Risk analysis webinar Q&A

Risk analysis process

- **How are risk assessment and risk management split at the FSA?**
  In line with international best-practice (e.g. Codex principles), we have separated our risk management and risk assessment functions to maintain the scientific integrity of our risk assessments. Risk assessment is led by our science directorate while the consideration of risk management options is led by policy officials. Risk assessment involves using a scientific approach to identify hazards and estimate the potential risk to human and/or animal health. This includes evaluating the likely exposure to risks from food and other relevant sources. Risk management is the consideration of potential measures to either prevent or control the risk. It considers the risk assessment and other factors related to consumers' wider interests in relation to food to identify an appropriate response.

- **Will all risk analysis and regulated products recommendations to Ministers go through Parliamentary scrutiny?**
  Recommendations themselves are not subject to Parliamentary scrutiny however any subsequent changes to legislation will be. Deadlines are set in some retained EU law for how long Ministers have to make a decision, which vary depending on the regulated product regime. In all cases, changes to permissions of use or the addition or removal of permitted substances or processes will require legislation (Statutory Instruments) which will be subject to the normal Parliamentary procedures.

- **How much notification needs to be given to the World Trade Organization (WTO) and trading partners before UK rule changes are implemented?**
  The WTO recommends that members notify any new or amended measures that will impact trade or that deviate from international standards at least six months before adoption/publication, except in emergency situations.

- **Will there be an opportunity for civil society contributions on food-related issues to be considered formally within the risk analysis process?**
  Our advice is underpinned by comprehensive analysis of the evidence, including the conduct of risk assessments and gathering information on other relevant factors. These will vary according to the food or feed safety risk but generally include:
    - public health, safety and wellbeing
    - wider consumer interests
    - consumer habits, perceptions, acceptability and preferences
    - economic impact
    - technical and feasibility considerations

  Where risk managers consider "other legitimate factors" these will be based on engagement with consumers, industry and civil society, through participation on surveys, focus groups and various participatory means of eliciting interested parties' views, and response to public consultations. Public consultations usually

include asking for views on regulatory impact assessments (assessing the costs and benefits of risk management options) and equality impact assessments.

- **Will the FSA remain closely aligned with European Food Safety Authority (EFSA) outputs and recommendations? Will the FSA consider opinions from other regulatory bodies?**
  The FSA has its own risk analysis process which follows internationally recognised approaches (e.g. Codex principles), using science and evidence as the basis of our independent risk management advice. Whilst EFSA opinions may be considered when the UK risk assessment is carried out, the assessment will need to be specific to the UK. FSA experts may come to a different conclusion on the safety of a product when compared to other risk assessment bodies (such as EFSA, JECFA, FDA) which could be due to several things, such as differences in UK exposure patterns for example. Risk management decisions and therefore GB law may diverge from the EU in the future. If international opinions differ and those are available for consideration, we would be clear as to the reasons for the difference. Anyone exporting to the EU or any other country must abide by the legislation specific to that country.

Transparency

- **Will non-confidential versions of the dossiers for regulated products be published online or would only the final FSA opinion be published?**
  Our recommendations, together with the science and evidence behind them, will be published to Ministers.

- **Will the UK be implementing the EU Transparency Regulation (EU) 2019/1381?**
  Elements of Regulation (EU) 2019/1381 do not apply until March 2021 and therefore will not form part of EU retained law.

4 country working

- **Will there be an attempt to harmonise regulations between England, Wales, Northern Ireland (NI) and Scotland even if there are differences of opinion?**
  Ministers in England, Wales and Northern Ireland will make the final decisions on food and feed regulations. However, under the Food and Feed Safety and Hygiene Common Framework, the four nations will seek to collaborate and aim to agree consistent policy recommendations.

- **Will reviews and approvals for bringing new regulated products to the UK market be completed by the FSA alone, or will Food Standards Scotland (FSS) be involved?**
  There will be a single application process for businesses applying for pre-market approvals and re-authorisations for the GB market. The FSA and FSS have developed this regulated product application process together. Applications will be submitted online. The EU law that applies in NI after the Transition Period is specified in Annex II to the Northern Ireland Protocol (NIP). Businesses applying for pre-market approvals and re-authorisations for the NI market will submit applications to the relevant body as set out in EU legislation.

- **Will FSS make different recommendations for regulated product authorisations resulting in differences in Scotland and the rest of the UK?**
  We are working together with FSS to implement a joint approach to risk analysis. The outcomes of the process, i.e. risk management advice, may vary, but this is likely to be the exception as the UK Risk Analysis approach will consider relevant issues for the UK as a whole.

Regulated products – approvals and process

- **How do I make an application?**
  There will be a short webform for applicants to complete before they are sent a secure link to upload their dossiers. Any forms/templates/letters set out in EU retained law must be followed. Where available, dossiers should be structured in accordance with current European guidance and should contain the necessary information to support the safety of your products. Applicants should ensure that they have provided all relevant information. Where additional information is included the covering letter should make clear that additional information has been provided.

  Applicants do not need to be based in the UK. Applications can be submitted by anyone including a manufacturer, a user, a trade association or a consultant acting on their behalf. Whoever is making the application will have one week to upload the dossier. As part of the application process applicants are asked to identify the main contact for the application and that is who we will correspond with initially on any follow up questions relating to the application.

  There are fees for animal feed and GM applications relating to the laboratory analysis requirements set out in legislation on these products.

  Applicants can contact us in advance of submitting their application if they have a specific question or require clarification on an issue. There are no plans to publish pre-application discussions on the FSA website.

- **Can you make an application to the FSA before 1 January 2021?**
  No, however applications can be submitted from 1 January 2021. The list of authorised products and any conditions of use as set out and in force in EU law on 31 December 2020 will become part of GB law on 1 January 2021. Any requests to market new products or to change existing authorisations need to be made via the new regulated products application service on the FSA website.

- **If we have an application that has received a positive opinion from EFSA, do we still need to re-submit the dossier to the FSA?**
  An applicant will need to show their interest in bringing the product to market in GB and must submit a dossier to the FSA. The FSA may consider the published EFSA opinion at the end of the Transition Period but reserves the right to undertake a full risk assessment if appropriate.

- **What is the estimated publication date for the new guidance documents for regulated products?**

The UK will continue to use guidance from EFSA for the preparation of safety dossiers and undertaking risk assessments in the short to medium term. We may consider revising these in future. Any changes will be consulted on in line with our engagement and consultation policy.

- **How does the FSA approach the use the start/stop of the clock process during the risk assessment?**
  We will aim to streamline the process as much as possible, minimising delays and consolidating questions where possible. Any timelines enshrined in retained EU law will be applicable from January 2021.

- **Will it be quicker to get authorisation from GB if I have already got an authorisation from the European Commission (EC)?**
  There will be no fast-track process for applications already submitted to the EU. If you wish to use a regulated product in both the GB and EU markets you need to apply separately to the EU and to GB via the regulated products application service on the FSA website. A fast-track process for applications is only available if there is a specific requirement in law for this to happen.

- **Will feed ingredients need authorisation? Under EU law feed ingredients must be notified by the manufacturer, but do not need authorisation.**
  The Catalogue of Feed Materials will form part of retained EU law. The person who, for the first time, places on the market a feed material that is not listed in the Catalogue of Feed Materials must immediately notify its use to the representatives of feed businesses in the United Kingdom. It is envisaged that the EU Feed Materials Register will be transferred to the UK. This will be an industry-led exercise and the FSA will work with industry representatives to discuss the process and the future of the Register.

- **Is there an appeal process if an authorisation is not agreed by Ministers?**
  There is no appeal process established within the regulated product frameworks if Ministers decide to reject an application. Recourse to judicial review would only be justified if there were concerns over how the decision was made, any such action would need to be based one of the three main grounds for review, these being:
    - if the decision-maker did not have the legal right to make the decision
    - if the process leading up to the decision being taken was improper; or
    - if the decision was so irrational, in a way that no reasonable person could have made it.

  However, the judicial review could not cover whether a decision taken by Ministers was right or wrong.

- **Will Extension of Use applications follow the same approval process as for new regulated products?**
  Yes, all requests for new approvals and changes of use should be submitted via the regulated products application service on the FSA website. The application should include the necessary information to support the request. In some cases, data for risk assessment may not be required however the application should include a justification why the requested changes do not affect the outcome of any previous risk assessment.

Regulated products - pipeline dossiers

- **Does an EU regulation have to be in force on 31 December or just published to be brought into GB law on 1 January?**
  The EU legislation must be in force and applicable on 31 December 2020 to become GB law on 1 January 2021.

- **If a regulated product application is under review by EFSA from 1 January 2021, will a new application to the FSA be required?**
  The applicant will need to express an interest in placing their product on the GB market and submit a supporting dossier of evidence to us in line with the legislative requirements using the regulated products application service on the FSA website. This can be the same dossier of evidence submitted for the application to the EU. The FSA and FSS will assess the application under the UK risk analysis process and may also consider any published EFSA opinion. However, any recommendations put forward to Ministers will be developed independently of any action taken by the EU.

- **What is the status of food additives that have already been reapproved but for which EFSA is now carrying out a further assessment for use by young infants and extra data requirements? Must these further re-evaluations be submitted to FSA?**
  Any food additive that is already authorised will remain permitted for use on the UK/GB market at the end of the Transition Period. We will continue to scrutinise any developments in the scientific evidence base relating to the safety of food additives, as we do now. Where necessary, we may request additional information to be provided following a case-by-case consideration and we would inform industry accordingly.

- **How do you plan to engage with stakeholders who manufacture supplements and nutritional feed for both companion and feed animals? Will you use NOAH (National Office of Animal Health) to do this?**
  Over the years, the FSA has built up good working relationships with trade associations across animal feed sectors to help keep their members up to date on feed additive authorisations. This relationship is expected to continue post-Transition Period and we would welcome feedback from all relevant trade associations during any consultation as part of the authorisation process.

- **There is currently a re-evaluation process at EFSA (for sweeteners and other feed additives) – how does this apply in the UK?**
  The programme of re-evaluation for food additives under which EFSA is re-evaluating food additives that were assessed for safety by the EU prior to January 2009 is not in retained EU law. However, we will be monitoring developments in the body of credible scientific evidence that support the safety of these substances. Article 26 of Regulation No 1333/2008 on food additives is in retained EU law, preserving the duty placed on producers or users of a food additive to immediately notify any new scientific or technical information which might affect the safety assessment of a food additive.

Regulated products regimes

Novel foods

- **Is the FSA on target to validate all novel food applications for CBD products by end of 31 March 2021 so that products already on the market can remain on the market or is there the possibility that the FSA will move this deadline?**
  The FSA is currently looking at several CBD dossiers on an informal basis in preparation for the formal process from 1 January 2021. We are encouraging the CBD industry to formally submit their applications as soon as possible after 1 January to reduce the risk of time pressures on the validation process.

Enzymes

- **Can enzymes continue to be sold in the UK after the Transition Period?**
  For most regulated product types, once products or processes are authorised, they are listed in relevant legislation, which also sets out how they can be used. These lists are referred to as positive lists. Up until a positive list is established enzymes can be used subject to the general rules of food law. A deadline will be established by which applications should be submitted to be evaluated and considered for inclusion on the first positive list. Further information on this deadline will be made available in due course. In the meantime, anyone wishing to submit an application may do so.

- **Is the 10 yearly re-authorisation required for GM food enzymes or is it only required for GM food?**
  Any GM enzyme falling within the scope of Regulation 1829/2003 must to re-authorised every 10 years and would need to be authorised first in accordance with Regulation 1829/2003, before it can be included in the eventual positive enzyme list.

GM and Genome Editing

- **There is a scientific and regulatory debate about the basis of GMO and genome editing risk assessment. Some are arguing that the current "process based" assessment should be replaced by an end product or "trait based" assessment. Does the FSA have a view on this?**
  The FSA's Advisory Committee on Novel Foods and Processes (ACNFP) is an independent committee of experts across many fields, including GMOs, that will consider GMOs and new genetic technologies. Internationally, regulatory and risk assessment frameworks for GMOs and genome edited products differ. The ACNFP will examine the possible approaches to safety assessment of gene edited food/feed products and the applicability of existing GM risk assessment frameworks. The FSA will look to learn from what has worked best from the various regulatory and risk assessment options and consider if any changes are required to its current regulatory framework. Should it be considered that changes could be made these will informed by evidence and will subject to consultation.

- **How confident is the FSA that they have been fully advised on gene-editing foods, crops and animals?**
  In addition to the work undertaken by the ACNFP, the FSA engages with the GMO industry on developments in this field and can assess if GMOs have been used in food products.

- **Please explain the relationship between the FSA's assessment of genetically modified organisms for food and feed and the role of Defra's Advisory Committee on Releases to the Environment.**
  Defra's Advisory Committee on Releases to the Environment give statutory advice to ministers on the risks to human health and the environment from the release of GMOs, whilst the FSA's role is to assess the food safety implications from consumption of GMOs. Defra and the FSA work closely to consider implications from potential GMOs.

- **Will the FSA undertake and publish a full independent risk and safety assessment of genome editing in advance of any implementation of any change in policy?**
  Defra are holding a consultation on whether genome editing and other new breeding techniques should be removed from the definition of GM. The FSA will consider what regulatory framework is required for any assessment of food products produced by these techniques.

Feed additives

- **What is the view on feed additives in Annex II to the NI Protocol - will they be considered non-authorised immediately or will UK legislation be needed to remove them?**
  Any feed additives which are authorised under EU law at the end of the Transition period will remain authorised under retained EU law from 1 January. These entries will be subject to review, including the option for their future legal withdrawal from the GB market.

- **For feed additives that need renewal in the EU, there is a one-year deadline to submit the renewal application to EFSA. Will this also apply if we wish to renew the product in the UK?**
  The requirements set out in Regulation 1831/2003 on feed additives will continue to apply as retained EU law. This includes submission of a feed additive dossier at least one-year prior to its expiry date. Businesses will need to use the regulated products application service on the FSA website for all GB feed additive authorisations and renewals as from 1 January 2021.

Risk Assessment

- **Can you tell us about the joint expert groups and scientific advisory committees?**
  We have a Science Council and several scientific advisory committees (SACs) to advise us on our science and evidence. The SACs provide risk assessment advice covering the whole of the UK.

For regulated products, three new joint expert groups have been established to take on the risk assessment of regulated products:

1. Food contact materials - joint expert group of Committee on Toxicity (COT) and Advisory Committee on the Microbiological Safety of Food (ACMSF)
2. Additives, flavourings, enzymes and other regulated products - joint expert group of COT and ACMSF
3. Animal feed and feed additives - joint expert groups of COT, ACMSF and Advisory Committee on Animal Feedingstuffs (ACAF)

The joint expert groups were established to try and minimise the impact of a high volume of dossiers passing through the already busy Scientific Advisory Committees (SACs). Consumer representatives have been selected through open competition on the basis of their interest and expertise in consumer perspectives.

Membership can be viewed on our SAC websites. We regularly review the expertise on our committees to ensure we have the relevant range of expertise. We also carry out committee-wide horizon scanning exercises to keep track of emerging issues including those that could potentially affect risk assessment.

- **What is your opinion on the current FEEDAP panel (Panel on Additives and Products or Substances used in Animal Feed)? They have been issuing many inconclusive opinions with more regularity this year. Do you think the FSA will do similar?**
  Our risk assessments on the safety of regulated products will be based on the data provided by the applicants. If this is not adequate or does not demonstrate safety, a product will not receive authorisation.

- **Will the UK accept EFSA Comprehensive Food Consumption Database intakes data or will they accept the National Diet and Nutrition Survey (NDNS) data?**
  We can accept both. We have exposure experts on hand to provide advice to the Scientific Advisory Committees on potential exposures using UK exposure data and applicants' projections.

- **For novel food applications, is it a requirement to use UKAS accredited labs only for the required tests or can other labs be used which have validated methodologies?**
  It is not a requirement to use UKAS accredited labs only, but UKAS accreditation does give us reassurance that analyses have been carried out to an excellent standard.

- **Who will be the UK reference laboratory?**
  The FSA will be setting out further details on the process and where to send samples in due course on our website.

NI Protocol

- **When will information be available regarding movement of regulated products from GB to NI?**
  The FSA is working closely with other government departments to develop further guidance for businesses placing certain regulated goods on the NI market. The FSA will be publishing guidance via the FSA website to update the sector.

- **If a feed additive is legally placed on the NI market under EU rules, can these goods be placed on the UK market? Will they need to be relabelled?**
  Where businesses have gained product approvals and certification for marketing additives in NI from EU authorities and bodies, the UK will recognise those for the purpose of facilitating unfettered access to the GB market. If a business wants to bring a new feed additive to the GB market they will need to apply via the new regulated products application service on the FSA website.

- **Can businesses in NI only market food and feed products authorised by EU and not those authorised by the FSA?**
  The EU law that applies in NI after the Transition Period is specified in Annex II to the NIP. Food and feed produced and placed on the market in NI will therefore have to comply with EU food and feed law, resulting in some different regulatory arrangements applying in NI than in the rest of the UK. Where NI traders gain product approvals and certification for the NI market from EU authorities and bodies, the UK will recognise those for the purpose of facilitating unfettered access to the GB market.

- **Can food and feed products imported into NI under EU rules be shipped into the UK without restrictions?**
  Where NI traders gain product approvals and certification for the NI market from EU authorities and bodies, the UK will recognise those for the purpose of facilitating unfettered access to the GB market.