

**CONSULTATION ON THE PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON  
NOVEL FOODS**

Issued: 29/04/2008  
Closed: 21/06/2008

**Issue: Centralisation of the authorisation procedure for novel foods**

<b>Respondent</b>	<b>Method of Response</b>	<b>Comment</b>	<b>Response</b>
National Farmers Union Scotland (NFUS)	Email	<ul style="list-style-type: none"> <li>• Support centralising authorisation procedure for novel foods.</li> <li>• However EFSA must be able to cope with the applications without resultant “bottlenecking” and unacceptable delays.</li> </ul>	<ul style="list-style-type: none"> <li>• Concerns over EFSA resources are noted. This is a general issue that is relevant to all areas where EFSA has a role in EU legislation. The operation of EFSA is overseen by its Management Board, with input from national food safety experts through the EFSA Advisory Forum. We note also that the Common Authorisation Procedure makes specific reference to the use of scientific networking, which may increase the scientific resource that EFSA can call on. The UK and other Member States will not support authorisation of products if they do not have confidence in the rigour of the risk assessment.</li> </ul>
Consumers Association (Which?)	Email	<ul style="list-style-type: none"> <li>• Welcome all authorisations to be conducted centrally by EFSA</li> <li>• However essential that it can be ensured that EFSA will have sufficient resources and available expertise to effectively fulfil this role.</li> </ul>	<ul style="list-style-type: none"> <li>• See above</li> </ul>
East Ayrshire Council	Letter	<ul style="list-style-type: none"> <li>• Support the principles of improving clarity of legislation and simplifying procedures.</li> </ul>	<ul style="list-style-type: none"> <li>• Noted</li> </ul>

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**Issue: Development of a simplified safety assessment system for traditional food from third countries**

Respondent	Method of Response	Comment	Response
NFUS	Email	<ul style="list-style-type: none"> <li>• Supports the proportionate approach taken in introducing a simplified assessment and authorisation process for foods considered 'novel' to the EU but which are traditionally consumed outwith the EU with a history of safe food use.</li> <li>• Also important to remember that without streamlining and reducing the time taken to achieve other authorisations there will continue to be a barrier which will discourage companies from investing in the development of such foods.</li> </ul>	<ul style="list-style-type: none"> <li>• Noted</li> <li>• Noted</li> </ul>
Which?	Email	<ul style="list-style-type: none"> <li>• Would like to see Article 8 amended to so that there are a clear set of criteria established for how a 'history of safe food use' is to be determined.</li> <li>• Concerned that a less robust process is proposed for 'traditional food from a third country' by relying on a 'history of safe food use'.</li> <li>• Concerned that the absence of any reporting of adverse effects does not necessarily mean that a product is safe and therefore would like to see this aspect of the proposal revised and strengthened.</li> </ul>	<ul style="list-style-type: none"> <li>• Noted. Detailed guidance on the definitions and data requirements are to be established through implementing measures.</li> <li>• Noted.</li> <li>• We understand that the procedure, as proposed by the Commission, would require the composition of the food also to be considered, in addition to the history of safe food use.</li> </ul>

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		<ul style="list-style-type: none"> <li>• There should be clear criteria of how a 'history of safe use' for traditional foods is to be determined.</li> <li>• Believe that novel foods which are traditional foods from third countries should also be included in the Community list.</li> <li>• Additional conditions for inclusion on the Community list set out in Article 6 should only be taken into account in relation to a 'traditional food from a third country' if a safety concern is raised.</li> <li>• Considerations within Article 6 and the additions proposed for that Article should also apply to traditional food from a third country regardless of whether safety concerns are raised.</li> </ul>	<ul style="list-style-type: none"> <li>• The proposal provides for implementing measures that will provide additional guidance on this point.</li> <li>• Agree –there should be a single list of novel foods that can legally be marketed.</li> <li>• Agree – there may be occasions where special conditions should apply to foods that are unfamiliar to European consumers</li> <li>• Noted. If there are safety concerns then this would require a full application.</li> </ul>
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**Issue: Clarification of the definition of Novel Food**

<b>Respondent</b>	<b>Method of Response</b>	<b>Comment</b>	<b>Response</b>
The British Society of Plant Breeders Ltd (BSPB)	Letter	<ul style="list-style-type: none"> <li>The definition of novel food in Article 3.2.a ii adopts a process based approach in relation to plant and animal breeding techniques and BSPB is concerned it would cause difficulties for the plant breeding industry.</li> <li>If varieties bred using novel technologies are to be regarded as novel foods and have to pass an additional regulatory hurdle, there will be confusion for industry, consumers, additional costs, additional uncertainty and reluctance to innovate, particularly for small and medium sized enterprises in the plant breeding sector.</li> <li>It is essential that the wording in Article 3.2.a ii is defined. Would like to see a product based approach rather than process based.</li> </ul>	<ul style="list-style-type: none"> <li>Point noted. However this part of the proposal does not differ significantly from the current regulatory requirements</li> <li>The Agency has requested additional information from stakeholders as to the current and future implications of this issue to the plant breeding sector.</li> </ul>
Which?	Email	<ul style="list-style-type: none"> <li>It should be made clear that 'novel food' includes novel food ingredients and the term 'used for human consumption to a significant degree' should be clarified.</li> <li>Article 3 (2) (a) (ii) should specify that the products of the progeny of cloned animals are also included as a novel food.</li> </ul>	<ul style="list-style-type: none"> <li>This is implicit in the definition of "food" in general food law (regulation 178/2002)</li> <li>We agree that this should be clarified.</li> </ul>

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		<ul style="list-style-type: none"><li>• Consider that products or ingredients modified by new production processes should be considered as novel. The extent to which any changes that have resulted are significant or not should then be determined by the risk assessment.</li><li>• There are two important categories that are included in the definition of a novel food under the current regulation that are missing from the proposal. Suggest that two additional paragraphs are included to address foods with a new or intentionally modified primary molecular structure and foods consisting of or isolated from micro-organisms, fungi or algae.</li></ul>	<ul style="list-style-type: none"><li>• This point was considered when the 1997 regulation was drawn up. Food manufacturers regularly make minor improvements to their processes and it would not be feasible for every change to be subjected to regulatory scrutiny.</li><li>• It does not appear necessary to introduce this level of sub-classification of novel foods. The categories in the 1997 regulation were needed because (a) different provisions apply to some of the categories and (b) the current regulation pre-dates the adoption of an EU-wide definition of "food".</li></ul>
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**Issue: Updating the scope of the novel food regulation in relation to parallel legislation on specific categories of foods**

<b>Respondent</b>	<b>Method of Response</b>	<b>Comment</b>	<b>Response</b>

**Issue: Providing a degree of protection for innovative food**

<b>Respondent</b>	<b>Method of Response</b>	<b>Comment</b>	<b>Response</b>
Which?	Email	<ul style="list-style-type: none"> <li>Concerned that Article 12 regarding data protection could be too limiting and would like its intention to be clarified.</li> </ul>	<ul style="list-style-type: none"> <li>We agree that the Commission's proposal is unclear and the text should specify clearly when and how the data protection system should apply.</li> </ul>

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Other comments:

Respondent	Method of Response	Comment	Response
Which?	Email	<ul style="list-style-type: none"> <li>• Concerned that Article 6(a) limits safety considerations to whether a novel food poses a safety concern to the health of the consumer under normal consumption conditions and fails to take into account vulnerable consumers or particular groups of consumers. Consideration should also be given to who is likely to eat the food in practice.</li> <li>• Concerned that the assessment of the safety of novel foods to be carried out by EFSA will be too narrow if it is based only on assessing if the food is as safe as food from a comparable category already on the market or as the food that the novel food is intended to replace.</li> <li>• Would like to see post market monitoring (PMM) made a requirement in all cases.</li> </ul>	<ul style="list-style-type: none"> <li>• Agree – risk assessment should take account of "high level" consumption and "at-risk" groups.</li> <li>• Agree – Article 10 should be amended to make clear that this is not the sole endpoint of the assessment.</li> <li>• Disagree; a requirement for formal PMM in every case would be disproportionate and inconsistent with principles of better regulation. The need for PMM should be judged on a case-by-case basis if there is a specific question to be answered e.g. to test assumptions made during the risk assessment or to test the effectiveness of risk management measures.</li> </ul>
Which	Email	<ul style="list-style-type: none"> <li>• Concerned that the conditions of inclusion in the</li> </ul>	<ul style="list-style-type: none"> <li>• The proposed criteria are unchanged from</li> </ul>

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		<p>community list are too limited. Would like to add that each novel food should offer advantages and benefits to the consumer and that any other legitimate factors such as social and ethical concerns have been taken into account, including any relevant opinions from the EGE.</p> <ul style="list-style-type: none"> <li>Concerned that the specific labelling requirements that are set out in the current regulation will be lost in this proposed regulation. These requirements should be included in order to ensure that consumers can make informed choices. These labelling provisions should also apply to traditional food from third countries.</li> </ul>	<p>the current regulation and do not include an assessment of benefits to consumers. In many cases, potential benefits would be examined under the legislation on health and nutrition claims. The handling of ethical concerns is under discussion, although it has been suggested that there is no legal basis for EU-wide authorisation decisions to be taken on ethical grounds.</p> <ul style="list-style-type: none"> <li>Agree</li> </ul>
Which	Email	<ul style="list-style-type: none"> <li>Recital 24 of proposal makes reference to the possibility of consulting the European Group on Ethics in Science and New Technologies but it's not clear how any issues they raised could be taken into account as part of the approval process</li> </ul>	<ul style="list-style-type: none"> <li>The EGE is a body that reports directly to the President of the European Commission. The proposal does not envisage that it will be involved in individual applications, but it could be consulted on fundamental issues related to novel foods and processes, as recently happened for animal cloning.</li> </ul>
NFUS	Email	<ul style="list-style-type: none"> <li>Welcomes aim to simplify regulatory process to reduce administrative burden on the European food industry. Important to avoid unnecessary delays associated with the authorisation process.</li> </ul>	<ul style="list-style-type: none"> <li>Noted</li> </ul>
Environmental Health Dept	Email	No comment	

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Aberdeen City Council			
REHIS	Letter	No Comment	

**List of Respondents:**

1. National Farmers Union Scotland
2. Consumers Association
3. British Society of Plant Breeders
4. Aberdeen City Council
5. Royal Environmental Health Institute  
Scotland
6. East Ayrshire Council