

AHDB response to FSA consultation: Proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed

This response is made on behalf of an organisation: the Agriculture and Horticulture Development Board (AHDB).

AHDB is a statutory levy board funded by farmers and others in the supply chain. Its purpose is to be a critical enabler, to positively influence outcomes, allowing farmers and others in the supply chain to be competitive, successful and share good practice. It equips levy payers with easy-to-use products, tools and services to help them make informed decisions and improve business performance. Established in 2008 and classified as a Non-Departmental Public Body (NDPB), AHDB supports the following industries: meat and livestock (Beef, Lamb and Pork) in England; Dairy in Great Britain; and Cereals and Oilseeds in the UK.

Responses are provided for the following consultation questions:

- Pre-market authorisation process
- Public register
- Traceability

Consultation question: pre-market authorisation process

Tier 1 PBOs: Developers will apply the ACNFP criteria to determine tier and notify the FSA of the PBO status. Tier 1 notification is acknowledged by the FSA. When the authorisation decision is taken by the Secretary of State, the FSA will communicate this to the developer and, if the decision is to authorise the PBO for food/feed, place it on the public register.

- a. To what extent do you agree with the FSA using a two-tiered approach for the pre-market authorisation of precision bred organisms used in food and feed?

Agree

- b. To what extent do you agree that the proposal for Tier 1 notifications meets the FSA's policy objectives in paragraph 7.9 of this consultation document?

Agree

- c. To what extent do you agree or disagree that the proposal for Tier 1 notifications is feasible?

Neutral or Don't know

- d. Please provide details of your thoughts towards the initial audit process for Tier 1 PBOs

Overall, the approach seems balanced and proportionate. There is a risk that the application of the approach introduces additional complexity - the question is what

degree of detail will be required and exactly what characteristics will need to be reported on? Will there be standard tests required or will it be up to the breeder to decide what needs testing? If the requirements are too onerous they will stifle innovation, squeezing small and medium businesses out, leading to domination by major multinationals. On the other hand, to ensure consumer confidence, it will be necessary for the FSA to have a robust process of verifying decision making on allocation to Tier One.

- e. Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposal being implemented

Requirements being too onerous, leading to stifling of innovation or too vague, leading to legal challenges from anti-GMO groups. The two-tiered approach should allow for a simpler process for low-risk PBOs.

- f. Please provide details of what you think the benefits and disbenefits of this approach are

If the approach works, it has the potential to accelerate the introduction of new traits and their benefits. This could result in increases in the efficiency of crop and livestock production which is of benefit to both farmers and consumers. There is potential to reduce the reliance on imported food and livestock feed. Additionally, new pest or disease resistances could result in a reduction in the use of plant protection products and any associated environmental impacts.

- g. If you feel there is anything missing from our proposal which would be required to ensure that the policy objectives can be met, or the proposal can be implemented please provide any additional comments you have on the Tier 1 process here.

Further detail, including on the specifics of the triage process, is needed.

Tier 2 PBOs: These would be subject to an application to the FSA, similar to other regulated products. Developers would apply the ACNFP criteria to determine tier. Developers with PBOs for use in food and feed falling within Tier 2 would be required to submit an application with the accompanying data described in ACNFP's Model 1. Applications would be subject to a bespoke risk assessment and risk management process. When the authorisation decision is taken by the Secretary of State, the FSA will communicate this to the developer and, if the decision is to authorise the PBO for food/feed, place it on the public register.

- a. To what extent do you agree with the FSA conducting bespoke risk assessments for Tier 2 PBOs prior to them being authorised for use in food/feed

Agree

- b. To what extent do you agree that the proposal for Tier 2 applications meets the FSA's policy objectives in paragraph 7.9 of this consultation document?

Neutral or Don't know

- c. To what extent do you agree or disagree that the proposal for Tier 2 applications is feasible?

Neutral or Don't know

- d. Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposals being implemented

The FSA will need clear objective criteria for the risk assessment to ensure the policy objectives are met and avoid inconsistent decision making. Without knowing the extent to which these 'bespoke' assessments can vary, it is difficult to judge their appropriateness.

- e. Please provide details of what you think the benefits and disbenefits of this approach are

The second tier provides confidence that PBOs are fully appraised and evaluated. However, a complex process has the potential to stifle innovation. True innovation is more likely with tier 2 than tier 1 PBOs. However, it may make the widespread introduction of PBOs more acceptable to consumers/the public if this extra layer of protection is included.

- f. If you feel there is anything missing from our proposals which would be required to ensure that the policy objectives can be met, or the proposal can be implemented please provide any additional comments you have on Tier 2 process here

Consultation questions: Public register

The Act makes provision for the FSA to establish and maintain a public register which will provide details of PBOs authorised for use in food/feed.

- a. To what extent do you agree that the proposal for a public register meets the FSA's policy objectives in paragraph 7.9 of this consultation document?

Agree

- b. Please provide details of what you think the benefits and disbenefits of this approach are

Openness and transparency are clear benefits, giving reassurance to consumers/the public.

- c. If you feel there is anything missing from our proposal which would be required to ensure that the policy objectives can be met please provide any additional comments on the Public Register here.

Consultation questions: Traceability

In relation to traceability the proposal is that no requirements beyond the existing traceability provisions in General Food Law which apply to all food and feed are necessary.

- a. To what extent do you agree or disagree that the proposal to use existing provisions in General Food Law for traceability meets the FSA's policy objectives in paragraph 7.9 of this consultation document?

Strongly agree

- b. Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposal being implemented

Likely higher cost of traceability testing for PBOs could pose a barrier to policy objective being met.

- c. Please provide details of what you think the benefits and disbenefits of this approach are

The use of General Food Law appropriately recognises the products of PB have no inherent characteristics that pose any greater or lesser risk to traditionally bred products. Therefore, General Food Law is sufficient to address any consumer confidence. Food businesses already operate under this law and their application will not impose any additional cost burden after authorisation.

- d. If you feel there is anything missing from our proposal which would be required to ensure that the policy objectives can be met, or the proposal can be implemented please provide any additional comments you have on Traceability here.