

Explanatory Memorandum: The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (Wales) Regulations 2024

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.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (Wales) Regulations 2024.

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Minister for Mental Health and Wellbeing
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PART 1

1. Description

1. The purpose of The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (Wales) Regulations 2024 is to:
 - Give legal effect to the Welsh Ministers' determination, in relation to Wales, of twenty-five feed additive applications in favour of authorisation and one amendment to the list of uses of feed intended for particular nutritional purposes (PARNUT) for use in animal feed in Wales.
 - Provide transitional arrangements to allow existing stocks of certain previously authorised feed additives to be depleted due to labelling changes and/or changes to conditions of authorisation as a result of provision made by this instrument.

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

2. None.

3. Legislative background

Authorisation of feed additives and amendment to one use of feed intended for particular nutritional purposes (PARNUT)

3. Regulated products are food and feed products which require authorisation before being placed on the market¹.
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', the 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 perform, in particular, one or more specific functions.

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.

7. The legislative framework for authorisation of feed additives is contained within Regulation (EC) No 1831/2003 on additives for use in animal nutrition (EUR 2003/1831). Legislative provision regulating the conditions of labelling and packaging for feed additives is contained in Article 16 of EUR 2003/1831.
8. Feed additives are regulated products and in order for these products to be made available on the market in Wales, they are required to go through a formal application process. The FSA manage the market authorisation of feed additives in Wales and England. Food Standards Scotland (FSS) fulfils the equivalent function in Scotland.
9. 'PARNUT' refers to "feed intended for particular nutritional purpose" as defined in Article 3(o) of Regulation (EC) No 767/2009 on the placing on the market and use of feed (EUR 2009/767). PARNUTs are feed which can satisfy a particular nutritional purpose by virtue of its particular composition or method of manufacture, which clearly distinguishes it from ordinary feed. Article 9 of EUR 2009/767 provides that a PARNUT may only be marketed as such if its intended use is included in the list of intended uses established under EUR 2009/767, and then only where it meets the essential nutritional characteristics for the nutritional purpose included in that list. That list is contained in Part B of the Annex to Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes.

4. Purpose and intended effect of the legislation

10. Before leaving the EU, the UK accepted the safety assessments of the European Food Safety Authority (EFSA) in support of authorisation for regulated food and feed products where directly applicable in the UK. Since the end of the implementation period, GB has also adopted the same technical guidance and quality assurance process to make independent GB safety assessments. After the end of the implementation period on 31 December 2020 assimilated law created consistent practices in certain devolved policy areas across the UK where the four governments agreed it was necessary to maintain UK-wide approaches. New enduring agreements, or 'Common Frameworks, on how the four countries will work together in these policy areas have been developed.
11. Applications for the authorisation of feed additives and one application to amend the PARNUT list were submitted to the GB appropriate authorities. This instrument makes the necessary changes to the relevant legislation to give legal effect to the determinations of the applications for these feed additives and PARNUT. As the 'appropriate authority' for Wales, the Welsh Ministers make decisions on feed additive authorisations in relation to Wales.

12. For applications concerning products for which applications had been submitted to the EU prior to the end of the implementation period on leaving the EU, FSA/FSS have made use of the EFSA risk assessment where appropriate in forming its own independent opinion.
13. The FSA provided the Welsh Ministers with the safety assessments. A copy of the FSA/FSS safety assessments are available on the FSA website, here [Consultation on 24 feed additive applications and one application for feed for particular nutritional purposes \(PARNUT\) for use in animal feed | Food Standards Agency](#) and here [Consultation on one feed additive application for use in animal feed | Food Standards Agency](#)
14. This instrument makes provision in relation to the authorisation of the placing on the market and use in Wales of feed additives. This instrument makes provision for; twelve new authorisations, eight renewed authorisations (including such requested modifications, consolidation and extension of uses as have been granted), and the modification of seven authorisations. The instrument includes transitional arrangements for certain previously authorised feed additives to allow existing stocks to be depleted due to labelling changed and/or conditions of use.
15. The FSA maintains a public register of feed additives permitted on the market in Great Britain. The register is available on the [FSA website](#).
16. This instrument also amends an essential nutritional characteristic of an existing entry in the list of intended uses for feed intended for particular nutritional purposes (PARNUT) in the Annex to EUR 2020/354. The amendment is made using powers under section 74A of the Agriculture Act 1970 (c. 40). The Agriculture Act 1970 powers have been utilised in lieu of Article 10 of EUR 2009/767, pending corrections to the defective wording rendering that article unusable.
17. This instrument is subject to the negative procedure, and applies in relation to Wales. Corresponding legislation has been made in England and Scotland. The legislation will come into force across Great Britain on 20 December 2024.

5. Consultation

18. On 03 April 2024 the FSA launched an eight-week [consultation](#) in England and Wales on the other legitimate factors relevant to twenty-four feed additive applications and one PARNUT application. An additional [consultation](#) on one feed additive application was launched on 5 August 2024 for a period of four weeks. Parallel consultations were launched by FSS during this time.

19. 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.
20. 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.
21. The FSA published the consultation responses on the [FSA website](#).
22. Responses to the FSS consultation can be found on the [FSS website](#).

6. Regulatory Impact Assessment (RIA)

23. The FSA has assessed the impacts that would result from the authorisation of the feed additives within the twenty-five feed additive applications and one PARNUT application. 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.
24. 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.
25. 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.