FOSTERING INNOVATION IN AGRICULTURE

through enabling regulatory policy

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LIST OF ABBREVIATIONS

- ACNFP - Advisory Committee on Novel Foods and Processes
- ACRE - Advisory Committee for the Release into the Environment
- EASAC - European Academies Science Advisory Council
- EC - European Commission
- ECJ - European Court of Justice
- EFSA - European Food Safety Authority
- EU - European Union
- FAO - Food and Agriculture Organization of the United Nations
- FSANZ - Food Standards Australia New Zealand
- GMAG - Genetic Manipulation Advisory Group
- ISAAA - International Service for the Acquisition of Agri-biotech Applications
- KBBE - European Knowledge Based Bio-Economy
- OTGR - Office of the Gene Technology Regulator
- SDGs - Sustainable Development Goals
- UK - United Kingdom
- UN - United Nations

GLOSSARY

Conventional breeding
A traditional method of developing new traits in plants or animals not involving gene technology.

DNA
DNA, or deoxyribonucleic acid, is the hereditary material for most living organisms. DNA is present in cells as two strands (double stranded) composed of a series of nucleotides.

Exposure
Estimation of the intensity, frequency, and duration of contact of an organism or valued entity with a hazard.

Food security
The state of having reliable access to a sufficient quantity of affordable, nutritious food.

Gene editing
A technique which can be used to make specific changes at targeted locations in the genome of an organism.

Gene technology
A method that alters the DNA of living cells or organisms using recombinant DNA techniques. May also be called GM techniques.

Genetic engineering (GE)
A type of genetic modification that involves the intentional introduction of a change in an organism to achieve a specific result.

Genetic modification (GM)
Range of techniques that alter the DNA of an organism.

Genetically modified organism (GMO)
An organism whose genome has been modified using gene technology.

Genome
The complete set of genetic material in a living cell or organism.

GM food
Food derived from organisms that have been modified using gene technology.

Hazard
An action or event which has the potential to cause harm to living organisms or environments.

New breeding techniques (NBTs)
A wide range of new techniques used to modify the genomes of plants, animals and microorganisms.

Null segregant
Progeny that have not inherited an introduced gene.

Risk
The possibility that human actions or events lead to consequences resulting in harm to human and animal health or the environment. Risk is a function of hazard and exposure and measures the probability that a hazard will lead to harm.

Risk Assessment
A specialised field of applied science that involves reviewing scientific data and studies in order to evaluate risks associated with certain hazards. It involves four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

Risk management
The management of risks which have been identified by risk assessment. It includes the planning, implementation and evaluation of any resulting actions taken to protect consumers, animals and the environment.

Sustainable agriculture
Sustainable agriculture is the production of food, fibre, or other plant or animal products utilizing techniques that protect the environment, public health, human communities, and animal welfare.

1. Executive summary

Agricultural biotechnology is a key tool for sustainable food production

It is widely recognised that the world faces serious challenges over the next decades. With the population expected to exceed 9 billion by 2050, the way in which food is produced and distributed needs to change.

The 2030 Agenda for Sustainable Development, adopted by the United Nations (UN) international community in September 2015, shows the commitment of member countries to deliver seventeen key sustainable development goals (SDGs) (United Nations, 2015). Among these goals is the recognised need for innovation in agriculture, to produce more food using the same amount of land in a sustainable manner that reduces adverse impacts to the environment (FAO, 2017a). In order to achieve these goals, international cooperation and the implementation of enabling national policies are critical.

Agricultural biotechnology can play a key contributing role to the achievement of the SDGs. Over the last two decades, biotechnology developments in genetic engineering have already delivered crops with proven benefits for the environment (Brookes and Barfoot, 2018; ISAAA, 2018). Research and development in this area is likely to produce further crop varieties that could help to solve some of the current challenges in agricultural production. However, in order to realise the potential of such technology, there must be a political will to implement efficient regulatory frameworks to enable the commercialisation of innovative products and their practical use in agriculture.

A functional regulatory framework fosters innovation

In this report we explore how some countries, in their vision to embrace innovation in agriculture and biotechnology products, have been modernising and streamlining their regulatory frameworks. We have chosen as examples, countries that have adopted very different regulatory frameworks, but all have resulted in functional and efficient systems that fulfil the purpose to enable innovation while protecting human and animal health and the environment.

We also review the current regulatory framework for agricultural biotechnology products in the European Union (EU), where despite alignment with the UN SDGs and heavy investment in research, the regulatory system has evolved to be so cumbersome that the only product currently approved for cultivation in the EU was approved in 1998 and import approvals are asynchronous with the rest of the world.

Fostering innovation in the UK

The UK has a strong reputation for scientific excellence and a pragmatic approach to risk assessment. However, currently the UK regulatory framework is intrinsically linked to the EU system, so progress in the adoption of agricultural biotechnology has been stifled.

Based on the review we have conducted on the EU regulatory framework and that of other countries, we offer a series of recommendations that could be taken into account in the implementation of enabling regulatory approaches. The recommendations would result in a functional regulatory system for agricultural biotechnology products that is broadly in line with that of the EU, but which incorporates elements from other countries that have successfully adopted these technologies. The recommendations include (1) the need to set clear policy goals for sustainable agriculture coupled with transparent protection goals, (2) adoption of a risk-based approach to safety assessments, (3) fostering technical excellence of UK risk assessors, (4) avoidance of overly prescriptive safety assessment guidelines and (5) adoption of a system that allows for pre- and post- consultation with innovators which will result in the generation of regulatory data that is proportional to the risk of the introduced product.

2. INTRODUCTION

With the world population expected to exceed 9 billion by 2050, the way in which food is produced and distributed needs to change (FAO, 2017a). The 2030 Agenda for Sustainable Development, adopted by the United Nations international community in September 2015 (United Nations, 2015), shows the commitment of member countries to deliver seventeen key sustainable development goals (SDGs). Among these goals is the recognised need for innovation in agriculture, to produce more food using the same amount of land in a sustainable manner that reduces adverse impacts to the environment (FAO, 2017a). In order to achieve these goals, international cooperation and the implementation of enabling national policies are considered of high importance.

Agricultural biotechnology has been identified as one of the tools that can help achieve SDGs related to food security, sustainable agriculture and climate change. Over the last two decades, biotechnology developments in genetic engineering have already delivered crops with proven benefits for the environment, with lower carbon footprints (Brookes and Barfoot, 2018; ISAAA, 2018). Research and development in this area and in emerging technologies, can help to solve some of the current challenges in agricultural production. However, in order to make use of these technologies, countries must implement efficient regulatory frameworks that are based on clear policy goals; a system that ensures efficient and proportionate measures to assess the risk of these technologies and a political will that allows their application in agriculture (EASAC, 2013; FAO, 2017b).

The European Union (EU) has fully subscribed to the UN SDGs goals (United Nations, 2015), and heavily supports the growth of a Knowledge Based Bioeconomy (KBBE) by investing in excellence in science, technology and industry to deliver innovation (EC, 2018b). This includes agricultural biotechnology, which is recognized as a means to increase the yield and quality of economically relevant crops (Masip et al., 2013), with the potential to deliver on the food security and sustainability goals. Unfortunately, this heavy investment in research and development has not translated into commercialised products, as the regulatory oversight for these products is not working as it should (Raybould and Poppy, 2012; Masip et al., 2013).

However, the negative shift in regulatory policy relating to crop protection and genetically modified crops, has contributed to a heavy reliance on imports for food and feed supplies. In recent years, applications for cultivation of genetic modified crops have either been withdrawn or remain in the system despite being submitted over 20 years ago (EuropaBio, 2014) and import approvals typically take over 5 years (EuropaBio, 2019) compared to 1-2 years in other jurisdictions. More recently, the European Court of Justice ruling that all forms of gene-editing are equivalent to genetic modification (ECJ, 2018) closes a door on EU innovation at a time when all solutions should be considered. Such negativity has implications not only for the sustainable goals in the EU, but also for continents such as Africa where investment and innovation are greatly needed (EASAC, 2013).

The UK has a history of fostering innovation and a solid reputation for science-based risk assessments. Nearly half a century ago, the UK considered the benefits of crop genetic modification and how to enable its introduction. This resulted in the UK being the first country in the EU to introduce a genetically modified product in 1996. Since that time, however, innovation resulting in commercial introduction of genetically modified products has been prevented in the UK because of the onerous application of legislation in the EU. This is having knock-on effects in the uptake of newer technologies such as gene editing (Brookes, 2018).

“Unfortunately, this heavy investment in research and development has not translated into commercialised products, as the regulatory oversight for these products is not working as it should.”

In the near future, the UK government may have an opportunity to implement an enabling regulatory framework for agricultural biotechnology. As such, now it is a good time to conduct a critical examination of the current EU system and to review the approaches undertaken in other countries that are actively fostering and adopting agricultural biotechnology products.

In this report we review the current regulatory framework for agricultural biotechnology in the EU and explore how some other countries have been modernising and streamlining their regulatory systems to support innovation. The information is then used to provide recommendations that could be taken into account by the UK government moving forward.

3. THE IMPORTANCE OF INNOVATION IN AGRICULTURE

The challenge of feeding the world is not new. With an ever-increasing population, the need to make food production more efficient has been a key goal for some time. In the second half of the last century, the developing world witnessed an unprecedented increase in food crop productivity. Even though populations more than doubled in that period, the production of cereal crops tripled with only a 30% increase in land area cultivated (Wik et al., 2008). This increase in productivity was largely due to high rates of investment in crop research, infrastructure, and market development along with appropriate policy support (Pingali, 2012). More recently, however, the global rate of productivity increase is slowing down (Pardey, 2011) at a time when the population continues to rise sharply and is estimated to surpass 9 billion by 2050 (FAO, 2017b).

Pressure on food production systems has therefore never been greater. The UN Food and Agriculture Organisation (FAO) estimates that farmers will have to produce 70% more food by 2050 to meet the needs of the world's growing population (FAO, 2009). This must be achieved without committing more land to agriculture and can no longer be carried out at the expense of the environment. At the same time, concerns about climate change continue to grow, with agriculture estimated to result in between 10 and 25% (Tilman et al., 2011; Wentworth and Plumpton, 2019) of global greenhouse gas emissions.

Just as in the last century, innovation can and should be utilised in the global solution to these problems. Plant breeding techniques have resulted in the production of higher yielding varieties resulting in, for example, a doubling of yields in rice (FAOSTAT, 2020). Crop genetic modification has resulted in the production of more food per acre (Brookes and Barfoot, 2017b) and the use of plant protection products has, for example, resulted in the prevention of nearly half of pest crop destruction in wheat (Oerke and Dehne, 2004). This enhancement of agricultural productivity has the added benefits of creating sustainable livelihoods and healthier diets; supporting water conservation and soil preservation, as well as protecting Biodiversity (CLI, 2013; Brookes and Barfoot, 2017b, a). Such innovation can also contribute to climate change targets, for example, through the use of high yielding crops using less land, drought tolerant crops that can withstand water shortages and through crops that reduce the need for tillage and keep carbon in the soil. In 2016, the amount of CO2 saved from the use of herbicide tolerant crops was estimated to be equal to removing 16.7 million cars from the road for one year (Brookes and Barfoot, 2018). The use of the next generation of crops involving gene-editing has the potential to create an even broader scope of products to help combat food security and climate change (Jorasch, 2019; Wentworth and Plumpton, 2019).

> "Farmers will have to produce 70% more food by 2050 to meet the needs of the world's growing population."

The societal need for innovative food production technologies has therefore never been greater and policy makers have a responsibility to ensure that every tool may be used to produce more food from the same land with less environmental impact. Agricultural biotechnologies, such as the GM crops commercialised over the last two decades, can contribute to achieve these goals (Brookes and Barfoot, 2018), but functional and effective regulatory systems need to be in place so these products can be commercialised and used in practice.

In summary:

- **Innovation in agriculture is key** to meet the challenges faced by a growing world population and contribute to achieving climate change targets.
- **Plant breeding techniques** have resulted in the production of higher yielding varieties producing more food per acre.
- **Genetic modification** and more recent innovative techniques can continue to further enhance yields.
- **Policy makers** have the responsibility to ensure that regulatory frameworks are in place to facilitate the application of innovation to produce more food from the same land with less environmental impact in the future.

4. RISK ASSESSMENTS AS A TOOL FOR DECISION MAKING

Agricultural biotechnology offers an array of potential tools that accelerate the process of producing crop varieties which allow the efficient use of land, reduction of pesticides and adaptation to climate change. As is the case with any new technology development, countries consider the benefits and potential harmful impacts that introduction may have on key protection goals such as human and animal health and the environment (Kates and Kasperson, 1983). Many countries have established regulatory systems dedicated to analyse the potential risks associated with certain technology (Tait and Levidow, 1992). Risk assessments play a key role in these systems, estimating the level of risk that a new product may pose to human and animal health and the environment before they are approved for commercial use.

To understand how risk assessments help in the decision-making process, it is critical to clarify some key underlying concepts. Risk, in the context of safety assessments, is defined as the possibility that human actions or events lead to consequences resulting in harm to human and animal health or the environment (Kates and Kasperson, 1983). The actions or events (e.g. a new technology or a new pesticide) constitute what is known as “hazard”. For the hazard to cause harm, the entity under protection (e.g. humans or animals) must be exposed to that hazard. So, hazards are the threats to valued entities, whereas risks measure the consequences of exposure to those hazards (Hohenemser et al., 1983), or in other words, risks measure the probability that a hazard will lead to harm. For example, the level of hazard associated with the intake of paracetamol is well known, and safe dosage levels have been established. Paracetamol could cause serious health issues if taken in large quantities, but has well known benefits when exposure is kept below the recommended dosage. Paracetamol only causes harm if the recommended exposure level is exceeded, therefore at low doses the risk is low, at excessive doses, the risk is high. The same principle applies to pesticides and other products, for a given hazard the risk is highly dependent on the exposure.

Risk assessments are not a tool to prove safety, they are tools to facilitate decision-making. The assessments use a structured, reasoned approach that considers the potential for harm from certain activities, based on scientific evidence and considerations of uncertainty (OGTR, 2009). To fulfil the purpose of informing decision making, risk assessments must be fit-for-purpose. Professional risk assessors are intimately acquainted with the array of tools that may be used to estimate risk and its associated uncertainty, but the acceptability of a given level of risk cannot be determined scientifically (Raybould, 2012).

Policy protection goals that dictate what entities must be protected and at what level, are set by policy makers and encompass values that are not set in a scientific context but are based on societal and political concerns (Johnson et al., 2007; Devos et al., 2013). Risk-based approaches are adopted in regulatory frameworks to improve regulatory efficiency through proportionality of regulatory enforcement and to target resources toward the greatest threats to the protection goals (Raybould, 2012). This approach, when correctly implemented, allows risk assessors to undertake the quantification of risk following a science-based technical exercise, focussing on the relevant information that will inform the assessment, as the protection goals and the level of acceptability of any risks identified have been previously established by policy makers (Evans et al., 2006; Devos et al., 2013).

In order to conduct fit-for-purpose risk assessments, it is crucial that policy objectives are clear (Garcia-Alonso and Raybould, 2014). It requires expert judgement to determine the relevance of data to fulfil the purpose of a risk assessment. Experienced risk assessors working under a regulatory framework where the policy protection goals are clearly outlined, can expertly determine what are the key data to assess the risk associated with a particular product (Raybould, 2010). Whereas inexperience or a lack of clarity on the policy protection goals can lead to the collection of large amounts of data, even when those data do not provide useful information for decision-making. There is sometimes a tendency to judge the thoroughness of a risk assessment by the amount of data it contains, however fit-for-purpose risk assessments should aim at providing relevant information to answer the specific policy questions posed, with the amount of required data being proportional to the level of risk. Thus, there is a big difference between data collection for fit-for purpose risk assessments compared to science projects. Scientific studies may fulfil the objective of large data collection, but these data may not address the relevant risk assessment questions with the result of confounding decision-makers (Raybould, 2012; Raybould and Poppy, 2012).

In summary: risk assessments that add value to decision-making

- **Science-based:** Using the universal scientific approach of formulating test hypotheses and using data to prove them or disprove them.
- **Conducted by professional risk assessors:** With in depth knowledge of risk assessment tools and methods.
- **Fit-for-purpose:** Addressing the relevant questions with relevant data for the risk assessment, avoiding accumulation of data of scientific interest but of no value for the assessment of risk.
- **Proportional:** The amount of data required to assess the risk and the complexity of the risk assessment depends on the product and the level of risk it poses. Risk assessments for products for which there is familiarity can be simplified by using data previously generated without compromising on safety. Risk assessments for novel products or for products that are considered to pose more risk may require more data and/or more complex assessments.

5. REGULATORY LANDSCAPE

5.1 Regulatory approaches in countries that support innovation in agriculture

Many countries have identified agricultural biotechnology as one of the tools that could help to achieve the UN SDGs relating to food security and sustainable food production. Some countries are acting on this, fostering research in this field and establishing functional and efficient regulatory frameworks to enable the commercialization of the products of that research. According to the latest figures on biotechnology GM crops, in 2018, a total of 70 countries adopted biotech crops, 26 countries planted these crops, while 44 countries imported the crops for food feed and processing. Of the 26 countries planting biotechnology crops, 21 are developing countries and 5 are industrialised countries (see Figure 1) (ISAAA, 2018).

In 2018, the global area of biotech crops was 191.7 million hectares, representing an increase of 1.1% from 2017, equivalent to 1.9 million hectares.

Source: ISAAA, 2018

Figure 2: Adoption rates in the top 5 countries that planted biotechnology crops (ISAAA, 2018).

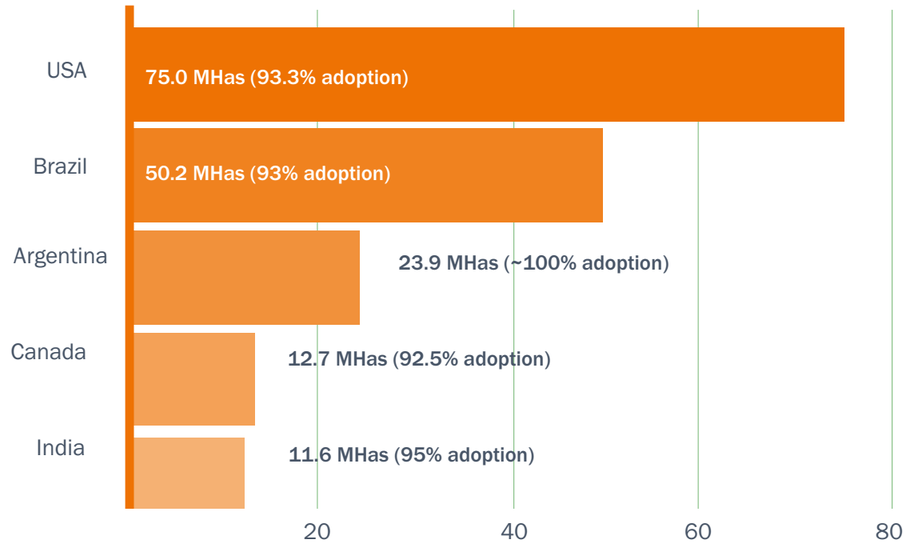
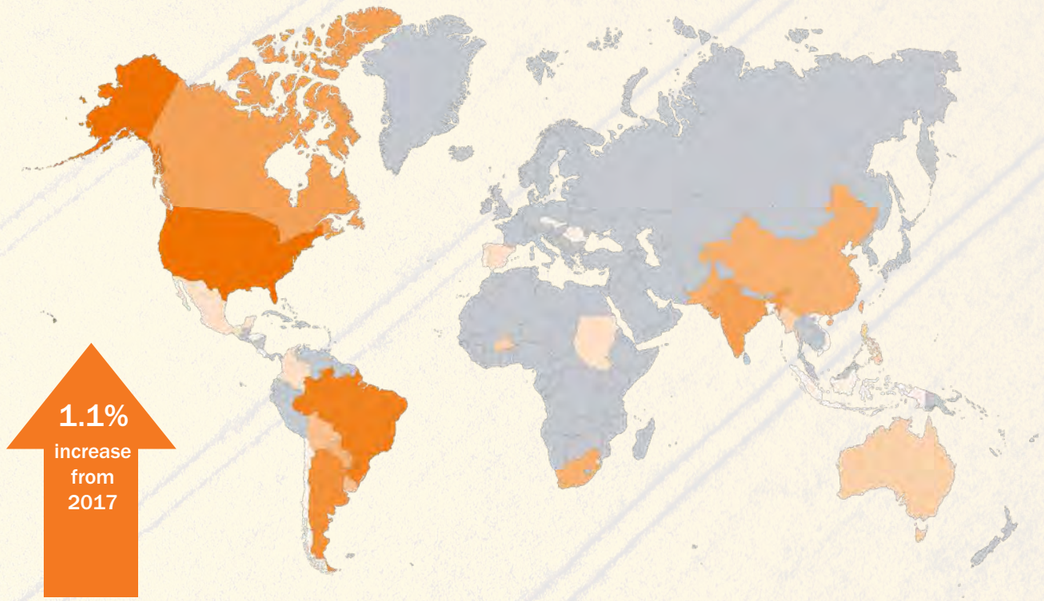


Figure 1: Global area (million hectares) of biotech crops by country (ISAAA, 2018).



Rank	Country	2018
1	USA	75.0
2	Brazil*	51.3
3	Argentina*	23.9
4	Canada	12.7
5	India*	11.6
6	Paraguay*	3.8
7	China*	2.9
8	Pakistan*	2.8
9	South Africa*	2.7
10	Uruguay*	1.3
11	Bolivia*	1.3
12	Australia	0.8
13	Philippines*	0.6
14	Myanmar*	0.3

Rank	Country	2018
15	Sudan*	0.2
16	Mexico*	0.2
17	Spain	0.1
18	Colombia*	0.1
20	Vietnam*	<0.1
21	Honduras*	<0.1
22	Chile*	<0.1
23	Portugal	<0.1
24	Bangladesh*	<0.1
25	Costa Rica*	<0.1
26	Indonesia*	<0.1
27	eSwatini*	<0.1

** Developing countries*

5.1.1 Canada, a unique product-based approach

In North America, the USA and Canada are among the five top producers of genetically modified crops, with high rates of adoption (See Figure 2).

These countries have functional regulatory systems that allow them to effectively review and approve agricultural biotechnology products in a timely manner. However, the two countries have set up very different regulatory frameworks. While the USA, has based their regulations on a consideration of how a biotechnology product was developed, Canada focusses on the novelty of the final product, regardless of the process that was used to produce it (McHughen, 2016). As such, in Canada the scope of the regulations is broader than GM and would cover products from conventional breeding, if they were sufficiently novel (CLI, 2016).

In Canada, food, feed and environmental safety is governed by the Food and Drugs Act; the Feed Act and Regulations and Seeds Act and Regulations respectively (Ellens et al., 2019). The approval of a novel plant product is carried out by different departments in Canada which have different expertise. Health Canada is responsible for carrying out the novel food assessment whereas different groups within the Canadian Food Inspection Authority perform the feed or the environmental safety assessment. The three authorisations given by these bodies are co-ordinated under a harmonisation of approvals policy to minimise the potential for introduction of unapproved products. The system encourages pre-submission consultations to assist with the determination of novelty and if a pre-market assessment is required. Approval of genetically modified products in Canada typically takes 1-2 years and assessment is performed by expert members of staff, as opposed to advisory committees.

Canada is the fourth largest adopter of GM crops (ISAAA, 2018) and enabling policies adopted have been instrumental in this. There have even been calls for the EU to adopt a similar product-based regulatory approach to that of Canada (EASAC, 2013). However, it should be noted that the Canadian regulatory system is not without its complications and it is interesting to note that such a system has not been adopted by other countries that grant approvals in a timely manner. The definition of novelty is not unified across the three organisations and determination of novelty can therefore be complicated and lengthy. Having three separate assessments can lead to duplication. In addition, Codex requirements (Codex Alimentarius, 2009) play a key role in the assessment process which creates reliance on a process-based system inevitable. There is also frustration among innovators because, in practice, the approach broadens the definition of what is regulated to products derived from technologies that do not require additional regulatory oversight elsewhere (EASAC, 2013).

Canada continues to assess products of gene editing under their existing Novel Food Regulations.

Key aspects to highlight from the Canadian regulatory framework are:

- **Flexibility:** although the framework offers guidance on the risk assessment and data requirements, they are not legally binding and can be flexible depending on the risk and type of product.
- **Technical expertise:** dedicated staff, with training in risk assessment that apply expert judgement based on many years of experience. Canadian risk assessors have an international reputation for technical excellence, they actively engage in international discussions and have participated in many joint programs training risk assessors from other countries.
- **Consultative:** consultations with developers are encouraged throughout the product development and regulatory process. This allows for early discussion on the regulatory pathway applicable for the product and possible data requirements that will allow for a fit-for-purpose risk assessment.

5.1.2 Argentina, a pragmatic approach pioneering approaches for gene edited products

In South America, Brazil and Argentina were the first countries to embrace agricultural biotechnology and are currently some of the top producers of biotechnology crops, with high levels of adoption (See Figure 2). Argentina in particular has taken a proactive approach in adapting their regulatory framework for biotechnology products and is actively advocating for other countries to follow. At first, decisions on GMO approvals in Argentina, particularly in GM maize, were made close to the EU. However, while Argentina identified agricultural biotechnology as a key focus for their development, the EU regulatory system was getting more stringent and cumbersome, leading to asynchronous approvals and trade issues. In recent years Argentina has reviewed their biosafety regulations for the release of GM crops in order to keep up with new scientific developments and regulatory experience and to foster innovation in the field (Whelan and Lema, 2015).

The process for approval of biotechnology products in Argentina is complex but straightforward and involves one Competent Authority (CA) which is the Ministry of Agriculture, Livestock and Fisheries. The Biotechnology Directorate is responsible for policymaking and the administrative proceedings necessary for the approval. The Directorate utilises the National Advisory Commission on Agricultural Biotechnology (CONABIA) as the senior technical advisory body on GMOs, its main role is biosafety assessment. CONABIA has been designated by FAO as a centre of reference for biosafety. A committee based in the National Service of Agrifood Health and Quality (SENASA) reviews food and feed safety and the Secretariat of Agricultural markets reviews the potential impacts on production and trade. These three technical assessments are used as input by the CA for reaching a decision. In addition, the National Seed Institute (INASE) enforces the observance of permit conditions.

The safety assessments are conducted by expert staff highly trained in risk assessment. Application forms provide general guidelines on the information required for submissions, but there are no guidance documents to specify data requirements. The Ministry encourages developers to request consultations, even during development, so that the best approach for each product may be established. This allows discussions regarding the nature of the product; which regulation may apply and what data may be required. It also streamlines the process of review by facilitating timely discussions on questions that may arise. Like many other countries, food and feed assessments in Argentina follow Codex guidelines (Codex Alimentarius, 2009), using scientific knowledge and expertise to further determine what specific data may apply depending on the product under assessment.

Regarding gene edited products, while many countries are still deciding on which regulatory path they should follow, Argentina has taken a leading role, proposing a classification of products derived from new breeding techniques in order to establish whether they need to be regulated as GMOs or conventional varieties (Whelan and Lema, 2015; Lema, 2019). Argentine regulations have established that null-segregants or other products that do not retain recombinant material are not regulated as GMOs and this criterion is reflected in Resolution no. 173/15 (Lema, 2019). However, the nature of these products is examined and if it is considered that they could pose potential risks to human or animal health or to the environment, they are referred by the regulatory commission to the appropriate regulator of varieties obtained by conventional breeding for assessment (Whelan and Lema, 2015).

It is interesting to note that recently, the Ministry of Agriculture in Paraguay, the sixth country with the highest area of biotechnology crops planted (See figure 1), adopted a resolution that authorizes their Biosafety Commission to take into consideration the safety assessments for authorizations carried out in other countries with regard to both human and animal food safety, but only in the cases where these evaluations have been based on Codex guidelines (Codex Alimentarius, 2009) and carried out in countries with trusted regulatory systems and transparent procedures. This would allow Paraguay to accept safety assessments conducted in Argentina and other countries that follow the Codex approach, simplifying the approval procedure and shortening the review timelines.

Key aspects to highlight from the Argentina regulatory framework are:

- **Pioneering:** strong focus on fostering innovation through agricultural biotechnology while protecting human and animal health and the environment. Argentina, in understanding the key role that gene editing has to play in agriculture, has taken a lead role in developing a framework for assessing which products should be regulated as GMOs.
- **Flexibility:** the framework offers guidance on the endpoints of the risk assessments and the types of data that may be required, but these are not prescriptive and offer flexibility depending on the product. This means that data requirements can be tailored to each product.
- **Proportionality:** data required to assess the safety of the products are based on the novelty and potential risks of the product. Products that are perceived to represent new risks or higher risk are likely to require more data and undergo additional assessment compared to those of negligible risk.
- **Technical expertise:** dedicated staff, with training in risk assessment that apply expert judgement. Argentinian risk assessors have an excellent reputation for technical excellence, actively engage in international discussions and have participated in many joint programs training risk assessors from other countries.
- **Consultative:** consultations with developers are encouraged throughout the product development and regulatory process. This allows for early discussion on the regulatory pathway applicable for the product and possible data requirements that will allow for a fit-for-purpose risk assessment. Public consultations allow public comments before products are approved.

5.1.3 Australia and New Zealand, an example of cooperation and joint approaches

In Australia, food safety is governed by the joint food regulation system which covers policy and laws in both Australia and New Zealand. An independent statutory authority was set up in cooperation with New Zealand known as the Food Standards Australia New Zealand (FSANZ), to develop government regulations that are commonly referred to as the Australia New Zealand Food Standards Code (the Code) and to perform the relevant risk assessments under the Code (FSANZ, 2019b). The main objectives of these joint standards were to reduce unnecessary barriers to trade; to adopt a joint system of food standards that would provide for timely development, adoption and review of food standards and to facilitate sharing of information.

Until 1999, food developed using techniques of genetic modification were assessed under the existing Food Standards in Australia. However, when products derived from GM crops cultivated in North America started to be exported, a review was initiated which focussed on the need to implement a new code for genetically modified organisms. The review concluded that a new Food Standard was required to provide a transparent regulatory pathway to market which would enhance consumer confidence in the food supply (FSANZ, 2018a). The Code uses a process-based definition to determine which products should be captured and, as with non-GMO food safety standards, approval is dependent on a successful pre-market assessment by FSANZ and sign off by the forum of ministers (Kelly, 2019). Products derived from "conventional breeding" such as those produced using mutagenesis and conventional breeding crosses of single event GMOs ("stacked" products) are not subject to the additional requirements necessary for GM crops. The data requirements for the safety assessments are specified in the Food application handbook (FSANZ, 2019a) and these are based on the Codex Alimentarius (Codex Alimentarius, 2009), although not all Codex data are requested for all products and there is flexibility depending on the product under assessment.

The joint food safety assessments are conducted by FSANZ staff, which are highly trained risk assessors that keep up to date with new scientific developments in food technology around the world and proactively gather information on potential products that may be submitted for review through consultations with developers. This provides them with extensive experience that feeds into the assessment and results in a pragmatic approach rather than a box ticking exercise.

FSANZ has recently performed a review of the regulatory status of food derived using genome editing under the Code. The review started in 2017 to determine whether the definitions in the code remain adequate for the range of gene-edited products being developed and whether there is any justification, based on likelihood of risk, of subjecting such products to a pre-market safety assessment (FSANZ, 2018b, c; Kelly, 2019). The final report, including recommendations, was published in December 2019 (FSANZ, 2019c) and concluded that the definitions in the Code were no longer fit for purpose and will need to be amended. This will commence in 2020.

Key aspects to highlight from the Australia and New Zealand regulatory framework for assessing the food safety of agricultural products are:

- **Joint approach:** Australia and New Zealand adopted a joint system to reduce unnecessary barriers to trade; to provide timely development, adoption and review of import applications for biotechnology products and to facilitate sharing of information.
- **Flexibility and proportionality:** the framework offers guidance on the data required to assess the safety of the products which are based on the potential risks of the product. Products that are perceived to represent new risks or higher risk are likely to require more data and undergo additional assessment compared to those of negligible risk.
- **Technical expertise:** dedicated staff, with training in risk assessment that apply expert judgement based on their experience in the field. Australian risk assessors have a long-standing reputation for technical excellence, they actively engage in international discussions and have participated in many joint programs training risk assessors from other countries.
- **Consultative:** consultations with developers are encouraged throughout the product development and regulatory process. This allows for early discussion on the regulatory pathway applicable for the product and possible data requirements that will allow for a fit-for-purpose risk assessment. The review process also involves at least one round of public consultation.
- **Transparent:** applications received by FSANZ are published in their entirety on their website. The process timelines are well established.

5.2 The EU regulatory environment

Despite an acknowledgement of the benefits that agricultural biotechnology could bring to food security and sustainable agriculture, the EU continues to lag behind the rest of the world in the uptake of these technologies. While on paper, the EU regulatory system for agricultural biotechnology appears to be risk-based and science-based and in line with other regulatory frameworks around the world; in practice, heavy political influence has resulted in a cumbersome system that does not approve the cultivation of GM crops (the only product currently cultivated in the EU was approved in 1998) and has one of the slowest approval systems for import in the world.

As in other countries, applications for the approval of GMOs in the EU require a food and feed assessment and an environmental risk assessment. Guidance on how to conduct these assessments can be found in the Commission Implementing Regulation (EU) No. 503/2013 (EC, 2013) and Directive (EU) 2018/350 (EC, 2018a). Each application is assessed by the European Food Safety Authority (EFSA) GMO panel. The outcome of this risk assessment is then published and used by the European Commission (EC) to draft a decision that is to be provided to Member States within three months. Member states then vote on whether or not to approve the product in a voting system based on a qualified majority. More often than not, the result of the vote is inconclusive (i.e. no opinion). A majority of countries maintain their position to object to the approval of GMOs, or abstain from voting regardless of the nature of the product and regardless of the results of the risk assessments conducted by EFSA. This triggers a second vote, which results in the same result (no opinion). Ultimately, the EC is required to make a decision. However, this process has been known to take months and sometimes years, leading to undue delays, an issue that was brought to the attention of the European Ombudsman which, after investigation, concluded that these delays constituted maladministration on the part of the EC (European Ombudsman, 2016).

> "...heavy political influence has resulted in a cumbersome system that does not approve the cultivation of GM crops ."

The general trend is that for import permits of food and feed containing GMOs, the EC follows the outcomes of the risk assessment conducted by EFSA and eventually issues an approval, but for commercial cultivation the EC either do not put the approval up for vote, fearing that no majority will be obtained, or do not take a decision. The result is that few GM crops are approved for import and food and feed uses per year, but over the last 14 years only one GM crop has been approved for cultivation. This has been described as a paradoxical approach, as the policy is actively working against the EU's own goals, driving research, development and innovation abroad, and granting commercial and economic benefits to other countries that then sell the products back to EU Member States (Masip et al., 2013).

A key aspect underlining this situation is the divergence in political agendas of the 28 Member States regarding agricultural biotechnology. Political stances not only influence the outcome of the voting at the EC level, but also have a heavy influence at the scientific level. Indeed, countries that oppose the implementation of agricultural biotechnology products have been using "scientific" arguments based on the precautionary principle and risk uncertainty to drive ever increasing data requirements into the risk assessments. The perception appears to be that more data results in more robust risk assessments, whereas, as discussed earlier, this is not necessarily the case (Raybould, 2010; Devos et al., 2013). An example is the mandatory request to perform 90-day animal feeding studies as part of the risk assessment for all GM food and feed. This data requirement was included in the Implementing Regulation (EC, 2013) following pressure from some Member States and against the advice of the EFSA that only recommends conducting these studies on a case-by-case basis, when there is an indication that the product may cause harm to humans or animals. The same regulation mandated a review of the requirement and a publication of the review results, several studies, conducted by independent scientists, were funded and all concluded that there was no scientific basis to make 90-day animal feeding studies mandatory. Many have also pointed out that this mandatory request goes against Directive 2010/63/EU (EC, 2010a), which foresees that animal testing should only be conducted when absolutely necessary and when no other experimental alternatives exist. Yet, the EC continues to request these studies on a mandatory basis (EuropaBio, 2018).

EFSA, under criticism from pressure groups of bias towards industry, have put measures in place to demonstrate thoroughness, independence and transparency. This has resulted in a number of issues such as the proliferation of EFSA guidance documents. Between 2006 and 2019 EFSA has developed 34 guidance documents regarding the risk assessment of GM crops. These documents specify in more and more detail not only what data developers must compile for their applications, but how these data need to be generated and analysed. This is an obvious deviation from the regulatory frameworks set by countries that support agricultural biotechnology, which use the expertise and experience of their risk assessors to judge what data may be relevant for the safety assessments and the quality of the data submitted. Further, with a view to protecting independence, EFSA do not allow consultations on specific data requirements with individual developers at any stage. This leads to uncertainty and limitations for example when products with novel characteristics that may require different approaches to assess the risk cannot be discussed before the generation of the regulatory data package. It also leads to lengthy reviews (currently estimated to take four to five years instead of the 6 months set in the regulatory framework). Questions that could easily be clarified through verbal discussions require instead formal written exchanges, which are often contrived as EFSA has taken the stance that a question will only be asked once.

Another problem in the EU is that the 28 Member States have different policy protection goals and different views on the acceptance of agricultural biotechnology. As discussed previously, clarity on the protection goals is key for the performance of fit-for-purpose risk assessments. EFSA have highlighted on many occasions the lack of clarity relating to EU wide policy protection goals. Despite efforts to foster discussions among the scientific and regulatory community (EFSA, 2013, 2016) these remain unclear. More worryingly, the different regulatory frameworks that oversee the risk assessment of different agricultural products in the EU (GMOs, pesticides, biological control agents and chemicals) appear to have different protection goals (EFSA, 2013). For example applications for the approval of herbicides must demonstrate the efficacy of the herbicide to control weeds, whereas applications for the approval of herbicide tolerant GM crops using the same herbicide, must demonstrate that certain weeds remain so biodiversity is protected. This shows that different EFSA scientific panels operate under different priorities regarding environmental protection goals.

Although EFSA oversees the risk assessment of agricultural biotechnology products, EFSA staff, despite their training in risk assessment, fulfil mainly an administrative role. The risk assessments are predominantly conducted by scientific panels composed by scientists eminent in their fields, but not necessarily trained in risk assessment. The panels are renewed every four years, resulting in a constant turn-over of experts. This can result in data requests relating to scientific curiosity rather than risk assessment and is reflected in many of the published guidance documents and explanatory notes, which detail data and methods that go well beyond what is typically needed for risk assessments in the rest of the world and which are of limited value for a risk assessment. For example, despite the Global reliance on Codex guidelines (Codex Alimentarius, 2009), dossiers submitted for import approval in the EU generally require much more data that those assessed in other countries.

This is even more apparent for GM crop cultivation applications, where the data requirements are even greater and the expectation is that field data has to be generated in the EU, a complex and costly exercise (Lheureux and Menrad, 2004). The constant request for more data has resulted in the withdrawal of the cultivation applications submitted by large companies. There is therefore little chance that small companies or research consortiums could obtain regulatory approvals under the current regulatory system. Whereas the real benefit of agricultural biotechnology seen in other countries is the solution of local problems, often with products developed by public institutions. Research consortiums operating under the KBBE program and public institutions are very unlikely to embark on this difficult path to see the products of their research approved.

Recently, the GM regulations have come under much scrutiny, due to the discussion around “novel breeding techniques” or gene editing. Gene editing involves making targeted changes to the plants DNA to introduce a beneficial characteristic. The changes that can be made range from minor deletions/insertions through to the introduction of whole genes from the same or “foreign” species. In effect, gene editing can produce changes that are, either similar to those induced by traditional mutagenesis and indistinguishable from conventional products and on the other hand, similar/ the same as “genetic modification”. Despite early activity, as in the case of GMO’s, the EU is lagging behind other countries in how to deal with gene editing. In 2007, the EC established a working group to assess the different categories of gene editing and a report was produced (EC, 2010b). The report was not endorsed, nor published by the EC and Member States were left to make decisions themselves. Innovation in this area was further stifled when the European Court of Justice concluded in 2018, that all forms of gene edited products would be considered to be GM (ECJ, 2018).

In summary, the EU is becoming increasingly uncompetitive and isolated in the international markets, which thrive on innovation and technological development in agriculture.

In summary:

- **Despite an acknowledgement of the benefits that agricultural biotechnology could bring to food security and sustainable agriculture, the EU continues to lag behind the rest of the world in the uptake of these technologies due to the regulatory policies it has in place.**
- **The divergence of the political agendas of the 28 Member States regarding agricultural biotechnology has led to politically motivated voting patterns that prevent and/or delay the approval of GM crops.**
- **Some EU countries, motivated by de facto opposition to agricultural biotechnology have imposed the inclusion of data requirements for GM crops that are not scientifically sound and which diverge from those in the rest of the world.**
- **The lack of clarity on EU wide policy protection goals has led to divergence of risk assessment criteria in the different regulatory frameworks that oversee the risk assessment of different agricultural products in the EU (GMOs, pesticides, biological control agents and chemicals).**
- **Risk assessments in the EU are conducted by scientists that offer expertise in their fields, but are not necessarily trained as professional risk assessors. This often leads to arbitrary collection of data, interesting from a scientific point of view, but of little value for risk assessment. This prevents efficient decision-making.**
- **EU risk assessments offer little option for case-by-case assessments. Highly complex requirements have resulted in an ever growing list of guidance documents which outline in-depth data requirements, along with how data must be collected and analysed, regardless of the type of GM product and the risk associated with the product.**
- **The EU fosters research in agricultural biotechnology but has a regulatory framework that prevents the products of this research from reaching the EU market. At the same time innovation is accepted by other countries and products derived from such innovation are imported into the EU.**

5.3 Regulatory oversight of agricultural biotechnology in the UK

In the UK, the main regulatory oversight of the cultivation and consumption of food and feed crops is provided by the Environmental Protection Act 1990, the General Food Regulations 2004 and the Food Safety Act 1990. These instruments provide for enforcement of the EU Regulation concerning food and the Environment. Such regulation takes measures to ensure that products placed on the market do not result in harm to human or animal health or the environment and applies to all products, irrespective of whether or not they were produced using "modern" technology.

Regulatory consideration of genetically modified products has a long history in the UK. Half a century ago, in 1970, UK scientists were working in this area and the Government, at that time, recognised the potential benefits as being: "substantial (though unpredictable) benefits" and "...application of the techniques might enable agricultural scientists to extend the climatic range of crops and to equip plants to secure their nitrogen supply from the air". They concluded that "it is not inconceivable that the technique might ultimately lead to ways to cure some human diseases known to be due to genetic deficiency" (Parliament UK, 1999). While recognising the benefits, because the technology was relatively new at that time, the UK set up an advisory committee known as the Genetic Manipulation Advisory Group (GMAG) in 1976 and subsequently introduced Regulation which required that any activity involving genetic modification should be notified to GMAG and the Health and Safety Executive (HSE).

The first piece of primary legislation in the United Kingdom dealing specifically with viable genetically modified organisms (GMOs) and the environment was Part VI of the Environmental Protection Act 1990. As noted above, the Environmental Protection Act is not specific to GMOs but was modified to establish a structured regime of risk assessment and notification with the aim of preventing or minimising possible adverse effects that might be associated with the release of GMOs. During this time the EC was developing EC proposals on the control of GMOs. These resulted, in the two Directives on contained use and deliberate release (Directive 90/219/EEC and Directive 90/220/EEC respectively). In the case of environmental release, the Directive 90/220/EEC was translated into UK National law, to assist in the review, the UK government appointed a statutory body known as the Advisory Committee on Releases to the Environment (ACRE) to advise ministers of the safety of proposed releases into the environment. In the case of field trials of GMOs, the UK have relative autonomy to approve activities, however in the case of commercial release, under the Directive, the approval must first be given at the EU level before the UK can grant approval locally.

In 1990, despite the introduction of the Deliberate Release Directive, there was no additional oversight of genetically modified food or feed products and the UK, along with the Netherlands, adopted a voluntary notification system for food products derived from genetic modification. A non-statutory independent committee, known as the Advisory Committee on Novel Foods and Processes (ACNFP) was created, in 1988, to review areas that might impact food safety such as irradiation, production of Novel Foods as well as products derived from the process of genetic modification (Burke, 2012). After a thorough review of each product, the opinion from the ACNFP would be sent to Ministers who then made the decision on whether or not to approve that product. The ACNFP reviewed and confirmed the safety of the first GM product to be introduced into the UK which was a genetically modified tomato paste (ACNFP, 1994). The ACNFP opinion was approved by ministers and the product was introduced in 1996. Although no labelling was required (because no viable DNA was present in the final product, (ACNFP, 1995), the product was clearly labelled to allow for consumer choice. The product was on the market for approximately 1 year and over time outsold its non-GM counterpart. At that time, the assessment process could be considered to be consultative, enabling and predictable and allowed the UK to be a leader in what was the first introduction of an innovative GM product in the EU. It is worthy to note that strict legislation was not necessary to introduce the product safely or to allow for consumer choice.

The voluntary process in the UK was replaced by the introduction of the EC Novel Food Regulation in 1997 (Regulation (EC) No 258/97 which was repealed in 2015 by Regulation (EC) No 2015/2283) and the general food law (EU Regulation (EC) No 178/2002) which established the European Food Safety Authority (EFSA) as the central risk assessor for food and feed as well as the Environment. Specific legislation concerning genetically modified food and feed was introduced in 2003 (Regulation (EC) 1829/2003). In the case of the commercialisation of genetically modified organisms, this legislation placed emphasis on a centralised risk assessment by EFSA so that the role of the ACNFP and ACRE moved from that of the primary risk assessor to assessing the EFSA opinion and making recommendations based on that. After this, effectively, the UK was therefore dependent on the EU to operate in a functional manner to allow for the introduction of GM products. In 2014, Pollock and Hails (2014) highlighted the need to reform the EU regulatory system, calling for the adoption of a proportionate approach that makes optimal use of existing evidence in the risk assessments for GM crops.

With regards to the regulatory considerations of "novel breeding techniques" or gene editing, as discussed earlier, no consensus was achieved in the EU and Member States were left to make their own decisions. In the UK, ACRE performed a thorough review of existing information (ACRE, 2011b) to conclude which techniques would be covered by the Directive 2001/18/EC definition and which would not. In addition, in 2011, ACRE, when assessing a field trial application of oilseed rape that had been produced using site directed mutagenesis, concluded as follows (ACRE, 2011a):

Advice: ACRE considers that herbicide tolerant (HT) oilseed rape plants produced by Cibus LLC have been developed using a form of mutagenesis. It considers that this technique does not involve the use of recombinant nucleic acid molecules. Consequently, the HT oilseed rape plants could be excluded from the GMO Deliberate Release legislation in accordance with Annex 1B of Directive 2001/18/EC

Sadly, innovation in this area was stifled when the European Court of Justice concluded in 2018, that all forms of gene edited products would be considered to be GM (ECJ, 2018). The EC will have to decide what to do and, in the meantime, despite ACRE's advice, all field trials of gene edited products will have to be regulated under the Deliberate Release Regulations.

In summary:

- **In the UK, each product, introduced onto the market, irrespective of whether or not it was derived from genetic modification, must comply with the existing food and environmental regulations**
- **Regulatory considerations and appropriate safety assessment of genetically modified products have a long history in the UK.**
- **Before the EU level regulatory framework and the EFSA were established, the UK was the first to approve a GM food in Europe.**
- **The UK system for regulatory oversight of agricultural biotechnology is currently linked to EU regulations.**
- **The UK makes safety decisions based on the scientific assessment of each product.**
- **The UK have previously reviewed products derived from gene editing and issued pragmatic opinions.**

6. DISCUSSION

The UK has a history of fostering innovation and a solid reputation for science-based risk assessments. UK scientists have been pioneering innovation for centuries to enhance the quality of life. Nearly half a century ago, the UK considered the benefits of crop genetic modification and how to enable its introduction. This resulted in the UK being the first country in the EU to introduce a genetically modified food in 1996. Since that time, however, innovation resulting in commercial introduction of genetically modified products has been prevented in the UK because of the onerous application of legislation in the EU. This is having knock-on effects in the uptake of newer technologies such as gene editing (Brookes and Barfoot, 2018).

However, the text of the EU regulation does not specify lengthy review periods or risk management decisions. It suggests that approvals can be possible in 1-2 years if risk assessors and risk managers are committed to do so. This would be in line with the majority of countries in the world. And yet, products for import from other countries, are rarely approved in under five years, and information requirements continue to rise.

Experience from other countries shows that it is possible to create enabling regulatory oversight that allows for the safe introduction of genetically modified products. Adoption, outside of the EU, has grown at a faster rate than any other crop technology in recent times, with the US, Argentina, Brazil and Canada cultivating a cumulative total of 161.8 million hectares in 2018 (ISAAA, 2018).

Countries such as Argentina, Canada and Australia have adopted legislation and procedures which enable the timely approval of genetically modified crops. They all have Codex Alimentarius Commission Guidelines (Codex 2019) as the basis for the safety assessment, but each country has implemented them in a different way while still allowing products to be approved in a timely manner.

Common factors in these countries are:

- **Guidelines that are not too overly prescriptive.**
- **Risk assessments conducted by dedicated, highly trained risk assessors enabled to apply expert judgement and a proportional approach to the risk assessments.**
- **Provision for extensive consultation with applicants both before application and throughout the assessment period providing advice on what data they may need for the assessment.**
- **Flexibility in the data requirements depending on the nature of the product.**

The latter point is highlighted by the fact that in Argentina, no formal guidelines exist for the safety assessment – rather the data package is tailored to the risk associated with the product and designed through consultation with the applicant. It is hardly surprising therefore, that in 2018, the average biotech crop adoption rate in countries such as Argentina and Canada was close to saturation at approximately 100% and 92.5% respectively.

As would be anticipated, such countries have also been considering evolving technologies such as gene editing. Argentina, using the definitions of the Cartagena Protocol, adopted an enabling regulatory approach as far back as 2015 and has assessed a diverse range of products, including gene edited plants. In the majority of cases, products have been determined not be a GMO and are therefore treated as conventional varieties. In addition, most products have been developed by small and medium enterprises (SMEs) with only a minority coming from multinational companies (Lema, 2019). In Australia, both the Office of the Gene Technology Regulator (OGTR) and the Food Standards Australia New Zealand (FSANZ) have been assessing the regulatory framework, with the OGTR recently publishing an amendment to take into consideration gene editing (OGTR, 2019). Under the new amendment, gene editing resulting in a targeted change (without a template) will not be regulated. Canada can continue to assess products of gene editing under existing legislation.

This is not the case in the EU. Despite convening a working group of member state experts in 2007, the EC has yet to endorse or publish the resulting report (EC, 2010b) and progress towards enabling commercial introduction of this technology in the near future have effectively stalled with the European Court of Justice ruling (ECJ, 2018) and the latest proposal that the EC should commission a report with completion date of April 2021 (EC, 2019). This is occurring at a time when resources are more limited than ever and climate change is causing devastating effects.

The discussion around gene editing has led many scientists in the EU to call for a change to the legislation from the current “process” based approach which regulates products derived from the process of genetic modification to a “product” based approach which assesses the novelty and safety of the product, regardless of how they were produced (EASAC, 2013). This would effectively bring all products including those produced by conventional breeding, under an additional new regulatory regime. While this move would treat traditionally mutagenized products and gene edited products the same, it should be considered if the additional regulatory burden to innovators would really add value and could be operational under the current EU regime? Raybould and Poppy (2012) clearly showed that despite numerous revisions to the text of the legislation, this did not result in timely approval or a proportionate data requirement. Similarly, a recent COGEM report concluded: “If the EU switched to a product-based regulatory system for GMOs, but the current decision-making procedures were retained, it is likely that the current problems of protracted decision-making and disagreement would remain for regulated crops” (COGEM, 2019).

We recommend that in order to establish a functional regulatory framework that fosters innovation, the UK applies their experience and while working within EU guidelines they adopt an approach to risk assessment that ensures the proportionality of the data requirements. Risk assessments can then be conducted according to Regulation (EU) No 503/2013 applying, where necessary, the derogation clause (Article 5), which allows applicants to provide scientific justification for the deviation from data requirements outlined in the regulation. This, coupled with pre and post submission consultation with the applicant, would result in a predictable, transparent, proportionate regime and allow the UK to continue to be a world leader in innovation.

7. RECOMMENDATIONS

The world is facing unprecedented challenges from issues such as food security and climate change. With a long history of innovation and a solid reputation for science-based risk assessments, the UK has the opportunity to address these challenges and progress towards achieving the SDGs agreed by UN countries. In order to do so, clear policy objectives, coupled with pragmatic regulatory approaches will be necessary.

We recommend that the following considerations are taken into account:

- **Set clear policy goals with regards to food security and sustainable agriculture, so any technology set to contribute to the achievement of these goals can be assessed in a pragmatic manner.**
- **Provide clear operational protection goals that need to be considered in the risk assessment, based on policy protection goals that apply to all agricultural products in the UK.**
- **Follow a science and risk-based approach performing fit-for-purpose risk assessments, proportional to the risks of the products.**
- **Foster the technical excellence of those performing the risk assessments, with dedicated staff engaged in the international risk assessment community.**
- **Enable consultative procedures that allow for discussions with the technology providers prior to and during the safety assessment of any given product. This will ensure data requirements that are tailored to the product and the risk it poses, avoid lengthy review timelines and enable early anticipation of scientific developments.**
- **Flexibility and proportionality to allow for case-by-case assessment and data requirements proportionate to the risk. The risk assessors should be able to apply expert judgment to determine data requirements for each product considering familiarity or novelty of the product and the potential risks associated with it. Flexibility should therefore be applied depending on the likely risk. This is foreseeable under the Regulation (EU) No 503/2013.**
- **Cooperation with other countries is encouraged, to ease the burden of duplication of efforts in assessing the same products for food and feed safety.**

In the case of genetically modified organisms, we recommend that the approval process is applied according to the timelines specified in the legislation. Data requirements should be streamlined based on scientific justification, along with application of the Regulation (EU) No 503/2013 derogation clause (Article 5) and the process should be based on consultation with the innovators.

In the case of gene edited products we recommend that the definition of the Cartagena Protocol can be adopted, along with a consultative process to determine which products would be classified as GMOs. This would bring the UK in line with the majority of other countries that have considered regulatory oversight to date.

"These recommendations would result in a predictable, transparent, proportionate regulatory regime and would allow the UK to continue to be a world leader in innovation."

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