

5th June, 2024

Re. Consultation on proposed reforms to the regulated products authorisation process

Dear Sir or madam

The Institute of Food Science and Technology is the UK's leading professional body that aims to advance the application of food science and technology for the benefit, safety and health of the public, and support the development and maintenance of professional standards and science-based food standards that underpin the success of British food manufacturing, retail and regulation. As an independent, charitable body, we bring professional expertise from across academia, industry and the public sector, centered around the professional, sustainable advancement of the UK food system.

Thank you for the opportunity to provide comments to this consultation, provided below:

1. Do you agree or disagree with the proposal to remove the requirement to renew authorisations every 10 years for feed additives, genetically modified organisms for use in food and feed and smoke flavourings?

a) Please indicate if you strongly agree, agree, neither agree nor disagree, disagree or strongly disagree.

AGREE

b) Please give your reasons for your response.

IFST are supportive of the proposal to remove the requirement to renew authorisations every 10 years for feed additives, genetically modified organisms for use in food and feed and smoke flavourings. We understand and agree that it is the responsibility of food and feed businesses to alert FSA/FSS of any changes. Mechanisms would need to be defined (methods and enforcement) if there is a reason to believe that food or feed is not compliant with safety requirements, and this should form part of businesses' ongoing risk assessment and HACCP programmes. Furthermore, it is important that FSA and Local Authorities have sufficient capability and capacity to enforce these responsibilities, and that adequate information is available to businesses (particularly SMEs) to support these requirements. Lastly, should advances in toxicology or the emergence of new evidence cast doubt on the original risk assessment IFST believes the current system allows the matter to be reopened. We would, however, prefer FSA to clarify this is so.

Furthermore, IFST would urge FSA to consider the opportunity for equivalency in risk assessment and vigilance provided by trusted risk assessment authorities in other countries.







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2. Do you agree or disagree with the proposal to replace requirements for regulated product authorisations to be prescribed by, and set out in, legislation after a ministerial decision to authorise the regulated products concerned, with a duty simply to publish authorisations instead after the ministerial decision to authorise the regulated products concerned?

a) Please indicate if you strongly agree, agree, neither agree nor disagree, disagree or strongly disagree.

STRONGLY AGREE.

b) Please give your reasons for your response.

IFST support the view of FSA that this is a procedural obligation that does not add to the safety assessment process and introduces significant delays to food and feed businesses and administrative burden to the FSA and others.

3. Do you have any comments on our assessment of the impacts of the proposed changes, or have any to add that have not been identified in this consultation?

As mentioned above, IFST support the equivalency and connection between trusted International Scientific Risk Assessment bodies (e.g. EFSA, FDA) and would urge FSA to consider how these can be better utilised in support of the overall aims of the reform of the regulated products authorisation. This is important to ensure that specialist input can be gleaned for novel products and processes where previous assessment methodologies (e.g. microbiological, toxicological assessments) may need to be adapted or not appropriate for new technologies and products, or for where there is limited previous data and/or no safe history of use. There may be possibilities to leverage specialist input via manufacturers, trade associations, research funding bodies for example.

IFST are aware that FSA are considering the risk assessment processes for Precision Bred Organisms and other new technologies for manufacture and risk assessment, hence it is important to consider in the wider authorisation process if/how these will differ in their assessment, further examples include:

- Alternative proteins
- Listeria monocytogenes bacteriophage for POAO (several non-EU approvals)
- Nitrates/nitrites
- CBD novel synthetic cannabinoids
- Toxicology New Approach Methodologies (to replace animal testing)
- QSAR -quantitative structure activity relationships,
- Performance characteristic infrastructure for non-targeted analyses

When considering the approval process, it is important to ensure that sufficient support is available for small businesses during the preauthorisation stage to improve the quality and efficiency of applications. FSA could consider a register of specialist support and a network

of approved analysts and laboratories to complete appropriate product analysis to support technical dossiers (e.g. clinical studies, exposure, toxicology).

IFST recommend that FSA put in place communication to consumers and broader stakeholders to articulate the benefits of the proposed changes. From the perspective of IFST, these include:

- Reducing inefficiency in managing regulated products
- Increasing the ability to focus on the more difficult problems in risk assessment to assure consumer protection
- Devoting freed resources to horizon scanning better to react speedily to emerging problems

IFST hope that these comments are useful in this consultation.

Best regards

Stephen French, Ph.D

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