EXPLANATORY MEMORANDUM TO

THE GENETICALLY MODIFIED FOOD AND FEED (AUTHORISATIONS AND MODIFICATIONS OF AUTHORISATIONS) (ENGLAND) REGULATIONS 2023

2023 No. 235

1. Introduction

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

2. Purpose of the instrument

2.1 The main purpose of this instrument is to authorise eight applications and three modifications of authorisation holders' details of genetically modified (GMO) food and feed uses, thus allowing them to be distributed and available on the market in England. Of the eight, six relate to new authorisations of maize, soybean and cotton and two are renewals of previous maize and oilseed rape authorisations. The three modifications relate to the authorisation holders name and addresses.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) 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). https://www.legislation.gov.uk/eur/2003/1829/contents

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 six new GMOs and the two GMOs for renewal are safe and has agreed to the GMOs to be authorised to allow their use in England.

6.6 Under Article 9 (2) and 21 (2) from Regulation (EC) No 1829/2003, authorisation holders must apply to the Appropriate Authority for modifications to their existing authorisations. This includes administrative changes such as change of address and authorisation holder details.

7. Policy background

What is being done and why?

7.1 This authorisation relates to eight GMOs for food and feed use, six new, two renewals for authorisation. The FSA opinion is that these GMOs are safe. There are also three modifications for authorisations to change the authorisation holders' details, this administrative change does not affect the safety of the products.

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 authorisations 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 Eight of these GMOs were originally submitted to the EFSA prior to the end of the transition period on leaving the EU and have been authorised for use in the EU.

7.6 The EFSA has published an opinion on eight of these GMOs and this opinion and all supporting documentation has been reviewed by the FSA, who have formed 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 and scientific opinion is available through this link: Consultation on applications for eight genetically modified organisms (GMOs) for food and feed uses and for the change of authorisation holder for fifty-one authorised GMOs | Food Standards Agency These GMOs are for import only and not for cultivation in the UK.

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

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

7.9 The modification of three authorisation holders' names and addresses; under Article 9 (2) and 21 (2) of Regulation (EC) No 1829/2003, authorisation holders must apply to the Appropriate Authority for any modifications.

7.10 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.

7.11 This will be the second 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?

Authorisations

7.12 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.

7.13 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.

Modifications

7.14 Modifications were enabled by EU legislation. Applications would be made to the competent authority of a Member State, with the Commission assessing the application and undertaking the necessary amendments to the addresses and authorisation holder details as required.

7.15 Following EU exit, previously authorised GMOs by the EU continued to be authorised in GB under REUL. Ministers are empowered under REUL to agree to the modification of authorisations of GMOs.

Why is it being changed?

Authorisations

7.16 The change is to authorise 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.

Modifications

7.17 To modify the authorisation holders' details.

What will it now do?

Authorisations

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

Modifications

7.19 Ensure that the authorisation holders' details are correct and up to date.

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 consolidate any legislation 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 on 12th October 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. 22,900 subscribers to UK wide FSA alerts, and a further 30,991 subscribers to country specific England, Wales and Northern Ireland alerts received automatic notifications.

10.5 On social media the FSA consultation was shared with 60,000 Twitter followers and 98,300 LinkedIn followers,

10.6 A total of 38 responses were received from England, Wales and Northern Ireland, 4 responses from 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.

10.7 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.

10.8 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.

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

10.10 The FSA published consultation with responses can be found here: https://www.food.gov.uk/news-alerts/consultations/consultation-on-applications-for-eight-genetically-modified-organisms-gmos-for-food-and-feed-uses-and-for-the-change-of

10.11 The FSS also published their own consultation and responses can be accessed through this link. https://consult.foodstandards.gov.scot/regulatory-policy/tranche2-gmo/

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, which can be found here: www.food.gov.uk/business-guidance/genetically-modified-organisms-authorisation-guidance

12. Impact

12.1 There is no significant impact on businesses, charities or voluntary bodies.

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, renews and modifies 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 Katy Williams at the Food Standards Agency email: katy.williams@food.gov.uk can be contacted with any queries regarding the instrument.

15.2 Mark Hitchen, Interim Deputy Director of Regulatory Services at the Food Standards Agency can confirm that this explanatory memorandum meets the required standard.

15.3 Neil O'Brien MP, Parliamentary Under-Secretary of State at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.