REGULATORY HORIZONS COUNCIL

Optimising the governance of genetic technologies

Issues paper

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Contents

Background

The Regulatory Horizons Council (RHC) is an independent expert committee, supported by a team of civil servants, established by the Department for Business, Energy and Industrial Strategy. A commitment from the White Paper on Regulation for the Fourth Industrial Revolution, it provides the Government with impartial, expert advice on regulatory reform to support the rapid and safe introduction of technological innovations with high potential benefit for the UK economy and society.

The RHC was commissioned by a cross-Government working group to examine how genetic technologies would benefit from regulatory reform and this was a priority topic for review within the first tranche of the Council's work (September 2020 - May 2021). The RHC has been 'deep diving' into this topic, engaging with relevant stakeholders and looking into the options available within our regulatory reform remit with an end output of recommendations to Government.

Over the last 6 months we have organised a series of 4 workshops with interested stakeholder groups (industry, academia, policy makers and advocacy groups), speaking to c.100 different experts / organisations, to understand better the needs and wants of each and to benefit from as broad a range as possible of innovative ideas on the regulation and governance of genetic technologies. This issues paper summarises the output from these workshops and other engagement we have undertaken, unpacking key themes and divergent views on how the governance of genetic technologies can be reformed in the UK. This issues paper will feed into our recommendations to Government and our full report which will be published later this year.

The paper was authored by a civil servant in the RHC secretariat[1] who collated views from transcripts taken from each of the workshops. The Council then approved the paper for circulation to invitees to the workshops for feedback. A full list of those who attended the workshops can be seen in our stakeholder list in the Annex B to the main report. A roughly equal number of representatives were invited from each type of stakeholder group listed above to mitigate against the risk of bias (although a lower number accepted invitations to the advocacy group workshop).

[1] Jamie Leurs – Senior Policy Advisor, Better Regulation Executive, Department for Business, Energy and Industrial Strategy (Contact details: Jamie.leurs@beis.gov.uk).

The regulatory trigger

One of the key issues discussed in the workshops was what the regulatory trigger should be for new entities produced via the platform technologies of genetic modification, genome editing, and synthetic biology (including plants, animals and micro-organisms). These discussions focused on whether and how the UK could move from the EU regulatory system based on the platform technologies themselves as the regulatory trigger to a new system based on the potential benefits and hazards of the final products.

Product- or trait-based approach

There was general recognition that a regulatory trigger based on the characteristics of the final product, rather than the way in which it was produced, would be a more scientific approach to any assessment of safety and in theory would be more proportionate in applying lighter regulatory requirements based on relative risk. For example, a single, simple alteration to DNA might result in toxicity or allergenicity, whereas the introduction of a foreign transgene may present no such risk: there is no distinction to be had between different genetic methodologies that maps neatly onto a spectrum of risk.

"I would encourage focusing on the outcome rather than the technology. It is important to think about each product in a risk appropriate way, where the genetic alteration is simple and the risk is small then it should be dealt with differently from a more complicated alteration."
SME developer of GM food

However, there was scepticism about how such an approach could be operationalised in practice. A frequently mentioned point was that only one country in the world, Canada, has operationalised a fully product-based form of regulatory trigger and in their context, it has had the unintended effect of including all types of traditionally bred plant varieties into a risk assessment base which their industry perceives as disproportionate and decreasing their international competitiveness. This was a significant concern expressed by the large plant breeders in the UK, who saw expanding regulatory oversight to products of traditional breeding as a risky step for their industry in terms of increased political involvement. In addition, some stakeholders with experience of the Canadian system stated that, despite the product-novelty trigger, their system still lacked comparative clarity and certainty concerning how their genome-edited products would be dealt with versus GMOs and the regulatory assessment was still more burdensome than other process-based systems, such as the US or Japanese market. A related criticism of the 'novelty' criterion used was that it unintentionally encouraged plant breeders to reduce the amount of novelty they introduce into the germplasm of their products to avoid the regulatory trigger meaning

potentially useful genetic changes like introducing new disease resistance traits are structurally disincentivised.

“My concern with a product-based approach is as a concept it's very sound but the practical applications in Canada as we’ve experienced it don't follow that nice concept that it could be. I’m afraid that use of this approach in the UK will create more issues for the commercialisation of products of genetic technologies than it resolves.”
Multinational biotechnology company

One counter argument to the Canadian example mentioned above was that these unintended effects on traditional plant varieties had occurred largely because of the use of a regulatory trigger of ‘novelty to Canada’. Novelty was considered disproportionate as a trigger for novel traditionally bred varieties because genetic alterations arising from these processes have such a long track record of safety and were not previously subject to this additional layer of regulatory oversight. If the UK was to adopt a product-based route it was suggested that either a more proportionate trigger could be used or that a system of exemptions could be used to make sure traditionally bred plant varieties were not caught by a new regulatory regime, given that existing seed variety regulations have an exemplary safety track record. Such exemptions could rely on and reflect the established competencies of breeders to characterise new products of any breeding method in order to ensure safety. Example exemptions could include any organisms that do not contain genetic alterations that: produce a protein of known allergenicity or toxicity, or increase levels of such a protein; impact key nutritional components or metabolism.

SME developers, particularly those that used / or intended to use a wider range of genetic engineering techniques than simple genome editing alone, were particularly supportive of new regulatory approaches, which they thought need to be explored to make sure the potential innovations arising from new technologies aren’t lost due to a focus on process for the regulatory trigger.

“I recognise the challenges that being seen by the public to permit transgenic techniques poses but that's a reason from a regulatory standpoint to think about a system that excludes a particular technology. If you start to set certain technologies or their applications aside and regulate those differently, you endanger the future innovations that could emerge and you make it more complicated for those who are looking at approaches that are outside the current mainstream thought process.”
SME developer of GM food

On the other hand, the underlying premise that SME innovation should be supported via regulatory change was challenged by a few advocacy groups who thought that small businesses should instead be supported by other business approaches ie financial grants.

There were a number of suggestions for how those novel (non-exempt) products should be assessed based on the particular product trait and with sensitivity to the manner in

which they were produced. For example, a product of genome editing might require screening for potential off-target edits and their elimination by selective breeding. The assessment would also reflect existing scientific data concerning the properties of a range of products with a history of safe use – such as those generated by traditional breeding methods - and those that are unsafe. Novel products would be subjected to a number of relevant tests to assess levels of key nutrients, metabolites, allergens, toxins etc to determine whether they fall into ranges associated with products generally recognised as safe.

"There should be an explicit method via regulation that allows a developer to show that the genetic techniques they've used in producing their product makes no difference to the end-product compared to conventional breeding techniques. This could be simple things like requiring proof that no unintended alterations in the genetics have been caused, or to the actual phenotype of the plant. I think that would go a long way to ensuring that they are more acceptable."
SME biotechnology company

Barriers to the UK trading internationally with a product-based system

However, multiple stakeholders from the Industry workshop pointed out that one of the major barriers to the UK moving to a product-based system would be the international picture with the Cartagena Protocol on Biosafety[2], namely its global definitions in trade in agricultural commodities being fundamentally process-based systems that are widely accepted and engrained.

"If the UK had a product-based system, then everywhere else the UK traded with you'd have to identify the product again based on process in order to gain access to other markets."
Multinational plant breeder

This barrier would be a particular problem for transgenic products where signatories of the Protocol (that currently includes the UK) have an explicit process-based regulatory trigger for international trade, which participants didn't think would change in the near future or could be influenced by a lone country such as the UK. It was pointed out that the US are not signatories of the Protocol and Canada hasn't ratified it's signature so both have had more flexibility in this aspect, but that it still puts a significant limit on their international trade opportunities and would for the UK too if it was to go down such a route.

[2] The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement on biosafety as a supplement to the Convention on Biological Diversity (CBD) effective since 2003. The Biosafety Protocol seeks to protect biological diversity from the potential risks posed by genetically modified organisms resulting from modern biotechnology.

"In the case of transgenics, it's extremely difficult to abandon the focus on GMO and just look at the product without global change as there's an existing system that you have to fit with in order to be able to trade."
Multinational plant breeder

The UK adopting a purely product-based system with no explicit consideration of GMO techniques as a trigger was seen by some as incompatible with its signatory status of the Cartagena Protocol. It was alleged this would be due to the definition of a GMO / LMO in Article 3. (g) and 3. (i) a. of the Protocol.

Concern over a bespoke UK regulatory system

More broadly, some stakeholders voiced a concern that wholesale divergence from the EU regulatory system and a shift to a bespoke UK approach could lead to increased costs and administrative burden for plant breeders that could hinder innovation.

"We hope the UK looks to work collaboratively with other countries around the world like Australia to align and reduce resource implications of a new regulatory approach, rather than deciding to attempt a new bespoke UK approach as that could be very challenging for applicants' resources potentially."
Representative from the plant breeding industry

Outcome-based system

Amongst those who were sceptical of a product-based system of regulatory trigger, there was support for a shift to a more outcome-based approach to regulatory approval, where benefits of new products could also be considered alongside risk assessment, in order to enable more balanced decision making. There was a suggestion that existing seed marketing regulations are a good example of an outcome-based approach, which ensures that new varieties coming forward are an improvement on previous varieties. It was pointed out that the biggest barrier to such a system is the lack of clear objectives and consistent metrics to demonstrate these benefits. Within existing regulatory frameworks, the point was made that it would be much harder to accept any risk in food safety terms regardless of benefit, but that there was more scope to balance benefit in consideration of environmental risks.

"If you can introduce a consistent set of metrics, for example, so that you can actually understand the objectives you're aiming for i.e. climate change, land use, soil quality, soil health, that is crucial for being able to set targets you can deliver against. I've been very impressed with an initiative in the US called field to market where they've developed a set of field-based metrics and they've been applying those consistently for about two decades now. It's a mutual way of demonstrating the benefit of access to innovation and access to

new technologies."
Representative from the agricultural industry

The exclusive focus on safety and risk as the fundamental purpose of regulation was questioned by several participants in our workshop with academics and innovators, who argued that regulation should instead actively guide how new technologies fold into our society and consider primarily if and how they address key societal challenges like environmental sustainability. This was contrasted with the current market-focused approach where, as long as a product doesn't harm human health or the environment, the market is allowed to be the arbiter of acceptability, with only a limited role for the fundamental ethics of responsible innovation.

There was also significant support for an outcome-focused system among those advocacy organisations we spoke to who were opposed to the Government's current position of altering the definition of a GMO. To these groups, such a system would address what they perceived as the gap between potential uses of genetic technology highlighted in the media and the existing impact of GM crops in cultivation on reducing environmental harms and the uncertainties that exist about these technologies.

"Having outcomes-based regulation is absolutely vital. There's lots of claims that gene editing has massive potential for producing healthy food and reducing environmental impacts and helping us reach climate biodiversity goals, but as far as I know there's no evidence that that will be the case. There's no evidence that they will be unless we put a regulatory system in place to make sure that is how they are used."
Representative from environmental advocacy organisation

Adapting the existing EU framework

A common view across all the workshops was that the existing EU framework could be adapted in various ways to make it more proportionate to the risks of different products without the need to overhaul the current process-focused form of regulatory trigger. There were a number of different ideas suggested to this effect which we cover below.

"I think that the legislation as written in Europe could be made to function adequately, but it's deployed in a very non-functional way currently."
Representative from the plant breeding industry

Especially among the larger plant breeders with experience of going through the EU regulatory approval process, there was a nervousness about moving to an entirely new system and opening up the industry to greater political uncertainty.

"I think we should explore what post-Brexit adaptation of existing rules and regulations might look like before leaping into a whole new approach based just on products. This is an industry that has lived through political interference and a dysfunctional system for so long that it's difficult to conceive of the ideal model."
Representative from the plant breeding industry

A common criticism among stakeholders was the length of time for approval in the EU system. Examples were given of how timelines in the EU for risk assessment of GMOs have doubled over the last 10 years from 20-30 months to over 60 months. This leaves an EU import approval taking over 6 years for GM crops compared with less than one year in Australia and two years in Canada. One cause of this was attributed to the EU's inflexible approach to data requirements, whereby there is no differentiation between requirements based on the type of products being submitted or adaptation based on the historical experience of approving certain products / genetic changes and knowledge of their safety. Given the critical importance of timelines for developers, it was suggested that streamlining regulatory assessment processes would be an easier starting point to encourage innovation as there is scope to do this politically in the UK within the existing EU regulatory framework.

"Don't equate rigor with the amount of data and length of time it takes. The EU is bureaucratic, inefficient and long winded in regulatory assessment of GMOs. While it likes to portray itself as having the most data as evidence of its rigorous approach, this is actually determined by the relevance of specific types of data that best indicate safety and risks of a product."
Regulatory expert

Tiered assessment for different groups of products

Tiering of regulatory assessment procedures based on different types of products, with more proportionate requirements for certain types of products considered to have lower risks, was a popular option which some participants suggested had avenues for implementation in existing EU legislation.

"If you know if there are particular products that are considered to be useful to government policy objectives, there's no reason why you shouldn't be able to expedite the review of those products under existing regulatory regimes."
Regulatory consultant

It was pointed out that Article 7 of the 2001 GMO directive has a provision for differentiated procedures with criteria in an annex allowing groups of products, where there is experience of safe use, to be subjected to less rigorous regulatory procedures. It was claimed that such a tiering system, based on certain types of product that could be generally recognised as safe (GRAS), has been used to make regulatory systems in the US and Argentina more light touch and encourage greater innovation. It was suggested that, based on existing regulatory experience, a list of the kind of genetic alterations that have GRAS status should be drawn up and there were a few specific examples brought up for immediate inclusion e.g. gene receptors to expand a plant's detection capabilities, to trigger defence responses, or to elevate disease resistance. It was suggested that a list of classes would be more future-proof to the kinds of products and new techniques that may arise which wouldn't otherwise have a clear regulatory pathway today.

"The reason that differentiated assessment procedures have not been used in the EU so far is because of the political overlay and the disagreements between member states rather than the system itself."
Regulatory consultant

It was suggested that tiering of different types of products could helpfully be differentiated by sectoral applications, relying on the existing non-GM sectoral regimes and standards to assess risks and safety wherever possible.

"Having clear pathways of regulation across different application sectors would provide the most flexibility and adaptiveness for the developers of emerging genetic technologies."
Innovator / researcher

It was further suggested that standards could link up such a classificatory grading system for different types of products to work alongside the process for regulatory approvals. This could involve hard standards to change regulatory requirements or more loose guidance that could still be a meaningful addition to the system. Actors from within industry would need to lead this and then it would need to be open for public comment. FLEX is a quick

way to develop standards that the British Standards Institute (BSI) has experimented with in other areas.

In order for the UK's GMO risk assessment processes to become more efficient, some stakeholders highlighted appropriate funding for them as a prerequisite and also suggested an increase in research funding for regulatory system experimentation. The lack of technical expertise and resources available to make regulatory decisions was held at least partially responsible for the long timelines that currently beset GMO risk assessment processes.

Utilising a case by case approach to regulatory assessment

Further to the above, policy officials pointed to the flexibility for regulatory assessment after initial capture in the UK's Genetically Modified Organisms (Deliberate Release) Regulations 2002. The regulations allow for a 'case by case' approach to assessment requirements, meaning that there is no automatic requirement for information about a product unless it is needed to show there is a risk. This gives flexibility through reduced data requirements and a lighter touch approach – the minimum amount of information required to demonstrate safety. This is in contrast to the current 'event by event' approach, by which each individual plant line or animal line is regulated, rather than a trait block or crop trait combination. For example, two herbicide-tolerant plants that are essentially the same but come from different transformation events would be regulated together in the same fashion, rather than receiving independent assessments.

An important consideration raised in moving to a 'case by case' approach would be to learn from past cases and approvals, so you were not applying the same requirements to every subsequent product. The US was pointed to as a good example here, where regulatory study requirements get dropped based on the regulator's experience of assessing previous similar cases, in contrast to the EU where requirements are only ever added rather than dropped. One concern raised was that while moving to a 'case by case' approach to environmental risk assessments was feasible this would not be the case for food safety and nutritional issues.

Greater flexibility in risk management decisions

Separate from the risk assessment process, a number of industry stakeholders pointed to the subsequent political overlay involved in approval decisions and lack of certainty in respect of the EU's approach to risk management, which discouraged innovators from developing products for the EU market. They made the case that having products go through the assessment process over several years, and being judged to have no safety concerns, and then still not be being given approval due to political wrangling between member states, had seriously undermined confidence in the system for developers and harmed innovation in the EU.

"Predictability is key for developers; if you know the timelines and criteria for regulators, that's a huge factor in where you would choose to develop the product and indeed which product you would choose to develop in the first place."
Developer of GM food

One suggestion was that there was scope within the existing regulations for the UK to add greater flexibility to risk management than the EU approach by trialling limited or phased approvals, rather than simply blanket decisions, and that this would give greater confidence to developers. Another suggestion was a framework for post-regulatory approval monitoring, so that in future the GRAS category could be expanded to a wider range of products. Again, this could be facilitated by standards.

The precautionary principle

The EU's interpretation of the precautionary principle was criticised by a number of stakeholders for being imbalanced in its exclusion of any consideration of benefits and its lack of focus on risk management strategies to mitigate any potential hazards that do exist with a particular product. Examples were given of products that could have had overwhelming societal benefit, but were stalled due to the inability of the regulatory system to adapt to new types of genetic technologies rather than because of any safety concerns identified. One case study described a synthetic biology biosensor to detect arsenic in drinking water, which could have helped over 100 million people in South Asia who are exposed to arsenic poisoning, that was stalled for several years despite a demonstrated absence of safety issues. The parallel use of an 'innovation principle' to balance the precautionary principle, allowing evaluation of potential benefits to prevent overly cautious and disproportionate regulatory decision-making was suggested as one potential solution to this.

Other stakeholders stressed that it should be incumbent on any regulatory framework based on a precautionary principle to also incorporate a post-cautionary principle. For example, putting time limits on precautionary regulatory measures would enable regulatory relaxation if future data show the level of precaution to have been unnecessary.

Gene restriction technologies

There was little support in the workshops for the use of gene restriction technologies to mitigate any risks of gene transfer from a proposed product being cultivated as part of the approval process. Some objections were fundamental to the precedent of containment becoming a regulatory obligation, with 'cross pollination' being key to crop growers. This was also seen as disproportionate given the long history of safe cultivation of GM crops. Others struggled to see a practical application of where they would want a product released for commercial use with any such risky traits not already removed as part of the regulatory assessment process. It was also pointed out that many of the underlying

technologies for gene restriction were banned under the Convention on Biological Diversity.

“GM crops and products are thoroughly risk assessed by innovators and regulators prior to commercial release so it should not be necessary to use technology to remove traits that could cause damage via cross fertilisation.”
Policy-maker

The use of blockchain technology in future to enable full and automated traceability and transparency of new products was considered a more important development in reducing the need for future regulatory oversight of deliberate release whilst ensuring public confidence.

Views on the Government's regulation of genetic technologies consultation

Some of the workshops were held after the Government's recent consultation on altering the definition of a GMO to exclude genome-edited products that could have been produced by conventional breeding methods was launched. These indicated a wide range of views on the consultation. Among major plant breeders, there was significant support for a regulatory adaptation on this basis; they claimed that singling out certain forms of genome editing for specific early attention, such as the above, is a pragmatic option, driven by the complex array of international regimes and political realities, that would create short-term opportunities to deliver safe products with societal, environmental and commercial benefits. They believed a majority of their potential future crops (which at the moment would be unviable) could be subject to a more proportionate regulatory hurdle under such a move.

In their view, the existing system for governing the recognition of new plant varieties would be sufficient for many aspects of future crop plant products of genetic technologies due to its strict criteria for marketing authorization (including both novelty and minimum thresholds for value and use) and its exemplary track record of safe innovation, by focusing on the characteristics of the crop when making safety decisions. The Plant Variety Rights and Seeds Office (PVS) performs tests and trials over two growing seasons to measure all the characteristics and then applies a statistical weighting calculation that gives a guide for a legally defensible decision. Similarly, the Seeds Marketing Regulations provisions for registration of operators and rigorous transparency and traceability requirements would further ensure that any products of genetic technologies could be appropriately labelled to maintain consumer choice. Where a new food may be developed, they pointed out that the regulatory regime covering novel food would apply and involves appropriate safety assessment.

"Mutation through genome editing is the same as that which occurs naturally, therefore the method of mutation has no rational basis for separate regulation relative to other seeds. We should not have the view that, outside GMO regulation, seeds varieties aren't regulated as that is not true. The Seeds Marketing Regulations have been around for several decades and have never had a new variety presenting safety concerns, showing the effectiveness of the regulations that genome edited plants would be subject to outside the GMO directive. Conventional plant breeding actually has a track record in improving the safety of food by ensuring safe levels of naturally occurring toxins."
Multinational plant breeder

However, there was concern expressed amongst a range of other groups that separating out genome editing from GMOs and tying regulatory exclusion to concepts of 'naturalness' or traditional breeding could effectively reinforce the public perception that there is something inherently risky about GMOs / transgenesis, which could have negative implications for further regulatory adaptation in future. The point was made by several participants that there is a plethora of potential opportunities / products that would rely on other genetic engineering techniques and transgenesis in future, particularly in the industrial biotech sector, and that could bring transformative social and environmental benefits, but these could be hindered by this short term move further down the line. As the UK is already a leader in several non-GE areas, it was seen by some as potentially high opportunity cost to focus exclusively on GE now and potentially compromise the viability and development of other GMO products in the longer term.

"There is no basis in science for the idea of transgenes being separated from other genetic engineering techniques; it's entirely a political construct. The idea of doing traditional breeding methods as a concept of deregulation reinforces the centrality of process-based distinctions of regulation, which tend towards disproportionality. Any scientific definition of that concept that you're likely to come up with would be quite conservative and thus not politically attractive and would exempt many of the applications that are being done precisely because they aren't likely to happen in nature."
Regulatory expert

Another criticism raised by some stakeholders was that the arguments being used to justify this regulatory adaptation, i.e. that the changes introduced using GE techniques could have been produced 'naturally' using traditional breeding methods, were vulnerable to legal exploitation and challenge, potentially leading to an overly restrictive regime for many innovative GE applications and delaying implementation of such an approach in the UK.

"How do you define what could have happened in nature? The regulatory systems I've looked at have done a really poor job of that. If editing and deleting one base pair, does it have to have actually happened in nature or could it just theoretically be possible to do so? If you do multiple edits, it gets incredibly unlikely that you will find an actual example of this occurring naturally. I'm currently doing a study of the US regulatory system and over half of GE products going through the Regulatory Status Review process are multiple gene edits so wouldn't qualify for exemption from regulation. The exemptions in the US system are actually pretty narrow and more so than most of the world understands."
US regulatory expert

Amongst some advocacy groups, there was also a strongly held feeling that the consultation was biased, with predetermined outcomes regardless of the responses and evidence submitted, due to decisions already having been made that the UK will focus on encouraging these technologies.

“It’s a highly biased consultation with what it seems a predetermined outcome. So lots of people will be inputting into that consultation, but it feels like decisions have already been taken unfortunately.”
Representative of advocacy organisation

If the UK was to adopt the position outlined in the DEFRA consultation, a related concern raised was how patenting should be applied to genome editing events. If edited varieties, and in particular, editing events are subject to patent protection rather than plant varieties rights protection, this could create problems for other breeders to breed from varieties carrying such events and would expand intellectual property control of plant germplasm by the major multinationals. On this basis, some stakeholders believed that gene edited events should not be patentable.

International regulatory adaptation

There were a number of countries highlighted in the workshops as leaders in regulatory adaptation that the UK could learn from in designing a new system of governance for the products of genetic technologies. The RHC has subsequently held meetings with various regulators in each of these countries to gather more evidence and will include these findings in its full report to Government.

Norway

Norway was seen as a useful example, given its explicit incorporation of a framework for the assessment of social, ethical and environmental concerns when a product is seeking regulatory approval. It was pointed out that these conditions were originally included as a precaution and extra layer of approval to the EU system due to the fear that the EU would be too permissive; but several stakeholders suggested that the UK could learn from the Norwegian approach in assessing the purposes of using genetic technology and how these align with public attitudes.

The Norwegian Biotechnology Advisory Board has proposed a reformed framework, which is now awaiting a Norwegian Government response later this year. This proposal incorporates a graded risk assessment process, based on the nature of the genetic change made, but also some assessment of public acceptability. The logic here appears to be that when people perceive greater benefit they might accept greater risk. The Board has a wide public engagement and education function and is unique in including lay people (e.g. priests, lawyers) alongside technical experts, in order to consider the broader social risks and benefits associated with a product when advising on regulatory approval.

Argentina

Argentina was frequently highlighted as a key case study for how an adapted regulatory system brought about significant changes in the pace of development and regulatory approval of products of genome editing. Data were provided on how the profile of developers and the composition of approved products had diversified since their regulatory adaptations in 2016, with many more SMEs and public sector collaborations submitting products for approval and a larger range of product types emerging aimed at more niche markets (e.g. nutritional improvement, tackling allergies). This was seen as evidence that the greatest inhibitor of innovation by SMEs, particularly products that could be disruptive of the business models of multinational companies, was the affordability of the regulatory approval process. This supported the conclusion that today’s regulatory systems are responsible for maintaining the dominance of multinational companies and the focus of

innovation on relatively simple products for large-scale commodity crops, rather than those with significant societal benefits.

USA

The USA regulatory approach was mentioned by a few stakeholders as resembling the Argentinian dynamic, in that regulatory adaptations in May 2020, aimed at streamlining the process for certain classes of product, had already resulted in many more innovative products being submitted for regulatory approval by SMEs and publicly funded laboratories.

Another aspect of the US system, that could be mirrored in the UK, was allowing developers to grow a crop, under a permit and notification scheme, on up to 5000 acres under what are effectively GM field trial conditions.

Canada

As covered in more detail in the first section of this paper, Canada was frequently mentioned for being the only country in the word to have an explicit product-focused system of regulatory trigger based on the product’s novelty to Canada. As explained in more detail above, this was seen by many stakeholders as a sub-optimal regulatory trigger that caught many conventional plant varieties in a disproportionate regulatory assessment regime. Canada is in the process of issuing new guidelines this year to try and give greater clarity and deal with some of these issues.

Concerns over the perceived encouragement of genetic technologies

In our engagement with advocacy organisations, there were concerns expressed about taking what they saw as a pro-innovation approach to genetic technologies. Some were keen to stress that they weren't against genetic technologies full-stop, but they needed certain reassurances and safeguards to be in place; while others questioned fundamentally the concept of regulatory adaptation as a means of promoting technological innovation and asked why the Government should support the development of genetic technologies rather than other kinds of innovation in farming.

Concerns over a 'deregulation agenda'

A few stakeholders questioned the premise that regulation should be involved in supporting businesses to commercialise genetic technologies and that it was more appropriate to use other financial or structural reforms to foster innovation. The argument behind this perspective was that there was always a risk of something going wrong - the case of unintended antibiotic resistance traits in gene-edited cattle in the US was referenced - and that safety should never be compromised in order to encourage innovation (although in this example there was no food safety risk).

"You don't reduce regulation in order to support small businesses; you look at business approaches to support small businesses and I think this is a really dangerous area. The anti-small business trope is used a great deal in the media to attack campaign groups regularly."
Representative of advocacy organisation

Intensification of farming methods

In respect of genetically altered animals, some stakeholders were concerned that companies would use the technological opportunities opened up by regulatory adaptation to target innovations focused on short-term efficiency gains and higher yields, ignoring the ethical issues raised by intensification of farming methods and erosion of welfare standards. In order to support regulatory change, these groups stressed that the principles by which products are assessed must incorporate both the direct effects on animal welfare and the indirect effects on the production system being facilitated, not just narrow commercial interests.

"We would like to see a move away from intensive factory farming, which we think is unsustainable on environmental grounds because of the dependence on grain from other

continents, but also on that sector on welfare grounds. We're not opposed to genetic techniques in principle, but we do have concerns. Genetic modification or editing of animals could be used to facilitate what we think is otherwise an unsustainable industrial system of factory farming."
Representative from animal welfare organisation

Public acceptance

There was disagreement among attendees about how much public acceptance of genetic technologies has moved on since the debates in the 1990s and early 2000s on first generation GM crops. In terms of new techniques such as genome editing, it was suggested by a number of participants that understanding of public acceptance was out of date and warranted further investigation through future research programmes.

Role of standards / labelling to aid consumer understanding

A commonly observed problem in public acceptance of the products of genetic technologies was the lack of awareness of the benefits they can bring, particularly in regard to reductions in environmental harms. Many workshop attendees thought that if a certain product ends up being more sustainable due to traits introduced by genome editing, it should be labelled as such so as to be transparent and encourage uptake; they thought that standards could have a role to play here. Similarly, other participants thought it would be useful to have GRAS labelling alongside GMO labelling.

Positive case studies

There was wide acknowledgement that the most effective way to secure public acceptance and trust of new genetic technologies was to demonstrate the positive environmental and societal benefits of the products that can result from them. The example of mRNA Covid vaccines was brought up frequently as the most influential and important case study of how the use of genetic technologies has already resulted in overwhelming public benefit and it was hoped that this application will continue to shift the dial towards greater public acceptance of such technologies. There was encouragement for plant breeders to get involved in public projects aimed at using genetic engineering to overcome environmental issues, so as to counter the perception that the technologies will only be used for increasing yields and profits.

“Our company is leading on a project with other plant breeders on using genome editing to achieve fungal resistance in wheat so we can have a clear positive example to the public of the benefits these techniques can achieve in terms of sustainable production and environmental protection.”
Multinational plant breeder

Use of language

Across all the workshops, there was concern over how language has been used, both by those for and against the adoption of genetic technologies, to manipulate public opinion

about them, and concern that this manipulation has had a detrimental impact on public trust and led to the polarisation of the debate. It was generally recognised that this is a very difficult issue to resolve, but the use of more inclusive language and greater engagement, dialogue and education initiatives are important factors in any solution to this problem.

“There is a constant rebranding of technologies as a way of influencing the debate. It's basically marketing and the language is often used to exclude lay contributions to the debate about technical issues. It is very important to engage with the public directly, they have a strong understanding of the law of unintended consequences and actually have very nuanced views.”
Representative of advocacy organisation