FSA response to Literature review on analytical methods for the detection of precision bred products

The below is a response to the 'Literature review on analytical methods for the detection of precision bred products.'

Precision Breeding (PB) is an umbrella term for a number of biotechnologies through which plant and animal genes are edited to produce a desirable outcome that could have occurred through traditional breeding methods. Current scientific evidence1 suggests that these organisms do not pose a greater risk than those produced by conventional means, and that most PB organisms (PBOs) are genetically indistinguishable from their traditionally bred counterparts.

The Genetic Technology (Precision Breeding) Act was introduced to establish a proportionate framework for PBOs, and the FSA is intending to implement a new framework to ensure the safety of PB food and feed. As the genetic changes in PBOs could have occurred naturally or through traditional breeding methods, it would not be proportionate to impose stringent regulation. The FSA believes that a more proportionate, evidence-based, regulatory approach is appropriate for PB food and feed. This approach will be underpinned by the FSA Board's agreed 5 key principles: safety, transparency, proportionality, traceability, and building consumer confidence.

The report by LGC was commissioned to identify whether there were methods of detection for PBOs and, if there were, which were most suitable. It recommends investing in more research to establish if detection is consistently possible and, if so, the best methods of detection available, and then to identify opportunities for future detection method development.

This report highlights that there are no methods of providing unequivocal detection of the genetic change in most PBOs defined by the Act, without prior knowledge of the altered genome sequence and suitable reference materials. For those PBOs where detection may be possible, it is not currently feasible to distinguish whether the genetic changes are the result of genome editing, natural variation, or traditional breeding methods. In cases where detection was possible, this is likely to be lost in subsequent generations.

Detectability of PBOs has been raised by stakeholders as a possible tool to facilitate enforcement. However, requesting additional data, outside of safety requirements, would add extra cost for developers and the PB market, reducing the incentives for food businesses to innovate and bring new products to market, which in turn minimises potential benefits. Even if data required to establish an appropriate detection method for some PBOs was obtained as part of the authorisation process, this would not enable the unequivocal identification of how the edit was generated. Since detection cannot currently be guaranteed to a sufficient level of certainty, the efficacy of detection methods as tools for enforcement is limited (Spok et al., 2022; Grohmann et al., 2019).

To maintain a proportionate approach, the FSA will rely on existing food and feed traceability measures and will not be pursuing detection as an enforcement tool at this stage. We do not

currently consider detection as practical due to the capability and capacity required for delivery, nor proportionate to the risks posed. Enforcement bodies would require sufficient intelligence to know what they were looking for, as screening for PBOs is not possible in the same way as it is for GMOs.

The FSA welcomes this report regarding the state of the art of analytical methods and challenges associated with detection of PBOs. However, given the issues of proportionality and feasibility described above, the FSA will not currently be taking forward the recommendations associated with implementing an infrastructure for further development of analytical methods for the detection of PBO products at this time as an aid to ongoing PB policy development. However, we do recognise that exploration of detection methods may be beneficial in the pursuit of knowledge and science in this area, given the fast pace of innovation within genetic technology. We would therefore welcome further research in this area in the future to ensure we have the most up to date scientific information available when reviewing policy and/or developing new policies related to genetic technologies.

1. FAO. 2023. Gene editing and food safety – Technical considerations and potential relevance to the work of Codex Alimentarius. Rome. https://doi.org/10.4060/cc5136en

2. European Network of GMO Laboratories, Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis, Publications Office of the European Union, Luxembourg, 2023, https://doi.org/10.2760/007925, JRC133689.

3. Spök A, Sprink T, Allan AC, Yamaguchi T and Dayé C (2022) Towards social acceptability of genome-edited plants in industrialised countries? Emerging evidence from Europe, United States, Canada, Australia, New Zealand, and Japan. Front. Genome Ed. 4:899331. https://doi.org/10.3389/fgeed.2022.899331

4. Grohmann L, Keilwagen J, Duensing N, Dagand E, Hartung F, Wilhelm R, Bendiek J and Sprink T (2019) Detection and Identification of Genome Editing in Plants: Challenges and Opportunities. Front. Plant Sci. 10:236. https://doi.org/10.3389/fpls.2019.00236