceded to the EU on January 1st 2007. The adoption of the LGMO was part of the years-long process of negotiation and legislation transposing required from candidates.

multinational GM seed producers and will thus protect organic and conventional farming – a strategically important sector for the Bulgarian economy.

Another MP, a scientist himself, and at the time a member of the parliamentary opposition, also stated the LGMO is a necessity, and was the only one to refer directly to the precautionary principle as the underlying foundation for this act. He was also the only person to refer to scientific uncertainty as sufficient motive for the adoption of the law, referring to the possibility for cross-contamination of non-targeted species with genetically modified material. His presentation of genetic modification as a technology, however, was framed entirely on notions of risk and threats, with a range of examples of what could go wrong – unexpected production of toxins or allergens threatening consumer health; possibility for intentional abuse of GM techniques for bioterrorism; even the theoretical possibility that an GM plant could “breath in” enormous amounts of nitrogen from the atmosphere, thus changing the chemical composition of breathable air causing environmental havoc. He further reiterated the same arguments for the threats to typical products of Bulgarian agriculture, calling for the introduction of market analysis prior to the deliberate release of any GMO. Other MPs, within the same flow of reasoning, directly objected to any deliberate release of any GMO, and called upon strict regulation of international trade and transportation of GMO crops, emphasising environmental risks and threats to biodiversity. One MP insisted, referring indirectly to the precautionary principle, that the LGMO should explicitly distinguish between products that are researched and developed in a lab, and those that are released to the environment and to the market for food or food ingredients.

The final set of arguments to this first draft proposal directly concerned issues of risk management, stricter regulation and control over contained use, as well as on the lack of clarity of how the different institutions tasked with monitoring and control were going to collaborate and coordinate their actions. Nevertheless, the draft was voted positively (so-called first reading) by a majority in the Parliament, which opened up an opportunity for the MPs to propose specific amendments before each text of the law was to be individually voted by the plenary (so-called second reading). Despite some criticism, the MPs agreed the law was long overdue and was in fact necessary in order to ensure that GMOs, including research, release and marketing, were all closely monitored and strictly regulated.

Despite occasional direct references to the precautionary principle, MPs called for additional precaution due to possible risk to particular economic sectors and higher opportunity costs. This kept the discussion focused not on scientific uncertainty, but rather on risks to the economy, which were, however, not substantiated by any (publicly available or referred to) economic impact analysis.

At the very beginning of 2010, a major revision to the LGMO was proposed, which spurred additional public attention, and even a number of citizen protests across major towns, including several in front of the Parliament building. In the month of February 2010, the term GMO was the most searched for in Bulgaria on Google, according to Google Trends. At no other time since 2004 up until the time of writing of this case study, has that term been so popular. That sudden spike in wider public interest on the matter had an impact on framing the debate in the parliament, which, in parallel with discussing the proposed amendment to the LGMO itself, submitted a draft for a decision to ban deliberate release and cultivation on Bulgarian soil of any GMO. For more than a month, the discussion on both drafts was proceeding in parallel, reinforcing the discourse on risk and uncertainty. A number of media at the time ran interviews with scientists, in an effort to balance the debate. Not surprisingly, none of the interviewed scientists would share the perception of inevitability of risks that was so openly put forward by most parliamentarians. One remarked with a subtle irony that “[Measures that are effectively] blocking [our] research

work actually limit the capacity and ability of Bulgarian scientists to properly identify potential risks of releasing GMOs to the environment, which is a key part of GMO science.”⁵²

The most detailed and heated debate on the LGMO happened at the beginning of 2010 when a large number of significant amendments were proposed by the Government. The major argument in support of the proposal, however, was to harmonise the LGMO with the then-current EU directives due to identified inconsistencies and a warning received from the European Commission. Unlike in 2005, when the majority of MPs expressed their support for the adoption of such a law, in 2010 the proposed amendments were met with far greater controversy. The key reason for that was that some of the amendments appeared to allow the release of GMOs in the environment, effectively easing the restrictions adopted in 2005.

To many MPs that was an unacceptable regression, mostly because, if passed, that would pose a significant threat to the continuing growth of organic agriculture, which is what Bulgaria considered to be a strategic economic advantage. Several organic farmers had provided motivated objections too, arguing that conventional and organic agriculture were both incompatible with GMO-based agriculture as there could not be an effective barrier for the uncontrolled proliferation of genetic material across both adjacent and remote fields. A representative of an association of organic farmers, who was invited to the introductory discussions on the draft in the responsible Standing Committee, even asserted that “Interfering with the laws of nature is dangerous and unpredictable, because GMOs cannot develop natively in the nature.”

Only one MP, a scientist, expressed concerns while referring to the precautionary principle. He considered the proposed amendments a significant step back from precaution and explained some of the risks from uncontrollable crossing of genetic material to non-targeted organisms – insects, bacteria, and possibly humans, citing possible toxicity, development of antibiotic resistance and irreversible mutations to human gut bacteria. He called for greater precaution, but not solely on grounds of scientific uncertainty. Instead, he asserted, there would be a significant threat to the successful market release of Bulgarian agricultural products, if they were seen as “contaminated by GMOs” by domestic and EU consumers. Other MPs, whose statements followed in the plenary, further motivated their concerns with the amendment not so much with uncertainty and risks to the environment and human health, but with economic uncertainty and the risk of losing even potential market shares of agricultural production. Another MP echoed this concern and further stated that GMOs present a serious risk of disruption of the well-functioning and competitive market of Bulgarian agricultural goods. “On so many levels, adopting this amendment would be a crime to the environment”, she concluded.

The debates continued in the relevant standing committees, and took place over a period of a few months. At the same time, the proposed amendment rapidly drew public attention, and caused an outcry among various societal groups – not only environmentalists, but also among less organised groups of consumers. Several spontaneous protests took place in the country, including in front of the Parliamentary building, prompting MPs from the governing party to propose a complete ban (moratorium) on any release to the environment or use of GMOs as food. Thus, while the Parliament was engaged in debates on amendments to the LGMO, a few MPs from the governing coalition proposed a draft for a Decree that would ban any GMO-relevant work or release for a period of five years. Debates on both drafts took place virtually at the same time, which prompted some criticism from opposition MPs on the questionable legislative practice of hurrying up to adopt an amendment to the law while discussing a 5-year-long ban on any of its provisions

⁵² Excerpt from an interview with Prof. Rositsa Buchvarova, Director of the AgroBioInstitute at the Academy of Agricultural Sciences. Published on January 28th 2010 at https://www.dnevnik.bg/biznes/2010/01/28/849542_uchenite_vurnaha_ni_s_20_godini_nazad_s_pulnata_zabrana/#comments-wrapper.

in regards to GMOs. Throughout these debates, it became rather clear that there is a strong assumption of damage, without any reference to scientific proof, but with a clear motivation to respond to the expectations to an already agitated public.⁵³ The public outcry was a major reason behind a turning point in the discussion on the LGMO itself, leading to the implementation of greater restrictions (refuting the Government's proposal) through the law itself, and withdrawing the draft of the banning decree, which became obsolete before it was even discussed in any of the standing committees.

As part of the discussions on the LGMO, which took more than two months, one of the debated topics concerned directly the re-assessment of risk when new information becomes available to anyone working with GMOs under containment. The precautionary thinking among some of the MPs resulted in proposing an amendment that changed the original provision in the law from "when new scientific information becomes available" to "when new scientific *or other* information becomes available".⁵⁴ The amendment was proposed by the Ministry of the Environment and Waters, and spurred a short debate in the Parliamentary Committee on the Environment and Waters during the second reading.⁵⁵ The argument focused on the scope and determinability of what "other information" was which "other information" would be considered legitimate in triggering a response. The Deputy Minister of Environment and Waters, who was explaining the Ministry's proposal, clearly explained that it is not necessary that only scientific information should be used as a trigger, and insisted that any kind of information should be monitored and acted upon, because "anyone who has been granted authorisation to work [with GMOs] under containment, is obliged to monitor everything. In a situation when there is so much public attention, we ought to demand that anyone with an authorisation for contained use should monitor, in addition to their own generated information, everything that is going on in the public space, as well as in the scientific literature." The Chairwoman of the Committee further emphasised that this would include "media information" as well.

This was not agreed upon immediately by the Committee's members. One objected that such a requirement would make reporting and acting upon new information unworkable, but also openly stated he did not object to the proposed change. All of the Committee's Members voted unanimously in favour of adding "other information". Later in the plenary, there was no further debate on that proposal, and it was adopted into the law and has not been changed since.

In March 2010, when the debates on the LGMO had finished, the topic of GMO re-emerged⁵⁶ in the discussions on proposed amendments to the Law on Food, where GMO-relevant risks were again highly contested. The debate took place in several of the standing committees, and was mostly focused on issues of food safety resulting from GMO-containing foods and how they were being sold to consumers. It touched upon improving public awareness on GMO content in food products by requiring specific labelling of GMO-containing products in cases when GMO content was above a EU-wide pre-set threshold of 0,9%. A particular concern with regards to food safety was expressed about imported foods for children. The author of the amendment argued: "I am confident that if Bulgarian companies produce

⁵³ Part of the debate took place in the Parliamentary Committee on Agriculture and Forests on February 17th 2010. Complete transcript is available in the Bulgarian language at <https://parliament.bg/bg/parliamentarycommittees/members/230/steno/ID/1561>.

⁵⁴ Art. 39(1) of the LGMO.

⁵⁵ Transcripts of relevant discussions within the Parliamentary Committee of Environment and Waters are available in the Bulgarian language at <https://www.parliament.bg/bg/archive/7/3/234/steno/ID/1554>.

⁵⁶ Transcripts of relevant discussions within the Parliamentary Committee on Legal Affairs are available in the Bulgarian language at <https://parliament.bg/bg/parliamentarycommittees/members/226/steno/ID/1608>.

GMO-free foods for children, this would be successfully realised not only on the Bulgarian market, but also in the EU. All people everywhere at the moment prefer GMO-free foods.”

The quotation is not randomly chosen. This kind of reasoning was presented as a major motivation behind the proposed changes, and it was not questioned by anyone. Besides being an illustration of cross-party consensus that closely reflects dominant public sentiment, at least at the given moment, it is also an illustration of the persisting “fear” of GMOs. That fear, much more than any relevant and valid scientific arguments, gave shape to the precautionary thinking of the lawmakers. Such precaution was additionally informed and encouraged, in a way, by the dominant public sentiments of widespread negativity to anything genetically modified.

Throughout the following years, no major changes have been proposed to the LGMO, which had become particularly restrictive, much like in the majority of other EU Member States. But in debates on various other laws, the topic of GMOs would resurface as an illustration of and in relation to added risks to human health in particular, and would sometimes even be used to ascribe guilt to MPs and political opponents for failing to oppose GMOs. For example, during a debate in the Plenary in January 2014, an MP from the then-ruling coalition used a number of negatively phrased references to the LGMO, and to several MPs who he claimed did not oppose GMOs during the debates in 2010, as “worthy of shame”. In January 2015, the then-Minister of Environment and Water, in a statement to the plenary during debates⁵⁷ on the ratification of the Transatlantic Trade and Investment Partnership (TTIP), presented the Government’s requirements for the negotiations, one of which is “keeping the ban on GMOs”. In January 2020, during discussions⁵⁸ on the ratification of the EU-Canada Comprehensive Economic and Trade Agreement (CETA), an MP opposing to the ratification spoke of GMOs as one of the risks of the Agreement, arguing “[it] will enable the silent entry of GMOs to the Bulgarian market and foods” – a claim, ultimately denied in official statements by several Standing Committees, but which did not receive any verification within the Parliament and went largely unnoticed. Another MP, from an opposition party, presented seven groups of arguments against CETA, one of them being GMOs, thus adding to the discourse of negativity around GMOs.

Certainly, none of the above represents an issue about or due to the precautionary principle as such. Nevertheless, these examples illustrate how it is not just the precautionary principle that shapes legal framings and legislators’ thinking on GMOs, and possibly on other issues marked by scientific uncertainty and public doubt.

5 The precautionary principle and its future

5.1 Reflection on the PP in the literature

The precautionary principle has been made foundational to GMO legislation thanks to the Cartagena Protocol on Biosafety to the Convention of Biological Diversity, which is a key international instrument in the GMO regulation and which has informed EU and national regulatory approaches, especially those in the EU.⁵⁹ It enables science-informed political decisions, based on identification of risks, acknowledgement of scientific uncertainty, and

⁵⁷ Transcripts of the relevant discussion within the Plenary is available in the Bulgarian language at <https://wap.parliament.bg/bg/plenaryst/ns/51/ID/5334>.

⁵⁸ Transcript of the relevant plenary discussion is available in the Bulgarian language at <https://parliament.bg/bg/plenaryst/ns/51/ID/9629?fbclid=IwAR0oivrER30EXJnvu2ZobX2VRkzLzlOWQJ27hSxXYwkC1cpEmrWKT7wxe-E>.

⁵⁹ Carroll, M. (2016). “The new agrarian double movement: hegemony and resistance in the GMO food economy”. In *Review of International Political Economy*, vol. 23(1), pp.1-28.

even safeguarding against ignorance⁶⁰, and is considered “the most robust and extensive international legal regime for regulating biotechnology.”⁵⁹ It make possible the greater control of governments over inquiry into GMO content of food imports, and allows them discretion in deciding whether or not such imports would be allowed if they deem the available scientific knowledge to be insufficient to make a proper risk assessment. Thus governments retain a high degree of agency in limiting the proliferation of GMOs.

The Cartagena Protocol was ratified by the Bulgarian Parliament in October 2000 and entered into force in September 2003, and currently more than 170 countries are signatories on the protocol. A notable exception are the United States, which follow a different regime concerning GMOs (in comparison to the EU, in particular), based on patent law and intellectual property rights. In addition to being products of science, GMOs under such a regime “come to be seen as patentable, ownable, and sellable commodities. [This regime] sets into motion the field of biotechnology as an industry of great potential profit.”⁵⁹

The Bulgarian parliamentary debates on the LGMO, as well as references to GMOs on several other occasions during discussion on unrelated laws, provide an interesting example of how precautionary thinking can shape legislative approaches based, to a large extent, on adopting a wider interpretation of risk as a socially constructed reality. This interpretation appears to disregard actual probabilities, and instead rests on the assumption that risk (of GMOs) is unavoidable, and should therefore be prevented.

All the experts we interviewed for this case study recognised the importance of the precautionary principle as a cornerstone in the GMO regulations, and no one criticised the principle as such. However, they all agreed that the problem is *how the principle is being used politically*. One of them was rather critical, stating that the current state of (GMO) affairs in Bulgaria is a “state of perversion, not a state of precaution”, because even though contained use is not banned, field experiments are impossible, which in turn makes it impossible for scientists to validate the results of their work and establish the safety of any GMO they developed. As a consequence, Bulgaria can import particular GM seeds from other countries, for which all risk assessments have been carried out, and use them as feed, but Bulgarian scientists cannot develop their own.

Another said that there has been an overwhelming “lack of convincing evidence” that GMOs (crops) have caused any negative impact on human health, and that some benefits far outweigh publicly feared, but sometimes not even proven, risks – at least those popularly perceived as likely. All of them seemed quite certain that to the extent that risks do exist, there are also ones that the general public does not see and is unaware of them. As an example of such a threat, one of the experts (a retired professor in molecular biology) explained of a case when clearing land to make space for fields of genetically modified soybeans has led to the aggregation of rodent populations that feed on the soybeans and proliferate the newly planted fields. These rodents however are known carriers of Hanta viruses potentially causing severe illness in humans. Thus there is a serious risk of contamination when the seeds are transferred to other locations through global export and import. In this expert’s opinion, the risk assessment procedures in place may not in fact be adequate to address such a risk appropriately, but it is real and exists, and the lack of wider awareness or recognition does not make it any less likely.

Notwithstanding opinions of scientists on the limitations enforced by the precautionary framing of the GMO legislation, it is important to consider if there is another viable alternative to how the LGMO could address the management of uncertainty.⁴⁷ The precautionary principle thus remains a particularly useful framing in ensuring that legal certainty does not in turn enforce greater scientific uncertainty.

⁶⁰ Myhr, A.I. (2007). “The precautionary principle in GMO regulations”, in Traavik, T. and Lim, L.C. (Eds), *Biosafety First*, chapter 29. Taapir Academic Press, Trondheim, pp. 457-67.

The review of the debates on the LGMO in Section 4 suggest of a variant of the precautionary principle that could be characterised as a *strong precautionary principle*. It is generally understood in opposition to cost-benefit approaches, ignoring the highest expected utility at the expense of adopting explicitly cautious approach to risk management.⁶¹ This is precisely the approach followed by several cohorts of parliamentarians since at least 2003.

5.2 Effect of the PP on innovation pathways

Bulgaria shares a lot in common with other EU countries when it comes to the scope of regulatory restrictions on GMOs – not just because as a Member State it has to follow many of the same rules. The precautionary principle is strongly rooted in the EU regulatory framework, and is also foundational to the Bulgarian LGMO. In the Bulgarian case, the *de facto* ban on GMOs did not lead to the pursuit of a clear alternative innovation path. None of the GMO-centred debates were found to contain any references to future developments in biotechnology, nor did they demonstrate much of a concern on the development of biotechnology as a sector of the Bulgarian economy with a potential high added value. In general, positive framings of innovation were missing from the debate. Notably, even scientists along the course of GMO legislation’s development over the years, did not target the precautionary underpinnings of the legal texts, but framed their critique thereof as being disproportionate to the risks involved.

5.3 Innovation principle

In the Bulgarian context, the dominant arguments have been overwhelmingly against GMOs, so virtually no discussion has been put forward on the potential – real or alleged – benefits of GMOs – not even in terms of advancing national scientific research. All stakeholders, including policy and decision-makers, have used arguments mostly addressed to the public, to assure “Bulgaria will stay free of GMOs”, while at the same time also referring to the requirements of the European Union as the key reason to enact the necessary regulations. Essentially, the debate was more closely focused on how not to allow any release of GMOs in the environment, how to limit GMO content in food, and how to ensure proper controlling and that the broadest restrictive measures are in fact in place.

The Innovation Principle is defined by the European Commission as “a tool to help achieve EU policy objectives by ensuring that legislation is designed in a way that creates the best possible conditions for innovation to flourish [, and is meant to] ensure that all new EU policy or regulations support innovation and that the regulatory framework in Europe is innovation-friendly.”⁶² It is not difficult to ascertain that the restrictive GMO legislation, strongly focused on risk avoidance, pays little to no consideration to innovation, particularly when it comes to biotechnology use in agriculture.

In Bulgaria the Innovation Principle has not been formally or informally invoked, especially in the form of legislation, particularly since it is relatively new. As a concept, it has slowly been gaining traction among EU policy makers since 2013, and was officially introduced by the European Commission in 2017 before becoming an official part of DG Research’s Work Programme 2018.⁶³ Thus, the LGMO debates, which were very few and very short since the major revision in 2010, and was last amended in 2017, could have hardly been

⁶¹ Koplin, J., Gyngell, C. & Savulescu, J. (2020). “Germline gene editing and the precautionary principle”. In *Bioethics*, vol. 34(1), pp. 49-59.

⁶² Definition available at https://ec.europa.eu/info/research-and-innovation/law-and-regulations/innovation-friendly-legislation_en.

⁶³ European Commission (2018). *DG RTD Management Plan 2018*. Available at https://ec.europa.eu/info/sites/info/files/management-plan-rtd-2018_en.pdf

influenced by any notion of the innovation principle. On the other hand, the theme of innovation has not been part of the two-decade-long Bulgarian debate affecting the LGMO. Instead, all the arguments against GMOs rested on notions of precaution and pre-emptive measures against an imminent threat. This has resulted in a restrictive regulatory framework on GMOs, without engaging parliamentarians in debates of alternative routes for innovation development.

The experts we interviewed (all of whom scientists with practical experience in biotechnology and agronomics) on the subject were cautiously optimistic about GMOs, which opened up a different perspective on the relevance of innovation (though not on the Innovation principle, which they did not acknowledge in the same way they were aware of the precautionary principle). One of them, himself a trained plant biologist, said that the highly restrictive LGMO in Bulgaria serves to calm a concerned public, while complying with the EU regulatory requirements, and that the entire philosophy of the restrictions is based on the assumption of imminent threat – though not only to human health and the environment, but frequently also to “traditional” Bulgarian plants, with roses and tobacco being the most sensitive topics.

“Innovation was nowhere in this debate. The restrictive regulatory framework essentially means absence of motivation (coupled with lack of investment and institutional support) for research, and therefore – for innovation. Even trained scientists have to make a choice – whether to apply their skills in a different field, or to move to a different country where they can continue with their research.”

Despite the absence of innovation as a focus of discussion in the debates on the LGMO, an interesting opinion emerged from one of the interviewees, who considered the GMO field at the moment as “closed for innovation”. Rather, he turned to the novel field of synthetic biology and to the latest advances in biotechnology, such as gene editing⁶⁴, as possible pathways for biotechnology innovation:

“With 30 years of history of development and research into their risks, GMOs are actually quite safe. The knowledge on the methods and their application is solid, and some applications represent not just novelty but actual benefits to society. Addressing remaining concerns on their safety is but a matter of time. The attention for innovation is no longer on GMOs though – it is on gene editing, which evolves really rapidly, and regulations still play catch-up in much of the world.”

However, in July 2018, the European Court of Justice already ruled⁶⁵ that organisms generated by mutagenesis, including targeted mutagenesis through CRISPR-Cas and other genome editing tools should be considered GMOs and should therefore be subjected to the same regulations. That decision has met a mixed reaction, with the division of opinion matching that developed over time towards GMOs. Media reporting (in the EU) in particular has been found to be biased and often one-sided, and journalists accused of providing biased and unbalanced accounts ignoring the breadth of different positions.⁶⁶ The division of opinion among environmentalist groups and the affected industry has also

⁶⁴ A key difference between GM technology and gene editing is that the former always involves the transfer of genes from one organism to another, while the latter involves direct manipulation of the genome of the target organism, is more precise, and takes significantly less time.

⁶⁵ European Court of Justice Case C-528/16. Summary of the ruling is available at <http://curia.europa.eu/juris/document/document.jsf?text=&docid=207002&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=5986525>.

⁶⁶ Gelinsky, E. & Hilbeck, Angelika (2018). “European Court of Justice ruling regarding new genetic engineering methods scientifically justified: a commentary on the biased reporting about the recent ruling”. In *Environmental Sciences Europe*, vol. 30(1).

been rather clear and polarised – no less than on the “traditional” GMO debate.⁶⁷ Therefore, it still remains to be seen whether, at least in the EU, novel gene editing techniques will change the dynamics of the precaution versus innovation debate, and how this might reflect future regulatory developments.

6 Synthesis

Bulgarian legislation follows closely that of the EU, and has explicitly included the precautionary principle in the national LGMO. Like the majority of EU Member States, Bulgaria has been quite conservative in its regulatory approach to GMOs, effectively banning all GMOs in food products (but not in feed), as well as any planting of GMO crops. The history of the public debate, and in particular – the legislative debate, has demonstrated an approach to precaution, which is not rooted into scientific arguments, however, but rather is based on the implicit assumption of harm. There is also a strong public sentiment against any GMO use. Thus, despite the inherent complexity of the subject, regulatory actions seem to prefer to not address complexity, but rather ensure GMOs are virtually impossible. That reflect also on how risk is being perceived – not as a possibility, but as a certainty, and therefore the legislation is as restrictive as possible, while also being compatible with the EU legislative framework.

This leaves little, if any, space for a discourse on innovation. In fact, GMOs are hardly even considered as innovative. As the experts we interviewed emphasised, even laboratory use is made impossible, and so are any experiments in the field, thus effectively stifling any applied research and making any further innovation highly unlikely. On the other hand, science is fast moving forward already, and attention is being shifted to new generation of gene editing techniques, such as CRISPR-Cas9 that until very recently did not fall into the scope of GMO regulations, and are a source of different controversies. Thus a very relevant question for GMO research in Bulgaria is whether there will be sufficiently motivated (young) scientists, who would build further the national knowledge base on GMOs, who would be capable of advising – impartially and objectively - regulators and authorities in the future should this become necessary. There is a very real threat that in a few years, such expertise would be impossible to find. However, such a presumably negative scenario has not been a part of parliamentary debates, so remains without regulatory legitimisation.

On the surface, it seems that indeed too much precaution has led to no innovation, at least with respect to GMO research. It remains however debatable to what extent this situation is in fact a direct result of the precautionary principle as the foundational framework of the LGMO. The precautionary principle is an interface between science and policy, where controversy, risk and uncertainty are formally recognised and institutionalised, and science is key. The application of the principle depends on scientific processes and protocols that have taken long time to perfect. But the Bulgarian case demonstrates something different – the debate on GMOs was not a debate *exclusively* on aspects of, or being informed by scientific arguments (in terms of uncertainty, ambiguity and complexity), not on the limitations of the scientific method, not on the economic and systemic complexities and externalities, but was instead highly politicised and value-driven. In short - it was more focused on political outcomes than on the rationale of precaution or innovation. Not one opinion over more than a decade of debate has been rooted into scientific evidence, findings, or understandings without connecting these to underlying values and attitudes. Instead, it was everything else, resulting in legislative provisions that equate scientific evidence of threat to any other source of information. That is certainly not an example of (principled) precautionary thinking, but one may well argue it is a responsive (rather than

⁶⁷ A summary example of the reactions of different stakeholder groups can be seen at <https://uk.reuters.com/article/us-eu-court-gmo/top-eu-court-gmo-rules-cover-plant-gene-editing-technique-idUKKBN1KF15L>.

a responsible) approach, whereby the opinions of lawmakers resonate with the aspirations of the general public rather than with prior experience with GMO cultivation.

The innovation principle can hardly provide or be a solution in this case. If the legislation is made less restrictive (it has been before 2003), it is questionable to what extent that would result in more (domestic) innovation. There will certainly be implications for the market of foods – crops for human consumption, as well as foods containing GMOs, as well as implications for national agronomic practices and agriculture. Such a scenario, however, has not been debated, even hypothetically. Instead, there has been remarkable consensus among political parties over the years that GMOs are harmful to human health and the environment, which exhausts the scope of the GMO debate.

7 Conclusion

Bulgarian society thus far remains conservative and seems to share a preference towards being overly cautious – a sentiment that is echoed consistently by politicians and legislators since 2003. Societal consensus on the risks and benefits of GMOs is hardly ever going to be accomplished given the long history of development and use of GMOs across food supply chains, as well as that of regulatory oversight and procedural detailing. There are too many sources of divisions and the complexities are not likely to be resolved. At the same time, science and technology continue their evolution and new regulatory challenges are already present.

This case focused on the Bulgarian regulatory context in order to exemplify how the perception of GMO risks is being influenced by strong normative assumptions about imminent threat, and how the part of science within at least the parliamentary debate can be easily trumped by non-scientific, but just as legitimate, arguments. As the authors of the case study, we consider this to be a specific example of how precautionary thinking can in fact have a wider scope than a normative interpretation of the precautionary principle/approach.

The Bulgarian LGMO in itself is hardly unique within the EU, the majority of whose Member States have very similar restrictive legislation. But the political debate, and the influence of public and stakeholder pressures at key points of the debate, are uniquely illustrative of the complexity of the societal dynamics with respect to understanding, accepting, controlling and, we dare say – taming – through legislation, a subject defined by uncertainty and distrust. Furthermore, the debates are also illustrative of how easily the lack of scientific certainty translates into legal uncertainty.

To that end, it might be a subject to further inquiry about the true effects and unintended consequences of a restrictive GMO regulation.

8 References

- ____ (2012). "Are Genetically Altered Foods the Answer to World Hunger?". In *Earth Island Journal*. Published online at https://www.earthisland.org/journal/index.php/magazine/entry/are_genetically_altered_foods_the_answer_to_world_hunger/.
- Abeyasundara, A.T., Aponso, M. & De Silva, G.O. (2017). "A review on edible vaccines: A novel approach to oral immunization as a replacement of conventional vaccines". In *International Journal of Food Science and Nutrition*, vol. 2(4).

- Aerni, P. (2019). "Politicizing the Precautionary Principle: why disregarding facts should not pass for farsightedness". In *Frontiers in plant science*, vol. 10.
- Alexandratos, N. & Bruinsma, J. (2012). World agriculture towards 2030/2050: the 2012 revision.
- Biddle, J. B. (2018). "Antiscience Zealotry"? Values, Epistemic Risk, and the GMO Debate". In *Philosophy of Science*, vol. 85(3), pp. 360-379.
- Brookes, G. & Barfoot, P. (2014). "Economic impact of GM crops: the global income and production effects 1996–2012". In *GM crops & food*, vol. 5(1), pp. 65-75.
- Carroll, M. (2016). "The new agrarian double movement: hegemony and resistance in the GMO food economy". In *Review of International Political Economy*, vol. 23(1), pp.1-28.
- Chandler, S. & Dunwell, J. M. (2008). "Gene flow, risk assessment and the environmental release of transgenic plants". In *Critical reviews in plant sciences*, vol. 27(1), pp. 25-49.
- Davidson, J. & Ammann, K. (2017). "New GMO regulations for old: Determining a new future for EU crop biotechnology". In *GM Crops & Food: Biotechnology in Agriculture and the Food Chain*, vol. 8(1), pp. 13-34.
- Dennis, C. (2002). "The brave new world of RNA". In *Nature*, vol.418, pp. 122-124.
- Devos, Y., Reheul, D., De Waele, D., & Van Speybroeck, L. (2006). "The interplay between societal concerns and the regulatory frame on GM crops in the European Union". In *Environmental Biosafety Research*, vol. 5(3), pp. 127-149.
- Ellstrand, N. C., Prentice, H. C., & Hancock, J. F. (1999). "Gene flow and introgression from domesticated plants into their wild relatives". In *Annual review of Ecology and Systematics*, vol. 30(1), pp. 539-563.
- Erikson, D., Custers, R., Björnberg, K.E. & al. (2020, forthcoming). "Options to Reform the European Union Legislation on GMOs: Risk Governance". In *Trends in Biotechnology*, vol. 38(4), pp. 349-351.
- European Commission (2018). *DG RTD Management Plan 2018*. Available at https://ec.europa.eu/info/sites/info/files/management-plan-rtd-2018_en.pdf
- Frewer, L. J., van der Lans, I. A., Fischer, A. R. H., Reinders, M. J., Menozzi, D., Zhang, X., van den Berg, I. and Zimmermann, K. L. (2013). "Public perceptions of agri-food applications of genetic modification—a systematic review and meta-analysis". In *Trends in Food Science & Technology*, vol. 30(2), pp.142–152.
- Gelinsky, E. & Hilbeck, Angelika (2018). "European Court of Justice ruling regarding new genetic engineering methods scientifically justified: a commentary on the biased reporting about the recent ruling". In *Environmental Sciences Europe*, vol. 30(1).
- Gelman S.A., Rhodes M. (2012) "Two-thousand years of stasis: how psychological essentialism impedes evolutionary understanding". In: Rosengren K.S. (2012). *Evolution Challenges. Integrating Research and Practice in Teaching and Learning about Evolution*. Oxford University Press, pp. 3-21.
- Hanssen, L., Dijkstra, A. M., Sleenhoff, S., Frewer, L. J., & Gutteling, J. M. (2018). "Revisiting public debate on Genetic Modification and Genetically Modified Organisms. Explanations for contemporary Dutch public attitudes". In *Journal of Science Communication*, vol. 17(4)

- Hayes, K. R., Gregg, P. C., Gupta, V. V. S. R. et al. (2004). "Identifying hazards in complex ecological systems. Part 3: Hierarchical Holographic Model for herbicide tolerant oilseed rape". In *Environmental Biosafety Research*, vol.3(2), pp. 109-128
- Hilbeck, A., Binimelis, R., Defarge, N. et al. (2015). "No scientific consensus on GMO safety". In *Environmental Sciences Europe*, vol. 27(4).
- Hill, R.A. (2005). "Conceptualizing risk assessment methodology for genetically modified organisms". In *Environmental Biosafety Research*, vol. 4(2), pp. 67–70.
- James, C. (2013). *Global Status of Commercialized Biotech/GM Crops: 2013*. ISAAA Brief No. 46.
- Jamil, Kaiser (no date). "Biotechnology – A Solution to Hunger?". In UN Chronicle. Published online at <https://www.un.org/en/chronicle/article/biotechnology-solution-hunger>.
- Jennings, R.C. (2015). "Conflicting Values in the GM Food Crop Debate", In *Journal of Clinical Research and Bioethics*, vol.6(5)
- Klümper, W. & Qaim, M. (2014). "A meta-analysis of the impacts of genetically modified crops". In *PloS one*, vol. 9(11)
- Koplin, J., Gyngell, C. & Savulescu, J. (2020). "Germline gene editing and the precautionary principle". In *Bioethics*, vol. 34(1), pp. 49-59.
- Kramkowska, M., Grzelak, T. & Czyzewska, K. (2013). "Benefits and risks associated with genetically modified food products". In *Annals of Agricultural and Environmental Medicine*, vol. 20(3).
- Kvakkestad V, Gillund F, Kjolberg KA, Vatn A. (2007). "Scientists perspectives on the deliberate release of GM crops." In *Environmental Values*, vol. 16(1), pp. 79–104.
- Myhr, A.I. (2007). "The precautionary principle in GMO regulations", in Traavik, T. and Lim, L.C. (Eds), *Biosafety First*, chapter 29. Taapir Academic Press, Trondheim, pp. 457-67.
- Odum, Mary (2015). "Arguments against GMOs". Published online at <http://prosperouswaydown.com/arguments-gmos/>.
- Oliver, M. J. (2014). "Why we need GMO crops in agriculture", In *Missouri medicine*, vol. 111(6).
- Phillips, T. (2008). "Genetically modified organisms (GMOs): Transgenic crops and recombinant DNA technology". In *Nature Education*, vol.1(1).
- Prakash, D., Verma, S., Bhatija, R. & Tiwary, B.N. (2011). "Risks and Precautions of Genetically Modified Organisms". In *ISRN Ecology*, vol. 2011
- Raman, R. (2018). "The impact of genetically modified (GM) crops in modern agriculture: A review". In *Biotechnology in Agriculture and the Food Chain*, vol. 8(4), pp. 195-208.
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Accessible at <https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32003R1829>.
- Saletan, W. (2015). "Unhealthy Fixation: The war against genetically modified organisms is full of fearmongering, errors, and fraud. Labelling them will not make you safer." In *Slate*. Available online at

https://www.slate.com/articles/health_and_science/science/2015/07/are_gmos_safe_yes_the_case_against_them_is_full_of_fraud_lies_and_errors.html?via=gdpr-consent

- Sandman P. (1994). "Mass media and environmental risk: Seven principles.". In *Risk*, vol. 5, pp. 251-60
- Smyth, S. J., & Phillips, P. W. (2014). "Risk, regulation and biotechnology: the case of GM crops". In *GM crops & food*, vol. 5(3), pp. 170–177
- Van Tassel, K. (2009). "Genetically Modified Plants Used for Food, Risk Assessment and Uncertainty Principles: Does the Transition from Ignorance to Indeterminacy Trigger the Need for Post-market Surveillance?". In *Boston University Journal of Science and Technology Law*, vol.15.
- Vos, E. & De Smedt, K. (2020). Taking stock as a basis for the effect of the precautionary principle since 2000. RECIPES Project Deliverable WP1.
- Wolfenbarger, L. & Phifer, P. (2000). "The Ecological Risks and Benefits of Genetically Engineered Plants". In *Science*, vol. 290(5499), pp.2088-2093.
- Zetterberg, C. & Björnberg, K.E. (2017). "Time for a New EU Regulatory Framework for GM Crops?". In *Journal of Agricultural and Environmental Ethics*, vol.30, pp. 325-347
- Zhang, C., Wohlhueter, R. & Zhang, H. (2016). "Genetically modified foods: A critical review of their promise and problems". In *Food Science and Human Wellness*, vol. 5(3), pp.116-123.