Explanatory Memorandum to The Feed Additives (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 Feed Additives (Authorisations) (Wales) Regulations 2023.

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Deputy Minister for Mental Health and Wellbeing
29 November 2023

PART 1

1. Description

1. The purpose of the Feed Additives (Authorisations) (Wales) Regulations 2023 is to:

- Give legal effect to the Welsh Ministers' determination of the applications for authorisation of thirteen feed additives in favour of authorisation.
- Provide transitional arrangements due to an ID code change for one previously authorised feed additive (Endo-1,4-beta-xylanase (3.2.1.8)), to allow existing stocks to be depleted.
- Revoke spent authorisations.

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

Revocation of spent Cobalt(II) authorisations

2. The Welsh Ministers, by administrative decision in accordance with the urgent authorisation procedure in Article 15 of Regulation (EC) No 18312003 (EUR 2003/1831), provisionally authorised the four feed additives of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate heptahydrate for a further 5 years in Wales. The forms of those provisional authorisations were prescribed by the Feed Additives (Form of Provisional Authorisations) (Cobalt(II) Compounds) (Wales) Regulations 2023 (SI 2023/678 (W. 100)). This instrument amends Commission Implementing Regulation (EU) No 601/2013 (EUR 2013/601) to remove the now-spent entries relating to the previous authorisations for those additives.

3. Legislative background

Authorisation of thirteen feed additives

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.

[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.

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. Feed additives are substances, micro-organisms or preparations (other than feed materials and premixtures) which are intentionally added to feed or water to preform, in particular, one or more specific functions.

7. The legislative framework for authorising feed additives is contained within retained Regulation (EC) No. 1831/2003 (EUR 2003/1831). Legislation to regulate the conditions of labelling and packaging for feed additives is contained under Article 16 of EUR 2003/1831.

8. Prior to EU exit, the 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, FSA has adopted the same technical guidance and quality assurance processes to make independent risk assessments

9. For twelve feed additives, EFSA had published their opinion prior to the GB risk assessment starting. The FSA and Food Standards Scotland (FSS) reviewed each opinion, along with all supporting documentation, when forming their independent safety assessment.

10. The thirteenth feed additive, 3-Nitrooxypropanol (referred to as '3-NOP') is the first application determined which underwent a full FSA/FSS safety assessment.

11. The FSA/FSS opinion in each case was that the feed additives, as described in the applications, are safe for the target species, users, consumers and the environment. A copy of the FSA/FSS opinions are available here: FSA/FSS opinions on twelve applications for feed additives: Summary | Food Standards Agency

12. This instrument applies in relation to Wales. Corresponding legislation has been made in England and Scotland. The legislation will come into force across Great Britain on 22 December 2023.

13. The feed additives authorised by this instrument are authorised for a period of ten years from the date that the instrument comes into force.

14. The FSA maintains a public register of feed additives permitted on the market in Great Britain. The register is available on the FSA website.

15. This instrument is subject to the negative procedure.

4. Purpose and intended effect of the legislation

16. The purpose of this legislation is to authorise, in relation to Wales, the placing on the market of thirteen feed additives.

17. The authorisations are for;

    - nutritional additives, the function of which is to provide essential micro-nutrients to animal diets such as amino acids.
    - technological additives, such as silage additives (substances including enzymes or micro-organisms intended to be incorporated into feed to improve the production, of silage).
    - zootechnical additives, such as digestibility enhancers (substances which, when fed to animals, increase the digestibility of diets through action on target feed materials) and also substances which favourably affect the environment.

18. Of the thirteen feed additives, ten concern new authorisations and concern renewals.

Transitional arrangements

19. This instrument includes transitional arrangements due to an ID code change on the renewal authorisation for one previously authorised feed additive (Endo-1,4-beta-xylanase (3.2.1.8)), to allow existing stocks to be depleted.

5. Consultation

20. On 25 May 2023 the FSA launched an eight-week consultation in England and Wales on the other legitimate factors relevant to the thirteen feed additives. Formal consultation took place for eight weeks, ending on 20 July 2023. A parallel consultation was also launched by Food Standards Scotland (FSS) during this time.

21. A total of seven responses were received from England, Wales and Northern Ireland. These included responses from trade associations who represent in excess of two hundred and fifty members and businesses with an interest in animal feed/ feed additives. Five responses were supportive, one response did not directly apply to the applications that were being consulted on other than a general response to the consultation launch. The other response was from a company that highlighted some minor drafting errors within the FSA/FSS opinion and proposed amendments to be considered for future consultation documents.

22. The FSA made Welsh local authorities (LAs) aware of the consultation 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.

23. Stakeholder responses have been thoroughly considered and addressed by the FSA/FSS. In line with the provisional Food and Feed Safety and Hygiene Common Framework, discussions regarding consultation responses were held on a four-nation basis (FSA in Wales, England, Northern Ireland and FSS). No stakeholder responses altered the FSA's recommendation to the Welsh Ministers.

24. The FSA published the consultation responses on the FSA website.

25. Responses to the FSS consultation can be found on the FSS website.

6. Regulatory Impact Assessment (RIA)

26. 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. This is in line with the policy set out in the Welsh Ministers' code of practice for carrying out regulatory impact assessments for subordinate legislation.

27. 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.