Regulated Products Reform

1 Purpose of the paper

1.1 This paper is for discussion.

1.2 In March 2024 we outlined proposals for initial reforms which are now progressing and briefed the Board on the preliminary recommendations of the FSA Board sub-group on regulated products delivery. This paper presents:

- Context for reform, and progress with initial reforms bearing in mind the General Election announcement and;
- A summary of the issues we propose to address through the reform programme.

1.3 The Board is asked to:

- **Note** progress on initial reforms
- **Discuss** the next steps for regulated products reform

2 Strategic aims

2.1 This work supports FSS Strategic Outcome 1 – Food is Safe and Authentic; 3 – Responsible Food Businesses are enabled to thrive and 5 – FSS is trusted and influential.

3 Background and Context

3.1 Since the UK left the EU, FSS – alongside the Food Standards Agency (FSA) - has taken on responsibility for running the process for granting authorisations for the sale of certain food and feed products in Great Britain (GB). There are 12 different regulated product regimes which together broadly cover food and feed additives, food contact materials and foods developed using newer technologies and production methods. Our job is to make sure these food products are safe before recommending that they are allowed on the market. We are here to protect people, and to give consumers confidence that the food they buy is safe and, where applicable, authorised for sale in the UK.

3.2 The food sector is rapidly evolving, with growth in new technologies and an increase in the pace of innovation. We are expecting demand for authorisations to continue to increase and to increase in complexity. Some new products could have potential benefits for consumers in terms of healthier food alternatives, more environmentally sustainable options, or increased choice generally.

3.3 First and foremost, our job is to keep people safe. We rightly have high standards for food and feed safety, and these will not change. However, we believe the process for regulated product authorisations in GB needs to improve, to meet future

demand, to fully assess emerging technologies and to support businesses and the UK economy by bringing safe new products to market. An effective, proportionate and transparent authorisation system which is efficient to deliver and 'safe by design' will keep consumers safe, support growth while removing unnecessary barriers to innovation.

3.4 We and the FSA have already taken steps to implement reforms that are possible in the short term, as presented to the Board in March 2024:

- The proposed removal of the requirement that some products previously authorised as safe must go through a renewal process at fixed 10-year intervals, regardless of whether evidence on safety has changed.
- A proposed change to allow authorisations to come into effect following ministerial decision, and then be published in an official register, rather than by secondary legislation.

3.5 The consultation on these reforms closed on 5 June and analysis work is ongoing. Given the announcement of the general election and the dissolution of the Westminster Parliament, the short-term reform items have had to be rescheduled. We intend to work with the FSA to progress the legislation as soon as possible after the general election subject to Scottish Ministers' agreement and the consent of the Scottish Parliament.

3.6 Additionally, officials have developed an implementation plan to take forward recommendations from the Board sub-group on regulated products delivery and how we can deliver the current service more efficiently. Some of the more administrative recommendations are already under consideration, such as active caseload management. Other recommendations will require further work and engagement with stakeholders, such as a review of the approach to public consultation and engagement.

3.7 In assessing the current deficiencies and improving the regulated products service we draw on detailed engagement with stakeholders across the UK that has already taken place, including with industry representatives. We have also worked closely with FSA who presented a similar paper to their Board.

4 Discussion

Current Deficiencies in the Regulated Products System

4.1 Since January 2021, FSS and the FSA have been running the regulatory framework inherited from the EU. It is complex and is set out in over 35 different pieces of legislation. To maintain food and feed safety standards and ensure continuity, only fixes necessary to maintain operability were implemented in preparation for EU Exit. Wider reforms or policy change were excluded. This has meant that the legislation continues to have unnecessary duplication and inconsistency across regimes and mandates overly prescriptive processes. The

system was designed to create detailed legalistic processes governing the work of almost 30 member states, something not necessary in GB.

4.2 All stages of the application journey have been considered across GB, identifying the problems and the opportunities for reform in each main phase:

- Pre-application: support given to applicants in preparing a dossier prior to submitting an application;
- Authorisation: all stages of the process from the point of submission through to the authorisation decision; and
- Post-authorisation: activity after authorisation, including post-market monitoring.

Pre-application

4.3 Presently, pre-application support is mostly limited to online guidance, which businesses have reported can be difficult to navigate. While responsibility for good quality dossiers rests with applicants themselves, pre-application support provides an opportunity to guide businesses and support them in developing their own dossiers. Indeed, poor quality dossiers may as a result increase the amount of FSS staff time required per application and extend the end-to-end authorisation process, slowing the pace of products entering the market. This is particularly pertinent for small and medium-sized enterprises (SMEs), many of which have less in-house expertise in this regulatory process. Improving the guidance provided before application would help stem these resource burdens and facilitate smoother movement of products through the system.

4.4 We have supported and participated in the extensive FSA-led engagement with industry stakeholders which produced consistent feedback that a shortcoming of the GB system is the limited pre-application support with an expressed need for meetings and workshops.

4.5 Limited engagement during the development of dossiers also means missing an opportunity to engage early on the development of innovative products, which can slow our response to a rapidly evolving industry.

Authorisation process

4.6 The legislative requirements for authorisation are highly prescriptive and duplicative, meaning that the system can be:

- Complex: Each regulated product regime has its own legislation that lays down the process of authorisation. Fundamentally they all have the same overarching authorisation process, based on risk analysis principles but the individual approach has led to unnecessary divergence, with slightly different legislative requirements, timelines, and division of responsibilities across the various regimes.

- Inflexible: Many of the current requirements, while helpful in providing details on what needs including, are too rigid to respond to innovative and new practices and variations between products because they are prescribed in legislation, rather than supplied as guidance. While some regulations have derogation clauses (which themselves are not always commonly used), this is not the case across all regimes. For example, the regulations on food additives, food enzymes and food flavourings are painstakingly prescriptive, down to the purely administrative details surrounding the necessity of including a contents page in dossiers.

- Disproportionate to risk: Not all products need the same level of fresh scrutiny during risk analysis, for example where the risk is well understood and has already been scrutinised.

Post authorisation

4.7 The risk analysis approach already provides explicit mechanisms for FSS and FSA to monitor new evidence regarding authorisations at any appropriate time, and each regime has provisions to enable FSS and FSA to act immediately if new evidence emerges. Authorisation holders are obligated to communicate to the food safety authorities any new evidence or information that may influence the evaluation of a product's safety, or if they have reason to believe that the food or feed product could do harm to consumers.

4.8 Existing responsibilities can be clarified and made more explicit by addressing the way FSS and FSA approaches post-market surveillance. Currently post-market surveillance is not defined consistently within legislation; in some limited cases there are provisions for industry to produce post-market monitoring plans and reports. Even across the regimes there is disparity in approach which is not necessarily proportionate to the risk: for genetically modified organisms (GMOs) post market environmental monitoring is applied to all authorisations across the regime, whereas feed additives requirements apply to specific categories only. For flavourings, we can request the producer or user of a flavouring substance to inform us of the amount of the substance added to foods in the UK within a set 12-month period. For novel foods, product specific risks are considered in determining if monitoring and reporting should be implemented.

A Modernised Authorisation Service

4.9 In line with the principles agreed by the FSS Board in 2022 (see Annex A), we envisage a system which upholds standards, while modernising the system to be **effective**, **proportionate**, and **transparent** where products are **safe by design.**

4.10 We will continue to protect public health and the interests of consumers by enabling timely access to safe new food and feed products. It will be a service in which consumers, businesses and investors can have confidence, keeping food and feed safe, whilst supporting economic growth and innovation.

4.11 Our proposals will include:

- **A common authorisation framework** for a streamlined service that ensures safe new products are authorised in a timely manner and has the in-built ability to keep pace with innovative developments.
- **Proportionate risk analysis** within the framework to allow flexibility, according to risks, in assessing the safety of products.
- **A "safe by design" approach**, with upgraded pre-application support to allow early dialogue between FSS and the FSA and applicants to ensure products are designed with safety in mind, and FSS and the FSA is ready to regulate them.
- **Clear and accessible opportunities for applicants to engage** with the service. This will include utilising digital tools to provide up-to-date advice and guidance for applicants, regularly updated and able to adapt quickly to regulate new and emerging product types.
- A service which supports **knowledge development and capability building** through horizon-scanning in partnership with industry, academia and other regulators both in the UK and internationally.
- A **sustainably funded service** to ensure appropriate use of public money; and
- A service which ensures **close four nation working** and, while recognising some divergence across the UK is possible, consistently working to minimise divergence across the UK.

4.12 If the Board agrees to our assessment of the current deficiencies, and our proposed vision, we will present more detailed proposals in September, including plans on what we can implement in the shorter term, and the legislative and financial considerations for delivery of comprehensive longer-term reform. The FSA intend to take a similar paper to their September Board meeting with the aim of getting joint agreement at the same time.

5 Identification of risks and issues

5.1 This paper provides an update on progress of priority reform as well as an outline of the current direction for longer term reform and as such does not address risks or issues which will be explored in a more detailed paper to be brought to the Board in September should the Board agree with the outlined position.

5.2 The risk of divergence in GB is being managed, as alluded to above, in terms of the broader reforms being considered in tandem by both Boards and a similar update has been provided to the FSA Board ahead of discussion in September.

6 Equality Impact Assessment and Fairer Scotland Duty

6.1 Equality Impact and Fairer Scotland Duty assessments are not considered necessary for this paper. These will be considered as necessary at a more appropriate stage.

7 Conclusion/Recommendations

7.1 The Board is asked to:

- **Note** progress on initial reforms
- **Discuss** the proposed vision for the future regulated products authorisation service

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Annex A

Assimilated Law: FSS Principles

1. In order to inform ongoing discussions on potential changes to food and feed law, and our advice to Scottish Ministers, the following principles were originally agreed in 2022 to guide FSS' engagement with UK Government leads and stakeholders more generally.

2. In addition, engagement with UK Government policy officials will be on a "good faith" basis, whilst recognising that ultimately it will be for Ministers to decide whether legislative change is appropriate for Scotland, and whether it is appropriate that change is made using the powers in the Retained EU Law (Revocations and Reform) Act 2023. Other powers, such as those set out in the Food Safety Act 1990 and the UK Withdrawal from the European Union (Continuity) (Scotland) Act 2021 are also available as are subordinate powers to amend aspects of assimilated law which are contained within the 2023 Act itself (provided these are preserved).

3. The principles are:

    - Consumer protection is paramount. Unless we can be reasonably assured that the removal or amendment of a provision will not be detrimental to public health, the provision(s) should be maintained. This is in line with the Precautionary Principle set out in General Food Law Regulation 178/2002.

    - Stakeholder views should be sought and considered before any recommendations to Ministers to amend legislation are made. There are also obligations on FSS set out in the Food (Scotland) Act 2015 which describes "Good decision-making practice" as: (a) consulting people who may be affected by decisions before taking them, (b) having good information on which to take decisions and taking decisions based on that information.

    - We should not make changes which are likely to reduce consumer or trading partner confidence in UK food, or which are inconsistent with Scottish Ministers duty to observe and implement UK international obligations including those arising from trade agreements.

4. We will consider supporting changes that support business in line with better regulation principles, as part of the normal review of law. We should be open to considering supporting changes to assimilated law that reduce the regulatory burden on businesses in line with our Strategic Outcomes described in our Corporate Plan[1]. Likewise, we should consider changes to assimilated law if they reduce the administrative burdens of the food safety authorities in the UK where these burdens do not provide additional safeguards to the public, and where their application drives additional cost to the public sector.

[1] Corporate Plan 2024 - 2026 | Food Standards Scotland