Consultation on proposed reforms to the regulated products authorisation process: summary of stakeholder responses

This consultation sought stakeholders' views on two proposed reforms to the market authorisation process for regulated products.
PDF
Gweld Consultation on proposed reforms to the regulated products authorisation process: summary of stakeholder responses as PDF(Open in a new window) (369.82 KB)

Introduction

This consultation ran from 3 April to 5 June 2024.

Our process for market authorisations is in urgent need of modernisation. Two targeted, impactful proposals have been identified as critical to reforming the system. These reforms will ensure our high standards for food and feed safety are maintained, while improving the process to make the service more efficient and fit for purpose. We propose:

- removing renewal requirements for feed additives, food or feed containing, consisting of, or produced from genetically modified organisms (GMOs) and smoke flavourings; and
- removing the requirement for statutory instruments (SIs) / Scottish statutory instruments (SSIs) to bring regulated product authorisations into effect, following a ministerial decision.

In this consultation, the Food Standards Agency (FSA) and Food Standards Scotland (FSS) were seeking stakeholders' views in relation to the two proposed reforms to the regulated products authorisation process outlined in the consultation pack.

Respondents were asked to indicate whether they 'strongly agreed', 'agreed', 'neither agreed nor disagreed', 'disagreed' or 'strongly disagreed' with the proposals, and to give their reasons for their view.

This report is a summary of the comments received. Each section of this report deals with a theme, providing a summary of the comments received and the stakeholders who made them. Our considered responses to stakeholders' comments are provided at the close of each section. A summary of next steps resulting from stakeholders' comments is set out in 'Conclusion and next steps' section.

Engagement and consultation reach

Consultation reach was comprehensive, with automatic notifications sent to 37,272 subscribers to FSA consultation alerts at the time of launch.

The link to the consultation was posted on the FSA's 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.

FSS shared the consultation with their 3,820 LinkedIn followers, 15,913 Facebook followers and 5,555 X followers. The consultation was also shared 103 times via their Stakeholder Engagement Management Service (SEMS). The consultation was shared directly with organisations that have engaged with us on the subject of regulated products in general, or a specific regime (e.g. food additives). These interested parties are listed in Annex A of the consultation document. These organisations, along with members of the FSA's Consumer Forum, were invited to attend online consultation sessions to discuss the proposals. The sessions, which gave interested parties an opportunity to express their views and ask questions ahead of formally responding, were attended by representatives from 30 organisations. The subject was also raised at a meeting of the FSA's Consumer Forum and has been on the agenda of a range of other events during the consultation period.

The consultation page received 3,520 views over the course of the consultation period.

Characteristics of respondents

We received 123 responses to the consultation, from food businesses (42), individual consumers (43), trade associations (25), non-governmental organisations (NGOs, 9) and enforcement bodies (4).

The trade associations that responded did so on behalf of extensive national and/or international memberships with an interest in regulated products.

Across the 123 respondents, 73 reported being located in England, 17 in Wales, 10 in Scotland and 3 in Northern Ireland (NI). Twenty reported being located outside the United Kingdom (UK).

A list of stakeholders who responded can be found at the end of the document.

The number of responses was low in comparison with actual numbers of stakeholders reached.

The FSA and FSS are grateful to those stakeholders who have taken the time to respond.

Summary of substantive responses

Section 1 - Proposal to remove the requirement for renewals

Of the 123 responses received to the consultation, 87 (71%) 'agreed' or 'strongly agreed' with the proposal to remove renewal requirements and 32 (26%) 'disagreed' or 'strongly disagreed' (the remainder having answered 'neither agree nor disagree').

The majority of those representing industry (62 of 67 respondents, 93%) were supportive of the proposal. Of those responding in an individual capacity, 18 (41%) supported the proposal. Similarly, the views of NGOs were divided. Campaign groups with a focus on GMOs strongly disagreed with the proposal. NGOs with a general consumer interest focus had no strong view or were supportive.

Enforcement bodies generally agreed with the proposal, although the Government Chemist (part of DSIT and hosted by LGC), expressed the view that the renewals process provides necessary scientific checks on the currency of validation methods.

The responses during the consultation engagement sessions, which were attended by three NGO s with a focus on GMOs and 26 attendees from industry (both individual companies and trade associations), and at the FSA's Consumer Forum, were generally aligned with the written responses.

Across all respondent types, the main themes in support of the proposal were that:

- timebound renewals are an unnecessary administrative burden and that maintaining authorisations indefinitely, until new evidence warrants a review, would be more efficient and conducive to innovation
- the existing risk analysis approach already provides mechanisms for monitoring new evidence and addressing emerging risks promptly, and
- resources should be targeted towards areas which hold the most risk.

The main reason given for disagreeing with the proposal was that renewals are necessary to ensure food safety.
The responses to the consultation have been analysed and the main themes identified. The FSA/ FSS's responses to the comments made are set out below.

Main theme of response: efficiency

Stakeholder comments: Seventy-seven (77) or 63% of respondents expressed the view that removing the requirement for renewals would increase efficiencies and/or that the process is an unnecessary administrative burden. These responses were from a range of food business operators (FBOs), trade associations with an interest in regulated products and individual consumers.
Respondents commenting on behalf of two enforcement bodies also expressed this view.

Many of the comments acknowledged that this support was on the basis that the FSA/FSS's current risk analysis approach already provides explicit mechanisms for the FSA/FSS to monitor and act on new evidence regarding authorisations at any appropriate time.

FSA / FSS response: Comments noted.
Around 22% of the current caseload are renewal applications. A further 300 renewal applications are expected in 2025 and 2026 as renewal periods are set to expire. Replacing the inflexible renewal process with a system in which reviews can be triggered at any time, when new evidence comes to light, will mean applications in the system decrease considerably, releasing resources to focus on new marketing authorisations, including innovative products.

Removing the requirements for renewals will promote a more proactive and dynamic approach to maintaining food and feed safety. The ability to set post-market monitoring requirements will be retained, and FSA/FSS's ability to review existing authorisations and take action to protect public health and food safety where necessary will be clarified. We will continue to proactively monitor emerging risks (see comment below).

Main theme of response: focussed use of resources

Stakeholder comments: Eleven (11) or 9% of respondents commented specifically that they wished FSA/FSS and/or Parliamentary resources to be used proportionately. Rather than a time-bound renewal process, they felt that regulators should direct their focus towards areas with the most risk and that assessments should be as a result of emerging risks.
Some of these respondents expressed the view that the proposed change would allow the regulators to also focus resources on the evaluation of new products, facilitating innovation.
One trade association commented: 'Removing the ten year renewal period will free up FSA and FSS resources to focus on their core missions…It will also mean FSA and FSS resources currently employed assessing product renewals will be available for assessment of new, innovative products. Innovation in the feed additive sector has the potential to improve the economy, the environment and animal welfare.'

FSA / FSS response: Comments noted.
The proposed reforms will streamline the current system, providing substantial efficiency benefits for businesses and the FSA/FSS. Consumers will benefit from new, safe products reaching the market more quickly, including novel foods and products which have sustainability and environmental benefits.
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.

Main theme of response: food safety concerns

Stakeholder comments: Twenty (20) or 16% of respondents were of the view that this proposal would have an adverse effect on food safety. The majority (14) of these were responding as individual consumers. Three (3) were responding on behalf of NGOs, with the point also being made by 1 FBO, 1 trade association and 1 public sector research establishment.

The comments primarily centred around the 10-yearly renewal process being a safeguard and a providing a formal point in time when evidence can be reviewed.

The public sector research establishment stated that they consider the renewals process important in terms of providing scientific checks to inform whether a laboratory-based method is still current.

FSA / FSS response: The FSA/FSS are committed to maintaining the highest standards of food safety. Our overarching mission is food we can trust, and we use a scientific, evidence-based approach to ensure food is safe and what it says it is.

We are retaining the ability to review authorisations and take action to protect public health and food safety where necessary. This change will bring smoke flavourings, feed additives and GMOs for use in food and feed in line with other regulated product regimes.

We proactively monitor emerging risks through horizon scanning and intelligence gathering activities. We will also continue to set post-market monitoring requirements within the terms of product authorisations where necessary, including requiring businesses to submit post-market monitoring reports. Where concerns are raised, existing provisions in the regulated products regulations enable us to review any change in the safety information, publish an opinion, request new information from businesses and provide a recommendation to ministers on whether to modify/suspend/revoke an authorisation.

We will ensure that updates to analytical/detection methods can happen in future outside the renewals process, to keep up with scientific developments and so the best available methods can be used for surveillance and enforcement purposes.

Main theme of response: resourcing post-market monitoring

Stakeholder comments: Five stakeholders across industry, enforcement bodies, consumers and consumer groups raised the issue of resourcing post-market monitoring.

A major consumer group expressed their view that, for the impact assessment to be correct in stating that there will not be any food safety or public health impacts for consumers because the FSA/FSS retain the power to review existing authorisations and to take action to protect public health and food safety where necessary, it needs to be ensured that the FSA/FSS have the capacity and expertise to do this effectively. They were concerned that it is not clear that there is the capacity to do this effectively in the current circumstances.

A consumer commenting on this theme said that regulated products should not be managed without adequate resourcing and that the system should be more robust as well as efficient.

FSA / FSS response: The process of renewing approvals is long and costly. Renewals currently comprise about one in five (22%) of total regulated product applications. The FSA is exploring the removal of these requirements to release resource and time to consider new product applications, which could be considered higher risk.

We anticipate that there will be a relatively small number of authorisations that will require a review on the basis of safety, compared to the large number of renewals currently processed. The FSA will ensure there is adequate post-market monitoring and that we retain the ability to review authorisations considering new evidence and act where necessary to protect public health and ensure food and feed safety. Our risk analysis process enables us to assess, manage and communicate food and animal feed safety risks, ensuring we maintain high standards of food and feed safety and protect consumers.

As we look to improve the process, we are continuing to explore future opportunities for modernisation, including the use of technology to support our horizon scanning for emerging risks.

Main theme of response: 'Article 10' and 'orphan' feed additives

Stakeholder comments: In support of the removal of the requirement for renewal applications for feed additives, three FBOs and three trade associations raised the issue of generic feed additives. One of the UK trade associations reported that these were also the views of the European umbrella organisations in the feed additives sector.

The trade associations commented that they have identified the risk to the feed additive industry of losing access to generic feed additives at the renewal stage, explaining that, 'These have become known as 'orphan additives' on the grounds that there is no incentive for businesses to prepare and submit renewal dossiers given that the additives are generic in nature and available from many different sources.' Another trade association commented that this proposal would prevent the need for emergency reauthorisations, where feed additives do not have an authorisation holder.

How the FSA/FSS plan to address the issue of 'Article 10' dossiers was queried by a further trade association with an interest in feed additives. They stated that, 'this issue requires attention, as it represents a significant area where we are beginning to observe notable differences between UK and EU additive regulation.'

FSA / FSS response: Comments noted. Long-standing feed additives (known as 'Article 10' feed additives) are not within scope of the reforms we are making in this SI and we will be reviewing them separately. We have already been engaging with trade associations representing manufacturers and processors of animal feed additives and will seek further industry engagement on our plans in due course. In the interim, we are tracking progress of these feed additives in the EU and taking action when necessary to ensure continued food and feed safety in GB.

Main theme of response: assessment process

Stakeholder comments: A wide-reaching industry trade association stated that it would be helpful for FBOs to be made aware or notified of new authorisations or the commencement of new evaluations or authorisation reviews, to enable the industry to provide data for risk assessment or input into proposed risk management measures.
Additionally, they felt it would be useful for the industry to be made aware of how FSA/FSS would plan to keep abreast of emerging evidence and long-term studies in the absence of the need for

authorisation renewals.

FSA / FSS response: Comments noted. The list of applications undergoing risk analysis is already publicly available, and we consult on applications for regulated product authorisations. The FSA, in collaboration with FSS, is reviewing the current consultation process to ensure it is proportionate and is delivering the needs of stakeholders.

We are committed to openness and transparency are investigating options for stakeholders to be informed of changes to the registers proactively. The feedback from this consultation will help shape our development of registers of authorised regulated products.

We proactively monitor emerging risks through horizon scanning and intelligence gathering activities. We will also continue to set post-market monitoring requirements within the terms of marketing authorisations for regulated products where necessary, including requiring businesses to submit post-market monitoring reports.

Main theme of response: divergence

Stakeholder comments: A trade association with a focus on feed additives expressed their view that they consider it vital that the FSA/FSS work on a cross-UK basis, in line with the commitments of the Food and Feed Safety and Hygiene Common Framework. They felt that a common approach to regulated product authorisations, to minimise and manage any divergence across the UK, is of utmost interest to the industry.

On this point, an international trade association whose remit is food additives felt that a unified approach across England, Wales and Scotland could ?minimise delays and economic impact. They suggested incorporating ministerial authorisations into UK regulation at ?set intervals, rather than after each decision.

FSA / FSS response: Food policy is a devolved matter and as such the FSA independently advises ministers in England, Wales and Northern Ireland, and has joint responsibility for the marketing authorisation of regulated products with FSS. Having had extensive discussions throughout the development of these proposals, we expect positive agreement across the nations. The FSA/FSS are strongly committed to achieving four-nation consensus in line with our commitment to the Food and Feed Safety and Hygiene common framework. Our approach to four-country working ensures that public health and consumer interests are protected across the nations.

We currently process the latter stages of product authorisations in batches to increase efficiencies. We have noted this comment for consideration as we consider future reforms to the process.

Main theme of response: Northern Ireland

Stakeholder comments: One trade association commented, seeking further clarification on the placing of regulated products on the Northern Ireland (NI) market, and stressed the complexity of preventing movement of products containing food additives only approved in GB from travelling onwards from NI to the Irish Republic.
A trade association based in NI, and an individual FBO, queried whether NI businesses using regulated products may be disadvantaged if the European Union (EU) does not accept, or accepts in a slower time, renewal applications for products which now no longer need to be renewed for the GB market.

FSA / FSS response: For placement on the NI and EU markets, NI businesses must continue to submit applications for the authorisation of regulated products to the EU.

Under Windsor Framework arrangements, regulated products authorised in GB may be placed on the NI market, provided they are eligible for, and moved through, the Northern Ireland Retail Movement Scheme (NIRMS).

Under current GB and EU legislation on renewal requirements, products can remain on the market pending a decision on authorisation, providing the application was received within the required time limit. The EU deciding not to renew an authorisation for a product would impact NI businesses (unless the business was exclusively supplying GB). However, if there was new evidence of a potential safety risk this would trigger our own review process.

Main theme of response: use of other regulators' opinions

Stakeholder comments: The use of other regulators' opinions in risk assessment was raised as an additional option that would make the authorisation process more efficient and make best use of resources.

A body representing food science and technology professionals, a trade association with a focus on feed additives and an organisation that provides support to food businesses all supported international collaboration and the sharing of risk assessments between equivalent, trusted, scientific risk assessment bodies.

FSA / FSS response: Comments noted.

FSA and FSS already make some use of other regulators' risk assessments to inform our approach. In doing so, we ensure that the outputs from other regulators meet our standards and enable us to consider the needs of UK consumers. We will continue to work proactively to explore opportunities to ensure efficiencies are realised, by expanding our use of other regulators' opinions.

Main theme of response: Pre-application support

Stakeholder comments: Two organisations made comments around the provision of advice to potential applicants, especially small and medium-sized enterprises (SMEs), to improve the quality and efficiency of submissions. One of them suggested that the FSA/FSS consider a register of specialist support and a network of approved analysts and laboratories to complete appropriate product analysis to support technical dossiers (e.g. clinical studies, exposure, toxicology). The other recommended that the FSA/FSS put in place communication to consumers and broader stakeholders to articulate the benefits of the proposed changes. From their perspective, these include:

- Reducing inefficiency in managing regulated products
- Increasing the ability to focus on the more difficult problems in risk assessment to assure consumer protection
- Devoting freed resources to horizon scanning better to react speedily to emerging problems

FSA / FSS response: We are improving our pre-application engagement to enable applicants to understand data and evidence requirements, to submit good quality applications.

We are currently piloting enhanced pre-application engagement on a small selection of 'first of kind' applications using new and/or disruptive technologies, to inform our approach across regulated products. Our ambition is to improve the quality of applications which in turn will reduce the re-work required by applicants and the regulator in the early stages of the process. Whilst we can offer some limited improvements within current resources, we are also developing proposals for early engagement at the product development stage and a more comprehensive pre-application service as part of our longer-term reform work.

Main theme of response: objections to the authorisation of GMOs

Stakeholder comments: Five respondents (all individual consumers) took the opportunity to express their negative views about the authorisation of GMOs in general.

FSA / FSS response: This is outside the scope of this consultation. These reforms do not change existing requirements to label products containing authorised GMOs, and do not change the existing laws governing cultivation of GMOs in any parts of the UK.

GMOs for use in food and feed will continue to be subject to authorisation requirements before they can be placed on the market. This authorisation is related to the use of GMOs in food and feed: their cultivation is dealt with under separate legislation. The safety assessments will continue to be conducted to international standards.

Main theme of response: current backlog

Stakeholder comments: Industry respondents took the opportunity to raise the issue of the speed of authorisations and the current backlog.
Trade associations with an interest in feed additives were concerned about the number of feed additive dossiers currently within the application service and seek these to be subject to back-dated implementation of the proposal.

FSA / FSS response: Currently, renewals comprise about one in five of total regulated product applications. Under the current legislation on renewal requirements, products can remain on the market pending a decision on authorisation, providing the application for renewal was received within the required time limit.

Under this proposal, the renewal requirements would be removed, and businesses would no longer be required to submit renewal applications to keep their products on the market.

We are considering the operational changes that may need to be implemented as a result of the proposed reforms, for example the process for handling the renewal applications currently in the service.

Main theme of response: other

Stakeholder comments: Three consumers thought that the proposal would affect the labelling of foods and expressed their concerns that the ability to make informed choices regarding food would be removed.

FSA / FSS response: This proposal will not affect the labelling of food or feed.

Section 2 - Proposal to remove the requirement for SIs/SSIs

Of the 123 responses to the consultation received, 86 (70%) ‘agreed’ or ‘strongly agreed’ with the proposal to remove the requirement for SIs/SSIs and 24 (19%) ‘disagreed’ or ‘strongly disagreed’ with the proposal. A significant proportion of respondents (13, which is 11%) neither agreed nor disagreed. Five of these were individual consumers.

The majority of respondents in support of the proposal identified themselves as responding to the consultation on behalf of a food business or trade association. Those responding on behalf of enforcement bodies were all supportive of the proposal or gave a neutral response.

Consumers were divided in their views – 19 agreeing with the proposal, 20 disagreeing and 5 neither agreeing nor disagreeing. Many of the respondents had not fully understood the change

(for example, several thought that the FSA/FSS currently make authorisation decisions and that the proposal would introduce ministerial decision making).

Having a range of remits, the NGOs / consumer groups gave mixed responses. Of the 8 responses from respondents identifying as representing NGOs / consumer groups, 4 agreed, 3 neither agreed nor disagreed, and 1 disagreed.

Across consultation responses and the engagement sessions, the main themes in support of the proposal were that:

- it would remove bureaucracy and reduce the time taken for authorisations, with no impact on food and feed safety,
- it would optimise the use of policy and parliamentary resources,
- registers are likely to be more accessible for all parties, including both UK and international businesses and consumers.

The main substantive reason given for disagreeing with the proposal was the view that removing the requirement for SIs/SSIs would remove scrutiny and accountability.

The responses to the consultation have been analysed and the main themes identified. The FSA/ FSS's responses to the comments made are set out below.

Main theme of response: reduction in time to authorisation

Stakeholder comments: Sixty-seven (67) or 54% of respondents expressed the view that the proposal would reduce the time taken for products to be authorised, which they welcomed.

Those in support for this reason included UK and international trade associations with a large membership, representing sectors such as agriculture, feed additives, food additives, specialist nutrition, food supplements and alternative proteins.

The view that removing the requirement to lay legislation to authorise regulated products would not compromise the scientific and technical rigour of the authorisation process and would not adversely affect safety was echoed by several other respondents, including those consumers who were in favour of the proposal. Comments included: 'I believe that this is a sensible proposal that still retains the important steps in risk management responsibility, but will help to speed up the authorisation procedure', 'these delays are significantly hindering the entry of products deemed safe by risk assessors to enter the market', and, 'this is a procedural obligation that does not add to the risk assessment process and an improved product safety credential for the consumer.'

In their comments, some respondents stated that time delays make it very difficult to plan for product launches and felt that reducing the time between a positive scientific opinion and authorisation will help industry, support innovation and enable consumers to have access to new products more quickly.

One organisation made the point that the lack of alignment in timeframes and recess timetables between England, Wales, and Scotland can contribute significantly to the time taken to authorise products once they have gone through risk assessment.

A consumer in favour of the proposal expressed the view that the current process seems an unnecessary waste of time, 'especially if a product has the potential to improve the health, welfare, efficiency and/or sustainability of animal feed production systems for example.'

FSA / FSS response: Comments noted. We are continuing to work towards modernising the authorisation process, to make it more efficient and proportionate. We anticipate that this reform will accelerate the approval timeline by at least 3 months.

Main theme of response: better use of public resources

Stakeholder comments: Eighteen (18) or 15% of respondents, across all categories of respondents, wanted to ensure efficient use of public resources (across the FSA and FSS, as well as Parliamentary time), and were in favour of the proposal for this reason.

Several respondents commented that they saw the current process as an administrative burden. The comment made by an organisation that supports food businesses, that, 'It currently introduces significant delays to authorisation to food and feed businesses and an administrative burden to the FSA, the wider civil service, government and stakeholders,' was echoed by other respondents. For example, a trade association with an interest in regulated products commented that efficiencies brought by this measure would include, 'Facilitating effective utilisation of policy, legal (across government) and parliamentary resources, and limited parliamentary time.' Similar comments were received from other interested parties.

A consumer expressed this view by stating, 'Ministerial time is valuable and should not be wasted on administrative tasks.'

Some respondents referenced supporting innovation in their replies, for example stating that 'this will also enable the government to concentrate on new authorisations and optimise the use of policy and parliamentary resources' and 'the FSA can focus its resources on ensuring safe and innovative products reach the market in a timely manner'.

FSA / FSS response: Comments noted. This proposal aims to deliver significant efficiencies in the Regulated Products Service, while ensuring food safety and standards are maintained, providing greater value for taxpayers.

Main theme of response: improved transparency and accessibility

Stakeholder comments: In expressing their views on moving to an official public register, comments were made (by industry representatives, enforcement bodies and consumers) that this would improve transparency and accessibility for all interested parties. Benefits to manufacturers, retailers, enforcement bodies and consumers were cited.

A trade association conveyed their views that, 'Having easily accessible information on what foods are approved for sale is a fundamental assumption of our food safety system. The current system makes this information available in theory, but the proposed changes would make it accessible to regulatory authorities and innovators in practice.'

An experienced regulatory affairs professional noted that they find the current SI system complicated to read and follow and that a systematic register for maintaining the authorisations - similar to the Generally Recognised As Safe (GRAS) Notice Inventory in the U.S. would be preferable.

The perceived benefits to trade were raised by several respondents. Comments included: 'This would bring the UK's process for publishing authorisations into the 21st century, and create transparency and clarity to domestic and foreign businesses as well as trading partners' (comment from a food business) and, 'Other jurisdictions widely employ registers or positive lists to facilitate the authorisation of products. Implementing such a register in GB would be crucial to ensuring clear regulatory status for GB products in international trade' (comment from a consumer).

A food business felt that companies using regulated products currently maintain their own libraries of the relevant regulations and the need for this would be eliminated if they could simply refer to a register.

FSA / FSS response: The FSA/FSS consider that online public registers will provide simpler, more transparent, and more accessible listings of authorised regulated products than is provided by SIs/SSIs. These are likely to follow the current e-register format and include the authorised product's associated terms of authorisation, including product details, conditions of use and date of authorisation.

For regimes where the FSA/FSS already maintain a register, features such as the links to relevant legislation will remain in any adaptation as part of these reforms.

Main theme of response: query legal status of registers

Stakeholder comments: Some industry respondents queried the legal status of an official register, and asked that this is made clear.

One respondent asked whether the legal status of a Ministerial decision will differ from the current legal instrument and pointed out that, if there is a difference in the legal status of the authorisations compared to previous authorisations, this may create confusion, especially if a legal challenge occurs between user and seller based on safety grounds.

An international trade association with an interest in regulated products said of registers, 'This would be a simple approach, but one that itself would need to be underpinned by legislation to ensure clarity and 'one truth' for the market, particularly for demonstrating the legal status of GB products to the external market exporting to GB.'

This point was raised by three FBOs, who requested that the legal status of a register be made clear as this may otherwise cause challenges when trading internationally.

A trade association with an interest in feed additives, together with other industry respondents, recognised that there are many countries with published positive lists of food and feed ingredients which provide a precedent for this type of approach.

FSA / FSS response: We are currently considering the operational impacts of this policy change, including the format and presentation of official register(s). In doing so, we will take these responses into account.

Products would only be permitted to be placed on the market if they are authorised under the relevant legislation, and the entries in the official register(s) will reflect those authorisations.

Main theme of response: functionality of registers

Stakeholder comments: We received several helpful comments regarding the required functionality of a register.

An association representing trading standards professionals agreed with the proposal because they felt that it would create a more efficient process and be similar to authorisation processes used by other UK regulators, stating that, 'there will need to be transparency and clarity about where the decisions are accessed and must contain the detail of the authorisation.'

This request was also received from an organisation that supports food businesses, who asked that, 'the suggested 'controlled' published authorisations register must be easy to locate and navigate with clear information, approval information e.g. dates and key product information.'

Several industry respondents stated they would be seeking a web-based system that includes both existing and new applications and authorisations with well-maintained updates on the current position of each.

Detailed comments regarding functionality were received from trade associations and FBOs and included suggestions that:

- the information on the register links to any product safety incidents related to the authorised regulated product,
- product approvals include e.g. an ID number for ease of reference in the register,
- the register can be downloaded or saved as a PDF for offline access,
- the register provides links to the relevant authorisations under EU Regulations,
- feed additives have been authorised for use in organic farming systems are highlighted in the register.

FSA / FSS response: We are grateful for the suggestions and will consider these as we develop plans for registers.
We will be engaging with key stakeholders when building registers and carrying out user testing to ensure functionality best meets users' needs.

Main theme of response: amendments to register

Stakeholder comments: An enforcement body queried what the process for modifications / removals from the register would be and how enforcement officers will ascertain if an authorisation has been amended or revoked, advocating that notifications of any changes to authorisations are communicated to local authorities through existing mechanisms.

Industry were also alert to this potential issue. An international trade association requested that, 'To streamline the authorisation process while ensuring that regulated parties are informed of new authorisations, a ?centralised notification system could be implemented. This system would alert stakeholders of any updates, withdrawals, or ?transitions required, allowing for adequate preparation time.'

The point was also made by a UK-based trade association, who asked for, 'A clear means by which revisions to the authorised products can be made and recorded in the register, such as extensions of use and revisions to specifications for novel foods…. A clear means by which the revocation of an authorisation and a product's removal from the register can be made public, so it is made known to industry and enforcement alike.'

FSA / FSS response: We are considering operational changes that will be required as a result of this policy change, such as the processes we put in place to ensure online registers contain all necessary details of authorisations, the status of authorisations (e.g. active versus revoked) and how stakeholders are notified to any changes in authorisation/lists.

We will continue to work closely with local authorities in the UK to help ensure food stays safe and what it says it is. We have agreements and protocols in place to support local authorities in their work. Information on the status of authorisations will be clearly provided in the register.

Main theme of response: the impact of post-marketing risk analysis on the register

Stakeholder comments: A representative from an enforcement body emphasised that there should be clarity and transparency around the work undertaken to review and revoke approvals where appropriate so there can be confidence that emerging risks are being reviewed and actioned.

An organisation that supports food businesses requested that consideration is given to whether a product incident would trigger a risk assessment or if the product would be suspended from the register pending the outcome of the investigation.

FSA / FSS response: Comments noted.

Information on the status of authorisations will be clearly provided in the register. We are considering how this will work in practice and will engage with relevant stakeholders to develop the approach on this.

Under our current risk analysis process, products undergoing a safety review are listed in our Register of Risk Analysis Issues. This supports our core principles of openness and transparency.

Main theme of response: removal of Parliamentary scrutiny

Stakeholder comments: Ten (10) individual consumers, together with an NGO with an interest in GM, disagreed with the proposal on the grounds that it will remove scrutiny.

A major consumer group responded neutrally, commenting that, 'It is important that there is effective scrutiny of the FSA and FSS authorisations of regulated products,' and made suggestions as to how this transparency could be achieved. They stated that, 'Although the procedure is a negative resolution procedure, it does still allows [sic] for issues and concerns to be raised. The FSA/FSS must ensure that their primary focus remains on consumer protection and if the procedure is changed ensure that there is a more effective mechanism to ensure public input prior to a Ministerial decision so that this can be made with a full understanding of all of relevant issues and that these are set out transparently.'

A consumer commented, 'Decisions around food safety should be subject to careful public scrutiny and be a matter of open public record and accountability.' Another expressed their view that, 'The requirement for legislation is an important safeguard that allows other informed participants to question ministerial decisions.' These comments are representative of those given concerning this view.

FSA / FSS response: The market authorisation process will continue to apply. As such, there are no safety concerns regarding removing secondary legislation and no changes to the technical and scientific scrutiny that the FSA/FSS and independent advisory committees are responsible for conducting.

Removing SIs/SSIs would not change ministerial decision-making as we would still require ministerial approval before adding products to the registers which will continue to be based on FSA/FSS risk management recommendations on whether to authorise a product or not There will be no changes in how the FSA/FSS submit risk assessment advice to ministers for authorisation decisions.

Currently all regulated product authorisations are confirmed by secondary legislation, which impacts on the time it takes for new products to gain market authorisation. This is an effect of the way the regulations were transposed into a UK context, with the Appropriate Authority (Ministers) being assigned the legislative steps previously completed by the European Commission.

The process of making provisions for domestic authorisations of regulated products by way of statutory instruments was introduced to address deficiencies in the operation of EU law at the time of EU Exit.

These proposals would 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. The scientific and technical details of authorisations do not intrinsically need to be set out in legislation. Published authorisations will contain the same information that is currently set out in

legislation.

Main theme of response: importance of transparency

Stakeholder comments: In addition to points raised around parliamentary scrutiny, several respondents stressed the importance of the authorisation process being transparent.

A major consumer group responded neutrally to the proposal, commenting that, 'Mechanisms to ensure transparency such as full declaration of interests, holding public meetings and appointing consumer interest representatives remain essential. Public consultation is also important to ensure that the full range of evidence is taken into account as part of the risk assessment and also that any other legitimate factors relevant to the risk management decision are taken into account… The FSA/FSS must ensure that their primary focus remains on consumer protection and if the procedure is changed ensure that there is a more effective mechanism to ensure public input prior to a Ministerial decision so that this can be made with a full understanding of all of relevant issues and that these are set out transparently.' The need for transparency and the opportunity for the public to input to decisions, was also raised by an individual consumer.

An FBO stated they agreed with the proposal, provided there was a statutory duty for a period of public consultation on any authorisation, where issues can be raised as to the adequacy of the data submitted and the final decision for approval or rejection. They felt that, currently, not all data are being taken into account, and this period would permit the highlighting of potential concerns.

FSA / FSS response: One of the FSA's guiding principles is to be open and transparent.

Risk management options are developed based on the evidence package generated during risk assessment, which includes a safety assessment and information on other legitimate factors as appropriate. As part of the regulated product authorisation process, stakeholders are given the opportunity to comment on applications by taking part in a consultation, before the final recommendation is made to ministers, who ultimately decide whether the product should be authorised for use in Great Britain.

Our advice and the evidence on which it is based, is published as part of the risk analysis process.

The FSA, in collaboration with FSS, is reviewing the current consultation process to ensure it is proportionate and is delivering the needs of stakeholders. In line with our guiding principles, we will continue to ensure that there are opportunities for stakeholders to input.

Main theme of response: ability to challenge decisions

Stakeholder comments: Two (2) respondents (one FBO, one individual consumer) expressed concerns that there is no clear route for challenging decisions on authorisations, other than judicial review. One requested a cost-effective process that could re-assess scientific advisory committee and FSA/FSS decisions.

FSA / FSS response: Comments noted. If an authorisation is rejected, applicants are not precluded from re-submitting, should further supporting evidence be obtained.

Main theme of response: decision should sit with regulator

Stakeholder comments: Seven (7) respondents (individual consumers and those representing industry) expressed the view that decisions concerning authorisations should ideally sit with the regulator (FSA/FSS), not ministers.

One of the comments elaborated on this by saying that all decisions should be evidence-based (the data supporting a safety assessment and risk management advice), and that this does not require political intervention, which should be minimised. They acknowledged that this may require a change in the status of the FSA and FSS.

An industry body stated, ‘The majority of ministers would not have the knowledge to review the regulations so asking them for their opinion by voting on the SSI adds nothing to the process & does not provide any additional safeguard.’

Alongside these comments, nine respondents cited a lack of trust in ministers. It appeared that several of these had misunderstood the proposal, as they cited their distrust of ministers as their reason for disagreeing with the proposal.

FSA / FSS response: Comments noted.

Decisions on authorisations being made by the FSA/FSS, rather than by ministers, is not something we will be considering as part of this reform. However, we will feed these comments into development of future modernisation proposals.
Under the current risk analysis process, authorisation decisions are based on safety assessments and evidence related to other legitimate factors such as animal welfare and environmental and economic impacts.

As part of the risk management of applications, the FSA/FSS also publish public consultations. All responses to consultation are considered, prior to providing robust advice to ministers, who make decisions on whether to authorise a product.

Main theme of response: other comments

Stakeholder comments: We received some comments that are specific to individual regulated product regimes and/or situations or raise issues that are not within the scope of this consultation.

FSA / FSS response: We greatly appreciate the time taken by stakeholders to respond. Where relevant, comments have been passed to the relevant policy teams, across all four nations, for consideration.

Conclusion and next steps

Respondents expressed a range of views on the proposals. There was broad support across industry, NGOs and individuals, with enthusiasm for the increased efficiency. Some consumer organisations, NGOs and individuals gave feedback on monitoring and the need for clear communications to ensure understanding and maintenance of trust in the process. Based on our analysis of responses and the corresponding conclusions that we have made with respect to each aspect of the proposals, we have not identified any reasons that would warrant recommendations to the FSA/FSS Boards to change the approach detailed in the consultation.

However, we recognise that some respondents disagreed with the proposals and that there are areas which require additional information, guidance and/or engagement. We have expanded on this in our responses to each section of the consultation and this feedback will be addressed through comprehensive engagement with stakeholders to explain our robust plans. We will take general comments regarding the regulated products application process into account during our planned wider reforms.

We plan to continue with these two proposals to reform the regulated products authorisation process. The outcome of this consultation will be used to inform finalisation of the legislation, in preparation for the next steps in the parliamentary process.

List of respondents

Below is a list of the organisations that responded to the consultation. We have not included the names of individuals.

Adact Medical
ADM
AIC
AIC Cymru
AIC Scotland
Alternative Proteins Association (APA)
Atova Regulatory Consulting
Bayer
Bayer CropScience
BASF
British Equestrian Trade Association (BETA)
British Association of Feed Supplement and Additive Manufacturers (BAFSAM)
British Society of Plant Breeders
British Soft Drinks Association (BSDA)
British Specialist Nutrition Association (BSNA)
BSPG Laboratories
Cannabis Industry Council
Cellular Agriculture Ltd.
Celtic Chemicals
Chartered Trading Standards Institute (CTSI)
Clasado Biosciences
Cornwall Council
Corteva Agriscience
Council for Responsible Nutrition (CRN) UK
Dairy UK
David Pickard Inroads International Ltd.
Devro
East Coast Viners Animal Nutrition
Elsoms Seeds Ltd
European Industrial Hemp Association (EIHA)
European Specialist Sports Nutrition Alliance (ESSNA)
Farmers' Union of Wales
Food and Drink Federation (FDF)
Feed, Food & Future Ltd.
Food Additives & Ingredients Association (FAIA)
GM Freeze
GMWatch
Government Chemist (LGC)
Greencoat Ltd.
Institute of Food Science and Technology (IFST)
Impossible Foods
International Food Additives Council (IFAC)
Intertek Scientific & Regulatory Consultancy
Kava Coalition
Lallemand Animal Nutrition
Legal Products Group Ltd (LPG)

MAIZALL, The alliance of maize growers from the U.S., Argentina and Brazil
Meatable
Mosa Meat
National Office of Animal Health (NOAH)
National Farmers' Union (NFU) Scotland
Norfolk Trading Standards
Northern Ireland Grain Trade Association (NIGTA)
Orffa Additives
Proprietary Association of Great Britain (PAGB)
Perstorp AB
Pilgrims Europe
Premier Nutrition
Provimi Ltd
Quality Meat Scotland
Red Mills
Sainsbury's
Tailsco Ltd.
The Food Technology Centre
Thompson & Capper Ltd.
Trading Standards Wales
UK Flavour Association
UK Petfood
Which?
ZERO2FIVE
Zinpro