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RSC response to the Food Standards Agency consultation on the 'Proposal for a European regulation on novel foods'

The RSC welcomes the opportunity to comment on the Food Standards Agency consultation on the 'Proposal for a European regulation on novel foods'.

The RSC is the UK Professional Body for chemical scientists and an international Learned Society for advancing the chemical sciences. Supported by a network of over 44,000 members worldwide and an internationally acclaimed publishing business, our activities span education and training, conferences and science policy, and the promotion of the chemical sciences to the public.

This document represents the views of the RSC. The RSC's Royal Charter obliges it to serve the public interest by acting in an independent advisory capacity, and we would therefore be very happy for this submission to be put into the public domain.

The document has been written from the perspective of the Royal Society of Chemistry.

If you would like further information or need anything in this document clarified, please do not hesitate to contact me.

Yours Sincerely

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1. Centralise the authorisation procedure for novel foods

The RSC supports centralisation of the authorisation procedure for novel foods, provided the new procedure is workable. Centralisation is in principle a good idea that will expedite the administrative process; however there must be provision for the competency and capacity to cope with the number of applications. This will require adequate resources, funding, and staff. An emphasis must be placed on ensuring staff have the necessary skills for this work, they must be appropriately trained. Failure to ensure all these requirements are in place will result in a backlog of applications, defeating the purpose of a faster centralised procedure.

Under the new system, safety evaluations are to be carried out by the European Food Safety Authority (EFSA). The FSA must engage with the EFSA and ensure that all safety evaluations and tests are fit for purpose. Novel ingredients for example, may exhibit different properties as small particles in bulk materials compared to nanosized particles. Toxic and allergenic effects as well as composition, nutritional value and metabolism may all be affected. Current safety tests may need to be amended or new tests developed to ensure they are appropriate to deal with novel foods and ingredients.

While the abolition of national administrative procedures and duplication is welcomed, the RSC urges the FSA to question the European Commission about the implementation and enforcement of new regulations concerning novel foods. Regulations are binding in all Member States (MS); therefore new regulations approved centrally must be implemented and actively enforced in all MS. There must be no exceptions to the rule in order to prevent a reduction in health and safety standards across Europe.

The RSC believes that transparency of the regulatory system is paramount. If approval for a novel food is rejected under the new centralised procedure, the basis of such a decision must be made public. From such disclosure, lessons may be learned by food business operators, thus reducing the number of applications that are likely to fail to be approved.

The RSC asks the FSA to question the European Commission on the procedures that will be put in place to review decisions made under this new centralised regulation. Chronic effects of novel foods and ingredients are unlikely to be identified during the initial safety assessments, which are often acute in nature. The FSA must ascertain what mechanisms

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will be in place to revoke the license of a novel food should negative chronic effects be proven in the light of new scientific evidence. This may require a follow-up programme of safety assessments or perhaps a probationary license for truly novel 'first in class' foods.

2. Develop a simplified safety assessment for traditional food from third countries

The European Commission is right to point out that the cost of applications and safety assessment requirements are not always proportional to the potential risks. However the RSC is concerned by the lack of clarity of terminology relating to the 'simplified safety assessment' for 'traditional food' from 'third countries'. We implore the FSA to question whether there is a workable definition for a 'traditional food'. Could it, for example, include foods from a 'third country' that would be subject to rigorous EFSA safety assessments were they directly introduced here? Furthermore, the FSA must question what warrants a 'history of safe food use elsewhere'? The FSA and EFSA must be satisfied that documentation describing the history of safe food use from third countries contains a complete and accurate data set from a reputable food safety authority, otherwise this simplified assessment may serve as a regulatory loophole and standards will inevitably reduce.

A simplified safety assessment is necessary to alleviate regulatory costs based on proportionality with potential risks, however this simplified assessment should only apply when sufficient and accurate data are available for clearly defined 'traditional foods'. Furthermore, it would be wise to extend this simplified assessment to new foods and ingredients that are significantly similar to existing products on the market in order to avoid the duplication of unnecessary safety assessments.

In the event that a Member State (MS) objects to the placing on the market of a particular traditional food, the new proposed regulation states that the MS must 'have reasoned safety objections, based on scientific evidence' (Article 8, paragraph 3). The RSC argues that reasoned safety objections should also be accepted on the basis that the food business operator intending to place such traditional food on the market has not provided enough scientific data; the onus to provide adequate scientific data with regards to safety should be on the operator. We reiterate the importance of a complete and reliable data set from these 'third countries'.

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3. Clarify the definition of novel food

The RSC agrees that the definition of 'novel food' must be clarified. Therefore, ambiguous phrases such as 'food that has not been used for human consumption to a significant degree within the Community...' and '... where that production process gives rise to significant changes in the composition or structure of the food...' (Article 3) should be avoided where possible. The FSA must question what the workable definitions of 'significant degree' and 'significant change' are.

An inconsistent approach is apparent in the draft European Regulation, switching from a product based focus (Article 3.2.a i) to a process based focus for 'food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique not used before 15 May 1997' (Article 3.2.a ii). Furthermore, food to which a new production process is applied (Article 3.2.a iii) is only considered novel if the process 'gives rise to significant changes in the composition or structure...', no such stipulation is made for food from new breeding techniques.

Breeding technologies have been employed extensively in animal and plant agriculture for over a century, allowing the propagation of superior genotypes and phenotypes. The new regulation would mean that all products developed through new techniques and current techniques developed since 1997 will be considered as novel foods, even though the food product they lead to does not differ from similar products derived from plants or animals bred by older breeding techniques.

The RSC are very concerned that this definition will lead to confusion for industry and consumers and cause great difficulties for the breeding industries, which are highly competitive, technology driven and thrive on innovation. It will also lead to additional costs for industry and consumers and potentially cause problems with imports from outside the EU.

The FSA must work with the EFSA to ensure that any decisions made under the new centralised regulation are based on sound science, and not on a politically driven fear of new technology. Where a new production process or breeding technology does not give rise to 'significant changes in the composition or structure of the food', the food should not be considered novel.

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4. Update the scope of the novel food regulation in relation to parallel legislation on specific categories of foods

The RSC welcomes the proposed harmonisation of the regulatory framework to facilitate a single application covering novel food and multiple food uses (such as additives, flavourings, and extraction solvents). This streamlined process must, as explained above (1) be workable. Removing the need for parallel authorisation and reducing the administrative burden are central to encouraging the faster and more widespread introduction of novel, innovative foods to the market.

5. Provide a degree of protection for innovative food

The RSC supports the system of data protection for newly developed innovative foods. We suggest it should be 10 years to be consistent with the GM Food and Feed regulation. Whilst it is important to provide sufficient information on health and safety into the public domain, this should not be at the expense of innovation. Information detailing the exact formulation of a new innovative product should be protected, this must be balanced with the public information required to manage potential risks. If this does not extend to the full disclosure of commercially sensitive material, innovation will thrive.

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