Novel Foods Regulatory Framework Review

Executive Summary

Authors: Report commissioned by the FSA from Deloitte LLP

Project Status: Completed

Date of Publication: 7th June 2023

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Executive Summary (1/3)

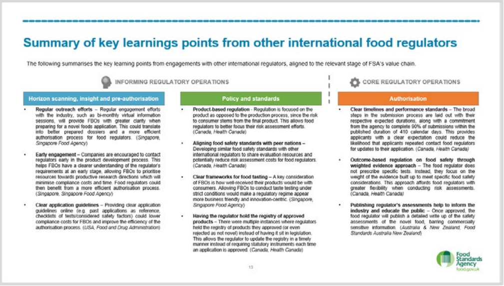
Context and project purpose

- **Innovation in novel foods is happening at pace** and the **FSA recognises that in order to keep pace with innovation there could be certain potential future challenges within the current regulatory framework**. The challenges range from anticipating and preparing to receive future innovative products, to ensuring the system works efficiently and effectively for applicants.
- As innovation continues to speed up, the FSA faces a longer term challenge around the sustainability of the existing Novel Foods Regulatory Framework; food regulators in **other jurisdictions are actively reviewing how they authorise novel foods as well**.
- **The purpose of the project** was to: strengthen understanding of the effectiveness of the current Novel Foods Regulatory Framework and where there are pain points and levers for change; understand broader international and sectoral approaches to the authorisation of new products (food and non-food); demonstrate the art of the possible in terms of how the Novel Foods Regulatory Framework could be improved; ensure relevant stakeholders across the FSA understand the implications, risks, and opportunities of the potential models. As such, this report is intended to develop the FSA's thinking on reform opportunities and is not intended to be implemented without further policy development and appropriate legal advice.

Insights to inform future models

Two main activities were conducted to inform the development of future models.

- **Extensive external engagement with Food Business Operators (FBOs); interest groups; food regulators in other jurisdictions and UK regulators** operating in other sectors provided insights around the experiences of those accessing the current framework and how other organisations establish the safety of novel products and processes. Key insights around alternative authorisation models such as conditional authorisation, early engagement with FBOs and robust application guidance were common themes arising from external interviews. The engagement was focused on the experience of applicants and regulators. Consumers and consumer groups were not part of this rapid review, although consumer interests have been taken into account throughout. Any future proposals for reform would be subject to public consultation and give full consideration to the interests of consumers, as well as those of other stakeholders including Ministers, Parliament and the devolved administrations.
- The **critical evaluation of the current framework was based around five evaluation criteria**: evidence-led and safety-based; collaborative and transparent; user centred; efficient; future proofed. A number of opportunities for improvement were identified in the current framework to refocus around the added value to consumers and FBOs. This included more tactical efficiency opportunities through reducing additional burden in the way processes are currently delivered; and more strategic opportunities such as a repositioning of FSA's current framework to better align to emerging technologies through revisions to novel foods definitions.



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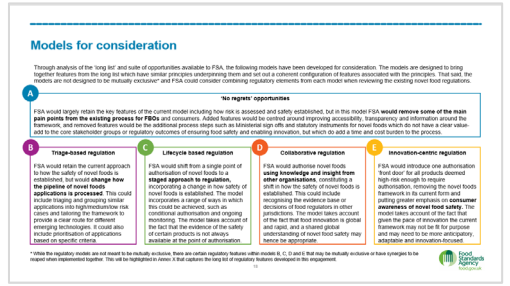
Future models

A long list of potential regulatory features for the Novel Foods Regulatory Framework was developed and from this **a series of models formulated to present a series of strategic choices around the framework**. The models include regulatory features that are:

- ‘No regrets’ opportunities, those which are likely to benefit all FBOs, consumers and those administering the regulations, and which do not have evident downsides;
- Centred around triaging applications based on the level of risk arising from the product/process, recognising novel foods is a broad category and a one-size-fits-all approach may not be appropriate;
- Underpinned by the principle that a single point of authorisation for novel foods is not sustainable long term given the pace of innovation and that evidence about safety may develop over time, leading to a conditional authorisation and supervision model, similar to that used in other sectors such as pharmaceuticals;
- Recognising that food innovation is global, and the FSA could leverage opportunities to more formally collaborate with other regulators, academia and other organisations; and
- Representative of a radical reimagining of the Novel Foods Regulatory Framework and based on greater consumer awareness of novel foods and a single front door for all food safety assessments in the FSA.



While the regulatory models are not meant to be mutually exclusive, there are certain regulatory features within the models that may be mutually exclusive or have synergies to be reaped if implemented together.

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Implementation considerations

In preparing to implement these features and models there are a number of considerations to be made.

- There are **factors relating to the level of complexity involved** such as: the FSA would have to consider whether the model might require legislative change to be implemented*; the scale of change involved as compared to the current framework; dependencies on internal or external factors and any known risks and issues relating to the implementation.
- There are also **factors relating to resource** such as: capacity within the FSA teams and in devolved administration teams responsible for design, oversight and implementation of the current process; capability and skills required to design and implement the options; and additional cost requirements such as third party spend on systems or other resources. Depending on the nature of any reforms, requirement for additional resources is likely to be permanent, for example if a more efficient process stimulates additional demand from industry.

* The legislative and regulatory implications highlighted in this Executive Summary are not based on any legal review, basis or analysis. This Executive Summary is not to be considered as legal or regulatory advice and may not be relied upon as such. Each of the options proposed or otherwise presented in this Executive Summary will require specific, detailed legal and/or regulatory review to consider the likely consequences of its introduction, both on the existing Novel Foods Framework but also on any wider related legislative and/or regulatory implications. Accordingly, while sections of applicable law and regulation may have been reviewed, legal and regulatory analysis will be required in respect of such options proposed or otherwise discussed in this Executive Summary.

The report does not represent scientific/technical advice and has been prepared based on a review of international comparators from published information and conversations with several other regulators. As such, it does not consider all international food regulators nor necessarily represent all possible regulatory options. The views expressed by the individuals engaged or interviewed for the purposes of or in connection with the Executive Summary may be their own rather than official policy and for the avoidance of doubt, not legal or regulatory views either.

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Summary of external insights on changes to the FSA's operating context

The following are changes to the FSA's operating context identified through stakeholder engagement and research. They formed a backdrop to the external engagements, framed the discussion guides developed and used, and have been reinforced multiple times by different parties during engagement.

Shift in regulatory context – With EU Exit, the UK has the option of updating its regulations without having to obtain consensus from other EU nations. Novel foods regulations can be better tailored to meet the needs of the UK.

Different business demographics – Businesses making novel foods applications tend to be smaller firms that may not have dedicated regulatory teams nor prior food regulation experience. They may require more clarity and guidance from regulators than more established operators.

Consumer demands are changing – There is a greater focus on sustainable and more environmentally friendly food options among consumers[1]. This may contribute to greater demand for new food options and, consequently, more novel foods applications that consumers and producers want approved at a faster pace.

Food is the new 'tech' – There is a surge in investments in novel foods, with global alternative protein companies securing US$5 billion in disclosed investments in 2021, which is 60 percent more than in 2020 and five times as much as the amount raised in 2019[2]. The volume of novel foods applications could increase significantly as a result.

Drive to enhance reputation or promote innovation to ensure the UK is the best place in the world to start and grow a business – Small and Medium Enterprises (SMEs) are increasingly recognised for their contributions to the economy and the UK Government published an action plan to support SMEs achieve sustainable growth. There may be greater pressure or opportunities for Government agencies to provide more support for SMEs and innovation (e.g. Sir Patrick Vallance Review[3]) in due course, especially with the current model of approving individual use cases for even small changes to ingredients, process, etc.

1. Record US$5 billion invested in alt proteins in 2021, surging 60 percent since 2020, Good Food Institute, 8 Feb 2023. 2. Sustainable Food Trends Will Become Centre Of The Plate With Modern Consumers, Forbes, 10 Nov 2020. 3. Policy paper: Terms of reference for the review of regulation for emerging technologies, HM Treasury, 18 Dec 2022.

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Summary of key learnings points from other international food regulators

The following summarises the key learning points from engagements with other international regulators, aligned to the relevant stages of the FSA's value chain.

INFORMING REGULATORY OPERATIONS

Horizon scanning, insight and pre-authorisation

- **Regular outreach efforts** – Regular engagement efforts with the industry, such as bi-monthly virtual information sessions, may provide FBOs with greater clarity when preparing for a novel foods application. This could translate into better prepared dossiers and a more efficient authorisation process for food regulators.
- **Early engagement** – Companies are encouraged to contact regulators early in the product development process. This may help FBOs have a clearer understanding of the regulator's requirements at an early stage, allowing FBOs to prioritise resources towards productive research directions which will minimise compliance costs and time. Food regulators could then benefit from a more efficient authorisation process.
- **Clear application guidelines** – Providing clear application guidelines online (e.g. past applications as reference, checklists of tests/considered safety factors) could lower compliance costs for FBOs and improve the efficiency of the authorisation process.

Policy and standards

- **Product-based regulation** – Risk assessments are more focused on the product since the risk to consumer stems from the final product. This may allow food regulators to be more efficient and focused with their resources.
- **Aligning food safety standards with peer nations** – Developing similar food safety standards with other international regulators to share evaluation resources and potentially reduce risk assessment costs for food regulators.
- **Clear frameworks for food tasting** – A key consideration of FBOs is how well-received their products would be with consumers. Allowing FBOs to conduct taste testing under strict conditions could make a regulatory regime more business friendly and innovation-centric.
- **Having the regulator hold the registry of approved products** – There were multiple instances where regulators held the registry of products they approved (or confirmed as not novel) instead of having it sit in legislation. This may allow the regulator to have less administrative burden, be more agile in updating the registry, and thus have a single source of truth in the registry without the need for separate communications.

CORE REGULATORY OPERATIONS

Authorisation

- **Clear timelines and performance standards** – the regulator sets a defined timeline for the review process and commits to achieving this timeline in at least 90% of cases This provides applicants with a clear expectation and could reduce the likelihood that applicants repeatedly contact food regulators for updates to their application
- **Outcome-based regulation on food safety through weighted evidence approach** – The food regulator does not prescribe specific tests. Instead, they focus on the weight of the evidence built up to meet specific food safety considerations. This approach may afford food regulators with greater flexibility when conducting risk assessments.
- **Publishing regulator's assessments to help to inform the industry and educate the public** – Once approved, the food regulator will publish a detailed write up of the safety assessments of the novel food, barring commercially sensitive information.

Summary of feedback from FBOs and interest groups

The following summarises the key learning points from engagements with FBOs and interest groups to provide a focused view of the industry perspectives towards the existing Novel Foods Regulatory Framework, aligned to the relevant stages of the FSA's value chain.

INFORMING REGULATORY OPERATIONS

Horizon scanning, insight and pre-authorisation

- **Clear guidance is key for nascent industries** – where there is rapid development and a lack of established standards in place, FBOs require more guidance than usual. This may be especially so if the FBOs are relatively small and do not have dedicated nor experienced regulatory compliance staff. Food regulators could work with industry and academia to keep pace with industry developments to help ensure that application guidelines are clear and fit for purpose for FBOs to follow.
- **Regulatory capture may not be a concern if industry guidance is published, consulted on and regularly updated in response to feedback** – Ensuring that any non-confidential information shared with specific applicants is then provided to industry through updated guidelines, regularly improving the guidelines through public feedback, would lower the risk of regulatory capture while accelerating the growth of the industry with food safety as a key tenet.
- **In a nascent industry, more information is better than less, even if this means sharing more information about individual applications and dossiers** – While not ideal, food regulators publishing details of approved novel food products and regulators' assessments is not a deal breaker for applicants when deciding which jurisdiction to first submit a novel foods dossier with. Instead, clear guidance and expectations, which can be informed by the above-mentioned publications, is of much greater importance.

Policy and standards

- **Changing industry circumstances require a different approach** – There has been more innovation in the past 10 years than the previous 40, and new products may have no precedents. (e.g. recombinant proteins)
- **Safety has multiple definitions** – There may be an opportunity to review UK's position on food safety, be it reasonable certainty of no harm (US), a precautionary principle (EU, EFSA) or somewhere in between.
- **Risk-benefit assessments as opposed to only risk assessments** – While food safety is key, there are opportunities to consider wider societal benefits as well (e.g. sustainability, carbon footprint) when approving novel foods applications.
- **Regulators have a role to educate the public as well** – Currently, companies are leading in terms of educating the public about novel foods – there is an opportunity for food regulators to help educate and shape the public narrative. Where the risks permit, food regulators could also focus on helping consumers make informed choices (e.g. clear labelling requirements) instead of making the choice for them through approving/not approving specific novel foods.

CORE REGULATORY OPERATIONS

Authorisation

- **Safety is paramount, efficiency is key** – Staff from certain FBOs, especially new start-ups and university spin-offs, may not be aware of, or have a good understanding of food safety considerations from the outset. However, these new organisations and existing FBOs understand that established food safety standards are there for a reason. It is in their interest to work with the FSA to streamline authorisation processes without compromising food safety.
- **Prioritisation of applications** – As application volumes increase, the FSA could consider some form of prioritisation (e.g. alignment with national strategies on net zero) between applications to maximise the impact of limited regulatory resources.
- **Greater transparency and better communication from the FSA to applicants** – The FSA has sometimes taken a more business-minded and transparent approach to keep businesses updated on the process. That said, more could be done to provide greater clarity and reduce compliance costs for businesses (e.g. detailed and up-to-date regulatory guidelines for novel foods applicants).

Evaluation criteria

The Novel Foods Framework has to achieve a **balance of outcomes for different stakeholder groups**, primarily: ensuring food safety and safeguarding wider consumer interests whilst delivering an efficient and effective process for applicants. A good regulatory process does not impose unnecessary barriers to innovation. To ensure the evaluation of the current framework is rounded and holistic, a series of criteria have been developed.

The criteria have informed by principles of good regulation (both for novel foods and more broadly) from a range of sources both within and outside the FSA (see below). The criteria have been tested and validated with the FSA novel foods and regulatory reform policy teams.

Evidence-led and safety based
Is the framework led by objective evidence around establishing the safety of novel foods? Consumer safety is at the heart of the FSA's strategy and is the primary purpose of the Novel Foods Framework. Establishing safety should be done objectively but also proportionately with a reasonable burden of proof.

Collaborative and transparent
Are all stakeholders, primarily consumers, decision-makers, applicants and representative groups, transparently and effectively engaged? There should be established processes to co-ordinate with all stakeholders - this also gives opportunity to the FSA, other regulators, and industry for mutual learning.

User centred
Does the framework meet the needs of FBOs, consumers, FSA teams and devolved administration teams in a proportionate and effective manner? Regulation should be accessible, consistent and tailored to the needs of the stakeholders. The Novel Foods Framework is a 'service' for FBOs to access and to get their products approved; how they interface with the framework is an important factor.

Efficient
Does the novel foods process achieve effective outcomes for optimal time/cost input? Good regulation should aim for efficient and effective delivery and this applies across all touchpoints within the Novel Foods Framework. Rapid innovation in the food industry is driving an increase in applications for novel foods which puts efficiency front-and-centre as a criterion for an effective framework. Enabling innovation is a UK Government priority.

Future proofed
Is the Novel Foods Framework robust yet adaptable? It needs to be able to cope with a rapidly changing food industry landscape, innovation and emerging technologies, alongside a complex political landscape and continued pressure on resources within the FSA.

Sources used to inform development of the criteria
Regulator's Code. Department for Business Innovation and Skills (2014); Principles of Effective Regulation. NAO (2021); FSA Strategy 2022-2027. FSA (2022); Better Regulation Framework. Department for Business, Energy & Industrial Strategy (2020)

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Conclusions of the critical evaluation of the current framework

A summary of the key conclusions from the critical evaluation of the current framework are outlined below.

Evidence-led and safety based

- The current risk assessment process is thorough, involves a wide range of experts and is generally perceived as robust by consumers and FBOs. However, the outcomes of risk assessment and evidence requirements are not always clear to applicants, and opportunities for synergy through grouping applications for similar products and/or drawing on evidence and conclusions in other jurisdictions are not always fully maximised.
- The risk management process as currently laid out in regulations does not allow for sufficient weighting of the potential benefits to wider society, demonstrating a need to review this in a refreshed food industry context.

Collaborative and transparent

- There is strong collaboration across the four nations in authorising safe novel foods across GB and the risk of divergence is managed through collaborative working.
- The FSA has high standards of transparency and openness; within this context, a priority for applicants is for the publication of detailed risk assessment outcomes and more regularly updated application guidance.

User centred

- FBOs would prefer guidance to be updated more frequently and dynamically, with advance guidance on emerging product classes. There is a great demand for more information and engagement across all stages of the authorisation process.
- Resources within the FSA, Food Standards Scotland (FSS) and the devolved administrations are constrained within the limits of agreed government funding. There is limited capacity to build resources in anticipation of future demand. The complexity of administering a new system in a devolved UK context has been a drain on resources in the first years of operation.
- Consumers are well protected through the current framework and it is essential to maintain their trust in the FSA's processes, but they are likely to demand access to a wider range of novel products in the future.

Efficient

- There are inefficiencies in the current framework in the form of: poor quality applications that may be ultimately rejected or require multiple rounds of processing; additional administrative effort around ministerial sign offs and statutory instruments for approved novel foods
- The high number of applications in the current pipeline compared to the number of applications which have been approved to date indicate a need for ongoing focus on efficiency and measures to speed up the authorisation process where possible without compromising principles of safety and transparency.

Future proofed

- Food innovation is happening at a swift and increasing pace and emerging technologies are driving FBOs to bring new products to market. There are perceived complexities and ambiguity in the way some innovative products and processes are dealt with in the current framework, including the definition of novel foods and the interdependencies between different regimes across the FSA.
- A review of the Novel Foods Regulatory Framework poses an opportunity to better align the framework, and potentially its legislation, to emerging food technologies.
- The FSA could benefit from more resources being invested into foresight and horizon scanning functions to better anticipate future food innovations.

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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 exclusive* 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 **could 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 could 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 could 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 could 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 could 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.

* While the regulatory models are not meant to be mutually exclusive, there are certain regulatory features within models B, C, D and E that may be mutually exclusive or have synergies to be reaped if implemented together.

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Key enablers for regulatory reform

Enablers will be critical to the successful implementation of new regulatory features/models. Some of the key enablers are outlined below. These are relevant to Novel Foods framework reform, but are also likely to be relevant to wider regulatory reform within the FSA.

Clear drivers, consistent risk appetite and leadership alignment are critical to building the buy in and momentum to successfully implement the desired regulatory features/models.

→ *The FSA needs to set out clear drivers for enabling innovation and align risk appetite to this. Senior leadership commitment also plays a crucial role in ensuring a successful reform.*

Cultural change across the whole organisation is needed if the revised novel foods regulatory model is to be successful. The models are only useful if put into practice and embraced by everyone in the organisation.

→ *How would the FSA develop the mindset shift needed to adopt a different way of working across the organisation (e.g. from 'prove to the FSA this is safe' to 'how can the FSA and applicant prove that this is safe') or with stakeholders (e.g. partnerships with academia to advance scientific capabilities)? The FSA needs to ensure people know when they have permission to experiment.*

Skills and capability are a critical enabler of any transformation, but especially so when dealing with novel foods on the basis that it may require a different approach and way of thinking than other regulated products.

→ *What skills and capabilities would the FSA need to make the revised novel foods regulatory model work? Where do we have strengths to build on and where do we need to do a lot more or leverage the strengths of others (e.g. collaborating with other international food regulators)?*

Funding and capacity to support a transition from an existing to a new way of working will require careful consideration. The FSA needs to ensure core regulatory operations can continue to function.

→ *What type of investment might be needed to make this happen? How would the FSA balance delivering on its core remit with transitioning to an revised regulated model? This is not a binary choice and the two can run concurrently.*

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