Submission from Beyond GM on the draft Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025

Beyond GM is a UK-based civil society organisation. Its aim is to raise the level of the discussion around genetic engineering and other novel approaches in food and farming to make it more thoughtful and inclusive. To this end, we undertake a range of advocacy activities from public-facing engagements and publications to more structured and formal events aimed at deep-dive discussions.

We submit, below, general comments about the above regulation and outline our concerns about removal of the ten-year reauthorisation requirement for certain regulated food/feed products. We have discussed some of these considerations with others who may also submit a response. These concerns are relevant to all the novel foods encompassed by the regulation, but are of particular relevance to genetically modified organisms (GMOs).

1. General comments

Lengthy post-Brexit regulation 'packages' like this may be viewed as an efficiency but we are concerned that the breadth of this regulation makes effective pre-legislative scrutiny more difficult. We are also aware that some of the EU regulations being amended appear to be awaiting updates on the government website. This, again, makes effective scrutiny difficult.

This lack of clarity makes a comprehensive Explanatory Memorandum (EM) even more important. However, we find the EM to be rich in rhetoric – e.g. 'streamline' (EM 5.4, 5.13, 5.18, 6.2), 'efficiency' (EM 5.1, 5.2, 5.19, 6.2) and 'proportionate' 5.2, 5.5, 5.15, 6.2) – but otherwise less helpful than it should be.

The decision to remove a reauthorisation process for a whole range of food/feed additives, including GMOs, may be considered a policy decision (albeit based on a consultation where most respondents represented industry interests). However, it has inevitable practical impacts on how the regulation will work in practice and on those agencies tasked with protecting food safety. These in turn can impact public safety and trust in the food system.

We note that in the consultation response, "the Government Chemist (part of DSIT and hosted by LGC), expressed the view that the renewals process provides necessary scientific checks on the currency of validation methods." This is our view as well.

The removal of ten-year re-authorisation requirements for GMOs and other novel regulated products represents a significant deregulatory shift in the UK's food safety system. While this reform might increase efficiency and reduce costs, it also introduces potential weaknesses in proactive food safety oversight which we believe have not been adequately considered:

- The proposed regulatory changes will lead to reactive rather than proactive oversight, reduce regulatory transparency and weaken consumer protection.
- The basis of these changes is predicated on certain presumptions that are not just a matter of policy but which have a real-world impact on how the regulation might function in practice.
- Given the rapid advancement of genetic modification technologies and the complex nature of their potential long-term effects, we urge the Committee to consider these implications – for public health, business liability and consumer trust – in moving from a structured review to an open-ended regulatory framework.
- The lack of a thorough and transparent impact assessment for this regulation is a significant deficit and is linked to a broader pattern of inadequate impact assessments in related GMO legislation.

We expand on these points below.

2. Questionable Presumptions

The regulation and EM make several presumptions which cannot be taken as fact. Regulating based on these presumptions could have adverse effects on food safety. We acknowledge this may be a borderline consideration for the Committee. However, the context is important to understand how the regulation might function and, what its impacts may be, in practice. These presumptions include:

- **Initial risk assessments are sufficient** The removal of ten-yearly renewal requirements presumes that once a GMO is authorised, it remains safe indefinitely unless new evidence emerges (EM 5.16). However, long-term safety (and indeed environmental) impact assessments for many GMOs are incomplete or evolving and should be assessed on a case-by-case basis, as risks may only become apparent decades after widespread use. The FSA's Advisory Committee on Novel Foods and Processes (ACNFP) has noted "Members commented that identifying potential food and feed safety risks associated with use of modern biotechnologies now and in the future is difficult."

- **Risk detection will be prompt and effective** Without scheduled reauthorisation, safety assessments depend on new evidence triggering a review. This raises concerns about whether surveillance mechanisms are robust enough to detect risks before harm occurs. While the FSA and FSS maintain powers to review authorisations if concerns arise (EM 5.3), eliminating the ten-year review shifts the burden onto post-market monitoring rather than structured pre-emptive safety assessments. This presumes that post-market surveillance and ad hoc safety reviews are robust and thorough enough to identify and mitigate risks promptly. It also relies on voluntary industry reporting, which has historically been inconsistent and

influenced by commercial interests. It further presumes a level of scientific certainty that does not exist.

- **All current and future GMOs will have the same risk profile** This regulation will apply to existing as well as future GMO authorisations, the volume (EM 9.3) and nature of which is unknown. Genetic modification technology is advancing rapidly on several fronts. The presumption of now and future equivalence of relatively simple genetic modifications (e.g., herbicide resistance in crops) and newer AIassisted genetic engineering techniques (e.g., computationally designed proteins, synthetic genomes and self-editing gene 'circuits') cannot be presumed.

- **All current and future GMOs can be treated like conventional foods** This assumption – implicit in the regulatory change – is scientifically, legally, and ethically flawed. GMOs are fundamentally different from conventional agricultural products and require ongoing, structured oversight. Removing the regulatory distinctions between GMOs (and other novel foods|) and conventional foods weakens consumer protections, increases liability risks and undermines public trust in the food safety system. Specific concerns include:

    - **Genetic modifications can have unintended effects** Unlike conventional breeding, genetic modification – including new techniques such as gene-editing (what the UK calls "precision breeding"), introduces foreign or synthetically altered DNA, which can result in unintended mutations, altered protein expressions and unexpected biochemical interactions.

    - **New allergens and toxins** Novel genetic modifications may create unanticipated allergenic or toxic compounds, which are difficult to predict and may not be immediately detectable during initial safety assessments.

    - **Unanticipated long-term health effects** Many GMOs have not been studied across multiple generations, making it impossible to fully assess their long-term health impacts on human metabolism, gut microbiota and immune responses. In addition, newer GMOs, such as precision-bred GMOs, are intended to be eaten as whole foods rather than highly diluted ingredients. This represents an entirely different risk profile which this regulatory change does not acknowledge.

- **FSA will have the resources to engage in adequate post-market surveillance** The FSA does retain powers of oversight (EM 5.3, 5.16). However, the agency has faced funding cuts and workforce shortages, which have limited its ability to enforce food safety rules. Between 2009 and 2019, the FSA's budget was cut by 51%. Recently it has had to limit recruitment to ensure it has an affordable workforce. This has meant the agency has had to scale back plans to support food

safety. There are concerns that the lack of resources is impacting the regulation of food businesses. Allied to this, there are fewer food safety posts funded across England, Wales and Northern Ireland than there were a decade ago. It is, therefore, not a given that these agencies will have sufficient future resources to exercise post-market surveillance on the safety of existing and new GMOs.

3. Risks of open-ended regulation

Unlike pharmaceuticals, which require post-market safety monitoring, GMOs often enter the market without structured long-term tracking of adverse effects. Without periodic reviews, regulatory agencies may fail to detect emerging risks in time to prevent harm. This gap in oversight presents significant challenges for food safety and consumer protection:

Food safety risks: cumulative and emergent hazards

- **Slow to emerge health risks** Whilst the explanatory memorandum (EM 5.1) suggests that "FSA and FSS is advising their respective ministers in England, Wales and Scotland on the approval of regulated products that need to be authorised as safe for consumption before they can be sold on the market" (also EM 5.4), the absence of structured reassessments leaves the UK without a formal mechanism to detect and address slow-developing adverse effects (e.g., allergenicity, microbiome disruptions, metabolic impacts). It is therefore important to ask, on what basis – and using what information – will these agencies be advising Ministers?

- **Lack of 'future-proofing'** Gene Drives, RNAI treatments for plants or soil, GMO starter cultures for meat and dairy analogues, AI-generated GMOs based on computer-generated rather than naturally occurring DNA – any of these emerging genetic modification technologies may lead to highly novel biochemical structures that regulators lack experience in assessing. A reliance on post-market monitoring, which may be inconsistent within and between the UK nations, may fail to capture unintended biochemical interactions in humans, animals (and the environment).

- **GMOs in the UK food system are currently labelled.** Our engagement with the government and FSA, however, suggests an intention to remove labelling, first from precision-bred organisms (via the Genetic Technology Act 2023), and then GMOs more widely. Clear and unambiguous labelling is crucial for effective post-market surveillance, making this regulatory change both a failure of foresight and consideration of existing and pending GMO legislation (see also 'Consumer backlash' below).

    - **Lists versus registers** The regulation describes "lists" and "registers" of GMOs and other products. It is not clear to us what the difference is or how these will be coordinated between different authorities. However, for food

shoppers, a list/register on a government website cannot be taken as providing equivalent information as a point-of-sale label on a food product. FSA's own research (here and here) shows that 8 out of 10 people surveyed want GMOs/PBOs to be labelled. This figure is supported by consumer research from Beyond GM and the Nuffield Council on Bioethics. FSA also found that most respondents said they would have no reason to use a register unless there was labelling.

Legal and business liability Issues

Structured, periodic reassessments encourage vigilance and ensure that information on individual foods or food additives remains up-to-date. Again, we acknowledge that this may be a borderline consideration for the Committee. Nevertheless, without reassessment, should safety concerns arise years after authorisation, it will be unclear whether the responsibility lies with developers/manufacturers, regulators or retailers. This is a real-world impact.

- **Potential for retrospective bans and product withdrawals** Future bans or restrictions could impose significant financial losses on businesses that had assumed perpetual authorisation. Food recalls can result in significant economic losses across the supply chain. Food allergen recalls, for example, are increasing and costly. FSA's own research shows food hypersensitivity-related hospitalisations cost approximately £80 million a year. For major retailers, the cost of a recall due to cross-contamination or the presence of unwanted allergens can be on average £1 million per incident.

- **Insurance and financial risk** The removal of periodic risk assessments increases uncertainty for insurers, potentially leading to higher premiums or refusal of coverage for companies engaged in producing GMO food/feed. This could create additional barriers for businesses operating in the GMO sector and potentially limit innovation and market growth.

Consumer backlash

The explanatory memorandum (EM 5.7) states, "This SI allows ministers to specify selected transitional measures (allowing time for existing stocks to be used, the product to continue to be produced and product labelling to continue to be applied) in future authorisation decisions and retains sufficient powers to prescribe by SI any other transitional provisions that may be necessary."

Implicit in this is Ministers' unchecked power to remove aspects of regulation, such as labelling in the future, in a way that will not benefit from full parliamentary scrutiny. This is a consumer as well as a constitutional issue. Key impacts include:

- **Erosion of consumer trust** Consumers might view the removal of structured safety reassessments as weakening food safety protections, leading to a decline in trust in regulatory authorities.

- **Erosion of consumer choice** If GMOs are treated the same as conventional foods, this may lead to weaker labelling laws, reducing transparency and preventing consumers from making informed choices.

Lack of labelling effectively hides GMOs in the food system (see also 'Lists versus registers' above). Consumer backlash against "hidden" GMOs in the food supply has been documented in several countries including the US, Canada and most recently Mexico. In the United States, in December 2024, swingeing deregulatory changes to GMO regulations brought in in 2020 were struck down by a federal court which ruled they were inconsistent with the government's previous positions and with the available evidence. The government has been ordered to reinstate pre-2020 regulations for GMOs. The Committee should consider the basis of the UK's changes in regulation and whether the same legal challenge might happen here.

4. Failure to produce a thorough impact assessment

The failure to produce a full impact assessment (EM 9.1) suggests that food safety authorities and the government have failed, or are deliberately ignoring, the broad and increasing scope of deregulation around genetically modified food products in the UK. We would like to draw the Committee's attention to:

- The lack of full impact assessment performed by the FSA for its Consultation on proposals for a new framework in England for the regulation of precision-bred organisms used for food and animal feed, the results of which are central to this regulation and the pending secondary legislation for the Genetic Technology Act.
- The consultation relied, in part, on the Impact Assessment for Defra's Genetic Technology Bill. However, the Regulatory Policy Committee opinion twice rated this impact assessment as "not fit for purpose".
- The misleading nature of the impact assessment for the Defra Deliberate Release Amendment 2022 which estimated only 1-2 applications for open-air trials of experimental precision-bred crops in the UK. Since that regulation was passed, there have been approximately 8 trials per year in 2023 and 2024 and this number will rise in 2025 when open-air trials will take place on up to 25 farms across England.

Thorough, realistic and transparent impact assessments are fundamental to good legislation. We urge the Committee to consider the increasing lack of transparency, inclusive and publicly available evidence and peer review informing impact assessments for GMOs in the UK.

5. Conclusion

This regulatory change places greater reliance on post-market monitoring rather than pre-emptive safety controls. In our view, the removal of periodic reauthorisations for GMOs and other novel regulated products puts the FSA (and potentially other UK regulatory authorities) at odds with its core mission, which, according to the Food Standards Act 1999, is: "to protect public health from risks which may arise in connection with the consumption of food (including risks caused by the way in which it is produced or supplied) and otherwise to protect the interests of consumers in relation to food."

Whether this shift in regulation protects public health – and indeed businesses – as effectively as the previous system depends on how rigorously the FSA and FSS conduct ongoing risk assessments and market surveillance. This, in turn, depends not only on available resources but on a steady and up-to-date flow of information which could be halted with the introduction of 'regulate-and-forget' legislation.

4 February 2025

Response from the Food Standards Agency

Q1: How do you respond to the suggestion that the removal of the 10-yearly renewal process would lead to more reactive, rather than proactive, oversight of regulated product authorisations?

- A1: Removing the 10-year fixed renewal requirement for certain products introduces a more consistent, proportionate and evidence-based approach.
- The reforms will remove the 10-yearly renewal requirement for feed additives, smoke flavourings and food or feed containing, consisting of or produced from genetically modified organisms (GMOs). All other regulated products, including products such as novel foods and food additives, do not have this requirement. All regulated product regimes already rely on the FSA/FSS's robust risk analysis approach for detecting any emerging risks.
- This existing risk analysis approach provides mechanisms for monitoring new evidence and addressing emerging risks promptly. The FSA and FSS use horizon scanning, risk analysis and post-market monitoring tools to identify and consider emerging risks and inform them whether products are safe to remain on the market.
- The FSA and FSS will focus on horizon scanning and risk assessment to respond to new safety evidence as it emerges. This will inform them whether already authorised products are safe to remain on the market at any time, instead of working to arbitrarily fixed renewal timetables that require comprehensive reviews for all products, even if there is no new evidence to suggest this is needed. If new evidence emerges that requires a review of an authorisation, the FSA and FSS will assess the evidence and

provide advice to Ministers to inform decisions regarding potentially modifying, suspending or revoking authorisations.

Q2: Given the removal of the 10-yearly renewals process would shift the burden onto post-market monitoring and surveillance to identify risks and issues that would trigger reassessment of product authorisations, how will you ensure that this monitoring and surveillance is prompt and robust enough to make sure issues are identified before any food safety issues or harms to consumers arise?

- A2: The FSA and FSS will continue to maintain food and feed standards through their rigorous safety assessment and risk management approach and post-market monitoring requirements.
- The FSA and FSS gather intelligence on all authorised products, regardless of the regime. They do so in different ways, such as by using:
  - Safety assessments produced by other international regulators, including the EU, the UN Food and Agriculture Organisation, and the World Health Organisation;
  - Global networks, such as International Food Safety Authorities Network (INFOSAN) and Rapid Alert System for Food and Feed (RASFF);
  - Horizon-scanning by the FSA and FSS Scientific Advisory Committees, and scientific community reporting;
  - Developments in analytical methodology to keep appraised of techniques used for detection and enforcement purposes;
  - Well established incident reporting mechanisms that cover all food and feed (including regulated products), which the public can use to report safety concerns to the FSA and FSS.
- If new evidence emerges that requires a review of an authorisation, the FSA and FSS will assess the evidence and provide advice to Ministers, to inform decisions regarding potentially modifying, suspending or revoking authorisations.

Q3: How robust is post-market monitoring and surveillance in detecting slow-to-emerge health risks from regulated products, compared to the 10-yearly review process?

- A3: The current legislation requires applicants to apply for a renewal of an authorisation for feed additives, smoke flavourings and GMOs at 10-yearly intervals. No other regulated product regimes have this requirement, and all regimes already rely on the FSA/FSS's robust risk analysis approach for detecting any emerging risks.
- This existing risk analysis approach already provides explicit mechanisms for the FSA/FSS to monitor new evidence and detect emerging risks regarding authorisations at any appropriate time. This evidence comes from a wide range of sources, including from food or feed businesses, other regulators or risk assessment bodies, and publications/studies in scientific journals.
- In addition to the current renewal requirements every 10 years, authorisation holders must also legally comply with other supervision obligations throughout legislation. This

includes informing the FSA/FSS at any time if there is any new scientific or technical information which might influence the evaluation of the safety in use of the food or feed.

- To date, revocations of authorisations due to safety concerns have generally been actioned through reviews of information that take place outside of the renewals process.
- Requirements such as the submission of post-market monitoring reports and post-market environmental monitoring and reporting will continue to be set within the terms of authorisation of products where appropriate and necessary. During the safety assessment of applications for authorisation, potential chronic effects that may be slow to detect are considered.
- Businesses will need to continue to conduct any post-market monitoring and post-market environmental monitoring requirements applied to current authorisations, including supplying reports to the FSA/FSS.

Q4: How confident are you that the FSA has enough resources to undertake sufficient post-market monitoring and surveillance of regulated products, particularly given concerns over recent funding cuts and workforce shortages?

- A4: Under the General Food Law (assimilated Regulation (EC) No 178/2002), it is the responsibility of businesses across all regulated product regimes to tell regulators if they have reasons to believe that placing the food or feed product on the market is unsafe.
- Businesses will continue to be required to undertake any post-market monitoring and post-market environmental monitoring requirements where applicable, including supplying these reports to the FSA/FSS.
- The FSA/FSS have a robust risk analysis approach in place that allows them to monitor new evidence about authorisations at any time. This evidence can come from various sources, such as food or feed businesses, other regulatory bodies, risk assessment organisations, and scientific journal publications or studies.
- By focusing on detailed reviews of products that potentially pose the most risk, rather than continually reassessing products that have consistently demonstrated safe use, the regulatory service will be more efficient and effective.
- We anticipate that there will be a relatively small number of authorisations that will require a review on the basis of safety, compared to the large number of renewals currently processed. The process of renewing approvals is long and costly. There are currently 481 live applications in the system of which around 100 are renewals, which will be removed when this SI comes into force. Nearly 500 additional renewal applications are expected in the next three years as renewal periods are set to expire.
- An evidence-based review system will ensure already authorised products are reviewed based on risk and new evidence, rather than on a fixed timetable that burdens industry and the public sector with a comprehensive review even if there is no new evidence to suggest this is needed.
- Removing set renewal periods will allow a more targeted approach to regulation. This will help focus resources on new and innovative products.

Q5: The submission argues GMOs are fundamentally different from conventional foods due to their sometimes unintended and unanticipated effects. How do you respond to the suggestion that GMOs should require more regular, structured reviews and not be treated the same as other regulated product regimes by removing the 10-yearly renewals process?

- A5: Before a GMO is authorised it is rigorously assessed for safety, including evaluation of unintended effects and consideration of potential chronic effects that may be slow to detect.
- Removing the 10-year fixed renewal requirement introduces a more proportionate, evidence-based approach to regulation. The FSA and FSS will be able respond to new safety evidence, including any emerging from this monitoring, instead of working to arbitrary 10-yearly fixed renewal timetables.
- The FSA and FSS will continue to set requirements within the terms of authorisations for these products, including for the submission of post-market monitoring reports and post-market environmental monitoring and reporting where applicable. Post-market environmental monitoring and reporting requirements are applied to all GMO authorisations. Businesses will need to continue to comply with any post-market monitoring and post-market environmental monitoring requirements applied to current authorisations, including supplying reports to the FSA/FSS.
- Businesses submit annual reports to the FSA/FSS. This monitoring and reporting confirms the environmental risk assessment for the authorised product and checks whether there have been any effects that weren't predicted. This helps ensure that GMOs don't have unexpected adverse effects on the environment.
- GMO authorisations include details of the laboratory-based methods that have been validated for the identification, detection, and quantification of the GMO. Following the reforms, businesses will continue to be required to notify the FSA and FSS if they have any new information which might affect the suitability of a validated method. This will allow the FSA, FSS and LGC (the UK National Reference laboratory for GMOs) to provide scientific checks to ensure that the previously approved method is still current.
- The FSA and FSS will make it clear in their guidance to businesses how they can supply information related to authorisations, including post-marketing monitoring reports, post-market environmental monitoring reports and updates or changes to analytical or detection methods.

Q6: Do you anticipate that the removal of regular, structured product assessments could erode consumer trust in the UK's food safety record and the FSA?

- A6: The FSA and FSS have earned the trust of the public through their rigorous approach to risk analysis. This approach is taken across all regulated product regimes, the majority of which do not have renewal requirements.
- Food safety will continue to be the priority of FSA and FSS, and these reforms will improve efficiency while maintaining robust safety standards.

- The reforms build upon existing powers where the FSA and FSS can request information for review, and for businesses to proactively provide it. The reforms ensure that the regulatory framework remains both comprehensive and adaptive and enables the regulators to respond swiftly and effectively to emerging risks. Where necessary, approvals can be modified, suspended or even revoked.

7 February 2025