Policy Development: Precision Breeding

FSA BC 24/09/06

1. Summary

1.1 This paper follows on from the Delivery Plan (footnote 1) for the new Precision Breeding Regulatory Framework that was presented to the Business Committee in June.

1.2 The Committee requested further clarity on the timelines for authorisation of applications for precision bred organisms (PBOs). This paper provides estimated timelines for authorising PBO applications, the interdependencies, and forward look to the expected pipeline of PB products.

2. Background

2.1 Applicants seeking a Tier 1 or a Tier 2 food and feed marketing authorisation for their PBO will need to determine which tier applies to their PBO through a triage process. The tier assigned to a PBO application dictates whether or not the PBO will require an assessment by the FSA to ensure food and feed safety.

2.2 The triage process consists of a set of food safety criteria concerning novelty, nutritional quality, allergenicity, toxicity and any other safety concerns. Applicants will need to use the technical guidance provided to assess the PBO against these safety criteria to determine whether there are any safety concerns associated with the PBO. If there are no safety concerns as a result of the applicant's triage, the PBO is suitable for a Tier 1 application for authorisation, whereas if any safety concerns have been identified, the applicant must submit a Tier 2 application for authorisation together with the data required for FSA officials to conduct a safety assessment of the identified safety concern(s).

2.3 To align with the objectives of the Genetic Technology (Precision Breeding) Act 2023, the PB framework has been designed for decisions on applications to be reached more rapidly than existing regulated products regimes. Within the service, some applications take longer than others to process, which is linked to the complexity of the application, and is especially true when dealing with first-of-kind applications. To reflect this, we have set out the anticipated timelines for less complex and more complex Tier 2 applications, alongside the estimated timeline for Tier 1 applications.

3. Estimated case flow – PBO market authorisations

3.1 The table below sets out the estimated timelines and the projected application volumes for PB applications. To help illustrate the range of applications we anticipate will go through Tier 2, we have set out the expected level of complexity from less complex to more complex applications.

3.2 The complexity of an application can depend on:

3.3 **Novelty**: The originality of the application (is a similar product already approved or is this a different new product) or of the risk or its assessment (is there an established approach for assessment or does advice on this need to be developed?).

a) **Scientific complexity**: Where the PBO is technically challenging due to the level, detail and range of scientific input required.

b) **Specialist expertise required**: Where the FSA (including the FSA scientific advisory committees) require the support of specialist scientific expertise to assess an application.

c) **Risk management complexity**: Where an application covers issues that are likely to be politically sensitive, high profile, controversial or require engagement with wider Government.

3.4 The quality of an application and the information it contains significantly affects the time needed for assessment. We will work with applicants to provide support through the detailed technical guidance and provide as much information as possible to ensure we can process their application as efficiently as possible. But the new nature of the policy may impact the quality of dossiers which could impact the estimated timelines.

3.5 The timelines below are based on the number of incoming PB applications we currently anticipate. However, these projections are highly uncertain. We have presented indicative numbers below based on the latest industry intelligence, and they may evolve as we get closer to launching the service.

Application Type	**Potential application characteristics**				**Estimated timeline for decision**	**Estimated number of incoming applications**
	Novelty	*Scientific complexity*	*Specialist expertise required*	*Risk management complexity*		
Tier 1	Low	Low	Low	N/A	Two months	5 per year
Tier 2 – Less Complex	Medium	Medium	Medium	Medium	12 Months	5 per year
Tier 2 – More Complex	High	High	High	High	24 Months	

3.6 The Tier 1 risk analysis process will enable market authorisations to be granted without the need for a FSA safety assessment, and we estimate that a decision on market authorisation could

be completed in around two months once the process is fully established.

3.7 The Tier 2 risk analysis process will require a product specific safety assessment focussed on the difference(s) from the traditionally bred comparator. Depending on the differences identified, this approach may result in fewer or similar requirements as compared to existing regulated product regimes.

a) **Less complex** Tier 2 PBO applications where the applicant has provided sufficient information to demonstrate safety in its initial submission, a safety assessment could be completed by the FSA science team, utilising in-house scientific expertise. These applications are expected to take around 12 months for a decision.

b) **More complex** Tier 2 PBO applications include those where there is a significant compositional change which has potential to impact the food/feed safety risks in relation to toxicity, nutritional quality or allergenicity and those where there is greater scientific complexity to the modification. This also includes applications submitted to FSA prior to commissioning required studies required to demonstrate safety. More complex applications are more likely to also require assessment by the independent scientific advisory committees (SACs). This could result in timelines comparable to a standard novel foods application (minus the requirement for a statutory instrument), with the process taking up to two years.

3.8 It will take around 3 months from the submission of a Tier 2 application for the FSA to understand the level of complexity involved in assessing it once the relevant checks have been completed by FSA scientists.

3.9 The estimates above are based on a series of assumptions outlined in **Annex A.** They are also highly subject to change based on a series of interdependencies, also outlined in **Annex A**.

4. Next Steps

4.1 We will work closely with the Board Secretariat to ensure the Committee and the Board are kept informed of any further clarity on projections and expected timelines as we gather further intelligence from key stakeholders such as DEFRA and developers. We will also ensure that the Committee is updated on the number and range of applications received during the early stages of the service delivery.

Annex A – Assumptions and Interdependencies

Assumptions

1. **Application volume:** These timelines are based on the current anticipated PB application volumes of five Tier 1 applications / year and five Tier 2 applications a year. If the volumes are higher, this will impact timelines.

2. **Resource**: no additional resource will be provided to the FSA to run the new PB regime, and therefore the estimated timelines are based on current resource levels.

3. **Regulatory Reform:** PB will not directly benefit from initial reforms proposed for market authorisations that were presented to the Board in March, as the PB framework was designed from the outset without the requirement to renew authorisations and without the need for a statutory instrument to give effect to the authorisation. However, the efficiencies made to wider regulated products by the reforms could enable resources to be released to focus on new authorisations for regulated products including PB.

4. **Scientific Assessment:** Tier 2 applications deemed as requiring input from external scientific advisory committees (SACs) will require more time than the assessment in-house**.**

5. **Public Consultations:** The estimated timelines reflect an assumption that public consultations may be required for Tier 2 applications, although a decision on this has not yet been reached. Currently, public consultations for regulated product market authorisation are held for eight weeks. We are assuming public consultations will not be a requirement for Tier 1 applications. The register of PB applications and register of PB market authorisations will provide transparency on FSA's handling of Tier 1 applications.

6. **Novel Foods checks:** More complex Tier 2 applications will be comparable to novel foods, either due to the novelty of the genetic edit itself, or the novelty of the overall product. They will therefore be subject to the existing novel foods checks, which currently take around two and a half years. The estimated timeline for a more complex Tier 2 application is slightly shorter than this, at around two years, as authorisation of PBOs will not require a statutory instrument (unlike novel foods).

Interdependencies

1. **Wider service:** The same officials will be managing the new PB regime as well as the other 12 regulated product regimes. In addition, the SACs required for PB assessments will also be assessing novel food, CBD and GMO applications. The volume and complexity of applications in the wider service will impact the timelines for PB delivery, and vice versa.

2. **First-of-kind service:** Delivering a new service and managing first-of-kind applications is likely to impact the estimated timelines early on in service delivery. As we have learnt, this will improve as officials become more familiar with running the service in practice, and new PB applications become less novel relative to applications we have already received in the service.

3. **SACs:** Depending on the nature of the application, various SACs from within FSA and across Government may need to feed into the assessment. This will vary on a case-by-case basis, and these SACs will also be managing other regulated product applications.

4. **Expertise:** It may become apparent that FSA, or the SACs, do not have all the required scientific expertise internally, which may need to be developed or sourced from other government departments.

5. **Applicants:** We anticipate PBO will attract a wide range of applicants with varying levels of experience. Applicants who are less familiar with food legislation and engaging with the market authorisation process (such as startups, academic developers etc.) may require more support and dialogue with FSA officials to complete their application.

6. **Batching:** To support efficient use of FSA resources in launching and managing public consultations, the FSA currently batches applications from multiple regimes together as part of the wider Market Authorisation service. We are assuming PBO applications are batched within this process, which may impact the timeline of individual applications depending on which batch they fall into.

1. FSA BC 24/06/05 - Precision Breeding- Delivery Plan