# Consultation pack on proposed reforms to the regulated products authorisation process

This consultation aims to gather stakeholders' views on proposed changes to the authorisation process for regulated products.

**Date launched:** 3 April 2024

**Closing date:** 5 June 2024

## Who this consultation may be of most interest to

- food businesses and industry trade associations with an interest in regulated products
- competent authorities (Local Authorities (LAs) and Port Health Authorities)
- consumers and wider stakeholders

A list of interested parties is included in Annex A.

## Purpose of consultation

This consultation seeks stakeholders' views on initial proposals for legislative reform to streamline the authorisation process for regulated products. The current authorisation process was inherited from the European Union (EU) and the Food Standards Agency (FSA) and Food Standards Scotland (FSS) Boards have agreed that significant change will be necessary to achieve a high-quality service that can keep up with the pace of innovation in the food industry. The two proposals contained in this consultation are to:

- remove renewal requirements for feed additives, food or feed containing, consisting of or produced from genetically modified organisms (GMOs) and smoke flavourings, and
- allow regulated product authorisations to come into effect on publication, likely to an official register, following a ministerial decision.

This joint FSA and FSS consultation is stakeholders' opportunity to input to the final advice given to ministers.

The FSA and FSS plan to bring forward further proposals for reform and modernisation of the Regulated Products Service. These proposals are a first step. More information about longer-term reform plans will be presented to the FSA and FSS Boards in June 2024 and, if taken forward, will be subject to separate consultation.

## How to respond

An online survey is provided for responses, and respondents are encouraged to use this. Alternatively, please email your response to: RPconsultations@food.gov.uk

If responding by email, please state in your response whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which nation you are based.

# Details of consultation

## Background

Certain food and feed products, called regulated products, require authorisation before they can be sold. Regulated products include food additives, flavourings, novel foods, GMOs as food and feed, food contact materials and feed additives. When the UK left the EU, regulated product legislation was retained as domestic legislation. The EU regulated food and feed products regulations were retained with only necessary operability fixes to ensure continuity of service and maintain food safety standards. As of 1 January 2024, retained EU law is now assimilated law. A non-exhaustive list of relevant legislation is included in Annex B.

The FSA (for England and Wales) and FSS (for Scotland) receive authorisation applications on behalf of ministers, carry out assessments (including a risk analysis process) and make recommendations to the respective ministers in England, Scotland and Wales. Ministers make the final decision whether to authorise products by way of prescribing the authorisation in a Statutory Instrument (SI) / Scottish Statutory Instrument (SSI). This includes applications for new products, along with renewals, modifications or revocations of authorisations for existing products.

Applicants wishing to place regulated products on the Northern Ireland (NI) and EU markets must submit applications to the EU. Under Windsor Framework arrangements, regulated products authorised in Great Britain (GB) may also be placed on the NI market, provided they are eligible for, and are moved through, the Northern Ireland Retail Movement Scheme (NIRMS).

## Renewals of authorisations

Currently, renewals of authorisations are required for the following product types:

- feed additives;
- GMOs for food and feed uses;
- smoke flavourings used or intended for use in or on foods.

At fixed intervals of ten years, the current legislation requires applicants to apply for a renewal, which generally involves reviewing any new evidence that has emerged since the last authorisation, reviewing new testing methods and providing any proposed amendments to the conditions of use granted in the last authorisation. The FSA/FSS's risk analysis approach already provides explicit mechanisms for the FSA/FSS to monitor new evidence regarding authorisations at any appropriate time. In accordance with the provisions of the relevant authorisation regime, the FSA/FSS have powers to act immediately if new evidence emerges that requires a review of an authorisation, for example if a food and/or feed safety risk emerges. This applies across all twelve regulated product regimes, can be triggered for different reasons, and uses evidence from a wide range of sources, including from food or feed businesses, other regulators or risk assessment bodies, publications/studies in scientific journals.

A review could result in the modification, suspension or revocation of authorisations. Additionally, there are powers under Article 53 of assimilated Regulation (EC) 178/2002 which enable emergency measures to be taken (which include the suspension of the placing on the market of a product or any other appropriate interim measure) in instances where a product is likely to

constitute a serious risk to human health, animal health or the environment. In addition, businesses are legally required to report to their food safety authorities if they have reasons to believe that placing the food or feed product on the market could do harm to consumers. Following a report, analysis of this safety risk is carried out by the FSA/FSS to inform a decision about whether the product can satisfy the accepted food safety standards to remain on the market. An example of a product where the FSA/FSS has proactively undertaken a safety review is for the food additive titanium dioxide (E171). See the register of issues undergoing risk analysis .

Details of how the FSA and FSS make evidence-based recommendations (the risk analysis process) can be found on the published flow diagram (PDF).

## Statutory Instrument process for authorisations

After a ministerial decision to authorise is made, under the current system an SI / SSI is required (under the negative resolution procedure) to give legislative effect to that decision before products can be placed on the market. Based on the applications that have been approved through the GB process since 2021, the period from ministerial approval to formal legal authorisation accounts for at least 3 months of the time taken for new products to gain market authorisation, and sometimes longer. The requirement to lay an SI/SSI was introduced at the time of EU Exit to accommodate the differences in the operation of EU Law and GB regulatory and legislative processes. The equivalent EU institutions and European Parliament provide no scrutiny of tertiary legislation by the EU Commission authorising individual regulated product authorisations.

The FSA/FSS work on a cross-UK basis, in line with the commitments of the Food and Feed Safety and Hygiene Common Framework. As part of this framework, we aim to have a common approach to regulated product authorisations to minimise and manage any divergence across the UK. The requirements for laying secondary legislation and Parliamentary procedure vary across England, Wales and Scotland with differences in processes, timeframes and recess timetables which can present challenges in aligning approaches.

The current methods for prescribing the authorisation of products in legislation, which vary by regulated product type, include lists within legislation or separate pieces of legislation for each authorisation. This is the source of information for local authorities, business and other interested parties to find authorisations.

## Policy objectives

The FSA's overall policy objective is to ensure that regulated products for use in food and feed are appropriately assessed for safety before they can be authorised for placing on the market. In so doing, our aims (in line with our guiding principles) are to:

- provide consumers with assurance that food is safe and what it says it is based on science and evidence;
- support innovation in the food system which can bring benefits to consumers;
- be proportionate in our approach, reducing unnecessary burdens on businesses, and basing our decisions on science and evidence and providing value to taxpayers;
- maintain openness and transparency.

FSS is the public sector food body for Scotland, which aims to protect the health and wellbeing of consumers in Scotland under objectives set in the Food (Scotland) Act 2015. In collaborating with the FSA to reform the legislation on regulated products, FSS will work in line with the five outcomes under Our Strategy 2021 to 2026:

- food is safe and authentic;

- consumers have healthier diets;
- responsible food businesses are enabled to thrive;
- consumers are empowered to make positive choices about food;
- FSS is trusted and influential.

The proposed reforms will streamline the current system, providing substantial efficiency benefits for businesses and the FSA/FSS, positively affecting consumer choice. They will bring benefits to consumers through an enhanced choice of safe food and feed whilst providing greater value for the taxpayer. The proposed changes will release FSA/FSS resources to focus on new authorisations, including innovative products such as methane-reducing feed additives, whilst maintaining effective regulatory practices for food and feed safety.

# Proposals

## Renewals of authorisations

Under existing legislation, renewals of authorisations are required every ten years for the following product types:

- feed additives;
- food or feed containing, consisting of or produced from GMOs;
- smoke flavourings used or intended for use in or on foods.

To keep these products on the market, businesses must make renewal applications so the authorisation information can be re-evaluated in light of technological and scientific developments. These requirements have been in law for over 20 years, are a disproportionate approach to maintaining the safety of these products, and an inefficient use of the FSA/FSS's and businesses' resources, with no additional benefits for food safety. Removing these requirements will promote a more proactive and dynamic approach to maintaining food and feed safety, while retaining the ability to set post-market monitoring requirements and clarifying FSA/FSS powers to review existing authorisations and take action to protect public health and food safety where necessary. The FSA will continue to proactively monitor emerging risks including, for example, biosecurity risk.

The FSA/FSS's proposed reforms will strengthen the powers and processes already in place to maintain food and feed safety standards set out in the above Background section. Products subject to renewal requirements have already been adequately safety assessed as part of their initial authorisation. Authorisation holders are required to proactively inform FSA/FSS if they become aware of anything new casting doubt on a previous safety assessment. The FSA/FSS are retaining this requirement and exploring how to make it clearer to businesses what their responsibilities are. This is consistent with the existing general obligations on all food and feed businesses to tell FSA/FSS if there is a reason to believe that food or feed is not compliant with safety requirements. In addition, if new evidence emerges that requires a review of an authorisation, FSA/FSS are exploring ways to retain the ability for the FSA/FSS to request information from businesses to inform that review and act accordingly. This would replace the duties on businesses to submit renewal applications, with the ability for FSA/FSS to request information from specific businesses on an ad hoc basis if a review of the authorisation is required.

These changes would result in a reduced burden on businesses without any reduction in current food safety standards. More targeted reviews will mean businesses will no longer have a fixed requirement to submit a renewal application every 10 years, and based on our engagement to date, businesses are supportive of proposals that reduce administrative burdens and maintain clear routes for reporting adverse data. The proposed amendments to renewal requirements will

improve FSA/FSS's ability to assess the evidence and provide advice to ministers to inform decisions regarding potentially modifying, suspending or revoking authorisations.

## Removal of requirement to lay legislation to authorise regulated products

The FSA/FSS propose seeking agreement from ministers to amend legislation so that regulated product authorisations can come into effect by publication after ministerial decision and do not have to be set out or listed in full in legislation. This would include replacing lists of authorised products (where they exist) and individual authorisations currently contained in legislation with published authorisations, likely in the form of an online official register. This will deliver significant efficiencies in the Regulated Products Service, reducing the risk of future delays to authorisations while ensuring food safety and standards are maintained. These efficiencies include:

- creating a more efficient process for bringing authorisations into effect following a ministerial decision, reducing the process by at least 3 months;
- facilitating effective utilisation of policy, legal (across government) and parliamentary resources, and limited parliamentary time;
- reducing the time and resource required to record and communicate which products have been authorised.

These efficiencies will allow FSA/FSS to focus on new authorisations, including innovative products such as methane-reducing feed additives that have environmental benefits and support the UK Government's agenda for economic growth. They will also improve service delivery for industry, provide greater value for taxpayers and ultimately facilitate consumers having wider choice or access to beneficial products that will come to market more quickly. The time taken between a decision being made and authorisation will be shorter, reducing regulatory burdens, fostering productivity and innovation, and allowing new, safe products to market quicker.

These benefits will not change the current process of ministerial decision-making: ministerial approval will still be needed in England, Wales and Scotland before products would be authorised. Once approved, an authorisation will take effect when a product authorisation has been published by FSA/FSS - the publication will enact the decision.

Published authorisations will contain the same information that is currently set out in legislation, the scientific and technical details of authorisations do not intrinsically need to be set out in legislation. Applications will be subject to careful examination by science, policy and legal representatives, and will continue to be subject to a public consultation, before recommendations are submitted to ministers for decision. This process aligns with internationally recognised risk analysis principles and ensures that decisions on a food or feed authorisation are based on the assessment of its safety.

The FSA/FSS proposals will make the authorisation process for regulated products similar to authorisation processes used by other UK regulators. There are comparable authorisation processes for veterinary medicines and plant protection products (pesticides) that do not require legislation to bring authorisations into effect. In both cases, the legislation details the information that must be submitted in an application for a safety assessment to be carried out and the procedure for authorisation. For veterinary medicines, a database is held on the government (Veterinary Medicines Directorate) website detailing current, expired and refused authorisations. For pesticides, the legislation details the requirements for a register of approved substances and there is a facility on the government (Health & Safety Executive) website where users can search for authorised substances.

For both key proposals, it is likely to be necessary to make minor technical and consequential changes to other legislation to implement the proposals described in this consultation.

### How stakeholder engagement has informed these proposals

In Spring 2023, the FSA completed an external review of the Novel Foods Regulatory Framework. A summary of the findings was published on 7 June 2023. This work identified potential options for future reform that are applicable across the whole system.

Stakeholders (including SMEs) from across the regulated product regimes were also invited to share their insights on the authorisation process via a survey and follow-up workshops, held on 29 and 30 November 2023. The workshops explored the challenges and opportunities for several policy features around reform. Industry representatives supported the reforms, noting that change to the current system is needed as it is currently inefficient and not supportive of innovation. They supported the need for reform to reduce administrative burdens without any reduction to current food safety standards. The proposals set out in this consultation, along with our planned further proposals for reform and modernisation of the Regulated Products Service, will deliver the key recommendations from attendees at these workshops.

The FSA and FSS Boards have been regularly updated on development of these proposals since 2023, when both Boards agreed that plans should be developed to improve the current system to ensure consumers have quicker access to a wider choice of safe, innovative products. In March 2024, the FSA and FSS Boards both confirmed their support for the proposals contained in this consultation. FSA and FSS Board meetings are held in public, enabling stakeholders to engage in the development of these proposals and questions were welcomed on the papers being considered. Papers presented to the FSA and FSS Boards are available on the FSA and FSS websites.

## Assessment of impact

The FSA/FSS have completed an early analysis of the potential impacts that would result from these proposals, should ministers agree to the reforms. A quantitative and qualitative assessment of the impacts will be set out in an explanatory memorandum when the implementing legislation is published. The impact has been assessed against the status quo - a baseline of the existing regulated products legislation. Overall, the impact of implementing these proposals is expected to impose minimal burden on businesses and public/enforcement bodies. No impacts were identified on food safety or consumer health. The following considerations were made:

### Consumers

- Costs: our collective assessment of the proposals did not identify any food safety or public health impacts for consumers, since the FSA/FSS will retain the power to review existing authorisations and take action to protect public health and food safety where necessary. Consumers interested in accessing lists of authorised products will be impacted as they will need to familiarise themselves with the new location of lists.
- Benefits: the removal of the SI process would shorten the authorisation process and enable products to reach the market more quickly, resulting in increased consumer choice. Consumers would likely find it easier to access information on authorisations due to lists not being kept within legislation.

### Businesses

- Costs: the main direct one-off cost will be for businesses with an interest in any of the three product types that currently have renewal requirements. This will be familiarisation with the proposed regulatory framework that removes these requirements. For businesses with an interest in any regulated product, there will be a one-off cost associated with familiarisation of the new location of lists that detail terms of authorisation.

- Benefits: there would be a reduced burden on businesses, as they will no longer be required to submit a renewal application every 10 years, resulting in a cost saving. Additionally, the removal of the SI/SSI process would shorten the authorisation process and enable products to reach the market more quickly once a decision is taken by ministers, resulting in an increase in the rate of return on investment. Businesses would likely find it easier to access information on authorisations due to lists not being kept within legislation.

### Local Authorities / Port Health Authorities

- Costs: there will be a one-off familiarisation cost with the new regulatory framework that no longer includes renewal requirements and with the new location of lists that detail terms of authorisation. Due to the Windsor Framework agreement, one-off familiarisation costs would also apply to district councils in NI.
- Benefits: enforcement authorities will no longer need to be alert to expiry dates, reducing resource burdens. Enforcement authorities would likely find it easier to access information on authorisations due to lists not being kept within legislation.

## Next steps

Following analysis of responses to this consultation, FSA/FSS officials will provide advice and recommendations to relevant ministers in England, Scotland and Wales (with ministers in Northern Ireland kept informed) for decision.

Following the consultation process, responses will be published and made available to stakeholders and ministers.

## Questions asked in this consultation

1. Do you agree or disagree with the proposal to remove the requirement to renew authorisations every 10 years for feed additives, genetically modified organisms for use in food and feed and smoke flavourings?
a) Please indicate if you strongly agree, agree, neither agree nor disagree, disagree or strongly disagree.
b) Please give your reasons for your response.

2. Do you agree or disagree with the proposal to replace requirements for regulated product authorisations to be prescribed by, and set out in, legislation after a ministerial decision to authorise the regulated products concerned, with a duty simply to publish authorisations instead after the ministerial decision to authorise the regulated products concerned?
a) Please indicate if you strongly agree, agree, neither agree nor disagree, disagree or strongly disagree.
b) Please give your reasons for your response.

3. Do you have any comments on our assessment of the impacts of the proposed changes, or have any to add that have not been identified in this consultation?

Please explain any views given in the response to the consultation and provide relevant evidence to support your views where possible. This will help us to analyse responses to inform our decision-making process.

## How to respond to this consultation

This consultation will run for 9 weeks. Responses are required by close of 5 June 2024. Please respond to the consultation via the online survey. If this is not possible, you can email a response to: RPconsultations@food.gov.uk.

If responding by email, please state in your response whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which nation you are based.

Once the consultation has ended, we will review the responses and a summary of the response report will be published on the FSA website.
For information on how the FSA handles your personal data, please refer to the Consultation privacy notice. Responses will be shared with FSS.

## Further information

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with HM Government consultation principles.

Thank you on behalf of the Food Standards Agency and Food Standards Scotland for participating in this public consultation.

Yours,

Regulatory Reform, Innovation and Engagement Team, Regulated Services

## Annex A: List of stakeholders

Key stakeholder trade associations which are represented across all four nations of the UK who have a strong interest in regulated products will be contacted directly for feedback on this consultation:

- AberInnovation
- Agricultural Biotechnology Council
- Agricultural Industries Confederation (AIC)
- Alternative Protein Association (APA)
- Beyond GM
- British Association of Feed Supplement and Additive Manufacturers (BAFSAM)
- British Dietetic Association
- British Equestrian Trade Association (BETA)
- British Nutrition Foundation
- British Retail Consortium (BRC)
- British Soft Drinks Association
- British Specialist Nutrition Association (BSNA)
- Business Wales
- Campden BRI
- Cannabis Trade Association
- Chilled Food Association
- Council for Responsible Nutrition UK (CRN UK)
- Croplife
- European Industrial Hemp Association
- Farmers' Union Wales
- FDF Sector Group: Food additives

- Federation of Small Businesses (Wales)
- Federation of Small Businesses (Northern Ireland)
- Food and Drink Federation (England)
- Food and Drink Federation (Wales)
- Food Additives and Ingredients Association (FAIA)
- Food Centre Wales
- Food Ethics Council
- Food Foundation
- Gene Watch
- GM Freeze
- Good Food Institute Europe (GFI Europe)
- Grain and Feed Trade Association (GAFTA)
- Health Food Manufacturers' Association
- Hybu Cig Cymru
- Institute of Food Science and Technology
- Leatherhead Food International
- National Farmers Union
- National Farmers Union Scotland
- NFU Cymru
- National Office of Animal Health (NOAH)
- National Sheep Association
- Northern Ireland Food and Drink Association
- Northern Ireland Grain Trade Association (NIGTA)
- Northern Ireland Retail Consortium
- Organic Farmers & Growers
- Provision Trade Federation
- Scotland Food and Drink
- Soil Association
- Sustain
- The Food Technology Centre
- UK Flavour Association
- UK Hospitality (Wales)
- UK Pet Food (previously the Pet Food Manufacturers Association (PFMA))
- Ulster Farmers Union
- Welsh Retail Consortium
- Which?
- WWF
- ZERO2FIVE Food Industry Centre

This is not an exhaustive list.

# Annex B: Non-exhaustive list of relevant legislation

The legislation listed below indicates some of the key legislation that will be affected by the proposals in this consultation. This is not intended to be an exhaustive list, and as mentioned in this document:

- we also propose replacing lists of authorised products (where they exist) and individual authorisations currently contained in legislation with published authorisations, likely in the form of an online official register; and
- it is likely also to be necessary to make minor technical and consequential changes to other legislation not listed below to implement the proposals described in this consultation.

### Assimilated legislation relating to feed additives, in particular:

- Regulation (EC) No 1831/2003 on additives for use in animal nutrition
- Regulation (EC) No 378/2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives
- Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives

## Assimilated legislation relating to relating to food additives, food enzymes and food flavourings, in particular:

- Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings
- Regulation (EC) No 1332/2008 on food enzymes
- Regulation (EC) No 1333/2008 on food additives
- Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods, etc.
- Regulation (EC) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008
- Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96, introducing it in Annex I to Regulation (EC) No 1334/2008 and repealing Regulation (EC) No 1565/2000 and Decision 1999/217/EC
- Regulation (EU) No 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008

## Assimilated legislation relating to food contact materials, in particular:

- Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, etc.
- Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods, etc.
- Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food
- Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

## Assimilated legislation relating to GMOs, in particular:

- Regulation (EC) No 1829/2003 on genetically modified food and feed
- Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation
- Implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003, etc.

## Assimilated legislation relating to novel foods, in particular:

- Regulation (EU) 2015/2283 on novel foods, etc.
- Implementing Regulation (EU) 2017/2470 establishing the list of novel foods

## Assimilated legislation relating to smoke flavourings, in particular:

- Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods
- Implementing Regulation (EU) No 1321/2013 establishing the list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavouring