Reforms to the market authorisations process for regulated products

Changes to the market authorisations process and how they affect food and feed businesses.

From 1 April 2025, a new Great Britain (GB)-wide, statutory instrument (SI) implemented two reforms to the market authorisation process for regulated products:

- Removing requirements for the periodic renewal of authorisations that existed for feed additives, smoke flavourings and food or feed containing, consisting of or produced from genetically modified organisms (GMOs); and
- Enabling authorisations to come into effect following ministerial decision, and then be published in an official register or list, rather than being prescribed by SI.

These reforms modernised the regulatory process and enabled it to better keep pace with innovation and emerging technologies, while continuing to safeguard public health. We consulted on these changes in 2024.

The Food and Feed (Regulated Products) (Amendment, Revocation, Consequential and Transitional Provision) Regulations 2025) ('reform SI') relates to the following regulated product regimes:

- feed additives;
- food additives;
- food enzymes;
- food flavourings;
- food contact materials (FCMs);
- GMOs;
- novel foods; and,
- smoke flavourings.

Removing the requirement for renewals

Previously, three of the regulated product regimes (feed additives, GMOs and smoke flavourings) required market authorisations to be renewed on a ten-yearly basis.

On 1 April 2025 this renewal requirement was been removed, bringing these regimes in line with others, such as food additives and novel foods.

All regulated product regimes already rely on the FSA and Food Standards Scotland's (FSS's) robust risk analysis approach for detecting any emerging risks. This existing approach provides mechanisms for monitoring new evidence and addressing emerging risks promptly.

The FSA and FSS will continue to focus on horizon scanning and risk assessment for all product types to respond to new safety evidence as it emerges. This informs the FSA and FSS whether already authorised products are safe to remain on the market at any time. This is instead of working to arbitrarily fixed renewal timetables that required comprehensive reviews for all products, even if there was no new evidence to suggest this was needed. If a safety concern is identified with a product, the FSA and FSS can review the authorisation and advise ministers on whether to revoke, modify or suspend the authorisation.

The reform SI removed expiry dates for authorisations that were subject to renewal. It ensures sufficient legislative basis for the FSA and FSS to request information from all businesses involved (not just authorisation holders) to aid safety assessment, in the event of any new information or developing concerns.

Renewal applications currently in the service

Renewal applications that had already been submitted prior to coming into force were checked for any potential safety concerns, extension of use or modification requests and for any post-market monitoring reports, post-market environmental monitoring reports or updates to analytical or detection methods that required review.

Renewal applications in the service prior to April 2025 did not continue through the market authorisation process. These authorisations remain valid and no longer have an expiry date, so the authorised products can stay on the market, unless they are suspended, modified or revoked in the future. However, depending on the nature of individual applications, some continued as extension of use or modification applications instead.

If new evidence of a potential safety concern is identified (whether this comes from information contained in a renewal applications that were in the service prior to April 2025 or elsewhere), the FSA and FSS have powers to review the authorisation, request new information from businesses, and advise ministers on whether to modify, suspend or revoke its authorisation.

Products with a renewal date after 1 April 2025

The reform SI removed expiry dates for products already on the market that were previously subject to renewal requirements. Renewal applications for these products are no longer required. These authorisations remain valid and no longer have an expiry date, so the authorised products can stay on the market, unless they are suspended, modified or revoked in the future.

Monitoring of products on the market

All businesses are legally required to report to the FSA and FSS if they have reasons to believe that a food or feed product placed on the market is unsafe. The provisions of General Food Law (assimilated Regulation (EC) No 178/2002) and the reform SI require businesses to report information if new evidence emerges on the safety of an authorised product.

Certain products also require post-market monitoring and/or post-market environmental monitoring and reporting to the regulator as part of their terms of authorisation. These continue to be set within the terms of authorisation of products where necessary.

Businesses need to continue to conduct any post-market monitoring and post-market environmental monitoring requirements applied to authorisations, including supplying reports to the FSA and FSS.

If new information about a product's safety emerges, the FSA and FSS will consider its relevance, analyse any potential risk, and may issue advice about whether the product is safe to remain on the market.

Not all information will trigger a full safety review; we will evaluate the necessity of action based on the information considered. If there is an immediate food or feed safety risk, the FSA and FSS will take action through our incident management approach.

How to provide information

If you need to contact the FSA and FSS about an existing authorisation, please email us at regulatedproducts@food.gov.uk. You should use this route to notify us of any new or developing safety concerns about an authorised product such as if you become aware of anything new casting doubt on a previous safety assessment.

Additionally, you must (where required) use this route to send us post-market monitoring reports, post-market environmental monitoring reports, updates or changes to analytical or detection methods, and any other information related to an existing authorisation.

When emailing, please mention the authorisation or product you are referring to, what type of information you are providing, and include the RP number if applicable.

Businesses are legally required to report to the FSA/FSS if they have reasons to believe that placing the food or feed product on the market could do harm to consumers.

You must report any food safety incidents to the FSA in England, Wales or Northern Ireland. If you are in Scotland, or the incident relates to a business in Scotland then please report the incident to FSS.

Regime-specific information

GMOs

The FSA and FSS will continue to set requirements within the terms of authorisations for GMOs, including for post-market monitoring and post-market environmental monitoring where applicable.

Businesses will need to continue to comply with any post-market monitoring and post-market environmental monitoring requirements applied to current authorisations, including supplying reports to the FSA and FSS.

GMO authorisations include details of the laboratory-based methods that have been validated for the identification, detection, and quantification of the GMO. Businesses continue to be required to notify the FSA and FSS if they have any new information which might affect the suitability of a validated method. This allows the FSA, FSS and LGC (the UK National Reference laboratory for GMOs) to check that the previously approved method is still current.

If you need to contact the FSA and FSS about an existing authorisation, please email regulatedproducts@food.gov.uk. You can use this route to notify the FSA and FSS of any new or developing safety concerns about a product. Additionally, you can use this route to send post-market monitoring reports, post-market environmental monitoring reports, updates or changes to analytical or detection methods, and any other information related to an existing authorisation. When emailing, please mention the authorisation or product you are referring to, what type of information you are providing, and include the RP number if applicable.

Feed additives

The FSA and FSS will continue to set requirements within the terms of authorisations for feed additives, including for post-market monitoring where applicable.

Businesses will need to continue to comply with any post-market monitoring requirements applied to current authorisations, including supplying reports to the FSA and FSS.

Feed additive authorisations include details of laboratory-based methods that have been validated for detection purposes. Businesses continue to be required to notify the FSA and FSS if

they have any new information which might affect the suitability of a validated method. This allows the FSA, FSS and LGC (the UK National Reference laboratory for feed additives) to check that the previously approved method is still current.

If you need to contact the FSA and FSS about an existing authorisation, please email regulatedproducts@food.gov.uk. You can use this route to notify the FSA and FSS of any new or developing safety concerns about a product. Additionally, you can use this route to send post-market monitoring reports, updates or changes to analytical or detection methods, and any other information related to an existing authorisation. When emailing, please mention the authorisation or product you are referring to, what type of information you are providing, and include the RP number if applicable.

Article 10 feed additives

Long-standing feed additives that are permitted to be on the market in GB under Article 10 of Regulation (EC) No 1831/2003 (known as 'Article 10' feed additives) are not within scope of the reform SI and will be reviewed separately. The FSA and FSS are developing a proportionate risk assessment and management approach to these additives, to facilitate their continued market use in GB and ensure that they remain safe.
The reform SI ensures the revoked renewals provisions can still be used in the future, if needed, for review of these long-standing feed additives. These Article 10 additive authorisations are listed in the public register will remain so long as they remain permitted.

Urgent feed additive authorisations

Urgent feed additive authorisations are provisional authorisations granted for a maximum period of five years. They are used only in exceptional circumstances, such as for the protection of animal welfare, following a pre-market assessment of safety.
The provisional nature of these authorisations has not changed. The expiry dates for existing urgent authorisations remain in place and will continue to be set for future urgent authorisations.

Food enzymes and 'flavourings under evaluation'

The reform SI covers provisions concerning the placement on the market of flavourings that are currently under evaluation. Requirements and definitions regarding the status of these products are now set out in assimilated Regulation (EC) No. 1334/2008 on flavourings.

These products are permitted to be placed on the market pending further assessment and authorisation decisions, provided they meet certain legislative requirements.

For food enzymes, changes were made to the process for initial authorisations and establishment of the first domestic list of food enzymes. Food enzymes that fall under assimilated Regulation (EC) No. 1332/2008 do not need approval before use, until initial authorisations are made.

The reform SI does not change the status of these products but alters the common authorisation process for food additives, flavourings and enzymes to allow any future authorisations to come into effect following ministerial decision and then be published in an official register or list (to be published and maintained by the FSA/FSS), rather than being prescribed by SI.

Active and intelligent materials intended to come into contact with food (a type of FCM)

The reform SI amends provisions about the placement on the market of active and intelligent materials (AIMs) intended to come into contact with food.

These products have not yet been through assessments and authorisation decisions in the same manner as other types of products referred to in the reform SI, but are permitted to be placed on the market pending further assessment and authorisation decisions, provided they meet certain legislative safety requirements.

The reform SI does not change the status of these products but allows any future authorisations to come into effect following ministerial decision and then be published in an official register or list (to be published and maintained by the FSA and FSS), rather than being prescribed by SI.

Regulated product regimes out of scope of the reforms

Extraction solvents, feed detoxification processes, irradiated food, recycled plastics, regenerated cellulose film, and feed for particular nutritional uses were not included in the reform SI. This is because the approval process they follow was either:

- not set out in legislation, or
- does not involve appropriate authority decision making, or
- the legislation that applies to them is not operable or is unlikely to be used in its current form.

Previous legislation and requirements continues to apply to these product types.

Enabling authorisations to come into effect following ministerial decision

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.

Under the previous authorisation process, after a ministerial decision, an SI was required before products could be placed on the market, prolonging the end-to-end approval process.

Now, authorisations to come into effect following ministerial decision. Ministers inform the FSA and FSS of authorisation decisions. The FSA and FSS are required to maintain a register that accurately represents the authorisation status for each product as determined by ministers. These registers contain the terms of authorisation for each product and are the primary source of information for stakeholders on the regulated products covered by the reform SI that are authorised for market in GB.

Finding details of authorised regulated products

The official online registers of authorised regulated products are publicly available here. They contain information that sets out what products are authorised and their terms of authorisation and are the primary source of information for stakeholders, such as businesses and enforcement officers, on the regulated products covered by the reform SI that are authorised for market in GB.

We are continuing to develop the registers with a view to making further improvements and refinements, including in response to user feedback.

Updating the registers

Entries in the registers will be updated when a ministerial decision affecting an authorisation comes into effect. The registers are also maintained for accuracy.

Where an existing authorisation is modified, details of any changes made will be recorded in the register, as will details of any transitional provisions.

Finding out about updates

Applicants are contacted directly when authorisation decisions are made. Other stakeholders interested in updates can sign up to receive the FSA's market authorisations newsletter.

The newsletter includes information and links to new entries to the registers, newly published safety assessments, consultations and authorisations.