EXPLANATORY MEMORANDUM TO

THE GENETICALLY MODIFIED FOOD AND FEED (AUTHORISATIONS) (ENGLAND) REGULATIONS 2022

2022 No. 486

1. Introduction

1.1 This explanatory memorandum has been prepared by The Food Standards Agency (FSA) and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The main purpose of this instrument is to authorise nine Genetically Modified Organisms (GMOs) for food and feed uses, thus allowing them to be distributed and available on the market in England. Of the nine GMOs, four relate to new authorisations of maize, four are renewals of previous maize authorisations and one relates to a new authorisation of soybean.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The GB feed industry has expressed concerns to the Department for Environment, Food and Rural Affairs (Defra) about supply risks due to the war in Ukraine. Ukraine had been a major exporter of maize before the war, and without that supply, industry is seeking other alternatives. As eight of the nine GMOs are maize products, the FSA intends to ensure legislation authorising the products comes-into-force as soon as possible, whilst still adhering to the 21-day convention in England and Wales.

3.2 The Scottish SI authorising the GMO products for placing on the market in Scotland will come into force on 31st May. This is due to the Scottish Government requiring legislation not to come into effect until 40 days after laying. Due to the market access principles of the UK internal market act, the nine GMOs (when imported into England and Wales) will be able to be marketed in Scotland from 20th May when the authorisations are scheduled to come into force in England and Wales (a separate instrument will authorise the products for placing on the market in Wales). Authorisations for the nine GMOs will expire ten years after coming into force in each country (unless renewed). Market access principles will similarly allow products imported into Scotland to be marketed in England and Wales until the end of 30th May 2032, when the authorisations are due to expire in Scotland.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England only.

5. European Convention on Human Rights

5.1 As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 GMOs are a regulated product and require authorisation in legislation to be available on the market.

6.2 The legislative framework around the authorisation of GMOs for food and feed uses is largely contained in retained Regulation (EC) No 1829/2003 (Regulation 1829/2003).

6.3 Existing authorised GMOs are required to be renewed after 10 years and follow the application and legislative process set out in Regulation 1829/2003.

6.4 Legislation is in place to regulate the conditions of labelling for GMOs for feed and food uses, these labelling requirements are referred to in this instrument.

6.5 The Secretary of State for Health and Social Care has accepted the advice of the FSA that the five new GMOs and the four GMOs for renewal are safe and has agreed to the GMOs to be authorised to allow their use in England.

7. Policy background

What is being done and why?

7.1 This authorisation relates to nine GMOs for food and feed use, five new and four renewals for authorisation. The FSA opinion is that these GMOs are safe.

7.2 GMOs are a regulated product and in order for these products to be made available on the market for use in food and feed in England, they are required to go through a formal application process with the FSA.

7.3 Following this application process the FSA advises the Secretary of State of which GMOs it recommends should be approved for use in England following an application for authorisation.

7.4 Before leaving the EU, the UK accepted the assessments of the European Food Safety Authority (EFSA) in support of authorisation for regulated food and feed products. EU Food Law on GMO uses continues to apply in Northern Ireland under the current terms of the Northern Ireland Protocol (NIP). Since the end of the transition period, Great Britain (GB) has also adopted the same technical guidance and quality assurance processes to make independent GB risk assessments.

7.5 These GMOs were originally submitted to the EFSA prior to the end of the transition period on leaving the EU.

7.6 The EFSA has published an opinion on these GMOs and this opinion and all supporting documentation has been reviewed by the FSA, forming an independent opinion based on risk assessment and safety conclusions. The FSA opinion is that the GMOs, as described in the applications, are safe to human and animal health and there are no concerns relating to the environment. The FSA opinion is available at the following website: https://www.food.gov.uk/news-alerts/consultations/applications-for-nine-genetically-modified-organisms-for-food-and-feed-uses

7.7 These GMOs are for import only and not for cultivation in the UK.

7.8 The individual GMOs offer a mixture of some resistance to pests, drought and herbicides.

7.9 All nine of these GMOs for food and feed uses have been authorised for use in the EU.

7.10 The decision to authorise these GMOs is made in the best interests of the UK where independent UK risk analysis has been undertaken.

7.11 As part of the common framework agreements with the devolved administrations since the end of the transition period, the FSA has worked alongside Food Standards Scotland. Relevant Ministers in Scotland and Wales have also agreed to the authorisations of the GMOs and will be submitting their own Statutory Instruments in their respective countries.

7.12 This will be the first set of regulated GMO products to go through the national authorisation process since the UK left the EU.

Explanations

What did any law do before the changes to be made by this instrument?

7.13 Prior to EU exit the authorisation of regulated products was undertaken by EU legislation where GMOs underwent the same processes before being added to the authorised register and made available on the EU market.

7.14 Following EU exit previously authorised GMOs for food and feed use by the EU continued to be authorised in GB under retained EU law (REUL). Directly applicable EU legislation for GMO food and feed has been retained in the UK as REUL. Ministers are empowered under REUL to agree to the authorisation of new GMOs for food and feed use for placing on the market.

Why is it being changed?

7.15 The only change is to authorise new GMOs for placing on the market in England. Legislation is the only route for regulated products, including GMOs to be available on the market in England.

What will it now do?

7.16 This policy will allow the specified GMOs to be available on the market in England for food and feed use.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 This instrument does not involve consolidation and there are no plans to consolidate the relevant legislation at this time.

10. Consultation outcome

10.1 The public consultation on the GMOs being authorised by this instrument was launched by the FSA and Food Standards Scotland (FSS) on 30th November 2022 and lasted for 8 weeks.

10.2 This consultation sought views from the public and stakeholders on the proposed regulated GMOs, to consider any relevant provisions under retained EU law and other legitimate factors, including other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors.

10.3 Stakeholders and enforcement authorities were informed of the consultation being launched and were encouraged to comment. This included animal feed manufacturers, importers/exporter and retailers, trade bodies representing the environment, farming and stakeholders known to be opposed to GMOs to ensure a broad spectrum of opinion.

10.4 The FSA public consultation had a broad reach, through the FSA website, subscription alerts, social media posts and direct contact with key stakeholders. 18,165 subscribers to UK wide FSA alerts, and a further 43,900 subscribers to country specific England, Wales and Northern Ireland alerts received automatic notifications.

10.5 The FSS consultation also had an extensive reach, through the FSS website, subscription alerts, social media posts and publication in relevant reports. A link to the consultation was sent to 114 subscribers to GM food and feed updates, 71 interested parties with Scottish Government and was also published in the monthly enforcement report which has 180 members including local authorities.

10.6 On social media the FSA consultation was shared with 58,300 Twitter followers and 87,200 LinkedIn followers, while the FSS consultation was shared with 5267 Twitter followers and 2095 LinkedIn followers.

10.7 A total of 76 and 37 responses were received to the FSA and FSS consultations respectively. Both consultations attracted responses from industry, non-government organisations (NGOs) and individuals.

10.8 76 responses were received from England, Wales and Northern Ireland, nine responses from private individuals and trade associations of whom represent in excess of 75,000 members, were in support of the authorisations. Those not in support included private individuals and non-government organisations.

10.9 37 responses were received in Scotland. Responses from three private individuals and a trade association representing 9,000 members were in support of the authorisations. Those not in support included private individuals and non-government organisations.

10.10 All those representing industry were in favour of the authorisations, citing the lack of safety concerns with GMOs and the potential for trade disruption and increased costs if they are not authorised as the main reasons for this view. Trade bodies did, however, raise concerns over the speed of authorisation and the desire for the UK to deliver authorisations at pace now that we have left the EU.

10.11 The private individuals and not for profit organisations who were not in favour raised concerns as to the adequacy of the EFSA risk assessments, the effects of the consumption of GMOs on human health and the environmental impacts including potential for increased use of herbicides.

10.12 Responses both for and against authorisations were low in numbers compared to the actual number of stakeholders reached.

10.13 Stakeholders' concerns were carefully considered, advice was sought from the FSA Science, Evidence and Research Directorate to review the scientific responses

provided on the FSA/FSS opinion. The responses did not alter the FSA and FSS views on safety.

The FSA published consultation with responses can be found at the following website: https://www.food.gov.uk/news-alerts/consultations/applications-for-nine-genetically-modified-organisms-for-food-and-feed-uses

10.14 The FSS published consultation with responses can be found at the following website: https://consult.foodstandards.gov.scot/regulatory-policy/publication-of-fss-opinion-and-consultation-on-app/

11. Guidance

11.1 No guidance is being provided, this relates to the addition of GMOs to be made available on the market in England. These are facilitative measures, and no guidance is required for enforcement authorities.

11.2 The FSA publish guidance on GMO authorisations on their website, this can be found at the following website: https://www.food.gov.uk/business-guidance/regulated-products/genetically-modified-organisms-guidance

12. Impact

12.1 There is no significant impact on businesses. This instrument will authorise the GMOs to be marketed in England.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument because the regulations are only designed to allow authorised GMOs to be placed on the market in England. The familiarisation costs are expected to be minimal and if so, would fall below the *de minimis* threshold.

12.4 Stakeholders were encouraged to highlight any potential impacts throughout the consultation period with potential impacts of trade disruption and increased costs highlighted.

13. Regulating small business

13.1 This instrument does not apply to activities that are undertaken by small businesses.

13.2 This instrument authorises regulated GMOs for food and feed onto the open market in England. GMOs are traditionally of interest to large national to international businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is that the authorisation holder must ensure that the monitoring plan for environmental effects is implemented. The authorisation holder must submit annual reports on the implementation and the results of the activities set out in the monitoring plan to the FSA.

14.2 This instrument does not include a statutory review clause. In line with the requirements of the Small Business, Enterprise and Employment Act 2015, a review clause is not deemed appropriate considering the legislation is expected to have an economic impact of less than +/- £5 million (net annualised). Other factors include the requirement in the legislation for the authorisation holder to submit annual reports

on the implementation of the monitoring plan and the validity of the authorisations set out in the legislation being limited to a 10-year period only. If authorisation-holders apply for authorisations to be renewed after expiry, the applications are further scrutinised before going through the same authorisation procedure.

15. Contact

15.1 Chris Stockdale at the Food Standards Agency email: Chris.Stockdale@food.gov.uk can be contacted with any queries regarding the instrument.

15.2 Michael Wight, Deputy Director for Food Policy at the Food Standards Agency can confirm that this explanatory memorandum meets the required standard.

15.3 Maggie Throup MP, Parliamentary Under-Secretary of State for Vaccines and Public Health at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.