

## FSS Board Update on Genome Editing

### 1 Purpose of the paper

- 1.1 To provide the Board with an update on the UK Government's Genetic Technology (Precision Breeding) Act 2023 and the EU's proposed Regulation on plants obtained by certain new genomic techniques, including food and feed derived from them.
- 1.2 The Board is asked to:
  - **Note** the update on the proposed legislative changes in England and the EU.
  - **Note** the intention to work with the Scottish Government to consider the impacts of these changes on Scotland with a view to developing advice on future policy options. FSS will return to the Board in summer 2024.
  - **Note** the outcome of consumer research recently undertaken by FSS to better understand consumer attitudes towards gene edited food in Scotland.
  - **Agree** that, given the complexity, challenges, reputational risks and differences between UK administrations that regular updates should be provided to the Board as appropriate.

### 2 Strategic aims

- 2.1 This work supports FSS Strategic Outcomes that food is safe and authentic and responsible food businesses are enabled to thrive.

### 3 Background

#### Regulatory Landscape In Scotland

- 3.1 In Scotland, genome editing is considered a method of genetic modification under the definitions currently laid down in Directive 2001/18 on the deliberate release into the environment of Genetically Modified Organisms (GMOs). This is the definition which is used in retained Regulation 1829/2003 on Genetically Modified Food and Feed which outlines the requirements that need to be met when it comes to authorising and assessing the safety of any genetically modified food and feed intended to be placed on the market in order to protect human and animal health. Enforcement provisions for these requirements are contained within The Genetically Modified Animal Feed (Scotland) Regulations 2004 and The Genetically Modified Food (Scotland) Regulations 2004.
- 3.2 The policy responsibility for plants, crops and cultivation sits with Scottish Government (SG) however policy on retained Regulation (EC) No 1829/2003 on genetically modified food and feed sits with FSS and applies the same definition of

genetic modification. In broad terms, the use of genome editing – e.g., in crops and cultivation – falls under the remit of SG until the product becomes food or feed or part of a food or feed product, at which point regulatory responsibility transfers to FSS.

#### Regulatory Landscape In England

- 3.3 The UK Government's Genetic Technologies (Precision Breeding) Act 2023 received Royal Assent in March 2023 and applies in England only. The purpose of the Act is to remove precision-breeding technologies, a term introduced by Defra to refer to new genetic techniques like genome editing where the change is equivalent to what could be achieved through conventional breeding, from the scope of the Genetically Modified Organisms Regulations (GMO Regulations) in England.
- 3.4 The Food Standards Agency (FSA) are currently developing a secondary regulatory regime for precision bred food and feed in England under powers in the Act. Details of the regulatory regime were set out in a public [consultation](#) launched on 8 November 2023 with an aim of bringing the new requirements into force later in 2024. FSS understand that this secondary legislation will be included as part of a Defra SI.
- 3.5 In the consultation, the FSA are proposing a two tiered approach to precision bred organisms. Those that are categorised as a "Tier 1" will be a precision bred variety which could have been produced through conventional breeding. These will be regulated in the same way as conventionally bred organisms. "Tier 2" organisms will be those where a triage has identified a potential hazard, for example novelty, composition (which could affect nutrition, toxicity or allergenicity) and/or other safety concerns. These will require bespoke safety assessment process, including a more detailed examination of the characteristics of the organism.

#### Proposed Regulations In the EU

- 3.6 On 5 July 2023, the European Commission published proposals for a new regulation for food and feed derived from new Genomic Techniques (NGT) an umbrella term referring to genomic techniques developed since 2001. These proposals have two routes that NGT plants and derived food and feed can be placed on the EU market.
- 3.7 Plants and derived food and feed that could have also occurred naturally or by conventional breeding will be classified as "Category 1". These will be subject to a verification procedure based on criteria set in the proposal and will be treated like conventional plants/food/feed and exempt from the requirements in the GMO legislation. While there will be a requirement for the labelling of seeds, no consumer labelling for food and feed has been proposed.
- 3.8 "Category 2" will cover all other NGT plants and derived food and feed and the current requirements of the GMO legislation will still apply with some adaptations to the risk assessment depending on risk profiles. There will be a requirement for category 2 NGT products to be labelled as GMOs.

### FSS Consumer Research

- 3.9 In 2022, FSS commissioned consumer research to better understand levels of awareness and attitudes regarding precision breeding, perceptions of potential risks and benefits, and opinions on how foods produced in this way should be regulated.
- 3.10 The first stage of this research comprised a quantitative on-line survey (jointly commissioned with FSA) with 4,177 respondents across the UK, including 1,005 people in Scotland. FSS followed up this survey with further in-depth qualitative research with consumers in Scotland. This involved a series of eight focus group discussions with a total of 43 participants, reflecting a broad mix of the Scottish population in terms of age, gender, ethnicity, socioeconomic status, and dietary preferences.
- 3.11 The findings suggested that people felt generally uninformed about NGTs, although this was expressed alongside similarly low levels of understanding around conventional breeding techniques. When provided with information about NGTs and how they compared to other breeding methods including genetic modification, participants expressed a wide range of views. Most people leaned towards the more accepting end of the scale, with only a small group remaining sceptical due to not seeing NGTs as distinct from older techniques of genetic modification involving foreign DNA, being more cynical about the motives and drivers behind their use or particular concerns about use in animals. Acceptance was facilitated by recognition that the changes made through NGTs were equivalent to those that could arise naturally, as well as a belief that systems and checks are in place to ensure foods produced in this way will be safe to eat.
- 3.12 Participants in the research were also presented with potential options for regulating NGT produced foods, and most expressed a preference for the concept of a 'tiered' system that had different requirements for authorisation based on risk and was informed through expert oversight and advice. When participants were asked about the information they would like to have regarding NGT produced foods, the majority expected that this would be readily identifiable on labels. The conclusions were very similar to those drawn from research that has been commissioned elsewhere in the UK and internationally, highlighting that consumer confidence in NGTs is contingent on trust in scientists and regulators, and that there is a need to provide balanced and impartial information on the use of these techniques which facilitates consumer choice in a meaningful way.

## 4 Discussion

- 4.1 As an independent science and evidence-based organisation, FSS recognise the current regulatory regime for genetically modified organisms has not kept pace with new scientific knowledge and technological advance.
- 4.2 There are clearly different views across UK administrations and while UK Government Ministers have taken a view, Scottish Ministers have not yet reached

any conclusions nor made decisions in relation to GE. However the political landscape, which will inform the Scottish Government's position, is a key element in determining what is appropriate for Scotland regarding Precision Breeding and New Genomic Techniques. As explained in paragraph 3.1, any change to the definition of a Genetically Modified Organism is a matter for the Scottish Ministers, who have not been in favour of the cultivation of Genetically Modified crops in Scotland.

- 4.3 However, Ministers are content for FSS and Scottish Government officials to jointly explore the impact of the UK Government Precision Breeding Act and the Commission's New Genomic Techniques proposal in more detail and for FSS to provide science and evidence-based independent advice. Over the next year, the FSA intend to develop a regime to regulate precision bred products. Given the timescale, FSS will shortly begin work to develop possible options for Scotland and return to the Board in summer 2024. Taking account of the views of stakeholders, including scientists, farmers, food producers, manufacturers and consumers will help consider how to approach developments in new genetic technologies

## 5 Options appraisal

- 5.1 This paper is for information only and no options are being presented at this stage.

## 6 Identification of risks and issues

- 6.1 The UK Government's Genetic Technologies (Precision Breeding) Act 2023 introduced a definition of a precision bred organism for England which created divergence with the rest of the UK. The Act also enables the Secretary of State to regulate food and feed produced from precision bred organisms and the FSA has begun work to develop a new regulatory approach needed to market such products in England. Looking ahead, this would have implications for Scotland because of the UK internal market. Applications could be submitted to the GB Regulated Products service for authorisation in England only with Ministers in England taking decisions. In turn, by virtue of the UK Internal market Act 2020, these products could legally be sold in Scotland with little or no involvement from FSS, as the independent Scottish food safety authority, or Ministers in Scotland.
- 6.2 The FSS Strategic Risk Register includes a draft risk for consideration at the next Audit and Risk Committee to reflect the need to ensure regulation in Scotland keeps pace with new products and any emerging technologies used in food and feed production. The risk considers the potential for divergent regulatory frameworks across the UK (and in this case, the EU) caused by FSS's inability to adapt and develop suitable regulatory frameworks that keep pace with and take account of changes in technology which will result in lack of clarity for consumers, industry and other stakeholders.

## 7 Equality Impact Assessment and Fairer Scotland Duty

- 7.1 Equality Impact Assessment (EQIA) and Fairer Scotland Duty assessments are not considered necessary for this paper. The purpose of the paper is to provide an

update on the UK Government and the EU's position on precision breeding/new genomic techniques.

## 8 Conclusion/Recommendations

- 8.1 Now that the UK Government has removed precision bred products from the GMO regulations in respect of England, this has led to divergence within GB with England taking a different approach to Scotland and Wales. NI of course is in a different position. Further to that the European Parliament and the Council are actively considering the Commission's New Genomic Techniques proposal which will remove genome edited food and feed from the EU GMO regulation and in turn this could create divergence between the EU and Scotland.
- 8.2 FSS will continue to be led by the science and evidence and it is clear that non alignment with either England and/or the EU would mean that in Scotland, genome edited food and feed products are regulated under a regime that has not kept pace with new scientific knowledge and technological advances in this area.
- 8.3 The Board is asked to:
- **Note** the update on the proposed legislative changes in England and the EU.
  - **Note** the intention to work with the Scottish Government to consider the impacts of these changes on Scotland with a view to developing advice on future policy options. FSS will return to the Board in summer 2024.
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  - **Agree** that, given the complexity, challenges, reputational risks and differences between UK administrations that regular updates should be provided to the Board as appropriate.

Please direct queries to:

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