Market Authorisations

FSA 24/06/07 - Report by Rebecca Sudworth, Director of Policy.

1. Introduction

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

1.2 We also reaffirmed our commitment to bring a further update forward in June for a modernised market authorisation service (footnote 1).

1.3 This paper presents:

- Context for reform, and progress with initial reforms (see section 2);
- A summary of the issues we propose to address through our reform programme (see section 3);
- Our vision for the future market authorisation service (see section 4),

1.4 We ask the Board to:

- **Note** progress on initial reforms
- **Discuss** our proposed vision for the future market authorisation service, in preparation for engagement with the new Government

2. Context

2.1 Since the UK left the EU, the FSA - alongside Food Standards Scotland (FSS) - has taken on responsibility for running the process for granting market authorisations for the sale of certain food and feed products in Great Britain (GB). There are 12 different product regimes (soon to be 13 with precision breeding) 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.

2.2 The food sector is rapidly evolving, with growth in new technologies and an increase in the pace of innovation. We are expecting demand for market 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.

2.3 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 market 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 market authorisation system which is efficient to deliver and 'safe by design' will keep consumers safe, support growth while removing unnecessary barriers to innovation.

2.4 We 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 public register, rather than by secondary legislation.

2.5 The consultation on these reforms closed on 5 June and we intend to bring the legislation forward as soon as is possible after the general election. To date, discussions with governments across the UK are showing a consistent level of support for the benefits that these changes will secure.

2.6 Additionally, officials have developed an implementation plan to take forward recommendations from the Board sub-group on regulated products delivery about how we can deliver the current service more efficiently. Some of the more administrative recommendations are already underway, 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.

2.7 In assessing the current deficiencies and articulating a vision of the future market authorisations service below, we draw on detailed engagement with stakeholders across the UK that has already taken place, including with industry representatives. Earlier this year we held extended workshops with the Welsh Food Advisory Committee, and the Northern Ireland Food Advisory Committee, as well as an event in Belfast with the Institute of Food Science and Technology. We have also worked closely with FSS, and we expect a similar version of this paper will be presented to their own Board in July.

3. The Problem We Are Trying to Solve: Current Deficiencies in the Market Authorisation System

3.1 Since January 2021, we have been running the regulatory framework we inherited from the EU. It is complex, set out in over 35 different pieces of legislation. In order 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 duplications and inconsistencies 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 Great Britain.

3.2 We have considered all stages of the application journey, 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 market authorisation decision; and
- Post-authorisation: activity after-market authorisation, including post-market monitoring.

Pre application

3.3 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 FSA 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.

3.4 We have engaged extensively with industry stakeholders and have received consistent feedback that a shortcoming of the GB system is the limited pre-application support with an expressed need for meetings and workshops.

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

Authorisation process

3.6 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 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

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

3.8 Existing responsibilities can be clarified and made more explicit by addressing the way the 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, the FSA 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.

4. The Future - A Modernised Market Authorisation Service: Our Vision to Uphold Standards While Overhauling the Process

Our vision

4.1 In line with the principles agreed by the FSA Board (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.**

4.2 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.

4.3 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 agility 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 the FSA and applicants to ensure products are designed with safety in mind, 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.

4.4 If the Board agrees to our assessment of the problem, 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.

Annex A

Principles for reform:

In the December 2023 Board meeting, the FSA Board affirmed the 7 core principles that will guide our reforms:

- **We will protect public health.** There will be no reduction in food safety or standards as a result of our reforms.
- **We will protect consumer interests.** Our new regulatory service will improve our ability to take consumer needs and preferences into account when making regulatory decisions.
- **Decisions will be based on science and evidence.** We will continue to set high standards for evidence, working collaboratively with others on issues of mutual interest in order to maximise efficiency.
- **We will be open and transparent.** We will continue to publish our risk assessments and the basis for our regulatory decisions; we will maintain our focus on excellent risk communication for consumers and we will improve communication with applicants at all stages of the process.
- **We will streamline our regulatory process.** We will design an agile, responsive, and future-proofed service that allows us to be flexible, proportionate, and proactive in our regulatory approach. Market access for safe products, processes and food technologies will be efficient, easy to navigate for businesses, and work for a UK context.
- **We will facilitate innovation and enterprise.** Our regulatory environment will be able to evolve with the developing food system, respond to emerging technologies, and will make the UK a preferred destination for approvals for safe, innovative products.
- **We will strive for four-country working.** We will minimise divergence within the UK and aim to have a common approach to regulatory reform with a framework that operates across the four nations.

1. Market authorisation (previously titled Regulated Products authorisation) refers to the process by which regulated products are checked and approved before being placed on the market.