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Precision Breeding team
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5th January 2024

Dear FSA Precision Breeding Team

Proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed

I write in relation to your ongoing consultation on a new framework in England under the Genetic Technology (Precision Breeding) Act 2023 (GT(PB)A) for the regulation of food and animal feed ('feed') produced from Precision Bred Organisms (PBOs), in lieu of submitting a response to the online form and on account of focusing on a few main and general aspects of the proposed regulations.

The Royal Society of Biology (RSB) is a learned society representing a diverse breadth of members and organisations in the life sciences sector[1]. Our mission is to be the unified voice for the bioscience community and to provide impartial evidence-based advice to policymakers. Ethical biological innovation is one of our priority areas for focus[2], and as part of this we have engaged extensively with the Government's review of the genetically-modified organisms (GMO) regulatory framework and provided the life sciences sector's view to Parliament during the passage of the Genetic Technologies (Precision Breeding) Bill.

We strongly support the intention of the GT(PB)A 2023 to remove certain products of modern biotechnology from the scope of GM regulations and regulate them in a more proportionate way. We previously recommended that new Government policy should enable the safe use of genetic technologies and the development of products of precision breeding through a proportionate, adaptable and science-based regulatory framework that focuses on outcomes, which should encompass expected benefits, policy objectives and protection goals[3].

[1] A list of RSB Member Organisations is available on our website

[2] Royal Society of Biology (RSB) science policy priorities (2022 – 2027)

[3] Royal Society of Biology (2021). Response to the DEFRA consultation on the regulation of genetic technologies – see paragraphs 1.12-14 & 6.8-11.

A summary of our key recommendations are outlined below:

- PBO-specific regulations should be proportionate and based on clear scientific criteria, with regulations that are adaptive and future proof
- A multi-tier regulatory system should not come at the expense of major time and cost requirements for the breeder
- Effective campaigns to inform and maintain dialogue with consumers, as well as ongoing engagement with the full range of supply chain stakeholders, should be considered in the process of building trust with both of these parties

Policy objectives and regulatory principles

In order to protect ecosystems and reduce biodiversity loss, agriculture must do more with less, while adapting to rising global demand and changing climates. Recent decades have seen increased risk to global food production from both biotic and abiotic stress factors, including the emergence and spread of plant and fungal pathogens, crop pests, zoonotic pathogens in livestock species, as well as increasing antimicrobial resistance. In addition, civil and political conflicts have exposed crucial dependencies in food supply chains leading to increases in food prices, driven by resource insecurity and rising cost of input materials, including energy price inflation[4]. Combined with a burgeoning food poverty issue and the cost-of-living crisis, these factors make it critical to consider the sustainability and longevity of food security in the UK and take stock of where technology can help tackle societal challenges for public benefit and wellbeing. No single development can address these complex challenges, and we will need to use all the tools available to deliver the world we need for human survival in acceptable quality conditions.

For all these reasons, we encourage the FSA to deliver the policy objectives of the GT(PB)A 2023 effectively and enable the products of precision breeding to be authorised and brought to market, while assuring food safety and consumer confidence in the regulatory system. In annex A (page 5) we summarise our position in support of the stated FSA guiding principles for regulation of PBOs in food and feed, namely: safety, transparency, proportionality and consumer confidence.

Tiered approaches to pre-market authorisation of PBOs in food/feed

We support a streamlined risk assessment of PBOs in food/feed, both in light of the fact that PBOs are inherently no riskier than traditionally bred organisms (TBOs) and the pressing need for products of agricultural biotechnology to meet the policy challenges mentioned above. PBO-specific regulations should be proportionate and based on clear scientific criteria.

We also acknowledge that the pace of technological development may lead to a range of novel products and possible outcomes, which would require regulations to be adaptive and future proof, and that consumers should always feel confident about the food they eat.

[4] House of Commons, 2022: The effect of the war in Ukraine on UK farming and food production

The implementation of a multi-tier regulatory system instead of a single process for PBOs in food/feed, which would still provide food safety assurance on nutrients, toxin, allergens and other statutory requirements under the General Food Law, should not come at the expense of time and cost required to obtain regulatory approval. Otherwise, smaller breeding companies and innovative food producers may be excluded from the system due to limited financial and administrative capacity.

In implementing new regulations, we agree that risk assessment should focus on the characteristics and potential impacts of PBOs in food/feed, including by defining the traits introduced via genetic technologies and the expected changes to any nutrient, allergen or toxicant. A comparative approach, where acceptability of risk is normally decided by comparison with a defined baseline or comparator, such as a TBO, has some merit. However, when considering the novelty of a trait/product, the application of additional risk assessment should be proportional, flexible, adaptive, and scientifically-justified, on a case-by-case basis. The FSA should avoid the blanket application of additional tests (and the associated data requirements) that may bear little relevance to any likely suspected hazards. In annex B (page 6), we report an earlier recommendation on the reduced need for animal testing, as part of our response to the 2021 DEFRA consultation.

Regulations need to be proportionate, scientifically-justified, adaptive, non-discriminatory and consistent. The risk assessment of PBOs in food/feed should be precautionary when there is little scientific information about the effects of a PBO, but safe use should then evolve in proportion to the improvement in scientific knowledge. Any regulations should therefore be adaptive to the level of scientific knowledge about safety. Some of this knowledge will only be derived from common use so it is important for regulations to be accompanied by robust systems of surveillance for any negative effects. Furthermore, the potential benefits and costs of action or lack of action, as a result of precaution, should be considered.

In order to provide clarity on the applicants' initial data submission under the current two-tier system, upcoming guidelines should include explanatory examples of how products will be assigned to the different tiers based on novelty (in relation to different potential traits introduced, such as disease resistance or nutritional profile). Guidance and effective information exchange between applicants and risk managers should provide clarity on the thresholds between the two tiers to avoid confusion and bottlenecks from the start of the application process.

On building trust with food producers and consumers

We understand the reasoning behind the FSA's position on food labelling – only limited to safety labelling for particular consumer groups, such as hypersensitive consumers or people with certain health conditions - and appreciate the FSA's role in maintaining the trust of UK consumers in the food system, through laudable initiatives such as 'Trust in a changing world'[5]. We previously listed a number of reasons why genome edited products might engender consumer opposition, besides safety

[5] Food Standards Agency (2018). Trust in a changing world

concerns[6], and we were pleased to see that the FSA Advisory Committee for Social Science has carefully considered them in its advice to the Board.

The RSB supports the policy intents of enabling transparent regulation and engendering public trust through the use of a public register of PBOs for food/feed. However, we would urge the FSA to involve supply chain stakeholders in discussion about the exact nature of information disclosed in the register, to safeguard intellectual property and ensure that the information is accessible and understood by a lay person.

By talking to innovative businesses, breeders and researchers, the Government can support needed innovation in this sector while keeping the regulated community on board through regulatory change that is fit-for-purpose and supports compliance.

Well-designed and effective campaigns to inform consumers about novel regulations for PBOs will equally support innovation, while building public trust.

We have not commented on the technical details of the current regulatory proposals in this letter but we would welcome the opportunity to take part in follow-up discussions with other sector stakeholders, when the new regulations are ready for review.

We have recently run one of our annual Animal Science Meetings on the policy and regulatory implications of the use of genetic technologies in farmed animals, and we were pleased to welcome members of the FSA team to the meeting. We offer to remain engaged on this topic and invite any proposals for further engagement, were it useful to you.

I look forward to your response or to discuss any further detail on the points expressed in this letter.

Yours sincerely,

Dr Mark Downs CBiol CSci FRSB
Chief Executive
Royal Society of Biology

[6] Royal Society of Biology (2021). Response to the DEFRA consultation on the regulation of genetic technologies – see paragraph 3.9.

Annex A: RSB position on regulatory principles for precision bred organisms

The RSB has previously engaged on a number of issues relevant to this consultation. Our previous messaging related to the guiding principles for regulations stated in the FSA's consultation pack[7] is summarised below and is derived from our response to the 2021 DEFRA consultation on genome editing[8]:

On **safety**, we previously stated that:

- "Whether a mutation is achieved by traditional methods or by genome editing has no bearing on the safety of the final product. [..] It is the characteristics of this final product, not the method by which the mutations are produced, that is relevant in decisions about safe use"
- "Overall GE/GM organisms present similar risks to traditionally bred counterparts but risks could be lesser or greater depending on the product under consideration. [..] In plant breeding, it is widely recognised that harmful unintended effects are no more likely to arise through GE than through traditional methods of plant breeding [..]. In animal breeding, [..] there are a number of factors that should be assessed when validating GE outcomes and an array of techniques to do so[9]". We discussed in more details the issues associated with GE in farmed animals in our submission to an earlier consultation by the Nuffield Council on Bioethics[10]. In that response, "we did not identify additional risks to human health and the environment specifically due to the techniques, but we raised important considerations for animal welfare". The RSB is now engaging with the relevant teams at DEFRA about the development of new regulations for precision bred animals under the Act

On **proportionality**, we previously stated that:

- "A proportionate, science-based regulatory system would assess new products by their characteristics, considering the particular traits of a product"
- "A future risk assessment for GE/GM organisms [..] should incorporate a number of factors, according to the product and in a proportionate manner, such as: the specific attributes of the product assessed, its intended use, considerations of the product development process, and the context in which the impacts are expected (e.g. in relation to human food and animal feed, to the environment or to animal health and welfare). [..] When considering the method of production, we must recognise that technologies are still evolving and new potential applications are developed continuously"
- "It could be advantageous for a reformed regulatory framework to adapt the requirements for risk assessment to the specific cases (organisms, products etc.) and applications in a proportional, agile and stepwise manner"

[7] Food Standards Agency, 2023. Consultation pack on proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed.

[8] Royal Society of Biology, 2021: Royal Society of Biology response to Defra consultation on the regulation of genetic technologies

[9] Burgio, G. et al. (2020). Anticipating and Identifying Collateral Damage in Genome Editing.

[10] Royal Society of Biology, 2019. Royal Society of Biology response to the Nuffield Council on Bioethics call for evidence on 'Genome Editing and Farmed Animals'

On **transparency**, we previously stated that:

- **"**Clarity and transparency about how products are created and approved will be needed to gain trust"
- "Breeders could be required to disclose the use of genome editing to allow for transparency"
- "Incorporation in plant variety registration of a genome edited status notification would provide transparency to support trade"
- "Transparency of the regulatory process should engender citizens' trust"

On **consumer confidence**, we previously stated that:

- "Experience from the introduction of GMOs in the 1990s indicates that changes to food products made without the informed agreement of consumers are likely to be met with resistance and rejection, even when scientists and regulators are satisfied with their safety. Public support is essential to realising the benefits of genome editing. A broad public dialogue is necessary, in which clarity and transparency will be essential to obtain and maintain trust"
- "This (regulatory) adaptation must safeguard public confidence in the regulatory system, which of course must remain trustworthy to engender such confidence. There is a risk that the perception of a major overhaul of the inherited UK legislation at this stage could cause a public reaction and the erosion of citizen's trust, which is a potential outcome that must be avoided. Citizens must be active participants in a dialogue towards a reform of genetic technologies regulations. However, pressure or interest must not steer the regulatory reform away from an evidence-based approach that supports sustainable and responsible innovation for the benefit of people and the environment"
- "Citizens must be supported and trusted to appreciate how robust the existing regulatory processes are. In reaching out to them with the right set of information campaigns and citizen involvement projects, Government can gain trust back, becoming a trustworthy guardian of public and environmental safety. The Food Standards Agency has already a track record for similar initiatives (see the project 'Trust in a changing world'), which should be built on"

Annex B - Reduced need for animal testing[11]

Risk assessments of GM food and feed introduced by the EU require 90-day feeding trials in laboratory rodents[12]. By focussing on safety assessment based on appropriate, science-based test guidelines, new regulation for genome editing could avoid unnecessary use of experimental animals. A thorough review of the available data, such as the seventh Framework Programme for Research (FP7) data and other relevant datasets, as foreseen in the Regulation (EC) No 503/2003, could inform strategies for replacement of animal testing. Where individual proteins expressed in an organism require testing, an OECD toxicity test can be used.

[11] Royal Society of Biology (2021). Response to the DEFRA consultation on the regulation of genetic technologies – see paragraph 3.22 (page 17).

[12] European Commission, 2013. Commission implementing regulation (EU) no 503/2013.