Risk Analysis and Regulated Products Service: Regular Update to FSA Board

23-06-07 - This paper provides a regular update on the current status of the risk analysis and regulated product service to ensure transparency on the progress of the service.

Summary

This paper updates the Board on the performance of the FSA's risk analysis process. This includes applications progressing through the regulated products service, and issues that the FSA has proactively chosen to consider. Section A considers current performance and discusses emerging risks, issues and mitigations. Section B highlights options for future reform.

Background information about the risk analysis process and regulated products service has been provided in previous reports to the Board and is available on the FSA website.

This paper should be read in conjunction with the detailed performance pack which provides data about workflow and performance.

The Board is asked to:

- **Review** the performance of the FSA's risk analysis process, and
- **Note** plans for continuous improvement and that we will be engaging with you in the Autumn on plans for longer-term regulatory reform.

Section A: Current Performance

Risk Analysis

Issues undergoing risk analysis include those that the FSA has chosen proactively to consider based on our policy work and horizon-scanning, and issues where work has been commissioned by another Government Department. As of March 2023, there were 22 issues recorded on the public register, an increase of 15 issues since March 2022.

The new risk analysis issues added to the register have been identified through policy analysis, horizon-scanning, and stakeholder engagement. The work includes commencement of risk assessment and evidence gathering in relation to several food contact materials, chemical contaminants and residues, meat hygiene, animal feed and foodborne disease issues. More information is in Annex A.

The growing caseload is in line with expectations. Risk analysis issues may take several years to progress, for example if a call for evidence from external sources is required, so the number of issues in the risk assessment stage will continue to grow before reaching a steady state. Other issues may be completed more quickly. Annex A provides more information about the estimated earliest completion date for each issue.

In our paper to the March Board, we discussed the risk to delivery if resources for risk assessment did not keep pace with growing demand. We have assessed the resource requirements to manage issues currently in risk analysis, giving reasonable assurance that we

can meet the planned timetable. Risks in relation to the regulated products service are discussed at paragraph 4.5 below.

We have agreed a set of qualitative performance measures for the risk analysis process, and completed issues have met these expectations:

- in accordance with the FSA's code of practice on openness, relevant information about the progress of risk analysis issues has been included in the public register and where appropriate, consultation has been undertaken in the development of risk management advice.
- where risk management advice has been provided to Ministers by the FSA, this has been informed by independent science and evidence.
- the FSA has continued to operate on a four-country basis, and the dispute resolution process provided for through the UK food and feed safety and hygiene framework has not been triggered in relation to a risk analysis issue.

According to the policy agreed by the Board, we may decide not to publish information in some circumstances, for example where this is material to a current trade negotiation. We are reviewing this policy in light of our early experience of running the risk analysis process, to ensure that we continue to uphold our principles of openness and transparency and provide the right level of information to external stakeholders.

Regulated Products Service (RPS)

As of March 2023, the caseload in the RPS was 438. As discussed in March, we have made steady progress with authorisations, meeting the expected timetables (allowing for 'stop the clock' periods where the FSA cannot progress applications until further evidence is provided by applicants). A further three applications have now been completed since March, bringing the total number of completed applications to 34 since the service went live in January 2021. We are on track to deliver around 60 authorisations in 2023-24. Expected authorisations due over the next 12-18 months are at Annex B.

Future Service Performance, Risks, and Mitigations

In our update to the FSA Board in March, we provided an early analysis of the growing caseload in the RPS, noting that we expect the caseload in risk assessment will continue to build over the next two years, and that the flow of products into the system will vary from year to year, which makes accurate future forecasting very challenging.

As discussed in March, the first year of operation was not typical. We received just under 300 applications and around 200 of those were in the first three months of operation of the service. We also received over 750 applications (which included incomplete applications) for CBD to meet the regulatory deadline of end-March 2021 of which around a 100 are still progressing through the system in March 2023. It will take some time for this peak of applications to work through the system; our most recent modelling suggests that we will reach the point of having the same level of intake as output on average around 2025, four years after the service began. This is based on the following assumptions:

- **We receive around 150 applications per year** on average – this is in line with our previous estimates and reflects the experience of the second year of operation.
- **From 2025, we authorise around 120 products per year on average** (not all applications that enter the system will progress to authorisation, some are withdrawn, and some are rejected during risk assessment).
- **The large number of CBD applications clear the system over the next 18-24 months**, with the earliest expected authorisations in 2024; CBD comprises around 30% of current

caseload, this group is being actively managed, 36 are currently awaiting evidence. This remains a complex issue and we continue to manage applications fairly and consistently. There will be a paper dedicated to the progress of CBD applications at a future Board meeting.

- **We continue to make good progress authorising the stock of routine applications**, for example renewals and routine applications for additives and flavourings; these comprise a substantial proportion of the caseload and can be processed efficiently in groups.
- **The FSA achieves and maintains planned levels of resourcing**, in particular recruiting six additional risk assessors, maintaining risk assessment capacity at planned levels and continuing to improve productivity as new risk assessors reach full capability.
- **We introduce planned service improvements which reduce workload and increase efficiency**, including the new Case Management System, making appropriate use of other regulators' risk assessments and completing more routine risk assessment work at official level, reserving Scientific Advisory Committee time for more complex and non-routine issues.

More detail about planned mitigations is set out below.

In 2025, we estimate we will have on average, around 500 applications in the system. It is typical for major food safety regulators to have a caseload of hundreds of products (for example, EFSA has a caseload of more than 1,200 assessments1); however, given the resource constraints for the FSA and the level of uncertainty about how the service will develop over the coming years, it is important to note the associated risks to delivery.

The main risks to future delivery are:

- **Ongoing pressure on FSA resources**; as discussed in December 2022, demands on the FSA have increased substantially and new work on Retained EU Law (REUL), border controls, market access requests, the implementation of the Windsor Framework and development of a new regulatory framework for Precision Breeding draw on many of the same officials who are involved in the authorisation of regulated products.
- **An unexpected surge in applications**, for example if a new product class such as novel proteins reaches market viability and a large number of applicants come forward at the same time.
- **Ongoing issues relating to Retained EU Law**, where the process of transferring into domestic regulations has not worked properly, creating problems in the authorisation process – these issues generally only come to light when a problem arises, for example the need to amend regulations in 2022 to enable certain edible insect species to lawfully remain on sale in GB.

We are managing these risks in three ways: **continuous improvement** dealing with issues as they arise and introducing changes that will help us do more with existing resources; **ongoing focus on staff recruitment, training and retention**; and **scoping options for future reform** maximising the opportunity created by the review of REUL and thinking creatively about longer-term, more fundamental reform (which would, however, require additional funding and resources to progress).

Continuous Improvement

A programme of continuous improvement and reform has been in place since the launch of the Regulated Products Service in January 2021. Examples include improved guidance, significant recruitment, forming additional advisory committee capacity with the establishment of the Products of Genetic Technology in food and feed subcommittee (PGT) to support consideration of Genetically Modified Organisms and Precision Breed Organisms and maximising efficiencies in the system such as 'batching' applications. A list of service improvements so far is in Annex C.

In the coming year, we will be implementing additional measures that will support the necessary increase in authorisation rates by reducing unnecessary work and increasing efficiency:

- **a new Case Management System**, an online application portal expected to improve workflow management and minimise the number of incomplete applications for example by providing a checklist of required information.
- seeking agreement from the Department for Health and Social Care, Food Standards Scotland, and the Welsh Government on **the use of other regulators' opinions to support some risk assessments**, extending the approach currently used in respect of applications started before EU Exit – this will further reduce the need to repeat work where high-quality evidence is available.
- **focusing Advisory Committee resource on key issues and complex applications** – currently all applications are considered by our Committees, while risk assessors are recruited and trained. In future, routine applications will be considered by officials, this will increase the number of risk assessments completed each quarter by removing Committee time as a potential pinch point.

Staff Recruitment, Training and Retention

Since January 2021, policy and science teams have expanded significantly as workload has grown. The risk assessment team has expanded from 5 full-time equivalents (FTE) to 31 FTE in post; a new Regulatory Services Unit has been created to oversee delivery, growing from 4 FTE to 18 FTE. Given resource constraints, staff recruitment has been responsive rather than in anticipation of potential future workload, and this remains the position. This means that, if there were an unexpected surge in applications (for example for novel proteins) it would take around 6-12 months to recruit additional staff if funding was made available.

Section B: Future Regulatory Reform

Regulatory Reform

Continuous improvement is important, but it will not produce the step change in delivery and customer experience that will be possible with more strategic reform. Creating a modern, streamlined and effective regulated products service will bring benefits to both businesses and consumers as new products come to market more quickly, including those with the potential to bring health and environmental benefits.

Fundamental reform will require additional resource for policy development and analysis. Current capacity to work on regulatory reform is focused on developing a new regime for precision-bred food and feed, and on maximising the opportunities created by the review of REUL, a current government priority. Despite this, we are using limited capacity to lay the foundation for potential fundamental reform in the future, should additional resource become available. An example of this preparatory work is the recently completed review of the Novel Foods Regulatory Framework (see paragraph 8 onwards).

Retained EU Law

The Retained EU Law (Revocation and Reform) Bill presents an important opportunity for us to deliver reform in targeted areas, while maintaining food and feed safety and standards. Within the specific constraints of the REUL Bill, we aim to be ambitious in using the opportunity to reform regulations by 2026 to streamline the application process, speeding up authorisations and making the process easier to navigate for applicants. As explained in the separate REUL paper, all proposals will be subject to consultation and Ministerial agreement.

As set out in March, our plans include:

- a common application gateway and standardised regulatory pathways for the different regimes;
- a quicker process through which authorisations come into force; and
- a more efficient process to record and communicate which products have been authorised.

Currently there are 12 separate regimes (including Novel Foods, GM Food and Feed, Feed Additives and Food Contact Materials) with different legislative requirements and timelines. This is burdensome for applicants as they must familiarise themselves with multiple requirements, creating additional work and increasing the risk of error. We want to create a **Common Authorisation Procedure (CAP)** that will consolidate the process set out in legislation and create a standardised system with a single front door for applicants, and consistent timelines and requirements so the applicant journey is more straightforward.

We would like to consider the scope for streamlining the process through which authorisations come into force after Ministers have made a decision. 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 legislation making process in the UK adds 3-6 months to the authorisation timeline and requires significant resource to lay regulations. We are therefore looking at what can be changed in this area.

We are also exploring the development of consolidated positive lists/e-registers of authorised regulated products published on the FSA website. This would replace the current methods for listing authorised products, which varies by regime, including lists in legislation or having separate pieces of legislation for each authorisation. Whilst the development and maintenance of e-registers has associated costs, this work could significantly streamline legislation and would enhance transparency and accessibility. It would provide industry and enforcement officers with a common location to view lists of authorised products.

Novel Foods Review and Longer-Term Reform

In the Benefits of Brexit Paper (HM Government, January 2022) the FSA confirmed a commitment to review the Novel Foods process to remove barriers to innovation. Following an external tender process, Deloitte was commissioned to undertake the review. The review commenced in January 2023 and reported in March 2023. A summary of findings will be published in late Spring. The review presented illustrative alternative approaches to reform ranging from adjustments within the scope of the current framework ('no-regrets' options) to more radical options such as conditional authorisation and fast-tracking applications with potential health and environmental benefits. A summary of the options is at Annex D.

We are reviewing the outputs of the Novel Foods review and considering the reform options that would be the best fit for the GB market. We will maximise the opportunities in reform of REUL to streamline the authorisation process for Novel Foods alongside other regimes, our proposals will deliver some of the 'no-regrets' options from the Review.

More fundamental reform would require additional funding and resources to pursue. Depending on the appetite for change, a new regime could represent a significant departure from the EU-based model of regulation that the UK has established over the past 40 years. This would require extensive stakeholder engagement, consultation, coordination and engagement with the devolved administrations and substantial policy and legislative resources to design and implement a completely new, bespoke regulatory framework.

We will return to the Board in Autumn 2023 for a further discussion on REUL reform plans for 2024-25, and on a longer-term reform strategy for risk analysis and regulated products. It is likely that potential reforms made using the REUL Bill powers (see paragraph 8.2) will be delivered in stages before June 2026.

Conclusions and Next Steps

In our first two years of live running, the FSA is making steady progress with regulated products authorisations and progressing issues in risk analysis. As expected, the caseload continues to build and is projected to reach the point of us receiving the same volume of applications as output, in 2025. We are continuing to improve efficiency, but risks remain; the main risk is that in the current environment our resources are constrained, and we lack capacity to respond rapidly to emerging work pressures. In the medium-term we propose using opportunities in the 'reform' phase of REUL to streamline and shorten the authorisation process by 2026. More fundamental reform would require additional resources.

The Board is asked to:

- **Review** the performance of the FSA's risk analysis process, and
- **Note** plans for continuous improvement and that we will be engaging with you in the Autumn on plans for longer-term regulatory reform.

Annex A: Summary Statistics for Risk Analysis and Regulated Products

Risk analysis issues recorded on the public register:

Detail of the risk analysis issues recorded on the public register.

Issue	Description	Estimated Completion
Imported Products Of Animal Origin (POAO) 2022 Controls Project	FSA work with Defra to consider the public health aspects of the Future Animal Imports Risk Review (2022). Our risk analysis input has been completed and has been sent to Defra to help with its policy development.	Complete

Issue	Description	Estimated Completion
Review of Controls on Imports from Japan following Fukushima Incident	Review of the controls in retained EU Regulation 2016/6 imposing special conditions governing the import of food from Japan following the Fukushima nuclear power station incident. Review will consider latest evidence on levels of contamination in food from Japan to determine whether controls should continue and, if so, whether any amendments to the controls are required.	Complete
Risk Analysis of Minced Meat and Meat Preparations - Review of Prohibitions and Restrictions on Imported EU foods.	FSA work with Defra to consider the risk associated with imported chilled meat preparations (all species), chilled minced meat (bovine, porcine, ovine and caprine) and minced meat (poultry).	Complete
Review of imported food and feed controls under Retained EU Commission Implementing Regulation 2019/1793	To ensure that the proposed changes to the list of certain controlled food and feed products not of animal origin (FNAO) in the annexes of Retained EU Commission Implementing Regulation 2019/1793 outlined are appropriate	Complete

Issue	Description	Estimated Completion
Extension of tolerance period for traces of Ms1×Rf1, Ms1×Rf2 and Topas 19/2 oilseed rape	Three Genetically Modified Organism events that were formally withdrawn from the market (Ms1×Rf1, Ms1×Rf2 and Topas 19/2) are currently granted a tolerance in a proportion of no higher than 0,1% mass fraction in adventitious or technically unavoidable presence. This is outlined under REUL 2019/1562 with this tolerance period expiring after 31 December 2022, wherein it would return to zero. The authorisation holder claimed that a technical zero presence would be unavoidable after the end of this tolerance period date and requested a review to extend the tolerance period to ensure its adventitious presence does not hinder the future trading of oilseed rape commodities.	Complete
Dioxin & Polychlorinated Biphenyls (PCB) Risk Analysis	Consideration of the need for changes to risk management measures following a reduction in the Health Based Guidance Value for dioxins. This may include changes to existing regulatory limits in food and/or revised consumer advice.	Risk assessment anticipated end 2025 at the earliest.
Perfluorinated Alkyl Substances (PFAS) Risk Analysis	Consideration of risk management measures associated with Perfluorinated Alkyl Substances (PFAS), a broad range of often persistent industrial chemicals some of which have been reported in food.	Risk assessment anticipated end 2025 at the earliest.

Issue	Description	Estimated Completion
Analysis of the safety of Titanium Dioxide (E 171) as a Food Additive	On 6 May 2021 the European Food Safety Authority (EFSA) published an opinion on the safety of titanium dioxide (E 171) as a food additive. The EFSA panel concluded that E 171 can no longer be considered safe when used as a food additive. UK Scientific Advisory Committees (SACs) will assess the EFSA opinion and any associated studies alongside the existing scientific evidence to provide a view on the safety of this permitted food colour. This will help inform what appropriate risk management action may be needed to safeguard consumers.	FSA risk assessment is anticipated to conclude in December 2023 (following data from COT/ Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) outputs). Subject to SAC timetabling, Advisory Committee on Animal Feeding stuffs discussions will be held in early 2024. The earliest delivery date for the formal RA opinion is April to June 2024.
Risk analysis procedure for bamboo-plastic composite Food Contact Materials (FCMs)	Bamboo and similar plant-based materials are not considered to be authorised additives in plastic FCMs in accordance with Regulation 10/2011 (retained under domestic legislation in Great Britain), therefore a decision needs to be taken in respect of the GB market. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) recently published their interim position statement on these articles.	Final COT statement and agreed risk management approach is expected early 2025 at the earliest.
Ocean-bound plastic and plastic obtained from the environment used in food contact applications	The FSA and Food Standards Scotland (FSS) are aware of the use of recycled plastic in FCM products that are in part, or fully, fulfilled using plastic material that has been obtained from the environment (ocean, ‘ocean-bound’ or land). We are carrying out risk analysis to assess the safety of using these materials in food contact applications.	The SACs (FCM Joint Expert Group and COT) are expected to carry out a full evaluation of this material from April 2023 at the earliest. Complete risk management will be provided in early 2024 at the earliest.

Issue	Description	Estimated Completion
Review of T-2/HT-2 Toxins in Foods	Review of occurrence data for T-2/HT-2 toxins in cereals and assessment of the exposure of UK consumers to these toxins from cereals and cereal-based foods.	Risk assessment anticipated March 2024 at the earliest. Complete risk management expected January 2025 at the earliest.
Direct supply of meat (including offal) to the final consumer (potential cold chain disruption) (Qurbani meat and offal during Eid al-Adha)	The FSA is evaluating whether there is any additional risk to consumers as a result of the supply and consumption of less than fully chilled Qurbani meat and offal during Eid al-Adha.	Although work has been completed on the public consultation exercise, progress to stage 2 and the long-term approach is currently paused due to work pressures associated with the Retained EU Legislation (REUL) Bill, and while we assess the impact REUL will have on the ability to introduce new measures in the current regulatory framework.
Country Profiles - Imported Food of Non-Animal Origin (FNAO) Phase 1	Production of Country Profiles for trading partners exporting food of non-animal origin (FNAO) to the UK. These profiles will assist the Market Access Assurance Team in monitoring the risk associated with each country and to inform on the need for follow-up action.	Project redefined with no risk assessment output. All prior country data have been delivered. Register to be updated accordingly.
Risk assessment on Avian Influenza infection via food chain	The purpose of this work is to produce an updated risk assessment for avian influenza in food, triggered by changes to consumer advice regarding egg consumption and the geographically widespread nature of Avian Influenza generating over 100 hundred confirmed cases in the 2021/22 Avian Influenza season.	Risk assessment was completed in spring 2023. Further work on risk management may be required during 2023.

Issue	Description	Estimated Completion
Assessment of TMBPF-DGE for use in can coatings	Following interest from industry, the FSA will evaluate the safety of a substance used as a coating in metal food contact materials in respect of the UK market	The risk assessment is expected to be completed in Spring 2023 with consideration of risk management advice to follow later in 2023.
Assessment of the risk to vulnerable consumers from Listeria monocytogenes in blue cheese	Reviewing the evidence behind FSA advice on blue cheeses and the risk to pregnant women and other vulnerable consumers.	Anticipate publication of a risk assessment and risk management advice in Summer 2023 at the earliest.
Assessment of the risk to vulnerable consumers from Listeria monocytogenes in smoked fish	Reviewing the evidence behind FSA advice on smoked fish and the risk to pregnant women and other vulnerable consumers.	Anticipate publication of a risk assessment in Summer 2023 at the earliest.
Assessment of HPMA for use in can coatings	In 2012, EFSA assessed methacrylic acid, 2-hydroxypropyl ester (HPMA) for use in acrylic resin coatings for food cans at use levels up to 20%. The FSA will re-assess its suitability for use in coatings for placing onto the UK market.	Literature review anticipated to be completed Mid-June with a view of publishing risk management recommendation together with a view to publish HPMA and TMBPF-DGE at the same time – likely summer 2023
Risk assessment of substrates used to rear insects for animal feed	The FSA has commissioned a comprehensive review of the safety of several currently non permitted substrates that could potentially be used to rear insect larvae for protein in animal feeds.	Final report publication, and dissemination meeting ~between January and March 2024 at the earliest.
Review of the prevalence of certain mycotoxins in animal feed	Work to increase understanding of group A Trichothecenes; T2, HT2, Diacetoxyscirpenol (DAS) and Neosolaniol (NEO) and determine their prevalence in retail pet foods.	Draft retail survey report issued May 2023. Risk management approach is being considered and is anticipated summer 2023 at the earliest.

Issue	Description	Estimated Completion
Assessment of plant-based drinks	The Scientific Advisory Committee on Nutrition/COT working group on plant-based drinks is considering the benefits and risks of plant-based drinks in diets across all life stages. The outcome of this analysis will inform public health guidance on the suitability of these products for different sub-populations.	Risk assessment phase due to conclude at the earliest end of 2023.
Vitamin D in infant and follow on formula	Review of the safety of vitamin D intakes from infant formula and follow on milks, in light of the updated regulations on the vitamin D content of these drinks and in the context of our existing advice for vitamin D supplementation in formula-fed babies.	The risk assessment has been completed in Spring 2023 with publication in preparation for Summer 2023.

Annex B: Authorisations expected in the next 12-18 months

Description of applications	(Estimated) Ministerial decision	Estimate of coming into force date (if approved by Ministers)
8 GMO products and 3 modification of existing GMO authorisation holders' details	Q4 22/23	Authorisations came into force across GB on 26 April.
2 Novel food 1 Flavouring 1 Food additive	Q4 22/23	Authorisations came into force across GB on 15 May.
12 Feed additives	Q2 23/24	Q3 23/24
34 varying regimes TBC. This will include GMO, Novel Foods, a Food Additive and Feed Additives	Q3 23/24	Q4 23/24
First CBD authorisation(s)	Q4 23/24*	Q1 24/25

* There is a dependency on the planned Home Office legislation on THC limits in consumer products.

Progress of applications is subject to change, for example if new evidence is required from applicants.

Annex C: Improvements to the Regulated Product Service since EU Exit

- Delegated administrative tasks from Health Ministers to the FSA and streamlined the process for launching consultations on applications.

- Established process to take into account EFSA risk assessments for applications started before EU Exit, shortening the risk assessment process for these products.
- Recruited and completed initial training for 25 new colleagues to risk assessment teams, from an original team of 5. We have also launched a new risk assessor training programme to improve capability.
- Established a new Regulatory Services Delivery Unit that brings together responsibility for design and delivery of the risk analysis process, increasing resources to 18 staff from an initial team of 4.
- Re-established the Advisory Committee on Animal Feeding Stuffs to assess animal feed additive applications and advise FSA on related feed matters, which provides greater capacity and capability to meet demand in this busy area.
- Established the Products of Genetic Technologies sub-committee, a new sub-committee of the ACNFP, to assess GM applications and support the development of processes and our scientific understanding on precision bred organisms.
- Established a streamlined process to progress multiple applications in batches, reducing duplication of work and enabling larger numbers to be authorised at the same time.
- Strengthened our governance and enhanced the joint project management approach to regulated product applications involving all key teams across legal, science and Devolved Administrations from the start.
- Improved website navigation to direct applicants to relevant guidance.
- Designed new standardised processes for FSA calls for evidence and the publication of FSA opinions.

Annex D: Novel Foods Framework Suggested Models for consideration

Through analysis of the ‘long list’ and suite of opportunities available to the FSA, the following models have been developed for consideration. The models are designed to bring together features from the long list which have similar principles underpinning them and set out a coherent configuration of features associated with the principles. That said, the models are not mutually exclusive6 and the FSA could consider combining regulatory elements from each model when reviewing the existing Novel Food Regulatory Framework.

A) ‘No regrets’ opportunities

The FSA could largely retain the key features of the current model including how risk is assessed and safety established, but in this model the FSA would remove some of the main pain points from the existing process for the FSA, FBOs and consumers. Added features would be centred around improving accessibility, transparency and information around the framework, and removed

features would be the additional process steps such as statutory instruments for novel foods which do not have a clear value-add to the core stakeholder groups or regulatory outcomes of ensuring food safety and enabling innovation, but which do add a time and cost burden to the process.?

B) Triage-based regulation

The FSA would retain the current approach to how the safety of novel foods is established but would change how the pipeline of novel foods applications is processed. This could include triaging and grouping similar applications into high/medium/low risk cases and tailoring the framework to provide a clear route for different emerging technologies. It could also include prioritisation of applications based on specific criteria.

C) Lifecycle based regulation

The FSA would shift from a single point of authorisation of novel foods to a staged approach to regulation, incorporating a change in how safety of novel foods is established. The model incorporates a range of ways in which this could be achieved, such as conditional authorisation and ongoing monitoring. The model takes account of the fact that definitive evidence of the safety of certain products is not always available at the point of authorisation.

D) Collaborative regulation

The FSA would authorise novel foods using knowledge and insight?from other organisations, constituting a shift in how the safety of novel foods is established. This could include recognising the evidence base or decisions of food regulators in other jurisdictions, and/or placing more responsibility on industry to assure safety. The model takes account of the fact that food innovation is global and rapid, and a shared global understanding of novel food safety may hence be appropriate.

E) Innovation-centric regulation

The FSA would introduce one authorisation ‘front door’ for all products deemed high-risk enough to require authorisation, removing the Novel Foods Regulatory Framework in its current form and focusing more on consumer awareness of novel food safety. The model recognises that given the pace of innovation the current framework may not be fit for purpose and may need to be more anticipatory, adaptable and innovation focused.

Regulation for Innovation – Government Initiative

In February, we updated the Board on the ongoing Regulation for Innovation Project led by the Government Chief Scientific Adviser to identify regulatory reform options to stimulate innovation and economic growth. Specific reforms on the Novel Foods regime were selected for further exploration as part of this Government initiative. The report was published on 26 May.

The FSA would require additional resource and funding to develop the ideas outlined in the Regulation for Innovation Life Science Report that do not fit within our REUL scope of work. The FSA will work with the Government to explore further reform opportunities. Future funding beyond 2024-2025 will be determined at the next spending review.

Annex E: Risk Analysis and Regulated Products Service Report to Board June 2023

Refer to Annex E: Risk Analysis and Regulated Products Service Report to Board June 2023 published separately.