Explanatory Memorandum to The Feed Additives (Authorisations) (Wales) Regulations 2022.

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 Feed Additives (Authorisations) (Wales) Regulations 2022.

Lynne Neagle MS
Deputy Minister for Mental Health and Wellbeing
7 November 2022

PART 1

1. Description

1. The purpose of this instrument is to give legal effect to the Welsh Ministers' determination of 11 Feed Additive applications 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, whilst the Welsh Ministers (as the 'appropriate authority' in relation to Wales) make decisions on authorisations.

6. The legislative framework for authorising feed additives is contained within retained Regulation (EC) 1831/2003 on additives for use in animal nutrition. Authorisations are valid for ten years. Authorisation holders may apply to renew the authorisation for continued marketing.

7. This instrument is subject to the negative procedure.

4. Purpose and intended effect of the legislation

8. The purpose of the instrument is to authorise, in relation to Wales, the placing on the market of eleven feed additives for specified feed uses.

9. The authorisations are for;

- nutritional feed additives, the function of which is to provide essential micro-nutrients to animal diets,
- silage additives intended to improve the production, fermentation and/or aerobic stability of silage in the preparation of animal feed,

[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.

- digestibility enhancers to improve the digestibility of animal diets and gut flora stabilisers, the function of which are to have a positive effect on gut micro-organisms to maintain animal health and performance, and
- coccidiostats which maintain the health of animals through the control of gut infections caused by protozoa/parasites.

10. 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 authorities, FSA/FSS have decided to make use of the EFSA risk assessment, where this is appropriate, in forming its own independent opinion.

11. All eleven feed additive applications received a positive risk assessment opinion from the FSA. The EFSA risk assessment produced in relation to the applications for the eleven 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. Ten of the eleven feed additives have since been authorised for use in the European Union. Due to the Protocol on Ireland/Northern Ireland, the ten feed additives are also authorised for use in Northern Ireland. Due to administrative changes to update the classification of active agents within a product, one application, Bacillus velezensis (ATCC PTA-6737), has been delayed in receiving formal authorisation by the EU. The proposed terms of authorisation in Wales are substantively the same as those under which the products are, or are expected to be, authorised in the EU/NI.

12. In cases where feed additive authorisations are renewed, the existing authorisation will cease to have effect. Where a specification or conditions of use are changed, transitional measures are implemented to ensure that substances produced in line with the existing authorisation can continue to be used (where this is considered appropriate) until existing stocks are depleted, to avoid supply-chain and economic impacts to businesses.

13. This instrument applies in relation to Wales.

14. Corresponding legislation has been made in Scotland and England. The regulations will come into-force on 24 November 2022 in Wales and Scotland and on 25 November in England.

5. Consultation

15. On 7 March 2022 the FSA launched a three-country wide consultation on the other legitimate factors of eleven feed additives (England, Wales

and Northern Ireland). Formal consultation took place for eight weeks, ending on 2 May 2022. A parallel consultation was also launched by Food Standards Scotland (FSS) during this time.

16. Two responses were received to the FSA consultation. One response was received to the FSS consultation (a duplicate of a response to the FSA consultation). The FSA responses were received from industry; firstly, the British Association of Feed Supplement and Additive Manufacturers (BAFSAM), a trade association representing manufacturers and processors of animal feed additives, speciality feed ingredients, premixtures and feed supplements products across the four nations of the UK and Ireland; secondly, from the Agriculture Industries Confederation (AIC), a trade association serving the agribusiness and agricultural supply industries across the UK.

17. AIC had no concerns with the safety of the feed additives and noted in order to mitigate any negative impacts from divergence with the EU, it was vital for the UK livestock feed sector that a wide range of safe and effective additives remain available to the industry. BAFSAM welcomed the publication of the feed additives consultation by the FSA. They also made a general comment on transitional periods, suggesting a case-by-case approach, as some feed additives have a shelf life of 12 months, while compound feed have a shelf life of 24 months. They made further comments around development of the FSA's ongoing approach to the regulated products process.

18. The consultation also sought stakeholder views on proposed transitional arrangements for three of the applications to allow for existing stocks to be depleted (RP130, RP131 and RP1030). No responses were received in opposition to the transitional measures proposed.

19. The FSA made Welsh local authorities (LAs) aware of the consultation prior to launch and sent LAs a link to the consultation once launched. 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 feed additives. 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.