REGULATORY HORIZONS COUNCIL

Reforming the Governance of Genetic Technologies

Policy Brief by the Regulatory Horizons Council

June 2022

Summary

This policy brief summarises the analysis and recommendations from the Regulatory Horizons Council's Report on Reforming the Governance of Genetic Technologies. The report was produced in response to a UK Government request to consider how to adapt our future regulation of genetic technologies in the agri-food sector, post-Brexit, to enable safe and beneficial innovation. It proposes that the future UK regulatory regime should:

1) **Focus on the properties of the end products rather than the methods used to develop them;**

2) **Progress as rapidly as possible towards regulatory reform for all products of genetic technologies, including those developed using cross-species genetic transfer; and**

3) **Incorporate more inclusive approaches to stakeholder dialogue and engagement along with formal company commitments to responsible innovation.**

For references of evidential claims, please refer to the main report.

Benefits and risks of products of genetic technologies and the regulatory opportunity

First generation genetically modified (GM) crops, introduced in the 1990s, have seen rapid uptake in many countries, currently occupying over 10% of the world's arable land. The consensus among regulatory bodies is that there has been no evidence of adverse effects on human or animal health, or on the environment, from the production and consumption of food or feed from GM crops. On the contrary, there have been significant reductions in insecticide poisoning of workers on crops engineered to be insect resistant, and also environmental and biodiversity benefits related to reductions in insecticide use. However, **the costs and delays imposed by regulatory regimes, particularly those of the EU, have significantly limited innovation in this area** and these benefits are restricted to other regions of the world and to the major commodity crops, soybean, maize, cotton and oilseed rape.

The products of second- generation genetic technologies - genome editing, synthetic biology and engineering biology - where the UK has a strongly competitive research environment, could transform our health, food and agri-tech sectors. They are opening up major new opportunities for large and small companies to develop crops, animals and micro-organisms that are pest or disease resistant, lead to

healthier diets, reduce greenhouse gas emissions, improve climate resilience, and contribute to meeting Net Zero and Biodiversity policy goals, as well as significantly boosting the UK economy. If products of genetic technologies are widely adopted in the rest of the world, but not in the UK, then British consumers will have restricted access to diverse new products, farmers will be at a competitive disadvantage, and opportunities to mitigate climate change and improve biodiversity will be missed.

Ensuring that the Government's investment in basic research delivers these returns to the UK, rather than to its competitors, will require a governance system that is agile, targeted and proportionate to the balance of potential benefits and risks of the products. The regulatory regime adopted should also be compatible with the standards of our future trading partners. **The RHC Report on Genetic Technologies charts a new direction for the UK regulatory system that would enable innovation by all companies, small and large, while maintaining the excellent safety record of the sector**. It also proposes mechanisms to ensure that decisions take account of the concerns and expectations of all relevant stakeholders. These reforms could make the UK an international leader in regulatory adaptation to support the development of products that can transform future agri-food systems.

The 2022 Queen's Speech included plans for a Genetic Technology (Precision Breeding) Bill to create a simpler regulatory regime for plants and animals with genetic changes that could have arisen through traditional breeding and natural processes, along with a commitment not to introduce changes to the regulation of animals until a regulatory system is developed to safeguard animal welfare. It received its first reading in the House of Commons on 25th May 2022 and is described as a Bill to make provision about the release and marketing of, and risk assessments relating to, precision bred plants and animals, and the marketing of food and feed produced from such plants and animals; and for connected purposes.

A new governance approach for products of genetic technologies in the UK

The following key recommendations would be applied to any product (plant, animal or micro-organism) obtained using genetic technologies (including genome editing, synthetic biology and engineering biology), to be used in agriculture, food production and other uncontained conditions (see Figure). This description is broad enough to apply to all current and expected future genetic technology developments, avoiding the need to redefine the regulatory focus for each new development in scientific methodology.

The proposed governance approach is intended to apply to products of all genetic technologies, including (i) those that involve cross-species genetic transfer (transgenesis), currently regulated in most countries as GM organisms, and (ii) simple genome edited products based on CRISPR and related techniques (site-directed nuclease (SDN) 1 and 2

genome editing), which do not involve permanent cross-species genetic transfer. The approach would speed up and simplify regulatory decision making by avoiding over-regulation of safe products and allowing work on different regulatory requirements to proceed in parallel rather than in sequence, as was the case for the rapid regulatory approval of Covid-19 vaccines.

Key recommendations

1. An overall regulatory body should be appointed, building on the role of the current Advisory Committee on Releases to the Environment (ACRE) with a broader range of expertise and responsibilities, referred to here as ACRE-2.

2. Regulatory scrutiny should focus on the product to be placed on the market and the balance between its risks and benefits, rather than the technology used to produce it.

3. Information about the altered genetic sequence of the new product should be used by ACRE-2 to assess its novel properties and the expected benefits and risks.

    - If there are no concerns about hazards arising from the product, it can proceed as normal for any other novel, non-genetic product in its sector. Most products submitted to the regulator for approval are expected to be in this category. Pre-submission dialogue between the regulator and the producer should be encouraged, to guide any necessary changes to the product to facilitate regulatory approval or deliver a 'no' answer as rapidly as possible.
    - If there are concerns about food, feed or environmental hazards, the product should be referred to the relevant sectoral regulator for assessment and advice on whether or not it should be approved for market use.

4. Regulatory data requirements should be proportionate to the nature and scale of risks; should include information on potential benefits; and should not require the collection of data that do not relate to a clearly specified policy.

5. Standards, guidelines, policy and technology initiatives (i.e. alternatives to legislation) should be considered as aids to regulatory adaptation, enabling product development to proceed with care. This is particularly important for transformative products for which there may be no obvious regulatory precedent. Technology can be a powerful enabler of regulatory reform, for example using blockchain to trace products along a supply chain in order to ensure that the end product on the market meets relevant standards and regulatory requirements.

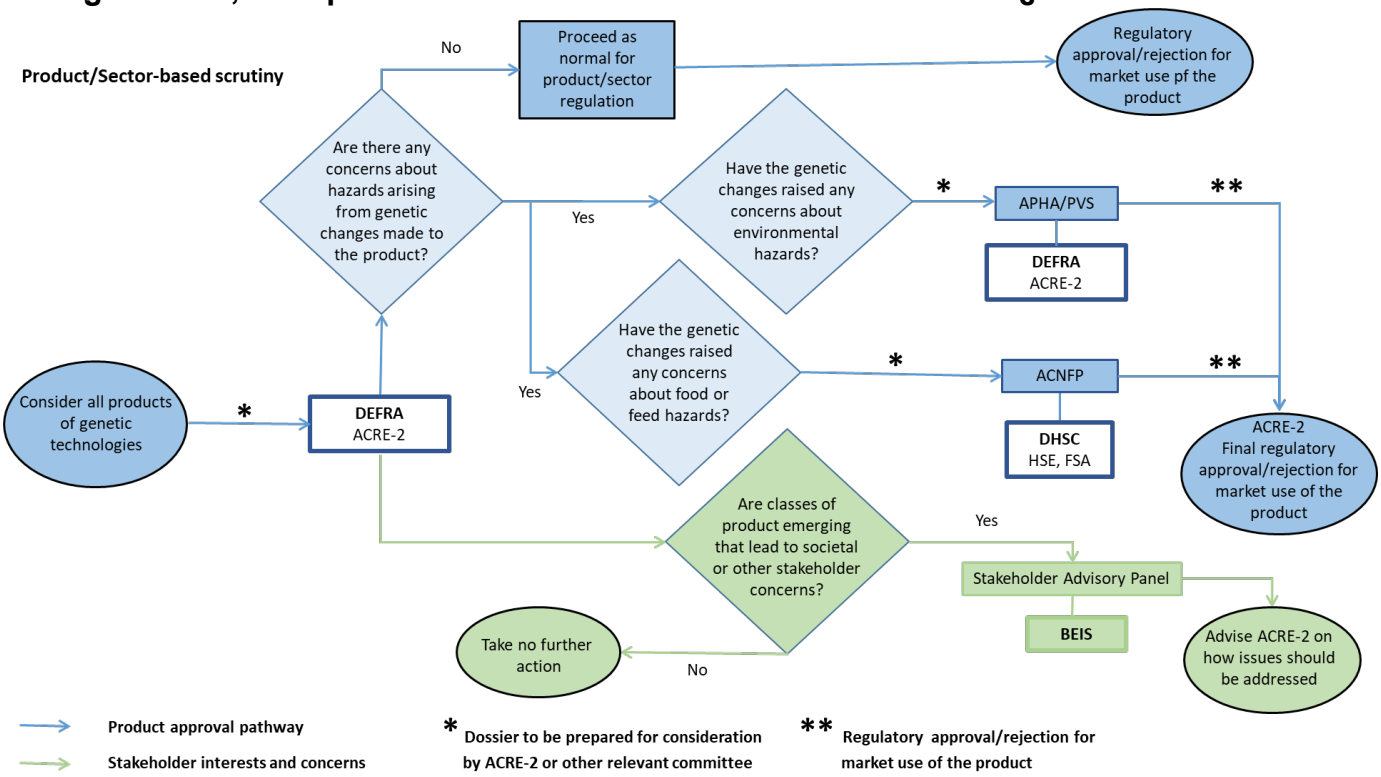
6. Product labelling should be required to inform consumers of a product's origins and its potential societal and environmental benefits.

7. A new, more integrated approach to stakeholder interactions should be introduced to support safe and equitable development of products of genetic technologies, involving:

- a standing Stakeholder Advisory Panel, potentially sponsored by the Department for Business, Energy and Industrial Strategy (BEIS), representing all stakeholders involved in the development, production and use of products of new genetic technologies along with public/lay representation, with a role to comment on and guide decision-making on market approval for new classes of product;
- where relevant, exploration of public attitudes to specific developments; and
- company compliance with a responsible innovation standard, including the ability to demonstrate compliance when required.

8. Once an applicant has demonstrated compliance with the required sectoral regulatory standards, sectoral regulators would inform ACRE-2 of the outcomes and ACRE-2 would be responsible for the final decision on market authorisation, considering where relevant any advice on a new product class from the Stakeholder Advisory Panel.

Proposed regulatory pathway for products of genetic technologies used in agriculture, food production and other uncontained conditions§.



§ ACNFP-Advisory Committee on Novel Foods and Processes; ACRE-Advisory Committee on Releases to the Environment; APHA-Animal and Plant Health Agency; BEIS-Department for Business, Energy and Industrial Strategy; DEFRA-Department for Environment, Food and Rural Affairs; DHSC-Department for Health and Social Care; FSA-Food Standards Agency; HSE-Health and Safety Executive; PVS-Plant Variety Rights and Seeds Office.

A regulatory system that is adaptive and agile

Regulating products developed using genetic technologies has been nationally and internationally divisive over the past 25 years, across all countries and regulatory systems; and only large multinational companies have had the financial and other resources needed to develop them, largely due to the lengthy time-scales and financial costs associated with regulation. This means that we have not yet seen much of the predicted transformative innovation that could move the agri-food sectors onto a new, more sustainable innovation trajectory, with the participation of numerous independent small companies. The regulatory approach proposed here for *all* products of genetic technologies was designed with the UK and its current circumstances in mind, but its individual elements would also be applicable to most other countries, potentially facilitating regulatory transformation of the agri-food sector internationally, which is likely to be a requirement in addressing climate change and other global challenges.

Where current regulatory approaches focus on the technology used to develop a product, rather than the properties of the product itself, this has not delivered an agile and adaptive regulatory system. It has required lengthy dialogue about the definition of a new genetic technology before its products can be captured (or not) within the relevant regulatory system. A recent example is defining genome editing so as to avoid capture of its products by the current regulatory system for GM organisms. Beyond agreement on the definition of genome editing, which has been problematic, there would then be an even more lengthy process of revising the current GM regulatory system, item by item, to accommodate the new definition. Every time there is a new genetic technology breakthrough this process would begin again, with all the attendant costs and delays.

The mechanism proposed here by the RHC opens up discussion on how to move on from today's stalemate to a new approach, to 'cut this Gordian knot'. The proposed approach follows logically from the recognition that there is nothing intrinsically hazardous about the genetic technologies themselves; hazards, if any, will emerge in the properties of the end products and how they are used and that is where regulatory attention should focus.

Genome editing as a candidate for special treatment

Many countries (e.g. USA, Argentina, Brazil, Japan, Australia, Canada, India) are already relaxing the rules for regulatory approval of crops, and in some cases animals, where they involve simple genome editing (for example, SDN 1 and 2 products developed using CRISPR techniques that do not involve permanent cross-species genetic transfer), to treat them in the same way as conventional crop varieties, as proposed in our approach. In January 2022, the UK Government announced plans to ease the requirements for field research on such genome edited crops, no longer requiring prior risk assessment and the subsequent Queen's Speech announced plans to create a new, simpler regulatory regime for precision bred plants and animals with genetic changes that could have arisen through

natural breeding or natural processes. The relevant Bill was placed before parliament on 25th May 2022.

The current messaging about genome edited products that underlies these changes involves claims that they are more 'natural' and less hazardous than products involving cross-species genetic transfer, arguments for which there is no scientific evidence base. The RHC report sees this as an unfortunate development with the potential to unjustifiably stigmatise products involving transgenesis, leading to future negative implications for public stakeholder responses to products of all genetic technologies.

Given the scale and extent of the potential benefits from all genetic technologies, it is important to ensure that the UK regulatory approach adopted for products of simple genome editing does not create regulatory precedents that would restrict its freedom to act in the near future on regulatory adaptation for products of *all* genetic technologies.

Stakeholder roles and responsible innovation

In the context of these recommendations, **engagement with stakeholders should relate to the products, their qualities and how they will be regulated, rather than to the technologies themselves**. Making the change to a product-based regulatory system could enable more equitable engagement with a wider range of stakeholders, taking account of the development stage of a product, its benefits and risks and the degree of certainty about its future properties, and considering how products should be developed and regulated. Our proposed regulatory pathway includes a new Stakeholder Advisory Panel to manage this new approach to dialogue.

Where a stakeholder concern relates to a broader societal issue, such as the nature of farming systems or animal welfare, these may be better addressed through other areas of public policy and regulation, such as the Animal Welfare (Sentience) Act, 2022. There are no benefits, and potentially considerable losses, if a safe and useful product is rejected because it might have an impact on a broader societal issue, particularly where that is already addressed by other policy or regulatory regimes.

Procedural innovation for the UK regulatory system

Enhanced regulatory capacity in the UK

The regulatory bodies managing the new UK regulatory approach will need more, better and permanent risk assessment expertise if they are to meet the requirements of their additional roles. This would **bring the UK more into line with regulatory systems in other countries and those for other technologies, such as medicinal products**. The additional costs of such an approach would be dwarfed by the resulting increase in revenues from UK based innovation.

Trade-related issues
The future UK regulatory system will need to be compatible with the standards of our trading partners and this limits the UK's freedom of action to some extent. However, given the extent to which regulatory adaptation is being discussed internationally, **there will be expanding opportunities for trade gains for the UK beyond the EU**. Although the EU market for the products discussed here is currently highly restricted, this could also change, given the increasing pressures there for regulatory change.

Improving efficiency
The commitment to operate regulatory regimes on a case-by-case basis is a precautionary component of the regulatory regimes of many countries and introducing an element of learning by experience would allow for adaptation over time. **Classes of product with similar properties could be assigned to a tailored regulatory regime that avoids unnecessary repeated testing**.

Testing our recommendations
Given the lack of understanding of the scale of the benefits to food and feed systems, the environment and the economy from all genetic technologies, and also potential disagreement about the nature of future regulatory systems, **we propose that the government designs and sets up a regulatory sandbox to test our recommendations** and to assess their viability in the UK context and their impact on the innovation capacity of companies, large and small.

An international role for the UK

Many countries internationally are currently revising their regulatory systems for products of simple genome editing and the RHC approach proposed here could contribute to the UK's current initiatives in that area. When it comes to the regulation of products involving transgenesis, where the benefits could dwarf those based on simple genome editing, **there is an opportunity for the UK to take on a path-finder role to define a dynamic regulatory regime that can readily evolve to cope with current and foreseeable technological changes**.