GENOME EDITING – UPDATE PAPER

Report by Sabrina Roberts
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1. Summary

1.1 The FSA is responsible for advising ministers in England, Wales, and Northern Ireland on the authorisation of Genome Editing (GM) for use in food and animal feed products, as part of a wider system to ensure that products are regulated in a proportionate manner which protects consumer interests.

1.2 Potential changes to amend the definition in England of Genetically Modified Organisms (GMOs) to exclude products achieved through new breeding techniques including GE, where the changes could have been introduced by traditional breeding methods – would have immediate impacts on the FSA. The Department for Environment, Food and Rural Affairs (Defra)'s consultation on the matter closed in March 2021 and a formal government response on the consultation is expected soon.

1.3 This paper sets out the FSA's locus in this area, the key strategic questions to be considered, and starts to distil the policy options that the Board may need to make decisions on in the future.

2. Decisions

2.1 The Board is invited to:

- reconfirm the position set out in the Chair's letter to Secretary of State Defra in March 2021 (Annex A), that there is a case for updating regulatory frameworks to reflect new scientific and technological advances in genome editing.

- review and advise on the principles underpinning the regulation of genome edited food and feed products (see para 3.11) to inform the FSA's views on the proposals in the consultation.

- agree that FSA officials should continue to work closely with our colleagues in Wales and Scotland and with Defra officials, endeavouring to achieve a coherent and proportionate GB wide approach for regulating GE products, in the event of legislative change to exclude them from the GMO definition in England.

3. Discussion

What is genetic modification and genome editing?

3.1 Genetic modification covers a range of techniques that allow genes or sections of DNA to be inserted into an organism's genome. It can include cisgenic changes which introduce genes from a sexually compatible organism; intragenic changes which introduce genetic material from a sexually compatible organism but in a way that would not be found naturally; and transgenesis which allows the introduction of genetic material from an unrelated species that could not naturally breed with the target organism. This allows the introduction of desirable traits which are not naturally found in the target organism.

3.2 Genome editing (GE) is the term given to a range of techniques used to alter the DNA of organisms, including plants and animals. It works by using enzymes to cut DNA at specific points. This method can be used to add, delete, or replace sections of DNA. It allows a broad spectrum of changes which can be introduced to an organism's own genome, some of which can be identical to those occurring naturally or achieved through traditional breeding. Desirable traits can be introduced more quickly and precisely using GE than through conventional breeding.

3.3 Any technique that alters DNA has the potential to alter traits within an organism, either the addition of desirable traits or unintended effects which may introduce less desirable traits. Therefore, although GE techniques can attain specific desirable genetic changes with greater control than some of the more traditional GM techniques, unintended effects may still occasionally occur, and this would need to be covered by any assessment process.

How genome edited food and feed products are currently regulated

3.4 The FSA and FSS are responsible for advising ministers in England, Wales, and Scotland on the authorisation of GM food/feed products. Both also consider potential developments (e.g., technological innovation) and how this might require reshaping of the regulatory landscape.

3.5 GE products are currently required to be approved under GM food and feed legislation and are subject to a mandatory pre-market safety assessment before being allowed on the market. Safety assessments are conducted for the FSA by the Advisory Committee on Novel Foods and Processes (ACNFP). These are judged based on science and evidence – assessing the risk to animal or human health, potential to mislead consumers or be of less nutritional value than the equivalent conventional foods.

3.6 Following a public consultation, the FSA then presents a recommendation to Ministers, which includes other relevant factors such as consumer choice and economic impact, ensuring that consumer interests are at the heart of decision-making. The regulated products authorisation process for GM involves numerous steps and can take a year or more to complete, with timelines dependant on individual applications. There are currently no genome edited

products authorised for use in the UK, although some are available elsewhere in the world - for example, GE tomatoes that can lower blood pressure have been authorised in Japan. Any health claims on GE products will need to seek approval under The Nutrition and Health Claims Regulation which is the responsibility of the Department of Health and Social Care in England in partnership with the Devolved Governments of the UK.

How other government departments are involved

3.7 Defra is responsible for granting consents for the deliberate release of GMOs into the environment (for example planting of GMO crops) in England (including field trials). Each devolved administration has equivalent responsibilities in respect of Wales, Northern Ireland, and Scotland.

3.8 HSE is responsible for regulations relating to GMOs in 'contained use' facilities like research laboratories and including the storage, transport, destruction, and disposal.

Impact of the proposed changes to the definition

3.9 If the legislative changes proposed in the consultation - *to amend the definition of a GMO as it applies in England under section 106 of the Environmental Protection Act 1990 so it does not apply to organisms products by genome editing and other genetic technologies if they could have been developed using traditional breeding methods* - were to be made, GE products could no longer be regulated under GM food/feed legislation in England, and would be covered by other existing regulated product regimes – Novel Foods legislation for GE food and Animal Feed legislation for GE feed. As the definition of a GMO will have not been amended in Scotland or Wales, GE products would continue to be regulated under GM food/feed legislation. As a result, GE products would be regulated under two different regimes across GB.

3.10 However, FSA officials advise that this legislation is not suitable for the regulation of GE products. Animal Feed law includes no pre-market safety authorisation and therefore GE feed products may enter the market unchecked. Novel Foods legislation was not written with GE regulation in mind, and therefore the criteria by which a process is clearly defined as 'novel' would be a grey area (i.e., a process approved through novel foods legislation could then be used in another product – while the process would not be novel, the outcome could be).

Principles for GE regulation

3.11 In a scenario where the definition of GMO is changed - we recommend that there are 5 key principles that should underpin GE regulation:

- ***Safety*** – as a food and feed safety regulator, we need to ensure that the regulatory framework reflects our role to ensure products produced using technologies such as GE are safe.
- ***Transparency*** – the regulatory framework must be clearly communicated and accessible to consumers and other stakeholders, with stakeholder participation in the development and operation of the framework, maximising open access to information.
- ***Proportionality*** – the regulatory framework should allow specific safety issues associated with GE products to be adequately assessed without the risk of measures that are too stringent (e.g., to ensure foods produced through some conventional breeding methods are not covered in this category).
- ***Traceability*** – Some edits that are made by GE are identical to those mutations introduced by natural variation and therefore could not be detected by routine testing. The inability to detect GE needs to be considered particularly in relation to labelling and enforcement of GE products. Any new framework needs to allow us to understand the processes by which the product has been developed.
- ***Building consumer confidence*** – the regulatory framework must demonstrate that consumer needs and views have been considered.

Safety considerations

3.12 The ACNFP, the independent scientific advisory committee which advises the FSA on the safety of novel and GM foods, and conducts GM risk assessments, responded to the Defra consultation earlier this year.

3.13 Their response highlighted that each production method - either conventional breeding, GM, or GE, carry a risk of unintended effects. The risk factor is not always associated with production method and is more specifically related to introduced changes. This is particularly relevant for GE as it may allow new trait combinations to be introduced that would not have been easy to produce via other methods. The committee suggested a proportionate assessment of GE products on a case-by-case basis using a fit for purpose safety assessment of the final products, independently of production method.

3.14 The FSA will continue to work with its scientific advisory committees to ensure safety assessments are proportionate and policy is developed in a science and evidence-based way, working in tandem with Defra and its scientific advisory committees.

Consumer research

3.15 Consumer research is at the heart of what the FSA does. We have an ongoing programme of work, involving consumers from England, Wales, and Northern Ireland, to understand the consumer perspective on genome editing and published the first report in July 2021. Evidence on which this first report was based was from a mixed method social science research project to understand consumer perceptions of GE food and potential consumer information needs, commissioned to run alongside the Defra consultation.

3.16 The key findings from consumers in this research were:

- The more informed consumers were, or became, the more accepting they were of GE food.
- However, consumers generally tended to have very low awareness and very low knowledge of GE food.
- Consumers tended to find GE food more acceptable than GM food. However, consumers found GM or GE applied to plants more acceptable than applications to animals, for example, due to human safety and animal welfare concerns.
- Most consumers felt it would be appropriate to regulate GE foods separately from GM foods - having recognised them as two separate techniques and should be treated as such. Categorising them in the same way may confuse and undermine the chance for consumers to learn and appreciate the differences. At the same time, many felt the safety assessment should be just as thorough as for GM.
- Most survey respondents had thought that labelling should indicate the use of ingredients that have been genome edited. Though participants, during the workshop sessions, did not all feel this to be necessary.
- Overall, most consumers wanted thorough regulation and transparent labelling if GE foods reach the UK market, with the suggestion that social media information campaigns and TV documentaries would help educate the public on GE food.

3.17 In line with our recent work on risk communication best practice, the next stage of this research would be to work closely with consumers to understand and co-create with them the level and type of information that they would require on genome editing in food, supported by experts from our Advisory Committee for Social Science.

Early thinking about potential options for regulation if the proposed change in the Defra consultation was introduced

3.18 As set out in para 3.10, there will be a range of challenges and inconsistencies if GE products are removed from the scope of existing GM legislation relating to England and consequently fall under other existing frameworks (such as Novel Foods and Animal Feed). Any potential regulatory options to address these issues may be constrained by wider factors, including the scope and timing of wider legislation in this area. It is worth noting that the Defra consultation also included a second section on the wider GM policy area, beyond the specifics of genome editing.

3.19 In terms of the early thinking on developing an FSA position to offer to Government Ministers if the changes proposed in the consultation were to be enacted, the FSA Board will wish to note the following potential options from which a position could be developed although there could also be a phased approach.

- **A new Genetic technologies food and feed framework, capturing GE products excluded from the GMO framework if the definition is changed.** A new regulatory system could apply a more proportionate safety assessment requirement than the requirements currently set out under the existing GM food and feed regime. This option would be the most straightforward approach and be targeted to the direct impacts of the definition change; but the drawback would be that it would add to the patchwork of other regimes and takes a less comprehensive approach to developing a framework for the application of new technologies. The FSA would continue working in close consultation with the ACNFP, colleagues in the devolved administrations, collaboratively with Defra and our industry partners, to ensure that any new framework would be as coherent with the existing GM regime as possible.

- **A refresh of the current GM food and feed framework, potentially creating a tiered system of assessment for products created by a spectrum of genetic technologies**. This flexible system could allow for more substantial changes (such as the addition of genes from a different organism) at one end of the spectrum to be assessed and regulated more rigorously, and more minor changes (such as GE equivalent to conventional breeding) to be regulated in a lighter touch way. This would demonstrate a more coherent reform of the whole GM/GE regulatory system and provide opportunities to look again at the subject matter in the round; but it is also a more complex and lengthy approach and would have to be balanced with wider legislative considerations and timescales. In the longer term, however, it may provide greater regulatory certainty. Therefore, it may be more logical to look at this approach at a later point in the future, in accordance with the second part of the Defra consultation, which covered wider GM considerations.

UK considerations

3.20 The proposed change to amend the definition in England of Genetically Modified Organisms (GMOs) to exclude products achieved through new breeding techniques (including GE) would only apply in England, and this may impact the UK internal market. To help ensure that consumers and stakeholders have a clear and coherent understanding of regulatory developments, any new GE regulatory framework would be developed in close consultation with our colleagues in Wales and in Scotland, offering the opportunity for a unified approach. The FSA is committed to four-nation working, working closely with Food Standards Scotland. While the proposed changes would only apply to England, we welcome any scope to work across governments to introduce changes consistently across the UK.

3.21 Northern Ireland is subject to EU legislation in areas covered by Annex II of the Northern Ireland Protocol, which includes GMO/GE legislation. The EU position on GE is evolving. In April 2021, an EU report on new genomic techniques was published. The European Commission plans to initiate a policy on plants produced by targeted mutagenesis and cisgenesis, which will involve an impact assessment and public consultation. The policy intention is for proportionate regulatory oversight, which would maintain a high level of protection of human, animal health and the environment whilst allowing benefits from innovation.

4. Next steps

4.1 We expect the government response to the consultation to be issued soon and will update the Board following this.

5. Summary

5.1 The Board is invited to:

- **reconfirm** the position set out in the Chair's letter to Secretary of State Defra in March 2021 (Annex A), that there is a case for updating regulatory frameworks to reflect new scientific and technological advances in genome editing.
- **review and advise** on the principles underpinning the regulation of genome edited food and feed products (see para 3.11) to inform the FSA's views on the proposals in the consultation.
- **agree** that FSA officials should continue to work closely with our colleagues in Wales and Scotland and with Defra officials, endeavouring to achieve a coherent and proportionate GB wide approach for regulating GE products, in the event of legislative change to exclude them from the GMO definition in England.

ANNEX
Annex A – Chair letter to SoS Defra, March 2021