Explanatory Memorandum to The Genetically Modified Food and Feed (Authorisations) (Wales) Regulations 2022.

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before the Senedd 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) (Wales) Regulations 2022.

Lynne Neagle MS
Deputy Minister for Mental Health and Wellbeing
27 April 2022

PART 1

1. Description

1. The purpose of this instrument is to authorise the placing on the market of nine genetically modified organisms (GMOs) for food and feed uses, thus allowing them to be distributed and available on the market in Wales. The named GMOs are referred to in the Statutory Instrument.

2. This instrument provides for the conditions of the authorisation, under which the nine GMOs may be used in Wales.

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

3. The GB feed industry has expressed concerns to the Department for the 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 authorised by the Deputy Minister for Mental Health and Wellbeing in March are maize products, the FSA intends to ensure legislation authorising the products comes-into-force as soon as possible. The instrument (and the corresponding statutory instrument for England) will come-into-force on 20th May.

4. The corresponding Scottish statutory instrument will come into force on 31 May. Authorisations of GMOs are valid for ten years. Due to the market access principles of the UK internal market act, the nine GMOs will be able to be marketed across GB from 20 May until their authorisation expires ten years after the coming-into-force date in Scotland.

3. Legislative background

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

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

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

[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.

8. The legislative framework for authorising GMOs for food and feed uses is contained within retained Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed. Authorisations are valid for ten years. After this period, authorisation holders may apply to renew the authorisation for continued marketing.

9. 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.

10. This instrument is subject to the negative resolution procedure.

4. Purpose and intended effect of the legislation

11. The purpose of the instrument is to authorise, in relation to Wales, the placing on the market of nine GMOs for food and feed uses.

12. The nine GMOs consist of both new (4) and renewal (4) GM Maize applications and one new GM Soybean application. The authorisations are for food and food ingredients and animal feed containing, consisting of or produced from the GMOs as well as other products containing or consisting of the GMOs. There is no proposal to authorise the GMOs for cultivation.

13. Whilst it was a Member State, the UK accepted the assessments of the European Food Safety Authority (EFSA) in support of authorisations for regulated food and feed products. Since the end of the transition period, the FSA and Food Standards Scotland (FSS) have adopted the same technical guidance, governance, and quality assurance processes to make independent GB risk assessments. Where EFSA, prior to the end of the transition period, evaluated an application for a product for which an application has also now been made to GB, FSA/FSS have decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own independent opinion.

14. All nine GMOs have received a positive risk assessment opinion from the FSA. The European Food Safety Authority risk assessments produced in relation to the applications for the nine products while the UK was part of the EU were reviewed by the FSA Science, Evidence and Research Directorate (SERD) to ensure appropriateness for GB. All nine GMOs have since been authorised for use as food/feed in the European Union/Northern Ireland. The proposed terms of authorisation in Wales are the same as those under which the food and feed products are authorised in the EU/NI.

15. This instrument applies in relation to Wales.

16. Corresponding legislation is being made in relation to England and Scotland.

5. Consultation

17. On 30 November 2021 the FSA launched a three-country wide consultation on other legitimate factors relevant to the nine GMOs for food and feed uses (Wales, England and Northern Ireland). Formal public consultation took place for eight weeks, ending on 25 January 2022. A parallel consultation was also launched by Food Standards Scotland (FSS) during this time.

18. A total of 112 responses were received to the FSA (76) and FSS (36) consultations. Both consultations attracted responses from industry, non-governmental organisations (NGOs) and individuals. Out of the 76 FSA responses, nine were in favour of authorisation and 67 were against. All but one of the respondents were based in the UK. Out of the 36 FSS responses, three were in support and 33 were opposed to authorisation. Two respondents submitted to both the FSA and FSS consultation; both of these responses were from individuals and were negative.

19. Out of the 76 FSA respondents, two were based in Wales. NFU Cymru (who have an estimated 15,000 members) were in favour of the authorisations citing no safety concerns, and that the availability of these crops as part of a balanced diet for Welsh Livestock is important. The response also noted a large proportion of NFU Cymru members rely on imported protein feed containing GMO maize and soya products to provide animals with optimal nutrition while maintaining economically viable businesses and that any disruption to global trade in feed ingredients and products will impact farm businesses and, ultimately, consumers.

20. The second response, which was negative, was received from an individual business in Wales with concerns regarding environmental impacts, and insect welfare in the countries in which the crops are grown, crop resistance to pesticides and they cited awareness of independent organisations that have criticised EFSA's risk assessments. FSS consultation received a negative response from an organic farmer in Aberystwyth, who advocated for food production without the need of chemical or genetic manipulation.

21. Stakeholder concerns were thoroughly considered and addressed by FSA/FSS. FSA GM Policy officials sought advice from the FSA Science, Evidence and Research Directorate (SERD) to review scientific responses provided on the FSA/FSS opinion. Discussions were held on a four-nation basis (FSA in Wales, England and NI, and FSS), in line with the provisional Food and Feed Safety and Hygiene Common Framework, to address any potential concerns.

22. No stakeholder issues were raised during the consultation that would alter the FSA's recommendation to the Welsh Ministers.

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

6. Regulatory Impact Assessment (RIA)

24. 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 or Small and Micro Businesses). The FSA did not identify any significant impacts therefore, a full regulatory impact assessment has not been produced.

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

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

7. Post implementation review

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

28. 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.

29. 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.

30. 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.