Explanatory Memorandum to The Genetically Modified Food and Feed (Authorisations and Modifications of Authorisations) (Wales) Regulations 2023.

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Deputy Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Genetically Modified Food and Feed (Authorisations and Modifications of Authorisations) (Wales) Regulations 2023.

Lynne Neagle MS
Deputy Minister for Mental Health and Wellbeing
29 March 2023

PART 1

1. Description

1. The purpose of this instrument is to give legal effect to the Welsh Ministers' determination of eight Genetically Modified Organisms (GMOs) applications and approval of the modification of authorisation holders' details (three applications) for food and feed uses in favour of authorisation.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

2. None.

3. Legislative background

3. Regulated products are food and feed products which require authorisation before being placed on the market[1].

4. As of 1 January 2021, Great Britain (GB) has been responsible for the risk assessment and authorisation of regulated food and feed products.

5. In Wales, the Food Standards Agency (FSA) is responsible for risk assessing regulated food and feed products. As the 'appropriate authority', Welsh Ministers, make decisions on authorisations in relation to Wales.

6. Genetically Modified Organisms (GMOs) are plants and animals with genetic make-up that has been modified using techniques of biotechnology. Genetic modification allows scientists to produce plants, animals, and micro-organisms with specific qualities.

7. The legislative framework for authorising genetically modified food and feed is largely contained within retained Regulation (EC) 1829/2003 on genetically modified food and feed. Authorisations are valid for ten years. Authorisation holders may apply to renew the authorisation for continued marketing.

8. The FSA, on behalf of the Welsh Ministers, will update the register of authorised GM food and feed, as required by Article 7(4) of retained Regulation 1829/2003.

9. This instrument is subject to the negative procedure.

[1] Regulated products include: extraction solvents, feed additives, feed for particular nutritional purposes (PARNUTS), feed detoxification processes, flavourings, food contact materials, food additives, food enzymes, genetically modified food and feed, novel foods and smoke flavourings.

4. Purpose and intended effect of the legislation

10. The purpose of the instrument is to authorise the placing on the market, in relation to Wales, of products covered by eight GMO food and feed applications and to modify, in relation to Wales, the authorisation holders' details for a number of existing authorisations.

11. The eight GMO applications consist of six new and two renewal applications. There is no proposal to authorise the GMOs for cultivation.

12. Whilst it was a Member State, the United Kingdom (UK) accepted the assessments of the European Food Safety Authority (EFSA) in support of authorisation for regulated food and feed products. Since the end of the implementation period, Great Britain (GB) has also adopted the same technical guidance and quality assurance processes to make independent GB risk assessments.

13. Where, prior to the end of the transition period, EFSA evaluated an application for a product for which an application has also now been made to GB authorities, FSA/FSS have decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own independent opinion.

14. The GMOs have been authorised for use in the EU. EU Food Law on GMOs continues to apply to food manufactured in Northern Ireland.

15. This instrument applies in relation to Wales.

16. Corresponding legislation has been made in England and Scotland. The regulations across GB will come into force on 26 April 2023.

5. Consultation

17. On 12 October 2022, the FSA launched an eight-week consultation on the other legitimate factors relevant to the eight GMO applications for authorisation or renewal, and the three applications for modification of authorisation holders' details. A parallel consultation was also launched by Food Standards Scotland (FSS) during this time.

18. A total of 38 consultation responses were received from trade bodies, non-governmental organisations (NGOs), and members of the public. Across the 38 respondents, the majority gave their location as the UK. Of the 38 responses received, all those representing industry (4) were supportive. Of those responding in an individual capacity or representing NGOs, (2 NGOs, 32 individuals) had concerns with the proposed authorisations.

19. The FSA made Welsh local authorities (LAs) aware of the consultation. Furthermore, the FSA made key Welsh stakeholders aware of the

consultation when launched, and updated Welsh stakeholders again one week prior to the consultation closing.

20. Stakeholder responses were thoroughly considered and addressed by the FSA/FSS. Discussions were held on a four-nation basis (FSA, FSA in Wales, FSA in Northern Ireland and FSS), in line with the Food and Feed Safety and Hygiene Provisional Common Framework, to address any potential concerns.

21. A summary of the consultation responses, and the FSA subsequent responses has been published on the FSA website.

6. Regulatory Impact Assessment (RIA)

22. The FSA has assessed the impacts that would result from the authorisation of these GMOs. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e., local authority delivery, health, environment, growth, innovation, trade, competition, consumer interests and small and micro businesses). The FSA did not identify any significant impacts therefore, a full regulatory impact assessment has not been produced.

23. The FSA did identify that the authorisation of these products should generally result in the greater market competition, supporting growth and innovation in the sector.

24. Stakeholders were encouraged to highlight any potential impacts through the consultation period and no impacts were raised.

7. Post implementation review

25. This instrument will be reviewed through the monitoring plans for environmental effects that are required to be implemented pursuant to each of the eight GMO authorisations.

26. The authorisation holder must ensure that the monitoring plan for environmental effects, as submitted in their application to the appropriate authority, 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 Food Safety Authority.

27. Retained Regulation 1829/2003 specifies that GMO authorisations are valid for ten years. After this period, a renewal of the authorisation will be required for continued marketing.

28. Articles 11(1) and 23(1) of retained Regulation 1829/2003, require that renewal applications must be received by the appropriate authority, at the latest, one year before the expiry date of the authorisation.