EXPLANATORY MEMORANDUM TO

THE FOOD AND FEED (REGULATED PRODUCTS) (AMENDMENT, REVOCATION, CONSEQUENTIAL AND TRANSITIONAL PROVISION) REGULATIONS 2025

2025 No. 361

1 Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency (FSA) and is laid before Parliament by Command of His Majesty.

2 Declaration

2.1 Ashley Dalton MP, Parliamentary Under-Secretary of State for Public Health and Prevention at the Department of Health and Social Care confirms that this explanatory memorandum meets the required standard.

2.2 Peter Quigley, Deputy Director for Regulatory Services, at the FSA, confirms that this explanatory memorandum meets the required standard.

3 Contact

3.1 Dominique Gabry, at the FSA, email: Regulatedproductsengagement@food.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the instrument

4 Overview of the Instrument

What does the legislation do?

4.1 This statutory instrument (SI) covers Great Britain (GB) and has two main objectives:

a. to remove requirements for the periodic renewal of authorisations for three regulated product regimes; and

b. to allow authorisations to come into effect following ministerial decision and then be published in an official register or list, rather than being prescribed by SI.

4.2 Regulated products require a risk-assessed authorisation before they can be placed on the market. This SI relates to several food and feed regulated product market authorisation regimes including feed additives; food additives, enzymes and flavourings; food contact materials (FCMs); food or feed containing, consisting of or produced from genetically modified organisms (GMOs); novel foods; and smoke flavourings.

4.3 This SI removes requirements for the ten-yearly renewal of authorisations for certain regulated products already on the market for three of the regulated product regimes (feed additives, GMOs and smoke flavourings). It maintains and does not change existing powers of the FSA and Food Standards Scotland (FSS) to carry out evidence-based reviews, as and when necessary or appropriate, that allow products already on the market to be assessed for safety at any time when new evidence emerges. The instrument removes expiry dates from existing authorisations that, as a result of the changes made by this SI, will cease to be required to go through a renewal process.

4.4 This SI also replaces the requirement to prescribe authorisation decisions by SI with provisions allowing authorisations to come into effect following ministerial decision, and then be published in an official register or list maintained by the FSA for England and Wales and FSS for Scotland.

Where does the legislation extend to, and apply?

4.5 The extent of this SI (that is, the jurisdiction(s) which the instrument forms part of the law of) is England, Wales, and Scotland.

4.6 The territorial application of this SI (that is, where the instrument produces a practical effect) is England, Wales, and Scotland.

5 Policy Context

What is being done and why?

5.1 The FSA is responsible for upholding food safety standards in England, Wales and Northern Ireland, and FSS has equivalent functions in Scotland. A key role for the FSA and FSS is advising their respective ministers in England, Wales and Scotland on the approval of regulated products that need to be authorised as safe for consumption before they can be sold on the market. This instrument simplifies the approval process for regulated products for food and feed that are put on the GB market. The FSA and FSS have jointly developed this SI to improve the efficiency of the Market Authorisation Service, which processes regulated products applications. Food standards and safety will be maintained.

5.2 The changes made by this SI help to provide a modern, efficient, proportionate, and transparent service, which continues to ensure that regulated products are appropriately and safely risk-assessed before being authorised for use as food or feed.

5.3 This SI removes the ten-yearly renewal requirement in three of the regimes, bringing them in line with other regimes (see paragraph 4.3). The instrument removes expiry dates for current authorisations that are subject to renewal and ensures sufficient legislative basis for the FSA and FSS to request information from all businesses involved (and not just authorisation holders), to aid safety assessment, in the event of any new information or developing concerns. For feed additives and GMOs, the FSA and FSS have existing powers to review the safety of an authorised product as new evidence emerges, which could result in the modification, suspension or revocation of an authorisation and removal from market, and this will be maintained. These powers will be introduced for smoke flavourings to bring this regime in line with the other two regimes.

5.4 This SI streamlines the approval process by removing the requirement to prescribe authorisation decisions by SI. Authorisation decisions will continue to be made by ministers for their respective countries, based on FSA advice for England and Wales, and on FSS advice for Scotland. Ministers in the respective countries will inform the FSA and FSS of authorisation decisions. The FSA and FSS will publish and maintain official registers or lists of authorisations. This SI does not change ministerial decision-making in England, Wales and Scotland, which will continue to be required for products to be authorised.

5.5 This SI ensures a level of scrutiny that is proportionate to the regulation of the products concerned. It is also more in keeping with the approval processes used by other regulators in the UK for similarly regulated products. It does not change the existing consultation mechanisms used as part of the approval process.

5.6 This SI revokes 630 legislative instruments, which includes both assimilated EU law and domestic law. These are instruments that contain the terms of authorisations for feed additives, GMOs, smoke flavourings and novel foods (but this SI maintains the validity of the existing authorisations themselves so that they can be published in the official register or list), along with instruments that are redundant by virtue of this SI. This SI preserves the effect of transitional measures that are still necessary (for example, for using up existing stocks), so that products that were permitted to be placed on the market or used solely under those transitional measures can continue to be placed on the market or used.

5.7 This SI allows ministers to specify selected transitional measures (allowing time for existing stocks to be used, the product to continue to be produced and product labelling to continue to be applied) in future authorisation decisions and retains sufficient powers to prescribe by SI any other transitional provisions that may be necessary.

5.8 This SI amends provisions concerning the placing on the market of flavourings under evaluation, food enzymes and active and intelligent materials intended to come into contact with food (a type of FCM). These products are currently permitted to be placed on the market, so long as they meet certain legislative safety requirements pending further assessment and authorisation decisions. This SI does not change the current status of these products.

5.9 This SI saves renewal provisions in feed additives legislation, for the purpose of the continued operation of legislative requirements regarding the status of existing long-standing feed additive products.

5.10 This SI saves existing urgent (provisional) feed additive authorisations, which have been granted for a maximum period of five years where necessary for the protection of animal welfare, with their expiry dates.

5.11 To ensure the continued operability of wider legislation, this SI makes consequential amendments to certain domestic and assimilated legislation, including some owned by other government departments, including devolved governments. This means amending any provisions (including those related to offences and enforcement), where references are made to regulated product regulations, paragraphs or annexes that are being revoked and replaced, to ensure they refer to the relevant replacement. The scope of enforcement provisions is not being changed.

5.12 The movement of goods to Northern Ireland is covered by the Windsor Framework. The UK Government is committed to implementing the Windsor Framework in good faith and protecting the UK internal market. Under Windsor Framework arrangements, regulated products approved in GB can be placed on the Northern Ireland market, if moved via the Northern Ireland Retail Movement Scheme. If there are differences in approach, this is managed through the relevant Common Frameworks. It remains the case that Qualifying Northern Ireland Goods continue to have unfettered access to the GB market. These arrangements ensure that NI businesses can benefit from unique access to the UK and EU markets.

5.13 These reforms create a more streamlined and effective regulatory regime that keeps pace with innovation in the food industry and brings benefits to businesses, through reduced administrative burdens. Wider impacts include the potential for increased variety of choice for consumers as new products come to market more quickly, without compromising consumer safety.

What was the previous policy, how is this different?

5.14 The FSA and FSS took responsibility for the approval of regulated products in January 2021. Working together as the Food Safety Authorities for England and Wales and Scotland, respectively, they operated the inherited processes for authorising regulated products, with only necessary operability fixes, to ensure continuity of service and to maintain food safety standards.

5.15 The inherited assimilated legislation required a ten-yearly renewal of authorisations for three product regimes, as explained in paragraph 4.3. These requirements had been set over 20 years ago by the EU.

5.16 Removing this requirement ensures a more proportionate, proactive and dynamic approach to maintaining food and feed safety. This is because products are thoroughly assessed during their initial approval application, and the Food Safety Authorities have the powers to take action to protect public health and food safety, as and when necessary, including setting monitoring requirements and to review authorisations at any time as new evidence emerges.

5.17 Ministers in England and Wales decide whether to authorise regulated products, based on FSA advice. Ministers in Scotland decide whether to authorise regulated products, based on FSS advice. After a ministerial decision, an SI or Scottish statutory instrument was required before products were placed on the market, prolonging the end-to-end approval process.

5.18 This SI enables a streamlined process by allowing authorisations to come into effect following ministerial decision, and then be published in an official register or list, rather than being prescribed by lengthy SIs setting out the details of authorisations.

5.19 In addition to facilitating a simpler approach to the authorisation of regulated products, this SI supports the delivery of efficiencies, in terms of costs incurred by businesses applying for authorisation, time for products to reach the market, and effective use of policy, scientific and legal resources for the Food Safety Authorities. The monetised savings for businesses and the public sector are laid out in Section 9 of this memorandum.

6 Legislative and Legal Context

How has the law changed?

6.1 The legislative context of this SI, together with the changes effected, are detailed in Section 5 of this memorandum. This SI is made under the powers in sections 14(1), (3), (4)(a) and (b) and 20(1) of the Retained EU Law (Revocation and Reform) Act 2023[1]. Parts 2 to 7 of this SI contain the amendments to assimilated direct legislation necessary to give effect to the objectives described above. That assimilated direct legislation contains provisions setting out the processes and procedure for the authorisation of the various regulated product types concerned and, in the case of food additives, food flavourings and FCM plastics, the legislation contains lists of authorised products and the terms of their authorisations. Schedules 1 to 8 of this SI, with savings where needed in relation to transitional provisions, revoke other instruments (both assimilated direct legislation and domestic SIs made since EU Exit under powers in assimilated direct legislation) that contain the terms of authorisations for feed additives, GMOs, smoke flavourings, and novel foods and other legislation

[1] https://www.legislation.gov.uk/ukpga/2023/28.

that is redundant by virtue of this SI. Schedules 9 to 12 of this SI contain the consequential amendments described in paragraph 5.11 above.

Why was this approach taken to change the law?

6.2 Changing the law is the best approach to achieving the combined policy aims of streamlining the process. It will provide for a proportionate level of scrutiny, removing unnecessary burdens inherited from the assimilated legislation, providing substantial efficiency benefits for businesses and the Food Safety Authorities, and positively affecting consumer choice whilst maintaining high standards of food and feed safety. This is because the approval process is set out in various secondary assimilated law instruments. Accordingly, the only way of making changes to simplify this process it through making legislative change.

7 Consultation

Summary of consultation outcome and methodology

7.1 The FSA, supported by FSS, invited stakeholders with an interest in regulated products to share their insights on the approval process through a survey and a follow-up workshop, held on 29 and 30 November 2023.

7.2 The workshop built on the results of the survey and explored the challenges and opportunities for several policy features around reform of the regulated products regime. Industry representatives supported the reforms, noting that change to the existing system was needed as it was inefficient and unsupportive of innovation. They endorsed the need for reform to reduce administrative burdens, without weakening existing food safety standards. The insights obtained informed the proposals subsequently presented in the consultation.

7.3 The FSA and FSS conducted a UK-wide public consultation, from 3 April to 5 June 2024, on the proposals outlined in Section 5 of this memorandum. Stakeholders were informed of the consultation being launched and were encouraged to comment. Targeted communication included industry trade associations with an interest in regulated products, non-governmental organisations (NGOs) and consumer groups, to ensure a broad spectrum of opinion.

7.4 The public consultation was promoted widely, through the FSA and FSS websites, subscription alerts, social media posts and direct contact with key stakeholders. The consultation was shared directly with organisations that have engaged with the FSA/FSS about regulated products in general, or a specific regime (for example, food additives). These organisations, along with members of the FSA Consumer Forum, were invited to attend online consultation sessions to discuss the proposals.

7.5 The reach of the consultation was comprehensive. There were 26,816 subscribers to UK-wide FSA alerts; a further 66,075 subscribers to country-specific alerts received automatic notifications. The link to the consultation was posted on the FSA Facebook, X (formerly Twitter), and LinkedIn pages. These have approximately 120,500, 61,600 and 57,500 followers respectively. The consultation alert was also sent to enforcement bodies across the UK. Following a press release, the consultation was reported by a number of trade publications. The consultation page received approximately 3,520 views during the consultation period.

7.6 A total of 123 responses were received: 103 from across the UK and 20 from outside the UK. The consultation attracted responses from industry (67), consumers (43), NGOs (9) and enforcement bodies (4). The number of responses was low compared to

the actual number of stakeholders reached. In Northern Ireland, three responses were received (two from consumers and one from industry), all of which either agreed or strongly agreed with the proposals.

7.7 Overall, there was broad support to both proposals, to remove the requirement for renewals and remove the requirement for authorisations to be prescribed.

7.8 Stakeholders' feedback was carefully considered. Based on the analysis of responses, the FSA and FSS have not identified any reasons that would warrant changing the approach. Despite broad agreement to the proposals, some respondents identified areas which will require additional information, guidance and/or engagement, which will be addressed (see Section 8 below). The outcome of the consultation was used to inform finalisation of this SI.

7.9 The FSA/FSS has published the summary of consultation responses on the FSA website[2].

8 Applicable Guidance

8.1 Existing market authorisation guidance for stakeholders, such as businesses and enforcement authorities, will be updated on the websites of the FSA[3] and FSS[4], when the new instrument comes into force. Current guidance is applicable and should be followed until the instrument comes into force. The updated guidance will reflect the technical changes made by this SI to the approval process. Communications will be issued to stakeholders, advising them of progress on implementing the changes made by this SI.

Part Two: Impact and the Better Regulation Framework

9 Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because the annual impact on business is below the de minimis threshold of +/- £10 million equivalent annual net direct cost to business (EANDCB).

Impact on businesses, charities and voluntary bodies

9.2 The impact on business, charities or voluntary bodies is positive, including small and micro-businesses, with an equivalent annual net direct benefit to businesses of £254,000. The impact on the public sector is an equivalent annual net direct benefit of £1.6m.

9.3 Removing renewal requirements will result in reductions in administrative burdens on businesses. Non-monetised indirect benefits to businesses include the reduced time in bringing products to market by removing the requirement to prescribe authorisation decisions in SIs. This may lead to increased return on investment for businesses due to a swifter approval process for bringing new products to market. It has not been possible to quantify and monetise the direct savings arising from this reduced lead time, because the volume and value of potential products being brought to market in the future is unknown.

[2] www.food.gov.uk/our-work/consultation-on-proposed-reforms-to-the-regulated-products-authorisation-process-summary-of-stakeholder-responses

[3] https://www.food.gov.uk/business-guidance/industry-guidance/regulated-products

[4] https://www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/regulated-products-and-processes

10 Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The FSA and FSS will continue to monitor and review this legislation, through routine engagement with stakeholders on its application of the process and through its standard performance and productivity monitoring.

10.2 As this SI is made under the Retained EU Law (Revocation and Reform) Act 2023, no review clause is required.

Part Three: Statements and Matters of Particular Interest to Parliament

11 Matters of special interest to Parliament

11.1 None.

12 European Convention on Human Rights

12.1 Ashley Dalton MP, Parliamentary Under Secretary of State for Public Health and Prevention at the Department of Health and Social Care has made the following statement regarding Human Rights:

"In my view the provisions of the Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025 are compatible with the Convention rights."

13 The Relevant European Union Act

13.1 This SI is made under the Retained EU Law (Revocation and Reform) Act 2023[1], but no statements are required.