

The Real and Perceived Risks of Genetically Modified Organisms – With a View on Changing Policy Following Brexit

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EXECUTIVE SUMMARY

The genetic modification of living organisms is a powerful technology able to lower the environmental impact and increase the productivity of agriculture. Its potential applications range from mine detection to public nutrition to pharmaceutical production. A comprehensive review and clear scientific consensus attest to the safety and efficacy of genetically modified organisms (GMOs). Despite the general evidence, there is ongoing debate and public concern regarding their cultivation and consumption.

In the United Kingdom (UK), GMO regulation has not substantially changed since 2001 and has yet to catch up with scientific findings and advances. Overly restrictive regulation has hamstrung innovation in the UK despite its position as a life sciences world leader. Principal GMO policy in the UK has been formulated at the European Union (EU) level. As such, Brexit presents a unique opportunity for the British government to reformulate GMO policy.

Following our comprehensive review of GMO safety and efficacy, we investigate the public perception of GMOs in the UK and the current legal framework of GMO regulation in the UK and EU. Aiming to be science based and proportionate, while fostering innovation, protecting the environment and creating an atmosphere in which the public feels safe to consume GMO products, we go on to formulate the following policy recommendations:

To maintain high safety standards, existing legislative structure should be maintained with regard to assessing transgenic expression of novel proteins for toxicity and allergenicity, as currently assessed by the Department for Environment, Food and Rural Affairs (DEFRA). Regulation should be applied to the gene and its protein product, not to the goods' mode of development. To extend the positive impact of genes previously shown to be safe for consumption, they should not require repeated safety assessments when introduced in different cultivars or species. In contrast, gene edited organisms should not require the same regulations as GMO products since they could equally be developed by conventional breeding or unrestricted mutagenesis techniques, and therefore should follow according regulations. To avoid economic harm to UK agriculture as well as the export of negative environmental impact, a GMO approved for sale should also be approved for cultivation. To further reduce potential environmental impacts, growth of GMOs should be managed to maximise

biodiversity and traits which confer pest resistance should be stacked to avoid the evolution of resistant pathogens. Additionally, transgenic GMOs should be produced to be sterile in order to minimise the risk of spread in the environment.

To create an atmosphere of transparency and guarantee consumer choice, we recommend fostering a public discourse and increasing public participation in deciding GMO labels. This approach should include a public information campaign and public consultation on views regarding GMOs, followed by a decision on GMO labelling requirements.

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GLOSSARY OF TERMS

ACRE – Advisory Committee on Releases to the Environment

BT – Bacillus thuringiensis derived insect resistance

CBD – United Nations Convention on Biological Diversity

CJEU – Court of Justice of the European Union

DEFRA – Department for Environment, Food and Rural Affairs

DNA – genetic material / deoxyribonucleic acid

EFSA – European Food Safety Authority

EU – European Union

FAO – The Food and Agriculture Organization of the United Nations

FDA – Food and Drug Administration

GHG – Greenhouse gas

GM – Genetic modification

GMO – Genetically modified organism

GURT – Genetic use restriction technology

IARC – International Agency for Research on Cancer

MNC – Multinational corporation

NGO – Non-governmental-organization

OECD – Organisation for Economic Co-operation and Development

SPS Agreement – Agreement on Sanitary and Phytosanitary Measures

UK – United Kingdom

US – United States

USD – US Dollar

WHO – World Health Organisation

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I. INTRODUCTION

The human population is growing and requiring increasing amounts of land for agriculture, with increasing environmental impacts that directly counterbalance our efforts for decarbonization and environmental sustainability. Since their conception, genetically modified organisms (GMOs) have represented a controversial, yet promising opportunity to transform our agricultural system, in much the same way as the Green Revolution of the 1960s. The negative impacts of agriculture on our planet can be mitigated with the use of carbon-efficient, low-nitrogen input, pest-resistant crops, which can be most efficiently delivered to the market using GMO and gene editing technologies. GMO agricultural applications are further complemented by a range of industrial and medical applications. GMO technology could significantly contribute to meeting several sustainable development goals of the 2030 Agenda, including: zero hunger, good health and wellbeing, responsible consumption and production, climate action, life below water and life on land. GMOs have the potential to increase yields, decrease losses and improve the sustainability of agricultural and industrial practices to ensure United Kingdom (UK) food security.

Legislation governing GMOs is highly variable around the globe and the EU (whose legislation is currently followed by the UK) has one of the strictest stances to governance of GMO growth and sale, reducing the potential for innovation and allowing other countries to streak ahead in their expertise and the benefits they derive in this sector. A very significant part of UK's biotechnology legislation implements EU rules, that applied to the UK on 31 December 2020 and have become domestic legislation under The European Union (Withdrawal) Act 2018.¹ In principle, since the transition period has ended the UK has become able to set its own approach to biotechnology regulation both internally and externally. Regulation which takes a science-based approach to judge the safety of GMOs to both humans and the environment whilst allowing the UK to take advantage of the benefits that GMOs can offer, would allow the UK agricultural and biotechnology sectors to fulfil the needs of its people whilst maintaining a competitive edge in the globalised food, feed and biofuels market.

Commercial adoption of GMOs has the potential to reduce the environmental impact of the

¹ The National Archives, 'EU Legislation and UK Law' <<https://www.legislation.gov.uk/eu-legislation-and-uk-law>> accessed 7 March 2021.

UK agricultural sector both in terms of greenhouse gas (GHG) emissions and effects on biodiversity.² With agriculture being a major source of emissions worldwide,³ GMO Technology represents a promising opportunity to aid reaching the net-zero GHG emission target set by the UK for 2050. This is of great importance in the context of climate change since Brexit offers the UK an opportunity to diverge from restrictive EU GMO regulation, towards innovation and implementation of this technology in a commercial sense. The UK's departure provides potential to improve its internal legislation and secure international trade agreements. Although the UK has significant expertise in biotechnology, its ability to produce certain agricultural goods is inherently limited by its climate. As such, trade is of great importance, with half of the food consumed in the UK in 2017 originating from outside the UK.⁴ Sensible policy and regulation with respect to GMOs is vital to maintaining UK traders' access to and competitiveness in foreign markets whilst also improving food security at home.⁵

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However, devising such legislation requires compromise between a number of often competing policy interests: scientific risk assessment and health protection; environmental and biodiversity protection; consumer information and public opinion concerns; food security and competition in markets at home and abroad; the tension between devolved competences and the need to ensure the unity of UK's internal market; the tension between a 'Green Brexit' and the need to secure trade agreements with GMO favourable countries. In other words, not only has Brexit entailed a change to the UK's legal framework for GMOs but, above all, it comes with tough political choices.⁷ The UK's exit from the EU is thus an opportunity and a challenge, and the regulation of GMOs is no exception to this.

² Graham Brookes and Peter Barfoot, 'Environmental Impacts of Genetically Modified (GM) Crop Use 1996-2016: Impacts on Pesticide Use and Carbon Emissions' [2018] GM Crops and Food.

³ Energy & Industrial Strategy Department For Business, '2017 UK Greenhouse Gas Emissions, Provisional Figures' (*Statistical Releases: National Statistics*, 2017).

⁴ Department for Environment Food & Rural Affairs, 'Food Statistics in Your Pocket 2017 - Global and UK Supply - GOV.UK' <<https://www.gov.uk/government/statistics/food-statistics-pocketbook-2017/food-statistics-in-your-pocket-2017-global-and-uk-supply>> accessed 7 March 2021.

⁵ By way of example, in 2017 in the UK, the value of food, feed and drink imports surpassed the value of exports in each category, except 'beverages' (where the UK had a trade surplus mainly due to Scotch Whisky exports) – Department for Environment Food & Rural Affairs, 'Food Statistics in Your Pocket 2017 - Global and UK Supply - GOV.UK' (n 5).

⁶ Relatively recent analyses revealed the UK is 76% self-sufficient ('production to supply ratio') in home-grown food, relying on exports for products which cannot be grown domestically due to the climate – Department for Environment Food & Rural Affairs, 'British Food and Farming at a Glance' (2016).

⁷ Ludivine Petetin, 'Brexit & Environment - GMOs Cultivation, Devolution & International Trade' (*GMO cultivation in the UK: Brexit, the devolved administrations and international trade*, 11 January 2018) <<https://www.brexitenvironment.co.uk/2018/01/11/gmos-devolution-trade/>> accessed 7 March 2021.

This paper seeks to explore the potential changes that could be made to UK legislation surrounding GMOs since leaving the EU. To do this, we will present: (II.I) The technology behind the development of GMOs; (III.I-III.II) The perceived and actual risks of GMOs; (III.III-III.IV) The legal framework currently in place under EU rules converted into domestic UK law, its problems and potential trade implications of changes.

I.I POTENTIAL BENEFITS TO THE UK

In 2019, the United Kingdom imported 45% of food consumed and in the Fruit and Vegetables category, operated a huge trade deficit between imports and exports.⁸ This makes it vulnerable to fluctuations in the global market such as occurred in 2008 where, due to factors including oil price changes and weather shocks in producing nations, prices of many foods spiked, with the price of wheat almost doubling.⁹ Such events are increasingly likely to occur due to climate change, resulting in more extreme weather events disrupting the global food network we rely on to achieve regular supply of produce.¹⁰ This may be both directly, via crop destruction, and indirectly, through the placing of social and economic strain on developing nations, which produce much of the food we import.¹¹ The global population will continue to grow, with much of this growth focused in developing, food-producing nations. Increasing domestic demand may decrease the willingness of these nations to export goods and result in higher prices.¹² ¹³ In addition, with the increased uncertainty and stricter immigration controls post-Brexit, UK farmers no longer have the same ready access to cheap, migrant labour they rely on for harvesting.¹⁴ British workers are both more difficult to find

⁸ Food Statistics Team, 'Food Statistics in Your Pocket: Global and UK Supply' (2020).

⁹ European Commission DG Environment News Alert Service, 'Causes of the 2007-2008 Global Food Crisis Identified' (2011).

¹⁰ SI Seneviratne and others, 'Changes in Climate Extremes and Their Impacts on the Natural Physical Environment.' in C. Field and others (eds), *Managing the Risks of Extreme Events and Disasters to Advance Climate Change Adaptation* (1st edn, Cambridge University Press 2012).

¹¹ Henri De Ruiter and others, 'Global Cropland and Greenhouse Gas Impacts of UK Food Supply Are Increasingly Located Overseas' (2016) 13 *Journal of the Royal Society Interface*.

¹² Jelle Bruinsma and (eds), 'World Agriculture towards 2015/2030 An FAO Perspective: Agricultural Trade, Trade Policies and the Global Food System' (2003).

¹³ Joseph Chamie, 'World Population: 2020 Overview' (*YaleGlobal Online*, 2020).

¹⁴ Katie Grant, 'Coronavirus Latest: Millions of Lettuces Left to Rot Because of a Shortage of Pickers, Farmers Say' *I.News* (May 2020); S Butler, 'Tonnes of Crops Left to Rot as Farms Struggle to Recruit EU Workers' *The Guardian* (October 2019).

and less cost-efficient, driving up costs for farmers and, thus, consumers¹⁵ These factors have the potential to cause disruption to the UK food supply, weakening the security of its food network.

The UK population is predicted to stay approximately steady over the next 30 years,¹⁶ but if we are to move toward a more sustainable, food-secure food system as part of the UK Government's commitment to net zero emissions by 2050, we must find ways to reduce the environmental impact of our agriculture which contributed 9% of total UK GHG emissions in 2019.¹⁷ Much of the growth in food production seen over the past 60 years can be attributed to increased land use and application of pesticides and fertiliser. These methods of improving a yield are almost at their limit and have caused significant environmental degradation.¹⁸ In order to meet commitments outlined by the Department for Environment, Food and Rural Affairs (DEFRA) in its 25-year environment plan,¹⁹ it will be necessary to restore farmland to a wilder state and avoid further conversion for agricultural use, whilst reducing application of fertiliser and harmful pesticides. The latter two measures both have a high ecological impact on application and are responsible for significant GHG emissions during their production.²⁰ This is particularly important as the UK is already failing to meet many of the targets outlined in the Convention on Biological Diversity²¹ including, by 2020, guaranteeing that 'areas under agriculture, aquaculture and forestry are managed sustainably, ensuring conservation of biodiversity.'²² A plethora of species are at risk of extinction, many of these due to intensive, unsustainable agriculture.²³

¹⁵ Henry Goodwin, 'British Fruit Pickers 44% Less Productive than Migrant Workers' *The London Economic* (August 2020).

¹⁶ UN, 'Replacement Migration: Is It a Solution to Declining and Ageing Populations?' (2001).

¹⁷ Committee on Climate Change, 'Reducing UK Emissions: 2020 Progress Report to Parliament' (2020).

¹⁸ Prabhu Pingali, 'Green Revolution: Impacts, Limits, and the Path Ahead' (2012) 109 Proceedings of the National Academy of Science 12302.

¹⁹ Department for Food and Rural Affairs, 'At a Glance: Summary of Targets in Our 25 Year Environment Plan' (2019).

²⁰ Sonja J Vermeulen, Bruce M Campbell and John S.I. Ingram, 'Climate Change and Food Systems' (2012) 37 Annual Review of Environment and Resources 195; E. Audsley and others, 'Estimation of the Greenhouse Gas Emissions from Agricultural Pesticide Manufacture and Use' (2009).

²¹ Phoebe Weston, 'Lost Decade for Nature' as UK Fails on 17 of 20 UN Biodiversity Targets' *The Guardian* (September 2020).

²² JNCC, 'Sixth National Report to the United Nations Convention on Biological Diversity: United Kingdom of Great Britain and Northern Ireland. Overview of the UK Assessments of Progress for the Aichi Targets.' (2019).

²³ National Biodiversity Network, 'State of Nature' (2019).

Genetic modification (GM) technology provides the potential to achieve greater food security for the UK through increased productivity of existing crops and enabling cultivation of those crops which were not previously feasible in the UK climate. Furthermore, it may help achieve this whilst enhancing the sustainability and reducing the environmental impact of our farming system by allowing the same, or even a greater production, on a similar land footprint. By reducing the amount of food imported, the UK could both achieve greater food security and resilience in its food network, whilst reducing its carbon footprint in line with international accords. The UK is a world leader in life sciences research but has a reputation for having in the past failed to capitalise on its discoveries, with much commercialisation happening in the US. If the UK creates a more amenable environment for GM technology deployment by reducing the regulatory burden which falls on companies, it may encourage development of new technologies and products. This will also open the door for the UK to become a centre for GM research in a market which is already worth ~20 billion USD and which will be worth 30 billion USD by 2026.²⁴ Whilst GM is not a silver bullet, it is certainly an integral part of renewing UK agriculture and making it more resilient in the challenging times to come.

²⁴ Fortune Business Insights, 'Genetically Modified Seeds Market Size, Share and Industry Analysis By Crop (Corn, Soybean, Cotton, Canola and Others), and Regional Forecast 2019-2026' (2019).

II. BACKGROUND

II.I. GENETIC MODIFICATION

i. What is Genetic Modification?

Genetic modification techniques are based on the principle that all measurable traits in a living organism (e.g., height, weight, yield, fat content, stress resistance) are regulated by a combination of genetic and environmental factors. To increase the output of any favourable trait, it is possible to modify the environment in which an organism is grown (e.g., application of fertilizers, pesticides and antibiotics). Or it is possible to modify the genetic material of the organism itself: the genes that control traits such as a plant's grain size or the muscle-to-fat ratio of livestock.

Genetic modification of crops and livestock for human consumption is a practice that has been performed for centuries across the globe, with the aim of increasing productivity and resistance to disease, to ensure food security. The traditional method for genetic modification of crops and animals is selective breeding, which relies on the mating of two different plant or animal varieties to generate genetic variation.

During the last 30 years, unprecedented advances in genomics and biotechnology have resulted in the development of new methods to genetically modify crops and livestock without resorting to breeding. Here, we describe the most widespread forms of genetic modification available in the 21st century (innovative and traditional) and we address the potential risks and benefits associated with each technique.

ii. Traditional Approaches to Genetic Modification

Breeding techniques are based on the principle of genetic recombination, for which the offspring of two individuals that undergo sexual reproduction will be a unique rearrangement of its two parental genomes. Complex eukaryotic organisms such as plants or animals contain thousands of genes: for example, the genome of rice (*Oryza sativa*) is estimated to contain around

37,000 genes.²⁵ When two rice plants are crossed, there are generally speaking 37,000 * 37,000 different combinations of the parental genes that can be produced in the offspring, and some of these combinations can give rise to more productive traits that can be selected for by the breeder, such as higher yield or resistance to a specific pathogen.

Breeding is an extremely effective tool that has greatly contributed to the advancement of agriculture. However, its power is limited by what range of genes are already existing in the genetic pool of the species of interest.²⁶ For example, if a gene beneficial to pathogen resistance is available in potato, this cannot be transferred to rice through conventional breeding, because the two species are not sexually compatible.

To partially overcome this limitation, modern agriculture often resorts to mutation breeding, which is the act of treating cultivars with mutagenic compounds or radiation. These treatments induce random mutations in the plant's genome and, thus, increase genetic variation.²⁷ After treatment, the mutagenized seeds are grown under selective conditions to identify mutants with favourable traits, which are then released into the market or back-crossed to commercial varieties.²⁸ To date, more than 3,200 mutant varieties with enhanced traits such as yield, stress tolerance and pest resistance have been released across the globe for commercial purposes²⁹ and, with few exceptions, they are regulated under the same laws as traditionally bred varieties.³⁰

One of the major drawbacks of mutation breeding is that all mutations occur randomly in the genome and at low frequency, and thus require screening of very large populations to identify

²⁵ International Rice Genome Sequencing Project, 'The Map-Based Sequence of the Rice Genome.' (2005) 436 Nature 793.

²⁶ RW (Robert Wayne) Allard, *Principles of Plant Breeding* (J Wiley 1999); Michael Hansen and others, 'Plant Breeding and Biotechnology' (1986) 36 BioScience 29; RA Mrode and R Thompson, *Linear Models for the Prediction of Animal Breeding Values* (CABI Pub 2005); Daniel Gianola and Guilherme JM Rosa, 'One Hundred Years of Statistical Developments in Animal Breeding' (2015) 3 Annual Review of Animal Biosciences 19.

²⁷ Yusuff Oladosu and others, 'Principle and Application of Plant Mutagenesis in Crop Improvement: A Review' (2016) 30 Biotechnology & Biotechnological Equipment 1; QY Shu and others, *Plant Mutation Breeding and Biotechnology* (CABI 2012).

²⁸ Plant Breeding and Genetics Section FAO-IAEA Joint Division and International Atomic Agency, 'Joint FAO/IAEA Mutant Variety Database' (2000) <<https://mvd.iaea.org/>>.

²⁹ Oladosu and others (n 31); M Maluszynski and others, 'Officially Released Mutant Varieties-the FAO/IAEA Database'.

³⁰ Henk J Schouten, Frans A Krens and Evert Jacobsen, 'Cisgenic Plants Are Similar to Traditionally Bred Plants: International Regulations for Genetically Modified Organisms Should Be Altered to Exempt Cisgenesis.' (2006) 7 EMBO reports 750.

desirable mutants for the trait under selection.³¹ Moreover, most mutations generated in each line are recessive, and render screening even more challenging as they do not show a phenotype in the heterozygote mutated individual.³²

iii. Innovative Approaches to Genetic Modification

Due to the limitations of the traditional methods and to the prodigious technological advancement of the genomic era, the last 30 years have seen the development of new biotechnologies in the field of agriculture, which allow for the modification of genomes without recurring to breeding or mutagens. The products from most of these new technologies are defined under the term: GMO. According to the official World Health Organisation (WHO) and the Food and Agriculture Organization of the United Nations (FAO) definition, GMOs are “organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination”.³³

Although from a regulatory perspective they all fall under the same umbrella term, these new biotechnologies can be very different in their mode of action and with regards to the final product they generate.

Transgenics

The first GMO products to be released into the market were transgenic plants in the mid 1990s.³⁴ Transgenic organisms are generated by inserting one or more genes from one species into another sexually incompatible species. This transfer can be performed between organisms of the same kingdom (i.e., plant to plant) or across kingdoms (i.e., bacteria to plant).

The foreign DNA can be inserted into the target species in different ways, some of which rely on direct delivery of the DNA molecules through microinjections, particle bombardment or

³¹ George Acquaah, *Principles of Plant Genetics and Breeding* (John Wiley & Sons, Ltd 2012).

³² *ibid*; Oladosu and others (n 31).

³³ World Health Organisation, ‘Food, Genetically Modified’ (2014) <<https://www.who.int/news-room/q-a-detail/food-genetically-modified>> accessed 17 February 2021.

³⁴ Clive James and Anatole F Krattiger, ‘Global Review of the Field Testing and Commercialization of Transgenic Plants 1986 to 1995’.

transformation.^{35 36 37}A widespread set of techniques exploits a bacterium or virus to infect the target organism and deliver the DNA. For example, in plant biotechnology, a common method of DNA delivery is through infection with the soil bacterium *Agrobacterium tumefaciens*. In the wild, *A. tumefaciens* is able to insert a piece of its own DNA inside the plant's genome to get it to produce essential nutrients necessary for its own survival.³⁸ In the lab, this process can be hijacked so that the bacterium inserts a specific piece of DNA containing the gene of interest.³⁹ In animals, the same outcome can be accomplished using modified viral vectors to infect the target cells.⁴⁰

Given that the building blocks of DNA are shared between all living organisms, the possibilities that transgenesis opens up are almost infinite. Current research is focusing on GMOs with potential high impacts on human health, the environment and productivity. For example, GM crops are being engineered to produce essential nutrients to prevent malnutrition, such as the beta-carotene-producing Golden Rice, which is being introduced in areas where vitamin A deficiency threatens hundreds of thousands of young children with blindness and death.⁴¹ From an environmental perspective, multiple independent projects are being developed to modify plants and livestock to significantly reduce methane emission from agriculture and farming, which are currently major contributors of atmospheric methane accumulation.⁴² Finally, multiple research institutes have been testing the use of genetically modified animals to produce complex drugs. These drugs are extremely expensive to produce because they can only be synthesised within a living organism.⁴³ One recent example of this technology was developed

³⁵ Götz Laible, 'Production of Transgenic Livestock: Overview of Transgenic Technologies', *Animal Biotechnology* 2 (Springer International Publishing 2018).

³⁶ Chen Zhang, Robert Wohlhueter and Han Zhang, 'Genetically Modified Foods: A Critical Review of Their Promise and Problems' (2016) 5 *Food Science and Human Wellness* 116.

³⁷ Philippe Vain, 'Thirty Years of Plant Transformation Technology Development' (2007) 5 *Plant Biotechnology Journal* 221.

³⁸ Stanton B Gelvin, "Agrobacterium-Mediated Plant Transformation: The Biology behind the Gene-Jockeying; Tool.," *Microbiology and Molecular Biology Reviews: MMBR* 67, no. 1 (March 2003): 16–37, table of contents, <https://doi.org/10.1128/MMBR.67.1.16-37.2003>.

³⁹ Zhang, Wohlhueter and Zhang (n 42).

⁴⁰ Laible (n 41).

⁴¹ X Ye and others, 'Engineering the Provitamin A (Beta-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm.' (2000) 287 *Science* (New York, N.Y.) 303; Robert E Black and others, 'Maternal and Child Undernutrition: Global and Regional Exposures and Health Consequences.' (2008) 371 *Lancet* (London, England) 243; WHO Global Database on Vitamin A Deficiency, *Global Prevalence of Vitamin A Deficiency in Populations at Risk 1995-2005* (2009).

⁴² Hinrich Schaefer and others, 'A 21st-Century Shift from Fossil-Fuel to Biogenic Methane Emissions Indicated by ¹³CH₄.' (2016) 352 *Science* (New York, N.Y.) 80.

⁴³ Lissa R Herron and others, 'A Chicken Bioreactor for Efficient Production of Functional Cytokines' (2018) 18 *BMC Biotechnology* 82.

at the University of Edinburgh, where researchers of the Roslin Institute were able to generate GM chicken that produce eggs with high levels of the human cytokine “Interferon alpha 2A”, used as an antiviral and anticancer drug.⁴⁴ This approach, although still a proof-of-concept, could be adopted by British pharmaceutical companies to produce a wide variety of drugs in a much more cost-effective manner compared to the current tissue culture-based methods, and it could contribute to lowering the cost of life-saving treatments.

To date, the most widespread GM organisms grown across the globe are in the agricultural sector: GM crops cover more than 12% of global arable land, and this figure has been consistently doubling every 5 years.⁴⁵ Two single transgenic technologies constitute more than 99% of all GM crops grown worldwide: insect-resistant (BT) and herbicide-resistant (i.e., Roundup Ready®) crops.⁴⁶

BT crops are plants that have been modified to express a toxin (CRY), naturally produced by the bacterium *Bacillus thuringiensis*. The spores of this bacterium have been widely used for organic farming since the 1920s due to its lack of side effects on non-target species.⁴⁷ Over the years different variants of the toxins were discovered that target moth larvae, flies and beetles and many of these have been introduced in staple crops (including potato, corn, cotton and soybean) to provide resistance against pathogens.⁴⁸ This technology allows for drastic reductions in the field application of broad range pesticides and, consequently, it minimises potential off-target effects on beneficial insects, lowering the environmental toll of industrial farming on the surrounding ecosystem.⁴⁹ Moreover, by reducing damage caused by insects and by eliminating the need for pesticide sprays, BT crops constitute a source of increased yield and increased income for farmers that use this technology.⁵⁰

⁴⁴ *ibid.*

⁴⁵ Clive James, ‘Global Status of Commercialized Biotech/GM Crops:2013’ (2013) 46 ISAAA brief.

⁴⁶ ISAAA Briefs, ‘Global Status of Commercialized Biotech/GM Crops in 2017: Biotech Crop Adoption Surges as Economic Benefits Accumulate in 22 Years’ (2017).

⁴⁷ Truong Phuc Hung and others, ‘Fate of Insecticidal *Bacillus Thuringiensis* Cry Protein in Soil: Differences between Purified Toxin and Biopesticide Formulation’ (2016) 72 Pest Management Science 2247.

⁴⁸ E Schnepf and others, ‘*Bacillus Thuringiensis* and Its Pesticidal Crystal Proteins.’ (1998) 62 Microbiology and molecular biology reviews : MMBR 775.

⁴⁹ Yanhui Lu and others, ‘Widespread Adoption of Bt Cotton and Insecticide Decrease Promotes Biocontrol Services’ (2012) 487 Nature 362.

⁵⁰ Michael D Edgerton and others, ‘Transgenic Insect Resistance Traits Increase Corn Yield and Yield Stability’ (2012) 30 Nature Biotechnology 493.

Herbicide-resistant crops are plants genetically modified to be insensitive to herbicides. The most famous varieties, Roundup Ready® crops (Monsanto), express a protein that renders them insensitive to the herbicide glyphosate. When fields of Roundup Ready crops are sprayed with glyphosate, the GM plants survive, whilst weeds die due to the action of the herbicide. To date, this technology is extremely dominant in the GM industry, with herbicide resistant crops constituting more than 90 percent of soybean, corn, cotton and canola fields in the United States (US) alone.⁵¹ A major impact of the introduction of herbicide resistant crops in agriculture was the reduction in herbicide applications both in terms of quantities and in the range of herbicides applied. Where these GM crops have been introduced, the system has shifted from multiple applications of selective herbicides to application of glyphosate only, sometimes in conjunction with one or two additional herbicides to prevent the emergence of weed resistance.⁵² Moreover, glyphosate has, on average, a lower environmental impact (Environmental Impact Quotient rating: 15.33) compared to other commonly used herbicides,⁵³ due to its low toxicity to humans and wildlife and its low risks of leakage into surrounding fields and water sources.⁵⁴ For a more detailed discussion of the toxicity of genetically modified organisms and glyphosate see Sub-section III.I.i.

Overall, the adoption of herbicide and pesticide resistant GM crops has been considered an important advancement for the environmental sustainability of agriculture. Indeed, the reductions in herbicide and pesticide sprays between 1996 and 2014, due to adoption of GM crops, were estimated to have decreased carbon emissions in agriculture by around 22 million kg of CO₂, equivalent to taking almost 10 million cars off the road for one year.⁵⁵

Herbicide-resistant GM crops alone contribute to lowering the carbon footprint of agriculture by favouring the adoption of reduced tillage or no tillage (RT/NT) farming.⁵⁶ Tillage (the overturning of soil before planting crops) is a common method used for mechanical weed control, which has been associated by multiple studies with a net negative impact on climate change. This is because it enhances the decomposition of organic matter in the soil and results

⁵¹ ISAAA Briefs (n 52).

⁵² Brookes and Barfoot (n 3).

⁵³ *ibid.*

⁵⁴ Antonio L Cerdeira and Stephen O Duke, 'The Current Status and Environmental Impacts of Glyphosate-Resistant Crops' (2006) 35 *Journal of Environment Quality* 1633; Wilhelm Klümper and Matin Qaim, 'A Meta-Analysis of the Impacts of Genetically Modified Crops' (2014) 9 *PLoS ONE* e111629.

⁵⁵ Brookes and Barfoot (n 3).

⁵⁶ *ibid.*

in the emission of CO₂.⁵⁷ The adoption of herbicide-resistant GM plants reduces the need for tillage, as the herbicide spraying alone is sufficient for managing weeds. It was estimated that the reduction in soil tillage associated with these GM crops, for North and South America alone, contributed to a reduction of 20,000 million kg in CO₂ emissions in 2014 (equivalent to taking 8.9 million cars off the road for one year).⁵⁸

Cisgenics

Genetic modification technologies (as described above) can also be applied to transfer a gene between different varieties of the same species, or between sexually compatible species. In this case, the genetic pool of the target organism is not affected, as the new variety generated through genetic modification could have equally been achieved through multiple rounds of crossing and selection. Indeed, the final cisgenic organisms would be indistinguishable from ones generated through selective breeding.⁵⁹ Essentially, Cisgenesis is a technological shortcut for the generation of new plant varieties in situations where crossing is technically feasible, but problematic and/or costly.

An example of such instances has been the breeding of potatoes for resistance to the potato blight disease caused by *Phytophthora infestans*. Breeding efforts to cross resistance genes from wild relatives into commercial potatoes date back as far as the mid-1800s, when the Great Irish Famine caused by an extensive *P. infestans* epidemic caused mass emigration and over a million deaths.⁶⁰ Over time, multiple resistance genes have been identified and crossed into commercial varieties, but this process was hindered by linkage drag: during crossing, genes that reduced the performance of the commercial variety were passed over together with the resistance gene, and could not be removed by backcrossing.⁶¹ The problem of linkage drag was recently overcome

⁵⁷ Donald Reicosky, 'Effects of Conservation Tillage on Soil Organic Carbon Dynamics: Field Experiments in the US Corn Belt', *International Soil Conservation Organization Conference Proceedings* (2001); AM Silva-Olaya and others, 'Carbon Dioxide Emissions under Different Soil Tillage Systems in Mechanically Harvested Sugarcane' (2013) 8 *Environmental Research Letters* 015014.

⁵⁸ Brookes and Barfoot (n 3).

⁵⁹ Schouten, Krens and Jacobsen (n 35).

⁶⁰ SM Bukasov, 'The Problems of Potato Breeding' (1936) 13 *American Potato Journal* 235.

⁶¹ R Lebecka, 'Inheritance of Resistance in *Solanum Nigrum* to *Phytophthora Infestans*' (2009) 124 *European Journal of Plant Pathology* 345; Schouten, Krens and Jacobsen (n 35).

by a successful cisgenic approach, where multiple resistance genes were stacked into a commercial potato variety through *Agrobacterium* transformation.⁶²

In addition to overcoming the technical limitations of breeding, cisgenic plants (as well as the examples below) overcome one major risk of transgenesis: gene escape. Multiple governmental bodies (including the EU) apply strict directives for the regulation of GMOs as a preventative measurement to avoid the leakage of potentially harmful genes into the environment through unintentional crossing. Since cisgenic organisms contain genes from within the gene pool of their species, they do not risk introducing a new gene into the wild and should be regulated consistently with selectively bred varieties.⁶³ If this type of regulation were to be implemented, development of cisgenic varieties could be achieved by small research centres and small-to-medium-sized enterprises and would no longer be limited to large multinational companies. Farmers would not need to buy new expensive seeds each year but could maintain and re-plant their variety in an approach similar to traditional farming. This would be considerably more affordable for smallholder farmers. Moreover, cisgenics could be crossed to local varieties, contributing to fight the rise in monocultures and to maintain local genetic diversity whilst introducing favourable traits.⁶⁴

Site-directed Nucleases

This category of genetic modification tools encompasses all techniques that use a nuclease (DNA-cutting protein) to target a specific sequence in the genome, as opposed to the random insertions generated by the transgenic approach described above. Different types of nucleases can be used to delete, edit or replace the target. The most well-known is CRISPR-Cas9.⁶⁵

⁶² Kwang-Ryong Jo and others, 'Development of Late Blight Resistant Potatoes by Cisgene Stacking' (2014) 14 *BMC Biotechnology* 50.

⁶³ E Jacobsen and HJ Schouten, 'Cisgenesis, a New Tool for Traditional Plant Breeding, Should Be Exempted from the Regulation on Genetically Modified Organisms in a Step by Step Approach' (2008) 51 *Potato Research* 75.

⁶⁴ E Jacobsen and HJ Schouten, 'Cisgenesis: An Important Sub-Invention for Traditional Plant Breeding Companies' (2009) 170 *Euphytica* 235; Jacobsen and Schouten (n 69).

⁶⁵ Frank Hartung and Joachim Schiemann, 'Precise Plant Breeding Using New Genome Editing Techniques: Opportunities, Safety and Regulation in the EU' (2014) 78 *The Plant Journal* 742; Nancy Podevin and others, 'Transgenic or Not? No Simple Answer! New Biotechnology-Based Plant Breeding Techniques and the Regulatory Landscape.' (2012) 13 *EMBO reports* 1057.

The genes encoding these nucleases (and associated molecules) are expressed within the cell to generate targeted changes in the genome. To do so, they can be transiently introduced into the cell or stably integrated into the genome and then removed through crossing, so that the final product is indistinguishable from one obtained through traditional breeding.⁶⁶ More recently, techniques have been developed that allow for the targeted delivery of nucleases to each cell without the need to be expressed by the cell itself, thus abolishing the need for stable genome integration.⁶⁷

Oligonucleotide-directed Mutagenesis

This technique exploits the use of a short fragment of DNA to introduce small, targeted mutations in a gene of interest. The DNA fragment is almost identical to the target sequence, except for a few specific mutations. Once the DNA is delivered into the cells (e.g., by microinjection) the cell's own DNA repair mechanisms will use it to stably introduce the desired mutations into the genome.⁶⁸ This technique overcomes the need for expressing a foreign gene into the target cells, since it only requires the delivery of a DNA molecule to generate the mutation. The DNA fragment is subsequently degraded by the cell itself.⁶⁹

The main advantage of site-specific mutagenesis techniques (nuclease or oligonucleotide mediated) is that they combine an exquisitely fine-tuned modification of the target gene with the lowest level of interference with the organism's genome. The final product generated is identical to the parental line except for the designed mutation. Moreover, the targeted sequence will be indistinguishable from one obtained through conventional breeding.⁷⁰

⁶⁶ Podevin and others (n 71).

⁶⁷ Je Wook Woo and others, 'DNA-Free Genome Editing in Plants with Preassembled CRISPR-Cas9 Ribonucleoproteins.' (2015) 33 *Nature biotechnology* 1162
<<http://www.ncbi.nlm.nih.gov/pubmed/26479191>> accessed 27 October 2019.

⁶⁸ PR Beetham and others, 'A Tool for Functional Plant Genomics: Chimeric RNA/DNA Oligonucleotides Cause in Vivo Gene-Specific Mutations.' (1999) 96 *Proceedings of the National Academy of Sciences of the United States of America* 8774.

⁶⁹ Noel J Sauer and others, 'Oligonucleotide-Directed Mutagenesis for Precision Gene Editing' (2016) 14 *Plant Biotechnology Journal* 496.

⁷⁰ Podevin and others (n 71).

Summary of Innovative Approaches

The innovative techniques presented in this paper are a brief introduction to the many possibilities available through the application of biotechnology to food production. In synthesis, transgenic crops and livestock provide an extremely useful tool for developing traits that can contribute to UK farmer's productivity whilst reducing the negative impact of agriculture and farming on climate change. Moreover, transgenic organisms can be further developed to provide additional services to society, such as low-cost drug production.

Independent of transgenic organisms, there is a suite of innovative technologies available for cisgenesis and gene editing. These techniques differ from transgenesis as the final product is the same as what could have been produced using traditional selective breeding. Cisgenesis and gene editing can drastically cut down variety development time and cost and they can overcome limitations of selective breeding, such as gene linkage. The application of these technologies to UK agriculture has the potential to enhance the quality and profitability of local varieties whilst maintaining competitive yield and disease resistance standards.

III. FINDINGS

To guide our exploration of potential policy changes, we have consulted the relevant scientific literature and reports and investigated the legal situation. Here, we present in turn our findings with respect to: (III.I.i-ii.) The actual and perceived risks of GMOs and (III.III-III.IV.) The legal framework currently in place under EU rules converted to domestic UK law, its problems and potential trade implications of changes.

III.I. DIRECT AND INDIRECT EFFECTS OF GENETICALLY MODIFIED ORGANISMS ON THE HEALTH OF HUMANS AND THE ENVIRONMENT

i. Human Health

A fundamental requirement for the promotion of any form of GMO is their safety and the absence of any ill effect on human health. There is a wide scientific consensus that GMOs do not inherently impact human health and may, in some cases, be beneficial by reducing pesticide use and improving nutrition. A major review based on over 900 scientific studies, by The National Academy of Science,⁷¹ one of science's most prominent bodies, and support by other organisations, including the Royal Society⁷² and the WHO⁷³, yield credence to this statement. Contrary to this scientific consensus, claims about ill health effects of GMOs are debated publicly. We will discuss these claims in detail in the below section on Toxicity but did not ultimately find any convincing evidence to support them. These claims may, instead, be indicative of a wider anti-scientific sentiment in parts of the public, also reflected in climate change denialism and anti-vaccination sentiments.

GMOs currently cultivated appear no more likely to be harmful than traditionally bred and grown food sources.⁷⁴ Despite this, it cannot be ruled out that the insertion of a new gene could not cause such effects. Thus, we support to the continued testing of crops where a new,

⁷¹ National Academy of Sciences, *Genetically Engineered Crops* (National Academies Press 2016).

⁷² The Royal Society, 'Genetically Modified (GM) Plants: Questions and Answers' (2016) <<https://royalsociety.org/topics-policy/projects/gm-plants/>> accessed 17 February 2021.

⁷³ World Health Organisation (n 38).

⁷⁴ National Academy of Sciences (n 77).

previously untested gene has been inserted.

There are several ways in which GMOs have been considered to cause harm to humans, including: toxicity, allergenicity and chemical exposure. It is important to remember that these problems are just as relevant when considering conventional breeding. We will consider them in turn.

Toxicity

Much has been made of the potential impacts that GMOs may have on the health of humans who consume them, with a widespread perception that they are in some way harmful or dangerous.⁷⁵ In the early years of GMO introduction, these beliefs were motivated by ostensibly scientific publications. This included one conducted by Arpad Pusztai who purported that lectin-producing GM potatoes caused stunted growth, harmed development and suppressed the immune system.⁷⁶ This conclusion was pushed by anti-GMO groups such as the Institute for Responsible Technology and long-time activists like Jeffrey Smith.⁷⁷ Similarly, between 2007 and 2012, Gilles-Eric Seralini published a number of papers reporting that GMO Roundup Ready crops caused a number of health problems from kidney and liver damage to cancer.⁷⁸

Although sensational in the public eye, these studies received huge criticism from the wider scientific community as regards their inadequate scientific methods and conclusions. Arpad Pusztai's work was poorly designed, with diets containing far too little protein and no clear causative link drawn between the GMO potatoes and the claimed findings.⁷⁹ Similarly, Seralini's 2007 and 2009 publications have come under fire from the European Food Safety

⁷⁵ Jeffrey Smith, '10 Reasons to Avoid GMOs' (2011); 'GMO Facts' (*Non-GMO Project*, 2016).

⁷⁶ Steve Connor, 'Science: Pusztai: The Verdict' (*The Independent*, 1999).

⁷⁷ Jeffrey Smith, 'Anniversary of a Whistleblowing Hero' (*Huffington Post*, 2010).

⁷⁸ Gilles Eric Seralini, Dominique Cellier and Joël Spiroux De Vendomois, 'New Analysis of a Rat Feeding Study with a Genetically Modified Maize Reveals Signs of Hepatorenal Toxicity' [2007] Archives of Environmental Contamination and Toxicology; Joël Spiroux de Vendômois and others, 'A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health' [2009] International Journal of Biological Sciences; Didier Hennequin Joël Spiroux de Vendomois, Gilles-Eric Seralini, Emilie Clair, Robin Mesnage, Steeve Gress, Nicolas Defarge, Manuela Malatesta, 'RETRACTED: Long Term Toxicity of a Roundup Herbicide and a Roundup-Tolerant Genetically Modified Maize' (2012) 50 Food and Chemical Toxicology 4221.

⁷⁹ The Royal British Society, 'Review of Data on Possible Toxicity of GM Potatoes' [1999] The Royal British Society; HA Kulper, HPJM Noreborn and Ad ACM Peijnenburg, 'Adequacy of Methods for Testing the Safety of Genetically Modified Foods'.

Authority (EFSA) and The French Commission du Génie Biomoléculaire (AFBV) for poor methodology and for drawing conclusions unsupported by data.⁸⁰ Furthermore, after suffering huge criticism regarding experimental group size and use of rats with a naturally high rate of cancer, his 2012 paper was retracted.⁸¹ Despite the inconsistent scientific evidence, these works have enflamed public opinion against GMOs, generating deeply negative public perception despite very little, well-conducted, scientific research suggesting that GMOs cause health problems.

Originally EFSA, and now the UK's devolved competent authorities, assess GMO safety using a comparative approach, that is, direct comparison with isogenic, non-GMO counterparts in terms of molecular, compositional, phenotypic and agronomic traits. With 90-day animal feeding trials considered useful but not strictly necessary.⁸² Many such studies have been done in multiple species with multiple different genetic modifications. Roundup Ready Soybean – one of the most widely grown GM crops, accounting for 48.2% of global cultivated GM hectareage – has been investigated thoroughly for its safety.⁸³ All such studies have found no toxic effects of the CP4 EPSPS protein which these plants express.⁸⁴ Similar work has been done in Roundup Ready and BT maize,⁸⁵ Sweet pepper/tomato resistant to Cucumber Mosaic

⁸⁰ J Doull and others, 'Report of an Expert Panel on the Reanalysis by Séralini et Al. (2007) of a 90-Day Study Conducted by Monsanto in Support of the Safety of a Genetically Modified Corn Variety (MON 863)'; and Jean-Michel Wal Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Lieve Herman, Marc De Loose, Niels Hendriksen, Sirpa Kärenlampi, Jozsef Kiss, Ilona Kryspin-Sørensen, Harry Kuiper, Ingolf Nes, Nickolas Panopoulos, Joe Perry, An, 'Statement of the Scientific Panel on Genetically Modified Organisms on the Analysis of Data from a 90-Day Rat Feeding Study with MON 863 Maize' (2007); EFSA, 'EFSA Review of Statistical Analyses Conducted for the Assessment of the MON 863 90-Day Rat Feeding Study' (2007).

⁸¹ Barbara Casassus, 'Study Linking GM Maize to Rat Tumours Is Retracted' *NATURE News* (November 2013); Joël Spiroux de Vendomois, Gilles-Eric Séralini, Emilie Clair, Robin Mesnage, Steeve Gress, Nicolas Defarge, Manuela Malatesta (n 84).

⁸² EFSA Panel on Genetically Modified Organisms (GMO), 'Guidance for Risk Assessment of Food and Feed from Genetically Modified Plants' (2011); EFSA GMO Panel Working Group on Animal Feeding Trials, 'Safety and Nutritional Assessment of GM Plants and Derived Food and Feed: The Role of Animal Feeding Trials'.

⁸³ James (n 51).

⁸⁴ LA Harrison and others, 'The Expressed Protein in Glyphosate-Tolerant Soybean, 5-Enolpyruvylshikimate-3-Phosphate Synthase from *Agrobacterium* Sp. Strain CP4, Is Rapidly Digested in Vitro and Is Not Toxic to Acutely Gavigated Mice.' (1996) 126 *The Journal of Nutrition* 728; R Teshima and others, 'Effect of GM and Non-GM Soybeans on the Immune System of BN Rats and B10A Mice' [2000] *J. Food Hyg. Soc. Japan*.

⁸⁵ R Teshima and others, 'Effect of Subchronic Feeding of Genetically Modified Corn (CBH351) on Immune System in BN Rats and B10A Mice' [2002] *Shokuhin Eiseigaku Zasshi*; B Hammond and others, 'Results of a 90-Day Safety Assurance Study with Rats Fed Grain from Corn Rootworm-Protected Corn' (2006) 44 *Food and Chemical Toxicology* 147; B Hammond and others, 'Results of a 13 Week Safety Assurance Study with Rats Fed Grain from Glyphosate Tolerant Corn' [2004] *Food and Chemical Toxicology*; Linda A Malley and others, 'Subchronic Feeding Study of DAS-59122-7 Maize Grain in Sprague-Dawley Rats' [2007] *Food and Chemical Toxicology*.

Virus⁸⁶ and potato resistant to bialophos, a natural herbicide.⁸⁷ Many critics argue that such feeding tests are insufficient to reveal long-term, sub-chronic effects of GMO consumption. However, studies which go well beyond the mandated 90 day period and which are conducted in a variety of species, show no evidence of deleterious health effects by commonly grown GMO crops.⁸⁸ Even in studies which span multiple generations, there is little to suggest adverse effects, with only minor changes in organ metabolism and immune responses which do not appear to be malignant and may well be a result of biological variation or confounding factors.⁸⁹ For an extensive review of all types of feeding study, please refer to Snell et al.⁹⁰

It must be remembered that many non-GMO crop plants naturally produce toxic compounds as defence measures. For example, potatoes produce the glycoalkaloid solanine whilst apple and cherry pips contain cyanogenic glycosides.⁹¹ Furthermore, there have been occasions where conventional breeding has produced varieties which are more toxic than previous ones. Such is the case of a celery variety conventionally bred to be more pest resistant, resulting in a 10-fold increase in the content of toxic furanocoumarins. This was not revealed until the crop caused human illness, namely, *phytophotodermatitis* in grocery store workers.⁹²

Many of the transgenic crops currently being grown have resistance to herbicides. For example, Roundup Ready crops are resistant to glyphosate. Glyphosate targets a key enzyme (EPSPS) in

⁸⁶ Zhang Liang Chen and others, 'Safety Assessment for Genetically Modified Sweet Pepper and Tomato' [2003] Toxicology.

⁸⁷ Seek Rhee Gyu and others, 'Multigeneration Reproductive and Developmental Toxicity Study of Bar Gene Inserted into Genetically Modified Potato on Rats' [2005] Journal of Toxicology and Environmental Health - Part A.

⁸⁸ NH Sissener and others, 'A Long Term Trial with Atlantic Salmon (*Salmo Salar* L.) Fed Genetically Modified Soy; Focusing General Health and Performance before, during and after the Parr-Smolt Transformation' [2009] Aquaculture; Manuela Malatesta and others, 'A Long-Term Study on Female Mice Fed on a Genetically Modified Soybean: Effects on Liver Ageing' [2008] Histochemistry and Cell Biology; K Steinke and others, 'Effects of Long-Term Feeding of Genetically Modified Corn (Event MON810) on the Performance of Lactating Dairy Cows' [2010] Journal of Animal Physiology and Animal Nutrition.

⁸⁹ R Tudisco and others, 'Fate of Transgenic DNA and Evaluation of Metabolic Effects in Goats Fed Genetically Modified Soybean and in Their Offsprings'; M Krzyzowska and others, 'The Effect of Multigenerational Diet Containing Genetically Modified Triticale on Immune System in Mice' [2010] PolJ Vet Sci.

⁹⁰ Chelsea Snell and others, 'Assessment of the Health Impact of GM Plant Diets in Long-Term and Multigenerational Animal Feeding Trials: A Literature Review'.

⁹¹ David A Warrell, 'Poisonous Plants and Aquatic Animals: Poisonous Aquatic Animals', *Hunter's Tropical Medicine and Emerging Infectious Disease: Ninth Edition* (2012).

⁹² YH Hui, Roy Smith and DG (Eds) Spoerke, *Foodborne Disease Handbook, Second Edition, Volume 3: Plant Toxicants* (2nd edn, Marcel Dekker INC 2001); SF Berkley and others, 'Dermatitis in Grocery Workers Associated with High Natural Concentrations of Furanocoumarins in Celery' [1986] Annals of Internal Medicine; Paul J Seligman and others, 'Phytophotodermatitis from Celery Among Grocery Store Workers' [1987] Archives of Dermatology.

the shikimate metabolic pathway which is vital for plant survival. Resistance is achieved by insertion of a gene encoding an EPSPS which is not susceptible to glyphosate. Thus, Roundup Ready crops can be sprayed with glyphosate, killing weeds but not the crops.⁹³ There is a widespread misconception that implementation of this technology has led to increased herbicide application while in actual fact the picture is far more complex and reflects more of a change in the profile of herbicides used than in that of the volume used.⁹⁴ The switch from using a large range of herbicides to primarily using glyphosate, in combination with one or two complementary herbicides, has led to a reduction of total herbicide active ingredient application in many countries. Where herbicide use has increased, this increase has been small and is mainly related to GM soybean growth, with adoption of GM maize actually reducing herbicide use.⁹⁵

In all cases, the environmental impact of agriculture was estimated to have been reduced by the adoption of herbicide tolerant GMOs. The safety of glyphosate is widely debated: there appears to be low risk of acute toxicity in animals as they lack the shikimate pathway but the classification of it as a ‘probable carcinogen’ in 2015 by the International Agency for Research on Cancer (IARC) instigated a wide range of research into possible low-dose effects.⁹⁶ Most other major agencies, including the EFSA and EPA do not recognise this classification.⁹⁷ The IARC’s conclusion has led to Monsanto, the producer of Roundup, being sued by multiple parties, with one Californian court awarding thirty-nine million dollars in compensation to a groundskeeper. Monsanto is still appealing this ruling at the time of writing.⁹⁸ However, a recent review of the literature around glyphosate, cancer and the 2015 IARC conclusion on genotoxicity suggests that at the levels consumers are exposed to, glyphosate does not pose a health concern.⁹⁹

⁹³ T Funke and others, ‘Molecular Basis for the Herbicide Resistance of Roundup Ready Crops’ [2006] Proceedings of the National Academy of Sciences.

⁹⁴ Brookes and Barfoot (n 3).

⁹⁵ Edward D Perry and others, ‘Genetically Engineered Crops and Pesticide Use in U.S. Maize and Soybeans’ [2016] Science Advances; Brookes and Barfoot (n 3).

⁹⁶ International Agency for Research on Cancer (IARC), ‘IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides’ [2015] Environmental Health.

⁹⁷ EFSA, ‘Glyphosate: EFSA Updates Toxicological Profile’ (2015); EPA, ‘Glyphosate Draft Human Health Risk Assessment for Registration Review’ (2017).

⁹⁸ Sam Levin, ‘Monsanto Trial: Judge Rejects Bid to Overturn Landmark Cancer Verdict’ *The Guardian* (October 2018).

⁹⁹ Jose V. Tarazona and others, ‘Glyphosate Toxicity and Carcinogenicity: A Review of the Scientific Basis of the European Union Assessment and Its Differences with IARC’.

While the debate on glyphosate's carcinogenicity continues, this it does not change the fact that pesticides and GMOs should not be conflated and that it is not GMO technology that is potentially harmful in this case. If there is any risk to the public due to the use of glyphosate, it is due to the nature of the chemical itself and not to the engineered ability of GM plants to withstand it.

Allergenicity

All food allergens are proteins and as such there is a possibility that, by introducing genes from another species - particularly highly allergenic ones like peanuts - there may also be transferral of allergenicity. This could pose a real risk for those who suffer from severe allergic reactions to certain food products. Individuals might no longer be able to identify foodstuffs that trigger a known allergy. There is also potential that the insertion of a gene from another species may create new allergenicity either by altering protein structure or expression levels.¹⁰⁰ As a result, the Food and Drug Administration (FDA) recommends that all transferred genes should be automatically assumed to be allergens until shown otherwise.¹⁰¹ This is simple if it is known that a particular protein is responsible for the allergenicity of a food but more complex when the basis for a foodstuffs allergenicity is unknown. However, it is possible to assess allergenicity of transgenic crops by assessing whether GM foods react with antibodies in the sera of individuals with known allergies and if the protein encoded by the transferred gene bears any similarities to known allergens. Furthermore, the use of animal models shows promise for predicting allergenicity.¹⁰²

Since only very few proteins in foods are allergens, it is relatively unlikely that one would be introduced in a GMO.¹⁰³ However, there have been some incidences of genetic engineering resulting in allergenicity of novel transgenic crops. In some cases due to the introduced protein having structural variation compared to its native host when synthesised in a non-native

¹⁰⁰ Trish Malarkey, 'Human Health Concerns with GM Crops', *Mutation Research - Reviews in Mutation Research* (2003).

¹⁰¹ FDA, 'Statement of Policy: Foods Derived from New Plant Varieties' [1992] Federal Register.

¹⁰² Kimber Ian and J Dearman Rebecca, 'Can Animal Models Predict Food Allergenicity?' [2001] *Nutrition Bulletin*; Babu Gonipeta, Eunjung Kim and Venu Gangur, 'Mouse Models of Food Allergy: How Well Do They Simulate the Human Disorder?' [2015] *Critical Reviews in Food Science and Nutrition*.

¹⁰³ Dean D Metcalfe and others, 'Assessment of the Allergenic Potential of Foods Derived from Genetically Engineered Crop Plants*' [1996] *Critical Reviews in Food Science and Nutrition*.

plant¹⁰⁴ and in other cases due to the introduction of a protein from a known allergenic food, e.g., the Brazil nut.¹⁰⁵ It is clear then that this is a potential risk of genetically engineered foods, which can only be mitigated by appropriate testing before commercialisation and by implementing of adequate labelling of food products.¹⁰⁶ On the other hand, genetic modification may even provide routes for making previously allergy-inducing foods non-allergenic, for example by suppressing gluten production in wheat¹⁰⁷ or by preventing allergen accumulation in soybean.¹⁰⁸

There have been no instances of allergens being found in GMOs approved for human consumption but there has been a reported incidence of cross-contamination of corn products by GM corn expressing pesticidal Cry9C protein. The latter had not been approved for human consumption but only for animal feed, due to concerns that it could be (and turned out to be) allergenic.¹⁰⁹ Though clearly a problem, this was not a failure of the product itself or of the safety testing in place to assess it, but of the regulations in place surrounding its growth and processing. Guidelines regarding planting distances from non-GMO corn were likely not followed and there was no robust surveillance in place to ensure that Bt corn did not enter the human food supply until after the contamination occurred.¹¹⁰

Human Transgenesis

It has been suggested that GM crops should not be used as animal feed due to the concern that transgenic DNA could be transferred to animals and from there, to the humans who consume them. DNA is a daily part of animal and human diets, most of which suffers degradation due to gastric acid and microbial damage either during feed processing or digestion.¹¹¹ However, it has been shown that small fragments are able to survive (up to 1.7 Kilobases) and can be found

¹⁰⁴ Vanessa E Prescott and others, 'Transgenic Expression of Bean α -Amylase Inhibitor in Peas Results in Altered Structure and Immunogenicity' [2005] *Journal of Agricultural and Food Chemistry*.

¹⁰⁵ Julie A Nordlee and others, 'Identification of a Brazil-Nut Allergen in Transgenic Soybeans' [1996] *New England Journal of Medicine*.

¹⁰⁶ Suzie Key, Julian KC Ma and Pascal MW Drake, 'Genetically Modified Plants and Human Health'; Malarkey (n 106).

¹⁰⁷ S Wen and others, 'Structural Genes of Wheat and Barley 5-Methylcytosine DNA Glycosylases and Their Potential Applications for Human Health' [2012] *Proceedings of the National Academy of Sciences*.

¹⁰⁸ Eliot Herman, 'Soybean Allergenicity and Suppression of the Immunodominant Allergen', *Crop Science* (2005).

¹⁰⁹ Andrew Pollack, 'Kraft Recalls Taco Shells With Bioengineered Corn' [2000] *New York Times*.

¹¹⁰ EPA, 'Starlink™ Corn Regulatory Information' (2008).

¹¹¹ Nicolas Gryson, 'Effect of Food Processing on Plant DNA Degradation and PCR-Based GMO Analysis: A Review'.

in Peyer's patches, peripheral white blood cells and cells of the spleen and liver of animals.¹¹² This occurs frequently with natural high-copy plant DNA such as genes encoding Rubisco.¹¹³ It is possible therefore that transgenes could also be taken up by the body. However, transgenic DNA would only make up an infinitesimal fraction of the total DNA consumed by animals. It is highly unlikely that it would be absorbed and even if it was, there is no reason to think it should be harmful since it cannot be used to produce protein.¹¹⁴ There is little evidence to suggest that transgenic DNA is transferred into animal products such as milk and eggs with several authors finding no evidence of transgenic DNA in these products.¹¹⁵ Similarly, transgenic proteins are degraded during feed processing and passage through the digestive system, with no evidence of their presence in animal tissues or products.¹¹⁶

Summary of the Effects of GMOs on Human Health

As such, the measures in place to assess the toxicity of transgenic crops seem to be more than sufficient and expose no evidence of either toxicity or sub-chronic effects of GMO products, with no further reason to suppose they should. Where genetic modification produces allergenicity, there are robust measures available to test it. Furthermore, exposure to either transgenes unapproved for human consumption or their proteins is highly unlikely via an animal route.

¹¹² M Palka-Santini and others, 'The Gastrointestinal Tract as the Portal of Entry for Foreign Macromolecules: Fate of DNA and Proteins' [2003] *Molecular Genetics and Genomics*; Aurora Rizzi and others, 'The Stability and Degradation of Dietary DNA in the Gastrointestinal Tract of Mammals: Implications for Horizontal Gene Transfer and the Biosafety of GMOs' [2012] *CRITICAL REVIEWS IN FOOD SCIENCE AND NUTRITION*.

¹¹³ Anne Nemeth and others, 'Sensitive PCR Analysis of Animal Tissue Samples for Fragments of Endogenous and Transgenic Plant DNA' [2004] *Journal of Agricultural and Food Chemistry*.

¹¹⁴ Gerhard Flachowsky, Andrew Chesson and Karen Aulrich, 'Animal Nutrition with Feeds from Genetically Modified Plants'.

¹¹⁵ A Korwin-Kossakowska and others, 'Health Status and Potential Uptake of Transgenic DNA by Japanese Quail Fed Diets Containing Genetically Modified Plant Ingredients over 10 Generations' [2016] *British Poultry Science*; Gerhard Flachowsky and Tim Reuter, 'Future Challenges Feeding Transgenic Plants' [2017] *Animal Frontiers*.

¹¹⁶ Patrick Guertler and others, 'Long-Term Feeding of Genetically Modified Corn (MON810) - Fate of Cry1Ab DNA and Recombinant Protein during the Metabolism of the Dairy Cow' [2010] *Livestock Science*; Qiugang Ma and others, 'Detection of Transgenic and Endogenous Plant DNA Fragments and Proteins in the Digesta, Blood, Tissues, and Eggs of Laying Hens Fed with Phytase Transgenic Corn' [2013] *PLoS ONE*; Lin Lu and others, 'Influence of Phytase Transgenic Corn on the Intestinal Microflora and the Fate of Transgenic DNA and Protein in Digesta and Tissues of Broilers' [2015] *PLoS ONE*; Patrick Guertler and others, 'Sensitive and Highly Specific Quantitative Real-Time PCR and ELISA for Recording a Potential Transfer of Novel DNA and Cry1Ab Protein from Feed into Bovine Milk' [2009] *Analytical and Bioanalytical Chemistry*.

ii. Environmental Health

There is considerable concern over the way in which GMOs could impact the environment they grow in, both in terms of biodiversity and in our ability to produce food. These concerns focus mainly on the potential effects of transgenic crops on non-target species and the creation of so-called ‘superweeds’. These risks are often used by anti-GMO groups to argue against the commercialisation of all genetically engineered crops.¹¹⁷ Whilst it is important to understand these risks and work to mitigate them, substantial research on the topic suggests it is possible to prevent and mitigate environmental risks without resorting to banning GMO products *a priori* of their environmental footprint.

Gene Escape

A concern regarding the growth of GMOs is the potential for the ‘escape’ of transgenes into wild populations, creating the possibility of a weed species which cannot be controlled with common herbicides and which could damage crop yields. There are multiple cases of GMOs growing far from where they are cultivated¹¹⁸ and, in some cases, introgression of transgenes into wild populations of related species.^{119,120} Such events could result in increased herbicide use and the necessity of more toxic herbicides, as well as having the potential to damage genetic diversity of wild populations.¹²¹ In the case of glyphosate, this is a risk factor inherent with the specific gene chosen for transgenesis (i.e. herbicide resistance), not a risk associated with genetic modification itself. Furthermore, recent research indicates that increased use of glyphosate has actually reduced the rate of incidence of herbicide tolerant weeds in the US due to it replacing many herbicides which are more likely to give rise to herbicide resistance.¹²²

¹¹⁷ Institute for Responsible Technology, ‘Dangers to the Environment’ (*IRT*).

¹¹⁸ Natasha Gilbert, ‘GM Crop Escapes into the American Wild’ (2010).

¹¹⁹ ML Zapiola and others, ‘Escape and Establishment of Transgenic Glyphosate-Resistant Creeping Bentgrass *Agrostis Stolonifera* in Oregon, USA: A 4-Year Study’ [2008] *Journal of Applied Ecology*; María L Zapiola and Carol A Mallory-Smith, ‘Crossing the Divide: Gene Flow Produces Intergeneric Hybrid in Feral Transgenic Creeping Bentgrass Population’ [2012] *Molecular Ecology*.

¹²⁰ A Wegier and others, ‘Recent Long-Distance Transgene Flow into Wild Populations Conforms to Historical Patterns of Gene Flow in Cotton (*Gossypium Hirsutum*) at Its Centre of Origin’ [2011] *Molecular Ecology*.

¹²¹ A Bauer-Panskus and others, ‘Cultivation-Independent Establishment of Genetically Engineered Plants in Natural Populations: Current Evidence and Implications for EU Regulation’ (2013) 25 *Environmental Sciences Europe*.

¹²² Andrew R Kniss, ‘Genetically Engineered Herbicide-Resistant Crops and Herbicide-Resistant Weed Evolution in the United States’ [2018] *Weed Science*.

There are a number of techniques available to stop GMO escape and transgene jumping, some simpler than others. In the case of GM microbes such as algae or yeast, it is possible to engineer dependence on a particular nutrient which does not usually occur in the environment such that if said microbe does escape it is unable to survive in the wild.¹²³ This method of biocontainment is useful but would be difficult to implement on a larger scale such as with field-grown crops. In the latter instance, a more practical approach may involve engineering sterility into GMOs alongside the desired trait. This can be achieved in a fairly blunt manner by engineering postponed flowering or floral sterility, something which has been shown to work in poplar.¹²⁴ This sort of approach would not be appropriate for many crops as the part we want to eat often develop from flowers.

A more functional approach in the context of food crops is to use Genetic Use Restriction Technologies (GURTs) which essentially act to ensure that any seed produced is sterile. These work by having a cytotoxic protein the expression of which is restricted to the plant embryo by a promoter or is chemically inducible.¹²⁵ Though initially developed for protection of intellectual property, that is, to prevent the seed being kept for use in the following season, this technology represents an important avenue by which transgenic crops could be kept under regulatory control. Despite this, there is currently a moratorium on this technology, primarily due to a failure to keep up with the pace of change in GMO research and activism by Environmental pressure groups.^{126,127,128}

Impact on Non-target Organisms

Many of the ecological concerns around GMOs are based on the possibility of negative effects on non-target organisms. Bees are one such example, their pollination services being of great

¹²³ Kei Motomura and others, ‘Synthetic Phosphorus Metabolic Pathway for Biosafety and Contamination Management of Cyanobacterial Cultivation’ *ACS Synthetic Biology* (2018).

¹²⁴ Amy Leigh Klocko and others, ‘Phenotypic Expression and Stability in a Large-Scale Field Study of Genetically Engineered Poplars Containing Sexual Containment Transgenes’ [2018] *Frontiers in Bioengineering and Biotechnology*.

¹²⁵ Luca Lombardo, ‘Genetic Use Restriction Technologies: A Review’.

¹²⁶ The Royal Society, ‘What Can Be Done to Prevent Cross Breeding of GM Crops?’ (2019).

¹²⁷ Convention on Biological Diversity, ‘DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY AT ITS EIGHTH MEETING’ (2006).

¹²⁸ Giovanni Tagliabue, ‘The EU Legislation on “GMOs” between Nonsense and Protectionism: An Ongoing Schumpeterian Chain of Public Choices’ [2017] *GM Crops and Food*.

importance both ecologically and to our food systems. Bees collect both nectar and pollen from plants, the latter being the most likely route of exposure to transgenes due to its high protein content. The risk to bees is unlikely to come from herbicide resistant GMO crops,¹²⁹ but from those which exhibit insect resistance. Bees are also insects and thus bear physiological similarities to the organisms targeted by insect resistance.¹³⁰ There have been a wide array of studies to try and assess the impact of Bt protein on non-target insects. These have shown mixed results, but there is no overall consensus that BT-resistant plants demonstrate toxicity or that they accumulate in the environment.^{131,132} There have also been several studies looking specifically at effects of the Bt toxin on honeybees with no indication of any toxicity.¹³³ This risk can nonetheless be mitigated during GMO design by ensuring the expression of Bt is regulated by a promoter which does not express in pollen. The Bt protein would then not be produced in pollen, preventing bees from exposure to the toxin. Furthermore, it appears that Bt toxins do not persist in large quantities in the environment, reducing the risk of non-target effects, although this depends to a degree on the particular conditions, they are exposed to.¹³⁴

In many ways, GMO insect resistance technology may in fact be beneficial to the environment. The reason being that commercialisation has reduced the application of exogenous insecticides, many of which are highly damaging to non-target insect populations.¹³⁵

It is also possible that GMO crops may have a more indirect impact on non-target organisms,

¹²⁹ Zachary Y Huang and others, 'Field and Semifield Evaluation of Impacts of Transgenic Canola Pollen on Survival and Development of Worker Honey Bees' [2004] *Journal of Economic Entomology*; J Pierre and others, 'Effects of Herbicide-Tolerant Transgenic Oilseed Rape Genotypes on Honey Bees and Other Pollinating Insects under Field Conditions' [2003] *Entomologia Experimentalis et Applicata*.

¹³⁰ Rosalind James and Theresa L Pitts-Singer, *Bee Pollination in Agricultural Ecosystems* (2008).

¹³¹ (Reviewed in O'Callaghan et al., 2005)

¹³² Daniela Chaves Resende and others, 'Does Bt Maize Cultivation Affect the Non-Target Insect Community in the Agro Ecosystem?' [2016] *Revista Brasileira de Entomologia*.

¹³³ Malone and Pham-Delègue, "Effects of Transgene Products on Honey Bees (*Apis Mellifera*) and Bumblebees (*Bombus* Sp.); Malone et al., "Development of Hypopharyngeal Glands in Adult Honey Bees Fed with a Bt Toxin, a Biotin-Binding Protein and a Protease Inhibitor"; Babendreier et al., "Influence of Bt-Transgenic Pollen, Bt-Toxin and Protease Inhibitor (SBTI) Ingestion on Development of the Hypopharyngeal Glands in Honeybees."

¹³⁴ Natalie A Griffiths and others, 'Occurrence, Leaching, and Degradation of Cry1Ab Protein from Transgenic Maize Detritus in Agricultural Streams' [2017] *Science of the Total Environment*; Mei Jun Zhang and others, 'Impact of Water Content and Temperature on the Degradation of Cry1Ac Protein in Leaves and Buds of Bt Cotton in the Soil' [2015] *PLoS ONE*; Yuanjiao Feng and others, 'Effects of Temperature, Water Content and PH on Degradation of Cry1Ab Protein Released from Bt Corn Straw in Soil' [2011] *Soil Biology and Biochemistry*.

¹³⁵ N Tsvetkov and others, 'Chronic Exposure to Neonicotinoids Reduces Honey Bee Health near Corn Crops' [2017] *Science*; BA Woodcock and others, 'Country-Specific Effects of Neonicotinoid Pesticides on Honey Bees and Wild Bees' [2017] *Science*; Brookes and Barfoot (n 3).

such as by reducing biodiversity. It is thought that this could occur due to the effective weed suppression that herbicide resistant crops allow which could reduce the amount of food and habitat for some species.¹³⁶ However, research indicates that loss of weed diversity is not necessarily a result of growing herbicide resistant crops and that if there is an effect it is fairly transient and also dependent on exactly which crop is grown. For example, growth of BT maize increases abundance and diversity of both weeds and insects due to suppression of the dominant weed species.¹³⁷ There is some evidence to suggest lower diversity in BT beet and oilseed rape.^{138,139} These differences between GMO crops appear to be the consequence of the variety of agricultural management techniques employed. For example, Heard et al state that “in glyphosate-resistant crops receiving only a single post-emergence application of herbicide, weed diversity actually increased because of suppression of the dominant species”.¹⁴⁰ As such, it may be wise to either alter some of the management techniques used for BT crops to try and preserve diversity of pollinators in particular. Furthermore, the implementation of sustainable agriculture practices alongside both traditional and GMO varieties is advisable, for example, utilising wildflower buffer zones around crop fields has been shown to be beneficial for various types of bees.¹⁴¹ Such schemes already exist in England under Natural England’s Environmental Stewardship programme, although participation is optional.¹⁴²

¹³⁶ Gesine Schütte and others, ‘Herbicide Resistance and Biodiversity: Agronomic and Environmental Aspects of Genetically Modified Herbicide-Resistant Plants’.

¹³⁷ MS Heard and others, ‘Weeds in Fields with Contrasting Conventional and Genetically Modified Herbicide-Tolerant Crops. I. Effects on Abundance and Diversity’ [2003] *Philosophical Transactions of the Royal Society B: Biological Sciences*; DR Brooks and others, ‘Invertebrate Responses to the Management of Genetically Modified Herbicide-Tolerant and Conventional Spring Crops. I. Soil-Surface-Active Invertebrates’ [2003] *Philosophical Transactions of the Royal Society B: Biological Sciences*.

¹³⁸ David A Bohan and others, ‘Effects on Weed and Invertebrate Abundance and Diversity of Herbicide Management in Genetically Modified Herbicide-Tolerant Winter-Sown Oilseed Rape’ [2005] *Proceedings of the Royal Society B: Biological Sciences*.

¹³⁹ C Hawes and others, ‘Responses of Plants and Invertebrate Trophic Groups to Contrasting Herbicide Regimes in the Farm Scale Evaluations of Genetically Modified Herbicide-Tolerant Crops’ [2003] *Philosophical Transactions of the Royal Society B: Biological Sciences*.

¹⁴⁰ Heard and others (n 143).

¹⁴¹ RF Pywell and others, ‘Effectiveness of New Agri-Environment Schemes in Providing Foraging Resources for Bumblebees in Intensively Farmed Landscapes’ [2006] *Biological Conservation*; C Carvell and others, ‘Comparing the Efficacy of Agri-Environment Schemes to Enhance Bumble Bee Abundance and Diversity on Arable Field Margins’ [2007] *Journal of Applied Ecology*.

¹⁴² Ian Hodge and Mark Reader, ‘The Introduction of Entry Level Stewardship in England: Extension or Dilution in Agri-Environment Policy?’ [2010] *Land Use Policy*.

III.II. THE PERCEPTION OF GENETICALLY MODIFIED ORGANISMS

We have established that there is a wide scientific consensus on the safety of GMOs. Despite this, a vocal part of the population remains concerned about the health impact of GMOs. According to the ‘Biannual Public Attitudes Tracker’ by the Food Standards Agency 17% of the respondents said they are worried about the use of GMOs when selecting issues from a prompted list.¹⁴³

Concerns regarding GMO safety can be traced to the flawed introduction of GM food to the UK and European markets from the mid-1990s to today. Large GMO producers, most prominently Monsanto, were perceived as *secretive and arrogant*. Monsanto’s fast entry in the UK market without prior introduction of sensible regulation left the government at odds with critics. Taking measures regarding regulation beforehand would have decreased delays in adoption and increased alleviation of public and opposition concerns. Furthermore, supply chain dynamics influenced GM adoption. In the late 1990s, UK supermarkets started dropping GM ingredients, as they were vulnerable to pressure from buyers in the competitive market. Moreover, mostly American biotechnology firms failed to secure buy-in from European processors, handlers, and retailers, who could have used their local influence to increase the acceptance of GM products.¹⁴⁴

The debate and public perception of GMOs with regard to their safety has been largely influenced by the media and non-governmental-organizations (NGOs) and too little by the scientific community and governmental institutions. By emotionally charging GMO coverage, the scientific evidence regarding real risks and benefits has been overlooked. In some instances, the media has used emotive language to exacerbate people’s concerns. Furthermore, the media conveyed messages from lobby groups, leading to a dissemination of information which was not based on scientific facts but rather political or economic interests. It is therefore important to create an environment in which consumers feel safe and have access to information based on facts.

¹⁴³ Biannual Public Attitudes Tracker, Food Standards Agency, November 2018.

¹⁴⁴ J Mohorčich, ‘What Can the Adoption of GM Foods Teach Us about the Adoption of Other Food Technologies?’ 1.

Since 2014, the Food Standard Agency (FSA) has been conducting a ‘Biannual Public Attitudes Tracker’ to monitor public perceptions of food safety issues in the UK. On average 2,000 respondents are asked without further direction to state which food issues they are concerned about, and subsequently asked to select food issues of concern from prompted lists. Looking at the conducted surveys of the last 5 years retrospectively, concerns about GM food among the respondents have remained at a relatively steady amount of about 17%, when choosing from of a prompted list.¹⁴⁵

In 2014 and 2015 there was a steady percentage of about 17% in concerns regarding GM food. However, in November of 2016 concerns about GMOs when selecting from a list of different issues increased from 16% (May 2016) to 19% (November 2016). This could be seen in the context of the turmoil happening in the UK around the Brexit-vote in June 2016. Only one year later in November 2017, the concerns upon the respondents went back to 17%, though Northern Ireland was more sceptical as compared to England and Wales. However, when asked without a prompted list, the study interviewees were significantly less concerned about GM-products. In May 2019 on average only 5% commented on having reservations regarding GM-foods. This included respondents from all categories of age, social grade, gender and region. This suggests that even though doubt does exist, the public is not actively contemplating GM-products as presumed.

The survey conducted in November 2018 showed an average concern in England, Wales and Northern Ireland of 23%, though the concern varied in-between the National Readership Survey (NRS) social grades. While in the upper middle class and middle class (known as social grade AB) 33% of the respondents reported concern with regard to GM-food, in comparison, those of the working and non-working class (social grade DE) only presented concerns of 15%.

Another poll, conducted by YouGov in the year of 2014 suggested that 4 in 10 British adults still held negative views of genetically modified food, with few feeling more positively than they recalled feeling 12 months ago. However, 31% also expressed that they ‘do not know’,

¹⁴⁵ FSA, ‘Biannual Public Attitudes Tracker - May 2014’ (2014); FSA, ‘Biannual Public Attitudes Tracker - November 2014’ (2014); FSA, ‘Biannual Public Attitudes Tracker - May 2015’ (2015); FSA, ‘Biannual Public Attitudes Tracker - November 2015’ (2015); FSA, “Biannual Public Attitudes Tracker - May 2016”; FSA, “Biannual Public Attitudes Tracker - November 2016”; FSA, “Biannual Public Attitudes Tracker - May 2017”; FSA, “Biannual Public Attitudes Tracker - November 2017”; FSA, “Biannual Public Attitudes Tracker - May 2018”, FSA, “Biannual Public Attitudes Tracker - November 2018”; FSA, “Biannual Public Attitudes Tracker - May 2018”, FSA, “Biannual Public Attitudes Tracker - May 2019.

when asked how their opinion has been formed. It may therefore be argued, that if they do not know how their opinion developed, this is because they have not held strong opinions until questioned. With these findings in mind, it appears that the majority of British adults is either in favour of GM food or indecisive, because of lack of knowledge and uncertainty resulting from diverging and sometimes emotionally biased views in the public debate.

Moreover, a 2016 poll of Populus, financed by Bayer, a German pharmaceutical company which launched a successful takeover bid for Monsanto in the same year, conducted a survey with 2,000 participants from across the UK. They did not provide information to all the questions which had been asked in the poll. The ones which have been published are formulated broadly: ranging from ‘To what extent do you think farmers are important or not important to the UK economy and way of life?’ to ‘To what extent do you think it is important or not important that the UK produces its own food?’.¹⁴⁶ Neither a survey report nor essential information including the questions about GM crops asked have been published, making this poll a questionable source of information. Despite this, newspapers such as the British ‘The Times’ have published articles based on the survey. ‘The Times’ article is titled ‘Two thirds of public would back growing GM crops, study claims’, however the creditability of this article cannot be assessed if the source and the data from the poll are concealed from the public.

The article claims that the poll is able to show that ‘two thirds of respondents said that they would support GM food so long as it did not harm public health or the environment. The article cites the Populus survey as suggesting fifty-four percent of respondents said that they agreed with the crops in principle and a further 10 percent said they were the only way to feed a growing global population. Only 27 percent said that they could not countenance the method’.¹⁴⁷ This shows how media may disseminate messages from lobby groups, leading to a distribution of information which is not based on scientific facts but rather on political or economic interests. With the vast amount of information about GMOs, from scientific facts to emotionally charged informational campaigns it has become difficult to differentiate between true and false information with regard to the GMO debate.

Moreover, in 2018 a survey was conducted by the Government of the UK on a range of possible paths for food, farming and the environment in England after Brexit. One of the findings with

¹⁴⁶ Populus, ‘Crop Science & Agriculture Survey’ (2016).

¹⁴⁷ Oliver Moody, ‘Two Thirds of Public Would Back Growing GM Crops, Study Claims’ *The Times*.

regard to the question: ‘What are the agriculture and land management policy areas where a common approach across the UK is necessary?’ was that there was a need for a common approach for consistent regulation on GMOs and pesticides, as the stakeholders felt that policy divergence would weaken safeguards in the rest of the UK. The Country Land and Business Association, a membership organization for owners of land, property and business in rural areas, argued that scientists see the prevalent EU regulation as a barrier to farmers and land managers applying the products of research. Furthermore, they suggested that with regard to GMOs, regulation should apply at the product level irrespective of the techniques used in development. Responses by GM sceptic public campaigns called for stricter GMO regulation alleging that this would protect the health of people, animals and the environment. They asked for clearer labelling, including of animals fed with GM feed.¹⁴⁸

Consumer negativity towards GM-food has been mainly thought to exist because of consumer’s balancing of real risks against the benefits of GM foods. However, past and recent studies exploring the perception of risk, have failed to include the impact of emotional language used in public and media debate when discussing GM foods. The individual’s perception of risk is affected by socio-cultural and media influences.¹⁴⁹ Hence, the avoidance of emotional language is crucial when trying to assess how to transform the public debate from a badly informed and emotionally charged one, to a debate based in scientific, objective facts and trust and lacking unnecessary anxiety and scaremongering.

i. Key Stakeholders in the Public Debate Surrounding GMOs

Consumers are key actors for policy makers trying to change the public perception and to have an open and scientific debate. However, this stakeholder group is influenced by NGOs. Therefore, the following sections will focus on these two stakeholder groups and seek to put into context the current debate on GMOs.

¹⁴⁸ DEFRA, ‘Health and Harmony: The Future for Food, Farming and the Environment in a Green Brexit’ (2018).

¹⁴⁹ Hélène Joffé, ‘Risk: From Perception to Social Representation’ (2003) 42 *British Journal of Social Psychology* 55.

Non-Governmental Organizations with an Interest in Biotechnology / Consumer Interest Groups

In the course of consultative meetings with NGOs and a conference in collaboration with the British government, the Organisation for Economic Co-operation and Development (OECD) has monitored the reservations, different views, positions and general differences put forward by NGOs. It subsequently identified that the group of **environmentalists** and the group of **consumer organisations** have the biggest impact on public perception. The former, being probably the most vocal one, allege that GMOs irreversibly upset the balance of nature. That is why they ask for a moratorium on the production and distribution of GMOs until more research is done on the potential effects on flora, fauna and, consequently, human beings. In contrast, the latter request a freedom of consumer choice, by asking for more informative labelling regarding GMOs in food due to inter alia ethical, religious, and health reasons. GMO labelling has already been implemented by the European Commission in the past.¹⁵⁰ Because NGOs are not seeking profits in the market in contrast to private enterprises which sell GMO seeds, they frequently seem more trustworthy to the public. Nevertheless, the success of anti-GMO campaigns remains a puzzle, given the absence of evidence related to new risks from the technology as well as an abundance of proof that it supports the fact that farmers are reducing chemical inputs and saving labour expenses.

This formerly-European debate, especially anti-GMO campaigns, regarding the desirability of GM agriculture has also reached developing countries, in particular across Sub-Saharan Africa. As a result, uncertainty in policymaking has evolved and lengthy as well as complicated approval processes for GM-crops are a widespread reality.¹⁵¹ This is especially unfortunate, due to the immense population growth in the region and the prevalence of malnutrition. The deployment of GM crops in Sub-Saharan Africa could offer both enhanced nutrient content, as well as increased crop yields and disease resistance.¹⁵²

¹⁵⁰ Jean Eric Aubert, 'NGOs on GMOs: The Reasons for Resistance' [2000] OECD Observer 47.

¹⁵¹ Justus Wesseler and others, 'Foregone Benefits of Important Food Crop Improvements in Sub-Saharan Africa' (2017) 12 PLOS ONE e0181353.

¹⁵² Christopher JM Whitty and others, 'Africa and Asia Need a Rational Debate on GM Crops' (2013) 497 Nature 31.

The original UK anti-GMO campaign success was powered by an unrelated, but thoroughly legitimate food safety scare. It was triggered by the acknowledgement of the UK government, in March 1996, of the existence of bovine spongiform encephalopathy (BSE), better known as “mad cow disease”. Prior to this statement, the UK government assured that there were no health risks when eating such meat. In the same month European officials approved the first imports of GMO food products, specifically herbicide-tolerant soybeans from the United States. This led activist NGOs to raise concerns about GM foods and crops on ‘precautionary’ grounds. The BSE case had eroded public trust in official bodies as guardians of food safety. Thus, subsequent efforts by European officials to reassure the public of GMO safety were unsuccessful.¹⁵³

Consumers and Potential Consumers

Due to the importance of socio-cultural beliefs, a study by Mallinson sectioned the public on the basis of their affective characteristics, as it seemed likely that they would also share similar views on GM food. In the second step of the analysis, how interpersonal anxieties and the belief in the sanctity of food and value of science has influenced their acceptance of GM food was examined. With the help of socio-cultural measures like segmentation variables, the consumer groups were divided into ‘Science-philes’, ‘Scientific Greens’, ‘Unconcerned’, ‘Disaffected’, ‘Risk-takers’, ‘Neophobes’ and ‘Cautious Greens’.

The socio-cultural measures comprised:

- Belief in the sanctity of food
- Investment in science is important for the future
- Food neophobia
- Science has benefited the world
- Knowledge of the GM debate
- Gender
- Average age

¹⁵³ Robert Paarlberg, ‘A Dubious Success: The NGO Campaign against GMOs’ (2014) 5 *GM Crops & Food* 223.

- Green behaviour
- Annual household income

Even though it is true that socio-cultural beliefs have a manifest impact on the view on GM food, not much research is available in this regard. The study by Mallinson and others is one of the first to apply this novel approach to GM perception.¹⁵⁴

Sectioning of Consumers into Distinct Groups

According to the study, ‘**science-phile**’ consumers have the most positive attitude towards GM-products. This group of consumers seems to possess the best understanding of the public debate on GMOs as well as general endorsing opinion to science. The prevalent scepticism of the sanctity of food might possibly reflect its gender composition. It follows values of hegemonic masculinity, while only few vegetarians are part of this group.¹⁵⁵

The other side of the spectrum is held by ‘**cautious greens**’ who have been shown to be least accepting of GM food products. It is a group mainly consisting of women and has the highest proportion of black and ethnic minority respondents. Members of this cluster showed to pursue green behaviour, strongly believed in the sanctity of food, showed high emotional dislike of GM-food, were food neophobic and generally distrusting of government and multinational companies.

‘**Scientific Greens**’ pursued green behaviour, but while they were weighing the benefits against the risks, they marginally accepted GM food. Generally, this group had a pro-science stance, saying that UK food security was important, but also had strong beliefs in the sanctity of food.

‘**Neophobes**’ rejection of GM food is related to a complex mix of science and food associated beliefs. This group was characterized by being neophobic and was shown to have an emotional dislike of GM food. ‘Neophobes’ have a low educational attainment and were generally

¹⁵⁴ Lucy Mallinson and others, ‘Why Rational Argument Fails the Genetic Modification (GM) Debate’ (2018) 10 Food Security 1145.

¹⁵⁵ *ibid.*

deprived from science education and the benefits of science. In contrast to the ‘science-philes’, the demographic make-up of this group was the opposite, collectively comprising over 69% women and black and ethnic minority men. This group’s detachment from science seems to deter acceptance of GM food.

The stakeholder group of consumers can further be divided on the grounds of demographic differences in attitudes to GMO food. For example, scientific education as well as household income have a positive impact on the GMO food acceptance.¹⁵⁶ By examining the latest scientific research, men were more likely to accept GMO food than women, whereas young adults (ranging from 18-24) had a higher rate of acceptance towards GMO food than older generations. Those differences due to gender and age are to a great extent congruent with other European surveys.¹⁵⁷

ii. Factors Affecting GMO Perception

In the past, the debate on GMOs has rather been one of risk communication. However, the study discussed above by Mallinson et al., based on a representative sample of British adults, suggests that public acceptance of GM food is more related to social, cultural and affective contexts.¹⁵⁸ Beliefs about the sanctity of food and an emotional dislike of GM food, and not a careful weighing of benefits to risks, were the primary negative determinants for public (lack of) acceptance of GM food. On the other hand, a cost-risk assessment, together with trust in science, were positive determinants of GM acceptance. Further positive determinants studied are institutional trust, general knowledge of the GM food debate and belief in the eco-friendliness of GM food. The study concludes by suggesting that ‘rational argument alone about the risks and benefits of GM food is unlikely to change public perceptions of GM-technology.’¹⁵⁹

¹⁵⁶ *ibid.*

¹⁵⁷ J Risk Costa-Font, M. & Gil, ‘Consumer Acceptance of Genetically Modified Food (GM) in Spain: A Structural Equation Approach’; Melissa L Finucane and Joan L Holup, ‘Psychosocial and Cultural Factors Affecting the Perceived Risk of Genetically Modified Food: An Overview of the Literature’ (2005) 60 *Social Science & Medicine* 1603.

¹⁵⁸ Mallinson and others (n 160).

¹⁵⁹ *ibid.*

The Belief in Sanctity of Food

Within socio-cultural factors, the belief in sanctity of food has by far the biggest effect on GMO acceptance. This belief entails different conceptions with regard to purity, naturalness and the integrity of food. This is generally realised through the avoidance of processed foods and those containing additives, the rejection of artificially flavoured food and food with pesticide use and the support of organic food.¹⁶⁰ Organic food consumers do tend to be more concerned about GM food than those who do not consume organic food.¹⁶¹

The media and public evolution of the perception of the sanctity of food and concerns for food safety in general has been driven by several European-wide ‘food scares’, propagated by different NGOs and consumer groups which managed to get broad media attention. Such organisations advocate for a scientifically unfounded anti-GMO movement. The resulting anxiety has been suggested to be a possible factor in GM mistrust at the European level.¹⁶²

Emotional Attitude Towards GM-foods

Emotive terminology, used by stakeholders of the GM debate who are against the use of modern agriculture, suggests that GM foods are alien, possibly harmful to nature and future generations as well as being an unnatural influence on the public, thus fostering anxiety and scepticism.¹⁶³ Emotional responses to GM foods are therefore a dominant factor when predicting the acceptance of GM food.¹⁶⁴

Food Neophobia

Another socio-cultural factor, food neophobia, meaning mistrust of new and different foods, negatively impacts the acceptance of GMO foods. This belief is underpinned by a public debate of food that demonises the new and artificial and endorses so called ‘natural’ and traditional foods. However, this perception is often flawed with respect to gene edited organisms that are

¹⁶⁰ *ibid.*

¹⁶¹ C Funk and B Kennedy, ‘The New Food Fights: U.S. Public Divides Over Food Science’ 1.

¹⁶² Lynn J Frewer and others, ‘Public Perceptions of Agri-Food Applications of Genetic Modification – A Systematic Review and Meta-Analysis’ (2013) 30 *Trends in Food Science & Technology* 142.

¹⁶³ Paul Slovic and others, ‘The Affect Heuristic’ (2007) 177 *European Journal of Operational Research* 1333.

¹⁶⁴ Mallinson and others (n 160).

indistinguishable from conventionally bred organisms. Nevertheless, food neophobia has shown a weaker direct influence on acceptance of GM products compared with beliefs in the sanctity of food.¹⁶⁵

Engagement with Science

Possessing scientific literacy as well as having family members which have a scientific employment background have been shown to have a positive impact on the supporting of GM food products.¹⁶⁶ It seems probable that engagement in the scientific field promotes openness towards innovation and, subsequently, to GMO technology in agriculture.¹⁶⁷

Benefits-to-risk Rating

The quasi-rational method of weighing the benefits against the risks of GM food¹⁶⁸ has a positive impact on acceptance.

Conclusion on Factors Affecting GMO Perception

Although former assertions and portrayals of the GM decision-making process were thought to be fully rational, the influence of emotional attitude and food neophobia have shown to have a tangible impact on the debate. The attitude towards GM food has thus been closely related to moral judgements, including emotion, intuition and social influence. However, the role of trust in governments and multinational companies seems to have been overstated, influence being minor on acceptance.¹⁶⁹

¹⁶⁵ *ibid.*

¹⁶⁶ George Gaskell and others, *Europeans and Biotechnology in 2010 - Winds of Change?* (2010); Costa-Font, M. & Gil (n 163).

¹⁶⁷ Mallinson and others (n 160).

¹⁶⁸ P Scott, S. E., Inbar, Y., & Rozin, 'Evidence for Absolute Moral Opposition to Genetically Modified Food in the United States.' [2016] *Perspectives on Psychological Science* 315.

¹⁶⁹ M Connor, M., & Siegrist, 'Factors Influencing People's Acceptance of Gene Technology: The Role of Knowledge, Health Expectations, Naturalness, and Social Trust.' [2010] *Science communication* 514; JM Lucht, 'Public Acceptance of Plant Biotechnology and GM Crops' 4254.

iii. Implications for GMO Policy

The drawing of final conclusions about GM foods by consumers cannot be solely described as involving conscious awareness of the benefits and risks. This would include thinking on the impact on health, food security, the environment and general safety. Instead, broader sociocultural attitudes appear to have a stronger influence on the acceptance of GM food. These attitudes entail stances towards science, the environment, food, food technology, food security, health risk-taking behaviour and knowledge of the GM food debate. A major conclusion from the study of Mallinson, is that emotionally-biased concerns about GM food and the level of trust in various bodies involved in the GM debate are of crucial importance for the acceptance of GM foods.¹⁷⁰

Dual process models suggest that people make decisions based on two separate grounds involving analytical or cognitive thinking on the one hand and experience and emotion on the other.¹⁷¹ Decision-making with regard to risk goes beyond individual thinking, which suggests that external messages about unfounded risk as disseminated through social networks and mass media shape individual judgment.

Within the group of UK consumers viewed as a whole, there are substantial differences in the acceptance by individual consumer groups. The variation in affective and rational thought about the benefits and risks of GM food is closely linked to sociocultural reasons. As a result, clear public information campaigns that build upon factual affirmation of the negligible risk posed by GM food as well as scientific explanations relating to GM food development provide little reassurance to certain public groups. They entail people who have vigorously adverse reactions towards GM food, who disenfranchise GM technology from the benefits of science and lack confidence in modern food production. Therefore, rational arguments alone are failing to actually connect with people's emotional response.¹⁷²

¹⁷⁰ Mallinson and others (n 160).

¹⁷¹ Slovic and others (n 169).

¹⁷² Mallinson and others (n 160).

III.III. OVERVIEW OF THE EU AND UK LEGAL FRAMEWORK GOVERNING GMOS

There are multiple legal instruments which govern various aspects of how GMOs are to be produced, handled and sold. Any sensible policy recommendations will have to assess the status quo and put forward revisions and amendments thereto.

In brief¹⁷³, one can distinguish between (i) rules specifically addressing GMOs and (ii) general rules which could have relevance for how GMOs are produced and traded – such as provisions on consumer protection, advertising, etc. The following only deals with special rules on GMOs (category (i)), as an inventory of all general legislation potentially impacting GMOs producers and consumers (category (ii)) is beyond the specialised remit of this paper.¹⁷⁴

On 30 December 2020 the EU and UK signed the EU–UK Trade and Cooperation Agreement, ending the transition period on 31 December 2020 at which point EU GMO rules were voluntarily retained in the UK as domestic law, via the Withdrawal Bill. Thus, the only material difference is that UK authorities have taken over authorisation prerogatives from the EU bodies.¹⁷⁵

Hence, one can distinguish between (i) EU rules; and (ii) UK rules; also, there exist some (iii) international rules (some of which do not deal specifically with GMOs but are highly relevant from a trade perspective). Not least, a discussion of the current legal framework must also take into account (iv) the legal consequences of Brexit.

i. EU Rules Governing GMOs

Since the 1990s, GMOs have been governed by a detailed regulatory framework in the EU.

¹⁷³ For further information on the EU and UK legal framework governing GMOs see e.g.: Petetin (n 10); Climate Change and Land Reform Cabinet Secretary for Environment, ‘Agriculture and the Environment: Genetic Modification - Gov.Scot’ (*gov.scot*) <<https://www.gov.scot/policies/agriculture-and-the-environment/gm-crops/>> accessed 7 March 2021.

¹⁷⁴ For an overview, see C. MacMaoláin, *EU Food Law. Protecting Consumers and Health in a Common Market*, Hart Publishing, Oxford-Portland Oregon, 2007.

¹⁷⁵ Department for Environment Food & Rural Affairs, ‘Developing Genetically Modified Organisms - GOV.UK’ (*gov.uk*, 31 December 2020) <<https://www.gov.uk/guidance/developing-genetically-modified-organisms>> accessed 7 March 2021.

One can differentiate, within this category, between rules on intra-EU production and trade of GMOs, on the one hand, and rules on the export of GMOs to third countries, on the other hand.

Intra-EU Production and Trade of GMOs

An essential principle underpinning EU GMO policy (and general environmental legislation and risk assessment) is the precautionary principle (a fundamental principle enshrined in the Treaty on the Functioning of the European Union). According to this principle, the regulators should err on the side of caution when confronted with scientific uncertainty. Another particularity of EU's food policy is the so-called 'farm-to-fork' or 'whole food chain' approach to food safety.¹⁷⁶

Other countries, notably the US, have been traditionally regarded as being significantly more lenient towards GMO regulation. Instead of employing the precautionary principle, the US adopted the so-called substantial equivalence principle, under which the regulators consider whether the GMO product and its alternative are substantially equivalent.

Intra-EU Production and Trade of GMOs: Relevant Legislation

EU legislation on GMOs has three main purposes: health protection, environmental protection and consumer information, all while seeking to ensure the free movement of GM products throughout the Union. The main pieces of legislation are:

- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

¹⁷⁶ For further information see - Robert Pederson and Guillermo Hernández, 'DIRECTORATE GENERAL FOR INTERNAL POLICIES POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY Food Safety: State-of-Play, Current and Future Challenges' (2014).

This directive covers environmental aspects of commercial release¹⁷⁷, mainly cultivation¹⁷⁸ of GM crops EU-wide. It was amended in April 2015¹⁷⁹, since when EU Member States have the right to ban the cultivation of specific GMOs based on grounds not related to human health, such as environmental policy, land planning or socio-economic impacts.

After authorisation, Member States can ban an authorised GM crop, based on the so-called safeguard clauses, but only provisionally and based on new scientific evidence suggesting a risk to health or to the environment (not to be confused with the ‘opt-out’ system enacted in 2015).

In the UK, the Food Standards Agency (FSA) is responsible for food safety aspects, while DEFRA and the devolved agriculture departments are charged with assessing environmental risks.

- Regulation (EC) No 1829/2003

This piece of legislation covers safety aspects, focussing on GMOs used in food or feed.

It lays down an EU-wide procedure for the scientific assessment and authorisation of GM food and feed product to be commercialised throughout the EU. It also requires labelling of all GM food and feed containing or consisting of GMOs, being produced from GMOs (e.g., glucose syrup from GM maize), or containing ingredients produced from GMOs (e.g., tomato juice). Commercialisation of crop seeds for cultivation¹⁸⁰ also needs authorisation.

Applications for these uses of GMOs are decided at the level of the EU; the safety assessment is conducted by the European Food and Safety Authority (EFSA), but applications are

¹⁷⁷ Note that besides commercial release (which is subject to the authorisation requirements in Directive 2001/18/EC and Regulation (EC) No 1829/2003 above), there are two further levels of authorization: (i) contained use of GM for research – subject to Directive 2009/41/EC; and (ii) research release – subject to Directive 2001/18/EC. For further information on all three levels of authorisation, see Department for Environment Food & Rural Affairs, ‘2010 to 2015 Government Policy: Food and Farming Industry - GOV.UK’ (*Department for Environment Food & Rural Affairs*, 8 May 2015)

<<https://www.gov.uk/government/publications/2010-to-2015-government-policy-food-and-farming-industry/2010-to-2015-government-policy-food-and-farming-industry>> accessed 7 March 2021.

¹⁷⁸ The directive also deals with other aspects, such as deliberate release for clinical use.

¹⁷⁹ Directive (EU) 2015/412 of the European Parliament and of the Council. As of 2017, 19 Member States relied on this new right to prohibit GMOs’ cultivation in their territories (the so-called ‘opt-out’). Scientific evaluation of the environmental and safety risk remains centralised at EFSA. Import is not covered by the opt-out, only cultivation – for further details and the background to this act (in short, Member States were unable to agree on a common approach to the regulation of GM crops), see - Tagliabue (n 134).

¹⁸⁰ Only one type of GM crop seed has approval for commercial cultivation in the EU as of the date of this paper: MON 810 maize (corn). – see European Commission, ‘Community Register of GM Food and Feed’ <https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm> accessed 3 March 2021.

scrutinised beforehand by Member States' expert bodies, which collaborate with EFSA (e.g., in the UK, the Advisory Committee on Releases to the Environment (ACRE)). After receiving EFSA's opinion, the Commission then prepares a draft decision, which it submits to the Member States' Expert Committee (MSEC), which votes on it.¹⁸¹ The European Parliament has no official say in the authorisation procedure and can only adopt (non-legally-binding) resolutions in this respect.¹⁸²

Following the end of the transition period, the EU's authorisation process has been retained in UK legislation as a devolved competence. Prior to a trial or marketing release of GMOs, authorisation has to be sought from the competent authority. These are:

England – Department for Environment, Food and Rural Affairs (DEFRA)

Northern Ireland – Department of Agriculture, Environment and Rural Affairs (DAERA)

Scotland – Scottish Government

Wales – Welsh Government

Separate authorisation is required for each of the UK competent authorities that are responsible for the countries in which the GMOs are to be trialled or marketed.

In the EU after authorisation Member States can ban an authorised GMO, again based on the so-called safeguard clauses, but only provisionally and based on new scientific evidence suggesting a risk to health or to the environment.¹⁸³ Notably, there is no possibility of a permanent ban by Member States based on non-health-related reasons, as opposed to the situation regarding cultivation (the opt-out right presented above).¹⁸⁴

¹⁸¹ Usually Member States oppose authorisations based on domestic concerns, as opposed to science-based reasons – see Tarja Laaninen, 'Imports of GM Food and Feed Right of Member States to Opt Out' (2015), pp. 3-4, where an outline on the authorization process can also be found.

¹⁸² See e.g., European Parliament resolution of 16 January 2014 on the proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests, in which the Parliament voiced its opposition to a Commission proposal for a Council decision authorizing the cultivation of GM 'Maize 1507', based on environmental concerns – European Parliament, 'European Parliament Resolution of 16 January 2014 on the Proposal for a Council Decision Concerning the Placing on the Market for Cultivation, in Accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a Maize Product (*Zea M*' (2014) <https://www.europarl.europa.eu/doceo/document/TA-7-2014-0036_EN.html?redirect>.

¹⁸³ However, such use has been rarer than provisionally banning *cultivation* – Laaninen (n 195), pp 4

¹⁸⁴ A Commission proposal to introduce such a right was rejected by the European Parliament in 2015, see – Baptiste Chatain, 'Parliament Rejects National GMO Bans Proposal | News | European Parliament' (*European*

Notably, non-commercial releases of GMOs (i.e., for research and development) are decided at the level of each Member State.

- Regulation (EC) No 1831/2003

This act covers information aspects, focussing on labelling and traceability (i.e., rules allowing the following of the ‘paper trails’ of approved GM products throughout their commercialisation) of GMOs. Food and feed which contain, consist of, or are produced from, a GMO must be clearly labelled, unless the GM content is below 0.9% or the ingredient is adventitious or technically unavoidable.

‘GM-free’ labels are neither prohibited nor specifically regulated under EU law (although the laws of Member States may vary on this point) and are subject to the general rules on food labelling (e.g., they must not mislead consumers).

Intra-EU Production and Trade of GMOs: Case Law

In July 2018, the Court of Justice of the European Union (CJEU) delivered a landmark judgment, in which it held that not only organisms obtained by transgenesis, (please see our discussion of transgenesis in Sub-section II.II.I.iii.) but also organisms obtained by mutagenesis (including by mutagenesis techniques that have emerged since the adoption of the EU legislation in the field) are GMOs within the sense of Directive 2001/18/EC, thus being associated with the obligations that that act lays down. Notably, however, CJEU excluded from the ambit of the directive organisms obtained by means of mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record (the Member States can individually regulate the latter category of organisms, but they are not subject to EU’s GMO regime.¹⁸⁵(please see our discussion of mutagenesis techniques in Sub-section II.II.I.ii.)

Aside from the above, there are also other relevant special EU rules and CJEU case law

Parliament, 28 October 2015) <<https://www.europarl.europa.eu/news/en/press-room/20151022IPR98805/parliament-rejects-national-gmo-bans-proposal>> accessed 7 March 2021.

¹⁸⁵ Court of Justice of the European Union, ‘Court of Justice of the European Union PRESS RELEASE No 111/18’ (2018) <www.curia.europa.eu> accessed 7 March 2021.

applicable to GMOs, but they are outside the ambit of this paper's focus.¹⁸⁶

Exports of GMOs Outside the EU

EU Regulation 1946/2003 sets out the requirements for notification and information for transboundary movements of GMOs from within the EU to third countries, with a view to protecting biological diversity and also taking into account risks to human health. It was adopted in furtherance of the EU's obligations under the Cartagena Biosafety Protocol to the United Nations Convention on Biological Diversity (CBD). The key obligation for companies exporting GMOs from within the EU to a third country is to notify that country in advance and to await its approval.

ii. UK Rules¹⁸⁷

The UK legal framework for GMOs is also detailed, not least because many of the UK statutes are intended to implement EU legislation. Relevant legislation includes, for example, the Genetically Modified Organisms (Contained Use) Regulations 2014, dealing with requirements for applications to release GMOs.

As regards deliberate release, the Secretary of State for DEFRA has competences in England and Wales. Similar regulations exist in Northern Ireland, Scotland and Wales.¹⁸⁸

There is also a statutory instrument, dated December 2018, for the Genetically Modified Organisms (Amendment) (Northern Ireland) (EU Exit) Regulations 2019, which made purely technical amendments to the existing UK legislation so as to ensure the rules implementing EU legislation in the UK will be operational post-Brexit (e.g., removing references to EU

¹⁸⁶ E.g., Decision 2004/204/EC, regarding rules on registers established for information on genetic modifications in GMOs.

¹⁸⁷ For a list of UK rules dealing with the other areas where the EU has legislated (GM food, GM feed, traceability and labelling of GMOs, transboundary movement of GMOs from the UK to third countries), see Department for Environment Food & Rural Affairs, '2010 to 2015 Government Policy: Food and Farming Industry - GOV.UK' (n 188).

¹⁸⁸ For other rules e.g., Scotland see Law Society of Scotland, 'Law Society of Scotland Briefing for Second Reading' (*Law Society of Scotland*, October 2018) <<https://www.lawscot.org.uk/media/361143/18-10-10-agriculture-bill-second-reading-briefing.pdf>> accessed 7 March 2021.

legislation).¹⁸⁹ ¹⁹⁰ The approach remains the same as in the EU legislation, but this does not necessarily mean that since the transitional period in the withdrawal agreement has expired, the UK's policy cannot change. The UK Government has also stated that there will be 'further substantive corrections' in a separate document, which will give the Secretary of State the competence (previously with EU bodies) to develop technical guidance on testing and sampling and establish and amend the thresholds below which products containing adventitious or technically unavoidable traces of GMOs do not have to be labelled as GM products.¹⁹¹

As stated above, the UK's exit from the EU carries an opportunity for the former to define its biotechnology policy in an autonomous fashion. However, the UK legislation will still be subject to a host of international treaties, the most important of which are identified in the following sub-section.

iii. **International Rules**¹⁹²

Brexit has not given the UK unfettered discretion to regulate GMOs, as it is expected to comply with the international agreements it concluded and ratified.¹⁹³

There are four main fora where international rules on GMOs have been, or are being, discussed: the CBD, the Codex Alimentarius Commission, the OECD and the WTO; other treaties touching upon environmental protection or agriculture may also be relevant but given their general nature, they are not dealt with in here.

¹⁸⁹ For further information, see Department for Environment Food & Rural Affairs, 'The Genetically Modified Organisms (Amendment) (Northern Ireland) (EU Exit) Regulations 2019 - GOV.UK' (*Department for Environment Food & Rural Affairs*, 18 December 2018) <<https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-genetically-modified-organisms-amendment-northern-ireland-eu-exit-regulations-2019>> accessed 7 March 2021.

¹⁹⁰ Notably, authorisations to market GMOs granted at EU-level are to remain valid post-Brexit – Department for Environment Food & Rural Affairs, 'EXPLANATORY MEMORANDUM TO THE GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (EU EXIT) REGULATIONS 2018 AND THE GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (ENGLAND) (EU EXIT) REGULATIONS 2018 NOS. [XXXX]' (2018).

¹⁹¹ Department for Environment Food & Rural Affairs, 'EXPLANATORY MEMORANDUM TO THE GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (EU EXIT) REGULATIONS 2018 AND THE GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (ENGLAND) (EU EXIT) REGULATIONS 2018 NOS. [XXXX]' (n 212), para. 7.2.

¹⁹² For a more detailed overview, see European Commission, 'International Affairs | Food Safety' (*European Commission Website*) <https://ec.europa.eu/food/plant/gmo/international_affairs_en> accessed 8 March 2021.

¹⁹³ However, such rules, agreed between tenths or even more of States from all over the world are by their very nature more flexible than EU legislation, which seeks a closer integration between States. See - Annegret Engel and Ludivine Petetin, 'International Obligations and Devolved Powers-Ploughing through Competences and GM Crops' <<https://services.parliament.uk/bills/2017-19/europeanunionwithdrawal.html>> accessed 8 March 2021.

The Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity.¹⁹⁴ The Cartagena Protocol regulates the safe handling, transport (transboundary movement) and use (e.g., for food or medicines) of living modified organisms (LMOs) which result from biotechnology¹⁹⁵ and which may affect biological diversity, also taking into account human health risks. The Protocol entered into force in 2003 and approximately 170 States are parties, including both the EU and UK (individually).

Codex Alimentarius Commission. The Codex Alimentarius Commission is an intergovernmental body with more than 180 members, under the auspices of both the FAO and the WHO. It adopts food standards that are highly influential for international trade in food. The UK, all EU Member States and the EU itself are members.

Given the highly diverse policies that states are employing when it comes to GMOs, it was impossible to reach an agreement within the Commission.¹⁹⁶ In 2011, it adopted a Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology – these texts are not GMO-specific, the most relevant provision being a reference to GMO labelling for safety purposes.¹⁹⁷ As explained below, the standards which the Commission develops can become relevant under WTO law – in case of technical regulations, standards and conformity assessment procedures, and of sanitary and phytosanitary measures.

OECD. The OECD Task Force for the Safety of Novel Foods and Feeds and the Working Group on Harmonisation of Regulatory Oversight in Biotechnology discuss issues related to GMOs. Most of EU's Member States (including the UK) are members of the OECD and the EU has observer status. There are no binding international rules on GMOs that this forum has issued – the so-called 'consensus documents' that OECD drafted are meant as a practical tool for regulators and risk/safety assessors.¹⁹⁸

WTO. By far the most important international organisation whose mandate touches upon the

¹⁹⁴ For an overview see Mashayekhi Mina, 'Training Module on the WTO Agreement on Sanitary and Phytosanitary Measures' (2005) <www.unctad.org/tradenegotiations> accessed 8 March 2021. Pp. 79-82

¹⁹⁵ Such as seeds and untransformed agricultural products (e.g., cereals), not derivative products, such as oil, tomato sauce, etc.

¹⁹⁶ Alberto Alemanno, 'How to Get Out of the Transatlantic Regulatory Deadlock over GMOs? Time for Regulatory Cooperation' <<https://papers.ssrn.com/abstract=1419928>> accessed 8 March 2021.

¹⁹⁷ Codex Alimentarius Commission, 'Foods Derived from Modern Biotechnology Second Edition' (2009).

¹⁹⁸ OECD, 'Safety of Novel Foods and Feeds and on the Harmonisation of Regulatory Oversight in Biotechnology - OECD' <<http://www.oecd.org/chemicalsafety/biotrack/oecdandriskassessmentinmodernbiotechnology.htm>> accessed 8 March 2021.

regulation of GMOs is the WTO.^{199 200} There are no rules aimed specifically at trade in GMOs but many of the disciplines of the WTO can have important consequences on the UK's ability to edict internally and agree, internationally, to new rules on GMOs. By way of example:

- the General Agreements on Tariffs and Trade (GATT) covers aspects such as non-discrimination against foreign goods (national and most favoured nation treatment), quantitative restrictions and exceptions for measures aimed at protecting public morals, human or animal health or the environment;
- the General Agreement on Trade in Services (GATS) covers aspects such as non-discrimination against foreign services and services suppliers (national and most favoured nation treatment), market access, domestic regulations and exceptions for measures aimed at protecting public morals, human health or the environment;
- the Agreement on Technical Barriers to Trade (TBT Agreement) provides that technical regulations, standards and conformity assessment procedures affecting goods should not be more restrictive than necessary and are encouraged to be based on international standards (such as those issued by the Codex Alimentarius Commission);
- the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) governs restrictions imposed on food products out of health concerns, allowing them on condition that they be scientifically justified or based on international standards (such as those issued by the Codex Alimentarius Commission). The SPS Agreement may also cover, besides strictly health measures, environmental measures;^{201 202}

¹⁹⁹ For a more detailed presentation of the principal WTO rules that could be relevant for UK's legal framework for GMOs, see Engel and Petetin (n 217).

²⁰⁰ For a more detailed presentation of the principal WTO rules that could be relevant for UK's legal framework for GMOs, see Alemanno (n 222).

²⁰¹ Jacqueline Peel, 'A GMO by Any Other Name. ... Might Be an SPS Risk!: Implications of Expanding the Scope of the WTO Sanitary and Phytosanitary Measures Agreement' (2006) 17 *The European Journal of International Law* 1009 <http://www.foeeurope.org/biteback/WTO_decision.htm> accessed 8 March 2021.

²⁰² An analysis on the consistency of any potential legal framework for GMOs with WTO law will of course depend on the specifics of UK's legislation. So far, the case law of the WTO has not directly tackled this issue, and in the famous 2006 report in the *EC-Biotech* case the panel did not have an opportunity to engage with the legal substance of the debate – Wto, 'EC-APPROVAL AND MARKETING OF BIOTECH PRODUCTS 1 2. SUMMARY OF KEY PANEL FINDINGS 2 General EC Moratorium' (2003). It is likely that non-discriminatory regulation which is not unnecessarily trade-restrictive passes muster under the WTO rules and, even if found in breach, UK could still rely on the legitimate aims of the regulation (ranging from public morals to protection of health and of the environment). As such, compliance with WTO law will probably not impose significant obstacles to a new policy, even if more restrictive than previously.

- the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) may be relevant, for example, for the patentability of GM products.

iv. The Legal Consequences of Brexit

The UK and the EU have concluded a withdrawal agreement prior to the date of Brexit (1 February 2020). The withdrawal agreement provided for a transition period until 31 December 2020, during which the UK has remained in the single market. On 30 December 2020 the EU and UK signed the EU–UK Trade and Cooperation Agreement. The transition period ended on 31 December 2020 at which point EU GMO rules were voluntarily retained in the UK as domestic law, via the Withdrawal Bill. The only material difference being that UK authorities have taken over authorisation prerogatives from the EU bodies.²⁰³ The UK is therefore able to autonomously modify its retained EU legislation from 01 January 2021.

Until Brexit was effected on February 1st 2020, the UK could not negotiate and conclude free trade agreements with third countries given that EU has exclusive competence in this area, known as the Union’s ‘common commercial policy’. However, since Brexit, and including during the transition period, the Withdrawal Agreement made provision for UK’s right to conclude (negotiate, sign, ratify) new trade agreements with third countries on condition that the UK’s agreements came into force after the implementation period.

III.IV. THE UK’S MAIN TRADING PARTNERS IN GENETICALLY MODIFIED ORGANISMS AND POTENTIAL IMPLICATIONS ON TRADE

i. Imports

The UK imports GM soybeans and derivatives (soymeal and oil), especially for use as animal feed (estimated at 90% of UK’s usage).²⁰⁴ Only one GM maize (MON 810) is commercially

²⁰³ Department for Environment Food & Rural Affairs, ‘Developing Genetically Modified Organisms - GOV.UK’ (n 183).

²⁰⁴ Agricultural Biotechnology Council (abc), ‘Going against the Grain’ (2015) <www.abcinformation.org> accessed 8 March 2021.

cultivated in the EU. A few tenths of GMOs are authorised in the EU for food and feed uses (maize, soybean, cotton, oilseed rape, sugar beet, etc.). As regards food products, in line with the EU27, GM products are a rare occurrence on UK supermarket shelves.

As regards agricultural products in general, the UK imports 50% of the food it consumes;²⁰⁵ approximately 70% of UK food imports come from the EU.²⁰⁶

ii. Exports

There are no commercial GM crops in the UK; experimental research on GM is being undertaken, most of which is in the public sector.²⁰⁷

As regards agricultural products in general, approximately 60% of UK's exports go to the EU.²⁰⁸ More specifically, the UK's biggest food exports markets are Ireland, France, the Netherlands and Germany (EU) and USA (non-EU).²⁰⁹

In total, the UK exports food to over 200 overseas countries and territories.²¹⁰ Currently, the largest export group of the UK is beverages (especially whisky), followed by cereals, meat and fish; other products include wine, bread, biscuits and wheat.

The UK's largest (negative) trade deficit is in fruit and vegetables, with the second sector being meat and beverages. Both imports and exports appear to be, as a rule, on the rise.^{211 212}

The EU has substantial imports of GM feed (more than 60% of the EU's plant protein

²⁰⁵ Department for Environment Food & Rural Affairs, 'Food Statistics in Your Pocket 2017 - Global and UK Supply - GOV.UK' (n 5).

²⁰⁶ Ian Hodge, 'Brexit: The Agricultural Issues | UK in a Changing Europe' (<http://ukandeu.ac.uk/>, 16 May 2016) <<http://ukandeu.ac.uk/brexit-the-agricultural-issues/>> accessed 8 March 2021.

²⁰⁷ Department for Environment Food & Rural Affairs, 'Genetically Modified Organisms: Applications and Decisions - GOV.UK' (gov.uk, 17 July 2020) <<https://www.gov.uk/government/collections/genetically-modified-organisms-applications-and-consents>> accessed 8 March 2021.

²⁰⁸ Hodge (n 234).

²⁰⁹ Department for Environment Food & Rural Affairs, 'British Food and Farming at a Glance' (n 8).

²¹⁰ *ibid.*

²¹¹ *ibid.*

²¹² Department for Environment Food & Rural Affairs, 'Food Statistics in Your Pocket 2017 - Global and UK Supply - GOV.UK' (n 5).

needs²¹³), and here the UK could play a role perhaps; the EU however imports very little GM food.²¹⁴ Most (90%) of the EU's imports of vegetable proteins for its livestock sector come from four countries: Brazil, Argentina, US (these three being the leading GMOs producers) and Paraguay.²¹⁵ ²¹⁶ Conversely, few GM products are available on the EU's food market, including because of the choice of food businesses not to put GMOs on their selves; it has been noted that this can be attributed to the labelling obligations and the availability of non-GM alternatives.²¹⁷ The UK would have to compete with those countries and overcome these consumer perceptions, should it wish to enter the EU's feed and respectively food market. However, it appears that the UK is currently not growing the most widely spread GM crops, such as soya beans or cottons, its major crop being wheat, which appears not be a GM product globally.²¹⁸

As regards the industries most likely to be affected by GMO use, given that GM commodities are mostly used (after being imported, as opposed to cultivated locally) in the UK for animal feed, the prime industry affected is the animal feed industry.²¹⁹ To a lesser extent, as stated above, food products also contain GMOs, and thus this industry is also impacted. Other affected industries could include flowers²²⁰ and the pharmaceutical industry (e.g., vaccines or insulin production).

²¹³ European Commission, 'Fact Sheet: Questions and Answers on EU's Policies on GMOs' (*ec.europa.eu*, 22 May 2015) <https://ec.europa.eu/commission/presscorner/detail/en/MEMO_15_4778> accessed 8 March 2021.

²¹⁴ *ibid.*

²¹⁵ In general, the following GM crops are grown commercially worldwide: potato, pumpkin, alfalfa, aubergine, sugar beet, papaya, oilseed rape, maize, soybeans, cotton, see – *ibid.*

²¹⁶ The Royal Society, 'What GM Crops Are Being Grown and Where?' (*royalsociety.org*, 2016) <<https://royalsociety.org/topics-policy/projects/gm-plants/what-gm-crops-are-currently-being-grown-and-where/>> accessed 8 March 2021.

²¹⁷ European Commission, 'Fact Sheet: Questions and Answers on EU's Policies on GMOs' (n 241).

²¹⁸ Tom Bawden, 'Would Brexit Be Good or Bad for the Prospect of GM Crops in Britain?' (*iNews*, 22 June 2016) <<https://inews.co.uk/news/science/brexit-good-bad-prospect-gm-crops-britain-11671>> accessed 8 March 2021.

²¹⁹ Department for Environment Food & Rural Affairs, '2010 to 2015 Government Policy: Food and Farming Industry - GOV.UK' (n 188).

²²⁰ Department for Environment Food and Rural Affairs, 'Draft Commission Decision on the Placing on the Market of Florigene's Carnation Lines IFD-25958-3 and IFD-26407-2 Genetically Modified for Petal Colour and Herbicide Tolerance' (March 2015) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/412922/Florigene-carnations.pdf> accessed 8 March 2021.

International Trade²²¹ ***in GMOs Post-Brexit***²²²

As a preliminary point, considering the controversy still surrounding GMOs, Parliament should be up to date on any international agreement negotiated by the Government throughout the process. In other words, merely seeking Parliament's assent (ratification) once the executive has concluded the agreement risks the faith of the treaty (*c.f.* the situation of the Withdrawal Agreement).

The approaches to be employed in a free trade agreement as regards GMOs' regulation vary and could include: (i) full harmonisation; (ii) harmonisation of essential requirements; (iii) mutual recognition of rules; (iv) mutual recognition of conformity assessment procedures; (v) equivalence.²²³ Precisely which option is the most suitable will obviously depend on the merits of the situation. Relevant factors include the importance of the agreement for the parties, the approach to GMO regulation in their jurisdictions, the extent to which the parties want to open up to outside competition, the regulatory affinities of the parties and the political palatability of potentially lower standards.

As regards trade with the EU post-Brexit, an especially relevant topic given the proximity and current trading relationship of the UK and the EU, under EU's internal legislation there is no mutual recognition or equivalence towards third countries in the field of GMO. Under the terms of the EU–UK Trade and Cooperation Agreement, the UK products exported to the EU have to comply with EU and Member State law and UK exporters may need to show import or export licences, obtain authorisation etc.²²⁴ ; should the UK wish to cultivate and sell

²²¹ For the Wilberforce Society's previous work on Brexit and trade, see Martino Davide and Smith Colby, 'Trade & Business' (*The Wilberforce Society*) <https://drive.google.com/file/d/0B2ex_9a5ZcYVmxMM21fTEswTzA/view> accessed 8 March 2021.

²²² This section briefly deals with the international trade aspects of GMOs i.e., imports and exports, as opposed to cultivation. Nevertheless, note that regulation of GMOs cultivation could also have a trade-enhancing effect, as it could stimulate investment in the UK (so-called 'commercial presence' or 'mode 3' trade in services under the GATS). However, even in such case, the 'Brussels effect' might be relevant – this consists of companies' constraint to comply with EU law even when operating outside the EU, due to factors such as third countries in which those companies wish to perform aligning to EU rules, potential incompatibility with EU and non-EU regulations (making companies decide which approach they need to adopt) - Engel and Petetin (n 217).

²²³ For more information, see Kathryn Wright and Dominic Webb, 'Future Trade with the EU: Mutual Recognition' (2018).

²²⁴ Prime Minister's Office, 'Agreements Reached between the United Kingdom of Great Britain and Northern Ireland and the European Union - GOV.UK' (*gov.uk*, 24 December 2020) <<https://www.gov.uk/government/publications/agreements-reached-between-the-united-kingdom-of-great-britain-and-northern-ireland-and-the-european-union>> accessed 8 March 2021.

GMOs, this will act as a trade barrier.²²⁵

The better solution would obviously be to secure a further trade agreement with the EU which would address regulatory convergence. In light of EU's position during the Brexit negotiation process, it is certain now that the EU would not accept an approach based on mutual recognition of rules. Also, given its sensitive nature, equivalence is probably also out of question²²⁶ (and would, in any way, entail amendment of EU's legislation). Harmonisation is also very unlikely, as it would defeat the very purpose of Brexit. Nevertheless, the absence of mutual recognition could also be advantageous for the UK, as it would leave it more scope to subject imported products to its own regulatory standards.

That leaves the UK with little option, and this could make access to the largest and closest UK export market for the UK's businesses difficult. The UK could seek to obtain mutual recognition of conformity assessment procedures²²⁷ ²²⁸ ²²⁹ or the two parties could establish a framework for informal regulatory cooperation.²³⁰ Nevertheless, it must be assessed whether the advantages of such an approach would bring significant benefits to UK's traders, which will still have to comply with EU's rules, in the creation of which the UK will not have (at least not officially) a say.

²²⁵ However, currently the impact on UK food businesses would be low, given that the only GM crop having approval for commercial cultivation in the EU (MON 810 Maize) is not commercially grown in the UK. In the same vein, see Richard Welfare and Josefine Crona, 'UK Government Publishes First No Deal Brexit Notices for Food' (*Hogan Lovells Brexit Hub*, 2018) <<https://www.hoganlovellsbrexit.com/blog/uk-government-publishes-first-no-deal-brexit-notices-for-food>> accessed 8 March 2021.

²²⁶ Saima Hanif, 'Equivalence: Panacea or Pandora's Box?' [2016] *Butterworths Journal of International Banking and Financial Law*.

²²⁷ The EU has concluded mutual recognition agreements (MRAs) with only a few countries and in limited sectors, none of which appear to include GMOs or food (the closest sector for which there is an EU MRA being medicines) - European Commission, 'Mutual Recognition Agreements | Internal Market, Industry, Entrepreneurship and SMEs' (*cc.europa.eu*) <https://ec.europa.eu/growth/single-market/goods/international-aspects/mutual-recognition-agreements_en> accessed 8 March 2021.

²²⁸ Indeed, MRAs are more suitable for not heavily regulated markets, and here GMOs do not make a good candidate; see generally – Alex Stojanovic, 'Mutual Recognition: Can the UK Have Its Brexit Cake and Eat It?' | *The Institute for Government* (*Institute for Government*, 1 July 2017) <<https://www.instituteforgovernment.org.uk/blog/mutual-recognition-can-uk-have-its-brexit-cake-and-eat-it>> accessed 8 March 2021.

²²⁹ For more information, see – Correia De Brito, C Kauffmann and J Pelkmans, 'The Contribution of Mutual Recognition to International Regulatory Co-Operation' <<http://dx.doi.org/10.1787/5jm56fqsfxmx-en>> accessed 8 March 2021.

²³⁰ Such an approach could also be employed for overcoming the deadlock in the transatlantic regulation of trade in GMOs caused by the divergent approaches of the US and European States, as harmonisation is for the moment an unrealistic solution – see Alemanno (n 222).

Therefore, not even a further trade agreement is guaranteed to be of much help in case the UK would like to influence EU's GMOs legislation. For example, in the EU-Canada Comprehensive Economic and Trade Agreement (CETA), the most Canada could obtain is a mere agreement to cooperate and exchange information regarding biotechnological products (Art 25.2), the EU's standards for agriculture and environmental protection not being affected. The failure of the Transatlantic Trade and Investment Partnership (TTIP) could also be in part attributed to the EU's and US's divergent approaches to GMOs regulation (and the EU public being outspoken against such products). Therefore, based on these past experiences, the EU will probably not modify its standards in this field, and access to EU's market will thus likely be conditioned on compliance with them by UK exporters.²³¹

The UK is able to set its own standards autonomously. This may take a while, considering that the Withdrawal Bill provided that EU legislation will be retained (effectively incorporated into UK law) after Brexit.²³² Nevertheless, as scholars have observed, the UK is able to repeal its EU-retained legislation.²³³

At the same time, the UK is, as a rule, not able to regulate less stringent standards just for domestic producers alone; any such regulation would, under international (and possibly also national) law need to be applicable as well to traders exporting to the UK. The fact that other countries (such as the US) have a more developed biotechnology industry which could achieve significant economies of scale, as well as the presumably lesser experience of UK businesses, means that such lower standards might attract intense foreign (price) competition in UK's internal GMOs market.²³⁴ While ultimately such competition will presumably benefit consumers (more choice, lower prices), the UK will need to seriously consider whether it wants to establish a developed biotechnology industry; if that is the case, mechanisms such as subsidies (provided they comply with the law) or a gradual phase-in of new, more lenient, legislation might be alternatives.

²³¹ Engel and Petetin (n 217).

²³² *ibid.*

²³³ *ibid.*

²³⁴ Charlotte Burns, 'All a Cluck about Nothing? Brexit, Beef and Chlorinated Chickens' (*ukandeu.ac.uk*, 25 August 2017) <<http://ukandeu.ac.uk/all-a-cluck-about-nothing-brexit-beef-and-chlorinated-chickens/>> accessed 8 March 2021.

III.V. SHORTCOMINGS OF THE CURRENT LEGAL FRAMEWORK FOR GMOS AND MAIN THEMES OF THE REFORM

In recent years, multiple critiques have been levelled at the current legal framework for GMOs, from different stakeholders, such as NGOs, the European Parliament, the media, industry groups or academia. The issues that have been flagged vary and it is beyond the scope of this paper to make policy recommendations regarding all but those which are perhaps the most stringent and realistically addressable. By way of example, however, criticisms have been raised towards:

- a ‘double standard’ created (by the Member States mainly) by refusing to allow cultivation of GM crops, while permitting the importation of GM feed²³⁵ – in fact, in 2014 research found that only less than 0,1% of global GM crops are cultivated in the EU, while more than 70% of animal feed is imported;²³⁶
- a somehow arbitrary approach created through a broad (but still not inclusive enough) definition, combined then with numerous exceptions aimed at making the legislation politically palatable; thus, two identical products may fall into different legal categories, based on their technique of development: ‘the same cultivars which express the same trait, for example tolerance of rapeseed to weed-killers or rebalanced starch content in potatoes, are subject to radically different authorization procedures, depending on whether they are created using one method rather than another’;²³⁷
- the lack of a requirement to label animal products derived from animals (e.g., meat, dairy, eggs) that have been fed GM feed,²³⁸ making most consumers unaware of GM crops’ presence in the food chain;²³⁹
- the threat to independence of the risk assessment procedure in relation to potential

²³⁵ Tagliabue (n 134)., where the author attributes this ‘paradox’ to political and economic incentives.

²³⁶ Baulcombe D, Dunwell J, Jones J, Pickett J, Puigdomenech P. ‘GM Science Update. A report to the Council for Science and Technology. 2014, www.gov.uk/government/publications/genetic-modification-gm-technologies.

²³⁷ Tagliabue (n 134).

²³⁸ ‘Response to Food Standards Agency Consultation: Proposed Approach to Retained EU Law for Food and Feed Safety and Hygiene’ (*GM Freeze*, 12 October 2018) <<https://www.gmfreeze.org/wp-content/uploads/2018/10/GM-Freeze-evidence-to-FSA-Retained-EU-law-consultation.pdf>> accessed 8 March 2021., para. 4.4.

²³⁹ *ibid.*, para. 3.2

conflicts of interests within EFSA;^{240 241}

- restrictions on access to research material on GMOs as part of the risk assessment;²⁴²
- creation of non-tariff barriers to trade, business uncertainty, increase of production costs, decrease in competitiveness as a consequence of the trade-restrictive legislation;
- most studies are funded by industry;²⁴³
- length of approval processes and consistent failure to pay due consideration to scientific opinions from the regulators, which inhibited research and development investment from sectors such as plant breeding.

i. Main Themes of the Reform

Any policy changes (both as autonomous UK legislation and as part of an international treaty, such a free trade agreement) would have to take into account the following imperatives:

- keeping restrictions to UK's internal market to a minimum, while ensuring due respect is paid to the devolved administration's differences in agricultural policies²⁴⁴ (Scotland, Wales and Northern Ireland are known for being more reluctant towards GMOs, having opted out of GM cultivation since this possibility was provided for in EU legislation in 2015)^{245 246 247},

²⁴⁰ Laaninen (n 195), p. 3

²⁴¹ 'Unhappy Meal. The European Food Safety Authority's Independence Problem | Corporate Europe Observatory' (*Corporate Europe Observatory*, 23 October 2013) <<https://corporateeurope.org/en/efsa/2013/10/unhappy-meal-european-food-safety-authoritys-independence-problem>> accessed 8 March 2021.

²⁴² David Quist and others, 'Late Lessons II Chapter 19 - Hungry for Innovation: Pathways from GM Crops to Agroecology — European Environment Agency' (2013) <<https://www.eea.europa.eu/publications/late-lessons-2/late-lessons-chapters/late-lessons-ii-chapter-19/view>> accessed 8 March 2021.

²⁴³ Pederson and Hernández (n 186), p16.

²⁴⁴ The UK Government's position seems to be in favour of devolution - Department for Environment Food & Rural Affairs, 'EXPLANATORY MEMORANDUM TO THE GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (EU EXIT) REGULATIONS 2018 AND THE GENETICALLY MODIFIED ORGANISMS (AMENDMENT) (ENGLAND) (EU EXIT) REGULATIONS 2018 NOS. [XXXX]' (n 212).

²⁴⁵ Engel and Petetin (n 217).

²⁴⁶ 'Response to Food Standards Agency Consultation: Proposed Approach to Retained EU Law for Food and Feed Safety and Hygiene' (n 266). p. 2.

²⁴⁷ Notably, however, the relatively small size of the UK, coupled with the reluctance of Wales, Northern Ireland and Scotland towards GM crops, means that seed developers may have little incentive to invest in creating crops

- and, on a related note, avoiding cross-pollination and cross-contamination between crops in administrations with different regulatory choices;²⁴⁸
- ensuring internal consistency between the approach of the UK's environmental regulators and the desire of its trade negotiators to secure agreements with GMO-exporting countries such as US, Argentina or Brazil;^{249 250}
- ensuring that the UK's own statutory bodies, such as ACRE, have the capacity to take over the risk assessment process regarding GM crop cultivation and placing on the market of GM food and feed from EU's authorities (e.g., EFSA);²⁵¹
- keeping the UK's food and environmental standards at a high level and avoiding a 'race to the bottom' (including in the context of free trade agreements);^{252 253}
- preserving transparency in risk assessment and risk ²⁵⁴management, factoring social and ethical concerns into the process, and consulting with civil society;²⁵⁵
- ensuring an effective liability regime for UK farmers and other businesses whose crops are contaminated with GM material, pesticides, etc.;²⁵⁶
- avoiding conflicts between the UK's international environmental and trade obligations.²⁵⁷

suitable for the UK's farmland and climate conditions, given the research and developments costs and the duration this process would entail – Bawden (n 246).

²⁴⁸ Engel and Petetin (n 217).

²⁴⁹ *ibid.*

²⁵⁰ Burns (n 262).

²⁵¹ 'Response to Food Standards Agency Consultation: Proposed Approach to Retained EU Law for Food and Feed Safety and Hygiene' (n 266). para. 2.3.

²⁵² Engel and Petetin (n 217).

²⁵³ 'Response to Food Standards Agency Consultation: Proposed Approach to Retained EU Law for Food and Feed Safety and Hygiene' (n 266)., p 2.

²⁵⁴ Engel and Petetin (n 217).

²⁵⁵ 'Response to Food Standards Agency Consultation: Proposed Approach to Retained EU Law for Food and Feed Safety and Hygiene' (n 266)., para. 4.2.

²⁵⁶ *ibid.*, para. 7.1.

²⁵⁷ For instance, the relationship between the rules in the Cartagena Protocol, which can operate as a trade restriction, and the trade-liberalising disciplines of the WTO are highly debated in the literature (see e.g., https://unctad.org/en/Docs/ditctncd20043_en.pdf; <http://www.meti.go.jp/english/report/downloadfiles/gCT0118e.pdf>), as is the case which much of the agreements outside the WTO system; the WTO dispute settlement system has not yet had an occasion to rule definitively on the issue. Given the approach of WTO panels and the Appellate Body to rules of international law outside the WTO system, which tends to give precedence to WTO rules in case of conflict, it is recommended that in its trade agreements the UK insert specific rules addressing potential conflicts between the

IV. POLICY RECOMMENDATIONS

In light of the government's public consultation about the regulation of genetic technologies, a change in the UK's GMO policy is possible²⁵⁸, and hence the purpose of this section is to provide a few recommendations so as to ensure the regulation of GMOs is sensible towards the interests of all stakeholders (mainly producers and consumers but also the general public) while trying to increase the UK's competitiveness in this sector worldwide.

The UK's approach to GMOs regulation should be guided by scientific and environmental concerns, while taking into account *informed* public opinion.

IV.I. GROWTH AND SALE OF GENETICALLY MODIFIED ORGANISMS

Genetically modified organisms in England and Wales are currently regulated by the Environmental Protection Act of 1990²⁵⁹ which essentially implements current European legislation outlined in EU Directive 2001/18/EC. This places the Secretary of State for the Department of Food, Environment and Rural Affairs in charge of oversight of deliberate release of GMOs.²⁶⁰ These powers are devolved to the National governments of Scotland and Northern Ireland which have both opted to ban GMO use. Under EFSA rules, toxicology of GMOs must be assessed according to OECD guidelines for testing of chemicals²⁶¹, including a 90-day feeding trial in rodents²⁶² and they apply even to gene-edited organisms.

If the UK leaves the EU with 'no deal', it is the current position that the status quo would be maintained.²⁶³ However, it is the position of this paper that a number of modifications should be made to this approach based on the evidence regarding the safety of GMOs in order to encourage their adoption.

Protocol and those agreements, especially when the other party has not signed and ratified the Protocol (an example for the latter case being Australia).

²⁵⁸ DEFRA (n 154).

²⁵⁹ Environmental Protection Act 1990 115.

²⁶⁰ Genetically Modified Organisms (Deliberate Release) Regulations 2002.

²⁶¹ OECD guidelines for the testing of chemicals. 2002.

²⁶² EFSA Panel on Genetically Modified Organisms (GMO) (n 88).

²⁶³ DEFRA, 'Developing Genetically Modified Organisms (GMOs) If There's No Brexit Deal' (2018).

- Existing legislative structure should be maintained with regard to assessing transgenic expression of novel genes for toxicity and allergenicity, assessment should continue to be performed by DEFRA.
- Where a gene has previously been shown to be safe for consumption, it should not be necessary to conduct safety assessments once more. That is, regulation should be applied to the gene in question, not the particular variety a gene was inserted in.
- Regulatory approval should not be required for gene-edited organisms.
- If a GMO is approved for sale it should also be approved for growth.
- Growth of GMOs should be managed to maximise biodiversity.
- Traits which confer resistance should be stacked and transgenic GMOs should be produced to be sterile in order to minimise the risks of pest resistance and gene escape.

i. Problems Surrounding Current Regulation of GMO Growth and Sale

The current legislation surrounding GMOs is highly restrictive, such that only one, Bt expressing MON 810 maize, are approved for cultivation in Europe.²⁶⁴ The lengthiness and costliness of the approval process is hindering innovation in agricultural research and leading to the UK falling behind other countries.

This paper argues that, given the lack of evidence to support the claim that genetic modification as a technology poses a health risk to humans either acutely or sub chronically, regulation ought to be relaxed and ought to be applied in a case-by-case manner. That is to say, regulation ought to be applied to the product and not the technology used in its development. For example, current legislation requires separate mandatory regulatory approval for all stacked GM events, meaning that new approval must be obtained even if both events have been shown previously to be safe.²⁶⁵ As an alternative, we propose that in such cases approval should be automatic. .

A recent ruling by the EU placed gene edited organisms under the same level of regulation as

²⁶⁴ European Commission, 'Community Register of GM Food and Feed' (n 193).

²⁶⁵ Robert Wager and Alan McHughen, 'Zero Sense in European Approach to GM?'

transgenic organisms.^{266,267} Putting an end to a large amount of CRISPR-based plant research. Such methods involve minor, targeted changes to DNA, in much the same way as chemical or radiation mutagenesis, but the latter are not subject to the same level of regulation. This distinction seems arbitrary and impractical given the difficulties of detecting gene editing. In the case of gene editing, there is no new gene being introduced which might cause toxicity or allergenicity, only a change that could happen quite ‘naturally’ through exposure to sunlight or errors in DNA replication, processes which are vital to creating genetic variation. Furthermore, it is likely that this ruling will mean that only large, corporate entities will be able to afford to bring gene edited organisms to market. It is the control of seed stocks by large multinationals that often concerns those opposed to genetic modification, loosening regulation would also pave the way for competition that could stymie the grip these companies have on the agritech industry.

There is a current disjoint between GMO approval for cultivation and the number approved for import and sale. For example, over 20 varieties of GM maize are approved for sale as food or feed by the EU (and by extension the UK) whilst only one is approved for cultivation.²⁶⁸ This places UK farmers at a disadvantage given the potential of GM crops to deliver economic advantages.²⁶⁹ As such, we suggest that, if a GMO is approved for sale it must also be approved for cultivation.

The latter point, of course, does not consider the environmental impacts of GMOs. It is the position of this paper, that GMOs are in fact beneficial to the environment, reducing the use of insecticide and of the more toxic herbicides which can be harmful to biodiversity. Of course, industrialised farming as a practice can be harmful to biodiversity but is necessary to achieve the yields needed to feed a growing population. To mitigate this, we propose that the approval of cultivation of GM crops is provided with good farming practice rules such as maintenance of buffer zones for biodiversity and to time spraying of insecticides and herbicides to minimise harm to non-target organisms. Such a scheme could be promoted by incentive schemes such as those operated by Natural England or could take the form of levying fines for those found to

²⁶⁶ Andrew J Wright, ‘Strict EU Ruling on Gene-Edited Crops Squeezes Science’ [2018] *NATURE News*.

²⁶⁷ Court of Justice of the European Union, ‘Organisms Obtained by Mutagenesis Are GMOs and Are, in Principle, Subject to the Obligations Laid down by the GMO Directive’ (2014).

²⁶⁸ European Commission, ‘Community Register of GM Food and Feed’ (n 193).

²⁶⁹ Graham Brookes and Peter Barfoot, ‘Economic Impact of GM Crops: The Global Income and Production Effects 1996-2012’ [2014] GM crops and food.

be in breach. This would prove to be beneficial in the long term as maintaining a healthy population of pollinators is demonstrably beneficial for crop yield.²⁷⁰ The only real risk to the environment that we see is the possibility of escape of transgenes, which has been shown to have occurred on several occasions. This could, in theory, disrupt ecosystems and damage yields by creating wild species which are immune to pests and which cannot be controlled by chemical means. As such, we recommend that all transgenic GMOs be sterile and suggest the use of GURTs to achieve this. Doing so would remove the potential for ‘superweeds’ to emerge but would prevent the common practice of farmers saving seed for the next growth season and would require farmers to go back to the seed producer each year. It is the fear of farmers being held ransom to multinational corporations (MNCs) that has led to GURTs being prohibited.²⁷¹ It is this latter point which in some cases may drive poor public perception of GMOs.²⁷² It is our view that this issue would be resolved by the loosening of regulations governing GMO cultivation and sale, enabling more, smaller companies to afford to bring GMOs to market, thus creating competition and preventing MNCs achieving a monopoly which could be used to negatively impact farmers.

IV.II. PERCEPTION AND LABELLING OF GENETICALLY MODIFIED ORGANISMS

Labels are a useful tool for the food (and other products) markets. This paper argues that the UK’s future approach to labelling (i.e., post- any potential Brexit transition period there might be) should take into account scientific and environmental concerns and be based on informed public opinion. As such, the following approach is proposed:

- Preserve the legislative status quo with respect to labelling during the transition period agreed upon with the EU (see Section III.III for an outline of the current arrangements regarding the transition period).
- Conduct a public information campaign.

²⁷⁰ Katharina Stein and others, ‘Bee Pollination Increases Yield Quantity and Quality of Cash Crops in Burkina Faso, West Africa’ [2017] Scientific Reports.

²⁷¹ Convention on Biological Diversity (n 133).

²⁷² Anthony John Bridgen, ‘Ademola A. Adenle, E. Jane Morris, and Denis J. Murphy, Eds., Genetically Modified Organisms in Developing Countries: Risk Analysis and Governance (New York: Cambridge University Press, 2017), 306 Pages. ISBN: 978107151918. Hardcover: \$125.00.’ (2018) 37 Politics and the Life Sciences 280.

- Consult the UK public as to their view regarding the labelling of GMOs.
- Finally, decide whether to require GMOs labelling and, if so, on what terms.

A new approach to GM products' labelling would have the benefit of avoiding the two main problems which surround the current GMOs labelling rules.

i. Problems Regarding Current GMO Labelling Legislation

One of the most important elements of the regulatory framework for GMOs in the EU and UK concerns labelling of GM products. As foreshadowed above, current EU (and, by extension, UK) legislation requires labelling food products with GM content over 0.9%. This paper takes the position that there are two *main* factors which challenge the conventional wisdom which GMOs opponents support, according to which labelling GM products is, in itself, good policy.

First, it is not entirely clear that labelling legislation in the EU serves the assumed function of conveying reliable consumer information. To the contrary, GMO labels may mislead public perception. Those sceptical about GMOs usually argue that labelling GM products is essential for safeguarding consumer preferences. Indeed, that labels serve the important function of avoiding market failure caused by information asymmetry between producers and consumers, ensuring consumer information and health protection cannot be denied – this is a universal proposition valid for labels in any field, be they food, pharmaceutical products, electronics, etc. In a way, they might also have something to say about a society's wider views as regards a particular food item, substance or other product – indeed, as it has been noted, because of its effect, labelling is an indicator of a state's policy towards the acceptance of GMOs in food products.²⁷³

Nonetheless, as this paper has shown, scientific evidence strongly supports the view that GMOs are not harmful to human health. (See Section III.I.) Moreover, when it comes to GM food, environmental (biodiversity) concerns have little to say, given that GM processed foods cannot

²⁷³ D Adeline Yeh, Miguel I Gómez and Harry M Kaiser, 'Signaling Impacts of GMO Labeling on Fruit and Vegetable Demand' (2019) 14 PLoS ONE </pmc/articles/PMC6821398/> accessed 8 March 2021.

contaminate the environment. As such, conveying consumer information seems to be the only realistic function that remains to be ascribed to labelling of GM foods: as consumers do not, as a rule, need such information to protect their health, they might need it to protect their ethical concerns against GMOs or for other reasons related to their ‘right of information’. Indeed, a state may consider that consumers have such right regardless of safety concerns.²⁷⁴

However, as this paper has shown, much public discourse against GMOs is dominated by misinformation (See Section III.II.). This finding turns on its head the assumption – on which the EU legislature seems to have based GM food labelling rules – that GM labels can act as a medium for spreading useful consumer information. In the current context, labels can attain the exactly opposite function i.e., propagating unfounded myths about why GMOs are inherently ‘bad’.²⁷⁵

Second, and perhaps more importantly, as this paper has shown, in some instances it is very difficult to test (i.e., based on the end-product itself, especially regarding highly refined items such as sugar or oil) whether a food product contains GMOs and, if so, whether the GM content threshold which triggers a labelling obligation is or is not met (See Sub-section II.II.I.iii.) On a related note, there has not yet emerged an international consensus on how to detect GM food.

Therefore, considering the two arguments above labels are relatively unhelpful. We recommend a transition period during which GMO labelling remains required, while our alternative approach is implemented, specifically a public information and education campaign discussed in the following section.

ii. Conduct a Public Information Campaign Regarding GMOs

The public attitude to a product or technology is generally linked to its perceived risks. Hence, benefits are of higher importance than risks in the course of determining the willingness to consume new products or accept new technologies.²⁷⁶ People are tolerating risks, if they perceive that there is a direct benefit to themselves.²⁷⁷ Looking at the case of herbicide-tolerant

²⁷⁴ *ibid.*

²⁷⁵ Although limited evidence suggests labelling GMOs improves public perception. However, it is not clear to what extent research conducted in a limited and, moreover, US-specific, context can be reliably used to reach reasoned conclusions regarding the effects of GMOs labelling in the EU.

²⁷⁶ Costa-Font, M. & Gil (n 163).

²⁷⁷ Frewer and others (n 168).

and insect-resistant crops, they directly benefitted farmers, by increasing productivity and lowering the costs of input. However, consumer benefitted only indirectly in reduced food costs, which might not be sufficient to outweigh the perceived risks. The benefits with the highest potential to improve acceptance of GM crops by consumers correlate to sustainability (lower energy use and less release of pollutants during production), food security (crops that are able to reduce hunger in the least developed countries) and improvement in health (addition of functional ingredients). Nevertheless, such benefits are not sufficiently, or not at all, communicated and consumers often see only the potential risks of GM food. There has to be a change with regard to perception of improvement in terms of quality, price or other advantages, without it, there will be no incentive to have a positive attitude to GMOs. Therefore, the public rejection of GM food and crops is not necessarily a misconception of scientific risks, but more the perceived absence of benefits for consumers.²⁷⁸

Specifically, we would recommend implementing the following two suggestions:

- **Funding of scientific outreach programs educating the public about genetic modification:** Putting in place funds to support scientific outreach activities that communicate the benefits and actual risks of GMO use outside the scientific community. Target groups are (i) people from educationally disadvantaged backgrounds, where there is a disengagement with science. Furthermore, such governmental funded campaigns should be directed to (ii) groups that support the idea of the sanctity of food. Here, it is important to raise awareness of the scientific background of GMO technology and its possible benefits for sustainability, food security and improvement in health and its interchangeability with conventional breeding. Those campaigns should present to be a positive response to unfounded statements and misinformation.
- **Implement a discussion of GMOs into school's biology syllabi:** It is of fundamental importance to educate children about how genetic manipulation works and how it can be used to bring improvement in agriculture and medicine and what the benefits are for consumers. The compulsory inclusion of the theoretical background of

²⁷⁸ George Gaskell and others, 'GM Foods and the Misperception of Risk Perception' (2004) 24 Risk Analysis 185.

GMOs should find its place in the compulsory school education in the National Curriculum within the subtopic of ‘Genetics and inheritance’. This should take place in the key stages 3 and 4 (Pupils’ age ranges from 11-14 / and 14-16). This scientific education is necessary to ensure that the GMO debate turns back in one of discussing information and not disinformation.

iii. Consult the UK Public as to their Opinion Regarding GMO Labelling

Public consultation is already a core component of the EU/UK framework for GMOs – according to EU/UK rules, the public has 30 days to comment before a GMO can be approved for cultivation and can also express its views on the risk assessment that EFSA conducted in relation to GM food and feed.²⁷⁹ However, it has been observed that such consultation, conducted either at EU or Member State level, does little to inform and educate the masses. This is because the information can only be understood by those possessing specific scientific knowledge.²⁸⁰ In this context, public consultation would do little to serve as a risk assessment.

Certainly, the same applies to consultations regarding GMOs legislation, which furthermore has a far-reaching and general character (as opposed to the authorisation of a specific product) – and therefore informing the public prior to asking for their views is even more important here. The UK has a relatively long history on seeking public opinion on GMOs,²⁸¹ and no further observations are warranted in this respect.

iv. Decide Whether to Require GMO Labelling and, if so, on What Terms

After having carried out the steps above, the UK would hopefully be in a position to know what the public’s informed opinion is with respect to labelling of (and perhaps also other aspects regarding) GM food and feed:

- The first question to be asked would be: **is government intervention warranted?** To

²⁷⁹ European Commission, ‘Public Consultations on GM Food & Feed Authorisation Applications | Food Safety’ (*ec.europa.eu*) <https://ec.europa.eu/food/plant/gmo/public_consultations_en> accessed 8 March 2021.

²⁸⁰ Marko Ahteensuu and H Siipi, ‘A Critical Assessment of Public Consultations on GMOs in the European Union’ (2009) 18 Environmental Values 129., p. 141.

²⁸¹ Burke Derek, ‘GM food and crops: what went wrong in the UK?’ (2004) 5 EMBO Rep. 5.

this, the public opinion collected would no doubt provide valuable input. If consumers regard as important information on GMOs in their food, producers and sellers may have an incentive either to misleadingly label their products as ‘GMO-free’ or to fail to label their GM food accordingly. Conversely, if the public does not deem information on the GMOs in their food of interest (which we estimate is unlikely to happen), then there should be no case for regulation. Also, the costs and trade-restrictiveness that verification of GM products, and segregation thereof,²⁸² entails must be taken into account (ultimately such costs might well be passed on to the consumers), and, at last, balanced against the public’s ‘right of information’, a trade-off between the two competing objectives (ensuring smooth trade versus informing consumers) being inevitable. Turning to the first scenario, having found that consumers regard, as important, labelling of GMOs is only the start of the process. Following this, the following policy questions arise:

- **How are GMOs defined?** For this problem, see this paper’s recommendations at above. (See Section II.I.)
- **How far should government regulation go: merely preventative action against fraud in labelling, or positive action by way of regulation of labelling? If the latter, should labels be voluntary or mandatory?** States can essentially adopt one of the following approaches to GMOs labelling: labelling is voluntary for non-GMOs and/or for GMO products; labelling is mandatory for GMO products; labelling is mandatory for GMO and non-GMO products. For example, mandatory labelling of GMOs is adopted in the EU, Japan, Australia and other countries, and voluntary labelling, in the US (but even in the latter case, labelling is mandatory if important characteristics of the product, such as allergens or nutritional content, are different). Voluntary labelling imposes fewer trade barriers, as it would have less impact on producers’ costs. On the other hand, it would limit informed choices of the consumers not only with respect to the safety of their food, but also because consumers today seem to be increasingly conscious of the environmental or ethical implications of their food.
- **Which products should be subject to labelling?** In the EU the labelling requirement currently applies across the board, to all food categories. An alternative would be to restrict such labelling to limited food categories, such as children’s products.

²⁸² Yeh, Gómez and Kaiser (n 301).

- **When should the labelling obligation be triggered?** Various approaches can be employed here, the obligation to label being triggered based on one or more of the following: the percentage of GM components in the product (this being the EU's approach); whether the most important ingredients of the product are GM, whether the GM ingredients modify the most important characteristics of the product (this being, to an extent, the US's approach).
- **What about GM products deriving from animals which have been fed using GM inputs?** The two possible scenarios are requiring labelling when animals from which the food products are derived were fed GM feed or conversely, not requiring GM labelling of food products in such case. The EU has adopted the second approach.
- **What statements should there be on the label?** The actual claim on the label is of utmost importance on how labels convey information to consumers. The current concept of 'GMOs' has arguably gained negative connotations in mainstream discourse. As such, it is unlikely that requiring labelling as 'genetically modified' for food and feed (as current EU legislation prescribes) is sound policy. Perhaps this is why the new rules applicable from 1 January 2022 in the US use the term 'bioengineered' instead, which appears to be more neutral.²⁸³ On a related note, whether to allow 'GMO-free' labels (as the EU currently does, on a voluntary basis) is also of concern here. As for some products, it is impossible to determine whether they have been subject to GM processes. (See Sub-section II.I.I.iii.)
- **How can labelling practices be reviewed?** Here, the options include self-certification by sellers (policed by adjacent regimes, such as consumer protection or misleading advertising laws), testing and certification by a public authority or testing and certification by a third-party provider authorised by a public authority.

²⁸³ The rules are part of the new 'National Bioengineered Food Disclosure Standard', see – Agricultural Marketing Service, 'Industry Fact Sheet – National Bioengineered Food Disclosure Standard | Agricultural Marketing Service' ([ams.usda.gov](https://www.ams.usda.gov)) <<https://www.ams.usda.gov/resources/industry-fact-sheet-national-bioengineered-food-disclosure-standard>> accessed 8 March 2021.

V. SUMMARY OF RECOMMENDATIONS

In summary this paper makes suggestions on how to regulate GMOs in a manner that is science based and proportionate. The overarching aim is to encourage policy that fosters innovation, improves productivity, decreases the UK's impact on the environment and climate, while fostering an atmosphere in which consumers feel safe. Here we briefly review each of the themes we discussed in this paper (For a more detailed discussion please see Section IV. above).

- **To foster agricultural innovation.** The UK is a renowned world-leader for innovation in life sciences. However, innovation in genetic modification technologies has been hindered by misguided regulation, which has halted the transition from pioneering research to in-field implementations. A deregulation of GMO technologies would encourage research centres, start-ups and small-to-medium enterprises to invest in practical and profitable applications for genomic engineering and agricultural biotechnology.
- **To reduce the environmental impact of agriculture.** Genetically modified crops have the potential to reduce the impact of agriculture on biodiversity loss and climate change. We presented, in the introduction, multiple examples of GM technologies which have reduced pesticide applications and greenhouse gas emission of agriculture and farming, whilst maintaining “economical profitability”.
- **To maintain high food quality and environmental standards.** The safety and quality of food for human consumption should remain a priority for the government independently of Brexit. Although GM technologies to date have been proved to be safe, we advise for transgenic organisms to require approval for growth and sale upon adequate testing for potential side effects on humans and the environment. Under our advice, cisgenic and gene edited organisms should be regulated like conventionally bred organisms and should not require special approval.
- **To maintain consumer trust with transparent labelling and dialogue.** The scientific consensus is that GM crops are safe, however public opinion has not caught on due to general misinformation. Given the bias in public perception against GMOs,

we propose regulatory methods that are scientifically founded but transparent to ensure consumer trust. We advise for an initial transition period of strict labelling of all GM food, coinciding with an information campaign aimed at ameliorating consumer misinformation with scientific evidence. At the end of this transition period, we advise the government to hold a public consultation on the need to label GM food to safeguard consumer information.

- **To encourage science outreach on the topic of GMOs.** A fundamental component of this policy proposal is to encourage dialogue between scientists and the public and renew public trust in science-based policy. We advise for the government to implement this through a public information campaign on GMO safety and by funding public awareness initiatives. Moreover, we recognise the importance of educating young generations on GM technology and science innovation and we advise to introduce the topic into the national curriculum for sciences.

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