Consultation question: Pre-market authorisation process

1. Triage and two-tiered system

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? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree] - 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? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree] – Agree (see comments in d. and g.)

c. To what extent do you agree or disagree that the proposal for Tier 1 notifications is feasible? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree] - Agree (see comments later in this section).

d. Please provide details of your thoughts towards the initial audit process for Tier 1 PBOs [Free text].

From the current information, it appears that FSA will make recommendations concerning Tier 1 PBOs based on the information provided on the website by the producer. IFST would like to understand in more details what mandatory information will be requested to effectively evaluate the safety and appropriateness of the material being classified as Tier 1. This information should allow FSA to ensure that the PBO generated material provides an improvement on current products and can be assessed adequately for safety, for example what criteria will be used to determine whether or not a PBO generated material is or is not nutritionally disadvantageous.

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

The main barrier that IFST can see is the capacity and capability within FSA to manage the applications for PBO-generated products. It is important that new applications can be judged on a consistent basis and with enough rigour to ensure that any safety concerns can be identified and

addressed with the producer. This will need to be done in a timely manner, particularly following the launch of this process when there may be a number of applications waiting for approval, both from the UK and overseas.

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

The benefits of this approach are to streamline the process and promote innovation in this important area, as opposed to the current requirements within the GM approval process. The disbenefits are the risk of lack of consumer trust and equity of approach against other approval processes. IFST also note that the key act powers cover the aim to establish a regulatory system for precision bred animals to ensure that the welfare of animals is safeguarded. Any precision breeding of animals is likely to be more controversial in the eyes of stakeholders than for precision bred plant materials.

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.

The main concern that IFST would like to raise in terms of missing areas is the lack of a 4-nations approach and agreement to this process. This could affect development and sale of products using this technology, i.e. will developers want to invest in this technology without certainty that the materials can be freely sold within the whole of the UK?

In terms of the early stages of implementation of this assessment process, IFST would like to propose that a full (Tier 2) assessment is conducted alongside the Tier 1 assessment in order to give confidence and calibration to the process, for a determined trial period.

IFST would like to understand the status of fermentation products and processes within this regulatory framework.

2. 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 [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree] 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? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree] Agree
c. To what extent do you agree or disagree that the proposal for Tier 2 applications is feasible? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree] Don't know (see below)
d. Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposals being implemented [Free text]
The feasibility of the approach for Tier 2 is dependant on the capacity and capability within FSA to be able to effectively operate a bespoke assessment process and determine safety and appropriateness in making a recommendation to Ministers.
e. Please provide details of what you think the benefits and disbenefits of this approach are [Free text].
The benefits of this approach are to provide a bespoke process to allow assessment of more complex applications and therefore promote innovation in this important area. The disbenefits are the risk of lack of consumer trust and equity of approach against other approval processes.

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.
The main concern that IFST would like to raise in terms of missing areas is the lack of a 4-nations approach and agreement to this process. This could affect development and sale of products using this technology, i.e. will developers want to invest in this technology without certainty that the materials can be freely sold within the whole of the UK?

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? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree] Agree
b. Please provide details of what you think the benefits and disbenefits of this approach are.
The benefits are to provide a freely available list of products that have been produced using this technology for stakeholders/consumers. The disbenefit is that it appears that there will be 2 registers, one for applications made (held by Defra) and one for those with marketing authorisation approved (held by FSA). From a stakeholder perspective, it would be better to have a single point of reference for both lists. Examples of good working lists are the GB Nutrition and Health Claims (NHC register), which provides a single list of applications, authorised claims, and a list of rejected claims, and the MHRA list which again shows the status of all applications.
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.
The IFST note that there is the opportunity for producers to self-define information as commercially sensitive and therefore exclude this information from the register. IFST would propose that FSA provide guidelines of what should constitute commercially sensitive information.

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/Agree/Neutral or Don't know/Disagree/Strongly disagree]. 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.
The main barrier that IFST note is that any assessment as to whether the material produced would need to enter into another assessment process (e.g.

novel foods) is dependent on the capacity and capability within FSA to be able to effectively conduct these risk assessments and judgements.
c. Please provide details of what you think the benefits and disbenefits of this approach are. See comments earlier in the document.
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. [Free text]. No additional comments

Consultation questions: Enforcement (England)

As part of the proposed regulatory framework for food/feed from PBOs, the FSA is proposing enforcement powers and tools for Local Authorities and Port Health Authorities ('enforcement authorities') in England. The Act does not allow for criminal sanctions beyond those available in existing food/feed law which may be used in respect of food/feed consisting or containing PBOs where appropriate.

a. To what extent do you agree or disagree that the proposed enforcement regime meets the FSA's policy objectives in paragraph 7.9 of this consultation document? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree]. Agree
b. To what extent do you agree or disagree that the elements of the proposed enforcement regime are practical and deliverable? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree] Don't know.
c. To what extent do you agree that this proposal meets your need as a stakeholder? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree]. Don't Know
d. Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposal being implemented. Within the consultation document, it states that:

"FSA proposes that secondary legislation will designate Local Authorities and Port Health Authorities in England as enforcement authorities for the new regulatory framework for food/feed from PBOs and provide the following enforcement functions."
IFST are concerned to ensure that there is adequate capability and training, in addition to capacity within the enforcement officers to effectively monitor and enforce. IFST are also unclear as to what markers or identifiers could be used to detect illegal use and import of unauthorised PBOs.

e. Please provide details of what you think the benefits and disbenefits of this approach are See above
f. What level(s) of monetary penalty do you think would be appropriate in respect of the 'relevant breaches' outlined in the consultation document? Don’t Know
g. If you feel there 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 Enforcement here. [Free text]. No additional comments

Consultation questions: Assessment of impact

We have carried out an assessment of the impact arising from our proposals.
a. Do you agree with the assumptions and estimates used to calculate one-off familiarisation costs to businesses? [Yes/No/Don't know] Don't Know
b. Do you agree with the assumptions and estimates used to calculate one-off familiarisation cost to Local Authorities in England, Wales and Northern Ireland? [Yes/No/Don't know] Don't know.
c. Do you agree with the assumptions and estimates used to calculate one-off training cost to Local Authorities in England? [yes/no/don't know] Don't Know
d. Do you agree with the impacts that the FSA has identified within this consultation? [Yes/No/Don't know] Don't Know
e. Are you aware of any impacts of the proposed new regulatory framework that the FSA has not identified in this consultation? [Yes/No] No
f. Do you agree with the wider impacts identified in this consultation? [Yes/No/Don't know] Don't Know
g. Please explain your reasons for your position [Free text]. These questions are outside of the scope of IFST remit.