5 Cambridge Court · 210 Shepherds Bush Road · London W6 7NJ · tel +44 (0) 20 7603 6316

28th March, 2024

Re. Consultation pack on applications for authorisations of four novel foods and three food additives, application for twenty-two food flavouring substances removals and proposal to set a limit for ethylene oxide in all food additives

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:

Novel Foods:

1. Do you have any concerns about the safety of the novel foods with respect to the intended consumers?

IFST cannot comment on the specific conclusions of each risk assessment, however we support the FSA risk assessment and risk management recommendation process and are keen that such a robust process remains in place. However, from the FSA/FSS Risk Management recommendations regarding LNFP-l/2'-FL and 3-fucosyllactose, it states that these novel ingredients are, as described in the application, safe and not liable to have an adverse effect on the target population, environmental safety and human health at the intended concentrations of use.

The guidance goes on to recommend that these food supplements should not be used if other foods with added LNFP-l/2'-FL or breast milk, or other foods with added 3-fucosyllactose or breast milk, are consumed on the same day.
We have concerns about the ambiguity of these risk assessments and the subsequent guidance, as it does not appear to be sufficiently robust to rely on guidance to consumers that these ingredients / supplements should not be consumed if other dietary constituents are consumed on the same day. We would expect that these novel ingredients should either be safe or not, and that if there are specific limitations to use, then there should be more stringent control in place (e.g. maximum levels in products based on a total dietary intake risk assessment approach). Furthermore, it is not clear how guidance concerning not using these novel food ingredients alongside other dietary constituents could be clearly and effectively communicated to consumers in a way that would mitigate the risks.

2. Do you have any comments or concerns on the impacts of authorising or not authorising the novel foods and, if in favour of authorisation, the terms on which the novel foods is authorised (as outlined in the FSA and FSS risk management recommendations)?

See above.

3. Are there any other factors that should be considered by Ministers that have not already been highlighted?

In the submission for Cetylated Fatty Acids, the original EU application states that using the ingredient in a product would not be nutritionally disadvantageous but that any supplements would not be intended for use by infants and young children, whereas the current risk assessment requires that:

The labelling of food supplements containing cetylated fatty acids shall bear a statement that: 'those food supplements should not be consumed by persons under 18 years of age'

It would be helpful to understand if there is a change in the risk assessment, resulting in this apparently more cautious wording compared to the original application.

4. Do you have any other feedback? Including consideration of any relevant provisions of assimilated law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors).

IFST support the ongoing management of regulated products provided that this is based on sound evidence and FSA have the competence and capacity to conduct risk assessments in a timely manner to ensure public safety and support ongoing innovation.

IFST welcome the harmonised approach taken across the 4 nations and alignment with EU risk assessments where appropriate. IFST support further international collaboration to expedite approval processes as long as the risk evaluation is based on sound evidence. FSA should further strive to input to international risk assessment to ensure they are completely appropriate for the UK population and industry.

IFST support the immediate, interim, and long-term reform of the regulated products approval process outlined in the December 2023 FSA Board paper.

Unrelated to the risk assessments, we note that IFST are not listed within Annex 1 of Interested Parties, it would be helpful to be included in the future.

<u>Food additives:</u>

1. Do you have any concerns on the safety of the food additives which have not been considered in the FSA/FSS opinions with respect to the intended consumers?

No.

2. Do you have any comments or concerns on the impacts in consideration of authorising or not authorising these food additives, and if in favour of authorisation, the terms on which these food additives is authorised (as outlined in the FSA and FSS risk management recommendations)?

IFST are not able to comment on the specific impacts of the decisions to authorise or not.

3. Do you have any comments or concerns on other impacts if authorised? (for example political, environmental, societal, technological, legal or economic)

No, however as highlighted above, IFST support the ongoing 4 nation harmonisation of risk assessments and authorisation.

4. Are there any other factors that should be considered by Ministers that have not already been highlighted?

5. Do you have any feedback concerning the proposed specification for E 960c(ii), Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from stevia leaf extracts?

We note that there is no proposed change to the ADI as a result of this risk assessment and authorisation. It would be helpful to clarify this within the statements associated with this authorisation.

6. Do you have any feedback concerning the proposed specification for E 960b, steviol glycosides from fermentation?

See Point (5).

7. Do you have any concerns or comments on extending the use of the food additive PGPR (E 476) in the new food category 03. 'Edible Ices' (with the restriction 'except sorbets') and at higher levels in 'Sauces' food category 12.6 (with the restriction 'only emulsified sauces with a fat content of 20% and more') with respect to the intended consumers or other impacts for example political, environmental, societal, technological, legal or to the economy?

No

8. Do you have any other feedback? Including consideration of any relevant provisions of assimilated law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors).

See comments to Question (4).

<u>Flavouring removals:</u>

1. Do you agree with the FSA and FSS's view that there should be no significant impact on UK businesses from removing these flavouring substances from the domestic list, as UK industry has indicated that they do not use them? Therefore, the only impact would be on third country imports.

Yes.

2. Do you believe that transition arrangements are necessary or should be considered for foods containing these flavourings which are placed on the market before the coming into force date of any legislation to remove them from the domestic list. Should any such transitional measures also apply for foods dispatched for export to GB? Please explain your answer.

Yes, provided that there are no safety concerns resulting from this transition.

3. If you disagree with the FSA and FSS's view or have particular concern about the removal of any of the twenty-two flavourings, please explain why and provide information to help us understand and evidence the impact. Please include details on which of the flavouring substances your feedback relates to and, if applicable, the type of product you are using it in.

4. For any of the twenty-two flavourings to stay on the domestic list, industry will need to commit to providing the necessary safety studies to allow the risk assessment to be completed. If you believe any of the twenty-two flavourings should remain on the domestic list, please identify who would be willing to provide the necessary safety studies?

IFST are not able to comment on this question.

5. Impacts on international countries, outside of those within the EU, need to be considered. The International flavourings association (IOFI) considers there will not be any impacts as they are not widely used across the global market. Do you agree with this assessment? If not, please explain your answer. Any information gathered via this consultation will help inform the drafting of the World Trade Organisation (WTO) notification.

6. Would you be willing to be contacted by FSA in relation to this application?

No

<u>Ethylene oxide:</u>

1. Do you have any concerns on the safety of setting a limit of 0.1 mg/kg for ethylene oxide and its breakdown product 2-chloro-ethanol in all food additives which have not been considered with respect to the intended consumers?
No.

2. Do you have any comments or concerns on the impacts in consideration of setting a limit of 0.1 mg/kg for ethylene oxide and its breakdown product 2-chloro-ethanol in all food additives, and if in favour of this proposal?

3. If a limit of 0.1 mg/kg is set for ethylene oxide and its breakdown product 2-chloroethanol across all food additives, this will replace the current limit of 0.2 mg/kg for following 8 food additives:
• E 431 polyoxyethylene (40) stearate,
• E 432 polyoxyethylene sorbitan monolaurate (polysorbate 20),
• E 433 polyoxyethylene sorbitan monooleate (polysorbate 80),
• E 434 polyoxyethylene sorbitan monopalmitate (polysorbate 40),
• E 435 polyoxyethylene sorbitan monostearate (polysorbate 60),
• E 436 polyoxyethylene sorbitan tristearate (polysorbate 65),

• E 1209 polyvinyl alcohol-polyethylene glycol-graft-copolymer
• E 1521 polyethylene glycol.
Does the reduction in ethylene oxide limit for these 8 food additives raise any comments or concerns?

No

4. Do you have any comments or concerns on other impacts of this proposal? (for example political, environmental, societal, technological, legal or economic)?

5. Are there any other factors that should be considered by Ministers that have not already been highlighted?

IFST support the avoidance of a “zero tolerance” legal compliance limits wherever possible; these are impractical and would require an additional risk-based trading limit when residues are detected (i.e. the position being that residues are legally non-compliant, but products can still be traded). IFST support the setting of a legal compliance limit, based on sound risk assessment in the first instance.

6. Do you have any other feedback?

No

IFST hope that these comments are useful in this consultation

Best regards

Stephen French, Ph.D

Scientific Policy Director, Institute of Food Science & Technology