Precision Breeding- Delivery Plan

FSA BC 24/06/05 - Report by Max Tollitt/Chris Stockdale/Rebecca Lamb/James Cooper

1. Summary

1.1 This paper responds to the ask from the Chair at the March 2024 Board meeting to present to the Business Committee a Delivery Plan for the new Precision Breeding Regulatory Framework.

1.2 We will have the service ready for launch no later than coming into force (CIF) date of the legislation plus the 90 days Defra has to complete their process ahead of applications reaching us.

1.3 This paper sets out how delivery of the Precision Breeding service will be integrated within the wider regulated products service, the steps required to get there and highlights some of the risks and dependencies.

1.4 Business Committee is asked to **note the planned approach**.

2. Context

Purpose and legislative requirements

2.1 The new regulatory framework for Precision Bred Organisms (PBOs) will enable a proportionate application and authorisation service ("the service") that prioritises consumer safety whilst delivering an efficient process with clear timescales for businesses and consumers. The aim is to launch a service within existing resources that is consistent, reliable and predictable for business which, in most cases, will be much faster at delivering authorisations when compared to the FSA's existing regulatory regimes.

2.2 The Precision Breeding Regulations were expected to be laid before summer recess; however, the General Election means this will not now happen. The Regulations are subject to affirmative resolution and therefore must be debated by both houses of Parliament. If an incoming government were to prioritise laying the regulations in September, the earliest they could come into force would be spring 2025. Our delivery plan will ensure we have the service ready to accept applications no later than coming into force date of the legislation plus the 90 days Defra has to complete their process (see below). Until the regulations are laid and in force precision bred (PB) plants will continue to be regulated under the legislation that applies to genetically modified organisms. If we are subsequently pushed to meet an earlier date, we have contingencies for a skeleton service.

2.3 We expect the Defra service, which requires the Defra Secretary of State (SoS) to confirm PBO status before a subsequent application is made to the FSA, to go live alongside the legislation. They will have up to 90 days from receipt to make a recommendation to Defra SoS. We have no such statutory deadlines in our regulations, but we are expected to process applications 'as soon as reasonably practicable.' The level of service we can offer to meet this requirement is dependent on resources and prioritisation within the wider regulated products system, this is discussed in section 4 below.

Existing regulated products and reform

2.4 Precision breeding will become our thirteenth regulated product service alongside the existing regimes covering food and feed products. It will be the first new regime since leaving the EU and as such has been designed to both integrate with the existing systems and align with planned reforms. This means:

- The service will be delivered using existing team structures and applications will be handled alongside the existing regimes.
- Tier 2 applications will follow the same administrative process as other regulated products; however, the legislation has been specifically designed with the FSA's structures and requirements in mind, and therefore administration of risk analysis will be more straightforward.
- Planned reforms such as the removal of the need to legislate for each authorisation and flexibility around consultations are already designed into the PB requirements.
- PB is being designed into process reforms such as the proposed reduced sign offs and active caseload management.
- 2.5 Where PB will be ahead of other regimes is delivering a service proportionate to risk which will therefore provide a more rapid service for many applications. The key differences will be:
- Products will be confirmed to be PBOs by Defra before an application is made to the FSA for a food or feed authorisation. (This Defra process confirms their equivalence to traditionally bred organism which are not subject to premarket approval and therefore of generally lower risk).
- Tier 1 PBOs will be granted a marketing authorisation without the need for a bespoke FSA risk assessment, instead using a lighter-touch new process to make, audit and register that decision.
- Tier 2 applications will also follow a bespoke risk assessment focussed on the issue(s) of concern. Depending on the risks identified this proportionate approach may result in minimal, fewer or similar requirements compared to other regimes. There is therefore the potential for a more rapid transit through some stages of risk assessment, but this will be product dependent.

3. Preparation of the service

3.1 The PB service readiness requirements fall in five parts which are discussed in more detail below:

- Legislation – We are working on the Precision Breeding Regulations with Defra with timelines outlined above and progress is on track but now pending the election outcome. The discussion in this paper focuses on business readiness, further details on the legislative dependencies can be found in Annex A.
- Tier 1 – development of a new service model and Public Register of Authorised PBOs (Public Register)
- Tier 2 – alignment with existing regulated products service model (using above Register)
- Developer support – technical and administrative guidance
- Enforcement – alignment with existing food law

3.2 Development of the above processes and products will happen in parallel. As the most innovative, the Tier 1 process is the critical path for delivery and sets the latest date for being ready to go live. We consider it low risk to estimate this to be the CIF date plus 90 days based on the earliest opportunity to lay the legislation post-election. This would allow us to make a strong commitment to developers by maximising certainty once a new legislative timetable is known and we could be ready earlier than this.

<u>Tier 1 authorisation</u>

3.3 As set out above, the Tier 1 process is greatly simplified compared to other regulated products processes in order remove unnecessary requirements. However, this also makes it novel for the teams delivering it, and it requires new IT systems to be in place to enable the process to function.

3.4 Key steps to readiness are:

- Application IT system – This will use CMS. Discovery work to include PB has been undertaken and the delivery partner is expected to start work on the necessary updates and builds early Summer with system ready at the earliest in January 2025. This is subject to dependencies on the technical guidance, audit process and our external delivery partner.
- Agreed interaction with the Defra process (may require data sharing agreement)
- Agreed performance expectations – in progress (see capability and capacity)
- Public Register - This will be consistent with the development of registers envisaged as part of the wider reform programme. However, as we are only required to build a blank register with no requirement to upload existing authorisations it will be more straightforward. It is currently under development and expected to be finalised by January 2025 at the earliest. This is also subject to dependencies on our external delivery partner.
- Documentation – (submission templates, guidance for example). This is being developed by the PB team – with finalised documents expected December 2024.
- Audit process and desk instructions – we expect to audit a low percentage of notifications, based on a combination of targeting and random criteria. The outline is in development and expected to be finalised by December 2024 at the earliest and is dependent on the technical guidance.
- Trained Regulated Products Approval Team (RPAT) resource – using existing team in place, training will be delivered by PB team (policy), Science, Evidence and Research (SERD) (technical guidance) once IT systems are available.
- Dry run testing – final stage early 2025. This is dependent on all enabling work being complete.
- Adaptations to account for known applications to Defra post CIF (can be omitted)

3.5 All the IT elements will be subject to a final decision about readiness at the end of June based on agreement of final requirements. If core IT aspects are delayed, then there is some contingency in the timetable, combined with fallback options that would allow the FSA to start receiving applications through alternative channels.

Tier 2 authorisation

3.6 The process for Tier 2 authorisations is closely aligned with existing regimes.

- The register and application system are the same as for Tier 1.
- Likewise, the same people will manage the administrative steps of both Tiers so training will be combined.
- Additional desk instructions will be required to support the transfer of applications between Tier 1 and 2 and the determination of the bespoke risk assessment and risk management requirements. These are in development and expected to be finalised by November 2024 at the earliest. This is dependent on the progress of IT systems development.

Developer support

3.7 There are two elements of developer support, technical guidance and administrative guidance.

3.8 Technical guidance will support applicants to complete a PBO tier determination using triage criteria and the requirements for bespoke safety assessments for PBOs submitted through Tier 2. It has been drafted by the FSA's science team and has been informed by the ongoing

discussions of the Products of Genetic Technologies (PGT) subgroup of the Advisory Committee on Novel Foods and Processes (ACNFP). The draft guidance has been subject to initial review by the ACNFP ahead of publication in draft form.

3.9 This draft publication is due in July following which it will be user tested with a select group of stakeholders reviewed and published in the Autumn of 2024.

3.10 Administrative guidance for applicants will be drafted by the Genetic Technology Policy team with support from the PB Programme Team (it will explain the PB system, set out the process for notifying via Tier 1 and applying via Tier 2) this is due December 2024 at the earliest. This guidance will build on the existing Regulated Products guidance on the FSA website and will be integrated into the wider Regulated Products service.

Enforcement guidance

3.11 The regulations place the responsibility on local and port health authorisations in England as enforcement authorities with the functions of monitoring compliance and investigating suspected failures to comply with the regulations. They will have new powers to carry out these functions along with enforcement of PBs with respect to general food law.

3.12 Guidance to support Local and Port Health Authorities (LAs and PHAs) in England has been developed. The guidance provides a summary of the key provisions laid out in the regulations and how they relate to enforcement.

3.13 Complementary guidance for enforcement authorities in Wales and Northern Ireland has been developed by a specific working group. This guidance will be supported by overarching UK Internal Market guidance, being developed by the UK and International Affairs Directorate and reporting into the Business Delivery Group.

3.14 The guidance has been drafted and is currently being finalised. The guidance is expected to be published in the Autumn of 2024. Incidents teams will be briefed to assist authorities in investigating any PB related incidents.

4. Capacity and Capability

4.1 The PB service will be delivered alongside existing regulated products using the same teams in RPAT, SERD and Policy. As such there will inherently be knock on impacts on other regulated products regimes. However, with an estimation of up to 18 PBO applications each year compared to approximately 160total regulated products applications currently per year across the other regimes, we expect the impacts to be tolerable. Wider regulatory reform and streamlining of the regulatory process will assist.

4.2 This approach also carries the risk that additional pressure on the wider regulated products service will also impact on PB. To mitigate against this, service levels will need to balance meeting the expectation of a more efficient service that authorises many products more quickly with the ability to guarantee resource availability. We have elected to prioritise certainty for developers, both in the start date and the turnaround time for the completion of authorisations. It is proposed to have initial service levels where:

- Sufficient resource will be allocated to Tier 1 processing to provide an average 1 month turn around on notifications and these will be in a separate ‘queue’ from other regulated products.
- Tier 2 applications will enter the regulated products service with other regulated project regimes. This administrative stage is aligned to the process of existing regimes using an overall application queue which PB applications would join in date order.

- However, as set out above, the risk assessment for Tier 2 PB application is bespoke and based on specific risk identification steps, consequently we expect the time spent in the system to be significantly reduced.
- KPIs will be based on the same stages as those expected for other regimes (post reform changes) but timings may differ.
- Applications may be grouped with other regulated product applications in line with our current approach.

4.3 For planning purposes, our initial estimates are based on an assumption of 18 received applications being split 50%/50% between Tier 1 and Tier 2. This assumption reflects that we do not currently have certainty about which products will come to market first and how they will be triaged into Tier 1 or Tier 2. Given this uncertainty, the likely nature of the initial products and novelty of the service we have adopted a relatively worst-case level and split of applications in terms of burden on FSA. We expect to understand in more detail over the next 6 months and once our technical guidance is completed. In the long term we expect applications to be much more skewed towards Tier 1.

4.4 We will keep these projections under review, working with Defra, and adjust turnaround estimates accordingly but currently they represent a high-end estimate. Governance of the service and decisions on resourcing etc. will fall within the wider regulated products governance process. Any request for greater resource to manage pressures will likewise be considered in the context of the wider service.

5. Dependencies and risks

5.1 Key dependencies are:

- Setting performance jump expectations (Service Level Agreements and Key Performance Indicators) will depend upon resource availability in the wider regulated products service. This is linked to successful delivery of regulatory reform and assumed application levels of no more than 18 applications per year.
- Final training and testing can only be delivered once IT systems are in place. There will be regular reporting to the programme and a go/no go decision point for this launch date in June 2024
- Defra have 90 days to process their applications so we will have warning of the pipeline and the opportunity to make any adaptations ahead of these coming to us (e.g. for large volumes)

5.2 Risks

- The service relies heavily on existing regulated products resource to deliver authorisations for both Tier 1 and Tier 2. This resource will be shared with other regulated products regimes and could impact on them and vice versa. This includes the policy and science resource for carrying out Tier 2 risk assessments and risk management.
- The delivery of the IT systems may be delayed if requirements cannot be agreed (June go/no go) workarounds are potentially available.
- The service may come under pressure from the outset if application numbers are significantly different to our planning assumptions. As with other regimes, this would be managed though active case load management.

6. Conclusions

6.1 As outlined above, the ambition is to deliver a relatively rapid authorisations service for most whilst also being able to provide certainty and familiarity for businesses. There is also the

broader ambition to align, where possible, with wider reforms to the existing regulated products regimes. Our scenarios for launching a live service are:

- The service will be ready in line with the most likely CIF date of the legislation plus 90 days as a defensible low risk commitment.
- Should CIF be at its absolute earliest possible, and/or Defra complete their stage quicker there is a high likelihood of readiness earlier to meet this.

Annex A

Legislation

1. Unlike other regulated products, the legislative basis and requirements for the new precision breeding framework will be contained in domestic regulations under powers contained in the Genetic Technology (Precision Breeding) Act 2023 ("the Act"). Currently, all other frameworks are based on the statutory requirements in assimilated law. Whilst the relevant regulations were amended as part of EU Exit preparations to ensure the operability of the legislation, they are still fundamentally based on EU practices, governance structures and processes.

2. As part of the reform programme, the FSA has already identified many areas in those regulations that could be amended to better fit the standard practices of the FSA in delivering the risk analysis process for regulated products, as well as changes that better reflect UK governance structures. Since the Precision Breeding Regulations have been developed with the FSA's vision for the service in mind, we will not be bound by the same challenges faced with the assimilated regulations in other areas of regulated products. Similarly, the approach taken with the Precision Breeding Regulations will help to inform how changes might be made in other regimes to bring them in line with FSA and (UK Government) processes.

3. The precision breeding programme team has completed the preparatory work for the delivery of the secondary legislation in advance of engagement work and Parliamentary debates. This work is similar to the programme of work completed to deliver the FSA sections of the Act and will be a top priority for the programme. We plan to prioritise resource within the programme on delivery of the new regulations.

4. This work will remain the responsibility of the programme and will be completed ahead of programme closure should the expected timeline remain unchanged.

5. Further legislative work in relation to PB animals will be the responsibility of routine policy teams, alongside other PB related policy work required once the service is live.

6. The Precision Breeding Regulations will implement the new framework; however, further legislation is still required with respect to animal welfare before applications can be made for PB animals. This legislation is not expected until 2025 at the earliest. We expect there to be a need for further policy and legal work to ensure the framework is ready to receive any potential applications for PB animals.