

SUMMARY OF SUBSTANTIVE COMMENTS TO THE FSA CONSULTATION – PROPOSED REGULATION ON NOVEL FOODS

DATE: 02 October 2008

REF: [NFU 710]

The proposed regulation of the European Parliament and of the Council on novel foods intended to replace and repeal the current Novel Food Regulation (EC) No 258/97

SUMMARY REPORT OF RESPONSES TO CONSULTATION FROM STAKEHOLDERS

The proposed regulation of the European Parliament and of the Council on novel foods intended to replace and repeal the current Novel Food Regulation (EC) No 258/97 consultation was issued 28 April 2008 and closed on 20 June 2008

- 1 The FSA is grateful to those stakeholders who responded and sets out in the table below responses in order of the issues considered.
- 2 The key proposals on which the consultation sought views were
 - Centralise the authorisation procedure for novel foods
 - Develop a simplified safety assessment system for traditional food from third countries
 - Clarify the definition of novel food
 - Update the scope of the novel food regulation in relation to parallel legislation on specific categories of foods
 - Provide a degree of protection for innovative food
- 3 The Food Standards Agency's considered responses to stakeholders' comments are given in the last column of the table. A summary of changes to the original proposal(s) resulting from stakeholder comments is set out in the final table.
- 4 A list of stakeholders who responded can be found at the end of the document.

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1. Centralised procedure

No	Respondent	Comment	FSA Response
1.01	4	Proposals for a centralised procedure are sensible.	Noted
1.02	9	Welcome move to simplify procedure and shorten lead time for gaining approval.	Noted
1.03	11	No specific issues with the proposal and is of the opinion that it is an entirely appropriate way forward to rationalize the handling of novel foods.	Noted
1.04	26	Support the principles of improving clarity of legislation and simplifying procedures.	Noted
1.05	20	Supports a centralised risk assessment carried out by EFSA however this should be initiated when the revised regulation enters into force; this procedure can then be superseded by the future common procedure.	Noted. The timing of the new regulation and of the application of the common authorisation procedure is currently under discussion.
1.06	14	<p>Concerned that the novel foods scrutinising process will be centralised with EFSA. Due to its location in an inaccessible part of Europe, most full-time practising scientists and clinicians are unable to commit themselves to being part of any committees established by EFSA. Those involved in making major decisions are often either retired or have less hands-on involvement with science or medicine. The consideration of allergy patients' needs would therefore be far less likely to be addressed effectively by a centralised committee.</p> <p>The current process where all MS make a decision on an application is the best way to represent the interests of consumers. Centralisation will considerably reduce the current rigour of the approval process.</p>	<p>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.</p> <p>The operation of EFSA is overseen by its Management Board, with input from national food safety experts through the EFSA Advisory Forum.</p> <p>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 are not confident in the rigour of the risk assessment.</p>
1.07	1	Support centralising authorisation procedure for novel foods,	(see 1.06 above)

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		however EFSA must be able to cope with the applications without a resulting “bottlenecking” and unacceptable delays.	
1.08	21	Concerns whether EFSA has the resources to put a centralised system in place: <ul style="list-style-type: none"> - Whether EFSA will be able to carry out assessments within the shorter time frame envisaged. - Whether there will be sufficient transparency. - Whether there is opportunity for an appeal if a notification for a traditional food is rejected. 	(see 1.06 above) We agree with the need for transparency and would wish to retain the current levels of openness and transparency, including the possibility of having public consultations before decisions are taken, in line with the procedures for GM food and feed (regulation (EC) 1829/2003)
1.09	23	Welcome all authorisations to be conducted centrally by EFSA however essential that it can be ensured that EFSA will have sufficient resources and available expertise to effectively fulfil this role.	(see 1.06 above)
1.10	24	There must be provision for the competency and capacity to cope with the number of applications. This will require adequate resources, funding and staff. Transparency is paramount.	(see 1.06 and 1.08 above)
1.12	17	For the centralised procedure to work there must be commitment from MS to follow the regulatory process with the minimum of political interference.	Noted
1.13	13	Proportionality is critical to the whole novel foods process and this aspect must be scrutinised very carefully for every application.	Noted
1.14	20	Role of national authorities support in the centralized system would need to be clarified, e.g. Recital 18 regarding post market monitoring.	Noted. Any PMM obligations would be defined at the point of authorisation of a novel food, and could be directed at applicants and/or member states (see also 7.12 below)
1.15	20	Consideration should be given to a fast-track procedure for food/food ingredients produced by simple hydrolysis or single	We do not see any need for a separate procedure for "simple hydrolysis

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		components isolated from a complex matrix. The fact that hydrolysis products have been a part of the human diet without giving rise to safety concerns justifies a simpler evaluation procedure.	products". The argument seems to be that the risk assessment of such products is straightforward, in which case the products should pass easily through the EFSA stage of the standard procedure, with the provision of relatively little new safety data.
1.16	20	It is not clear how novel plants/herbals will be dealt with under the new proposals. Current developments in this area should be considered.	Novel plants and plant product will be handled by the same procedure as products from other sources
1.17	6	Clinical Trials are not mentioned-how is assessment going to be carried out?	According to Article 9 of the Common Authorisation Procedure, EFSA will identify data requirements for the risk assessment of novel foods. The Commission will then develop a formal measure to replace Commission Recommendation (EC) 97/618, which sets out the current requirements for applicants.
1. 18	17	Also essential is that applicants are able to discuss with EFSA and the national experts what information requirements would be necessary to ensure safety of the novel food in question.	We Agree. The Agency currently spends a significant amount of resource advising and support for applicants before and during the evaluation of safety dossiers, in order that the evaluation takes as little time as possible
1.19	22	As an alternative to providing an initial opinion, Member States could provide a "completeness check" prior to submission to the Commission. Publishing the authorisations and notifications on Community lists is a positive step forward.	(see 1.18 above)
1.20	18	Completeness check process should be part of a	(see 1.18 above)

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		development process during which applicants could work with the relevant panel secretariat.	
1.21	18	Would like to see time taken for completeness checks reduced. Co-operation between applicants and EFSA secretariat or equivalent within a Competent Authority should be written in as part of a pre-presentation requirement.	(see 1.18 above)
1.22	13	Guidance for risk assessment and dossier structure for novel ingredients/additive categories must be harmonised and should be available before any new regulation is adopted to avoid confusion.	We agree. The content of application dossiers will be set out in implementing measures (under the Common Authorisation Procedure). The Common Authorisation Procedure specifies that it will not come into force for a new area of legislation until the relevant guidance is in place. The timing of application of the new novel foods regulation is under discussion, and will presumably be tied to the Common Authorisation Procedure.
1.23	18	Technical guidance for applicants should be made available before the revised regulation applies. There is no indication in the proposal the date this guidance would be available. The text should make clear that pending development of new guidance by EFSA, the existing SCF guidance should remain in place for use by applicants in the interim.	(see 1.22 above)

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2. Definitions

No	Respondent	Comment	FSA Response
2.01	5	Welcomes simplification of definition and the process for approval which would enable local authorities to advise businesses in a more meaningful way.	It is envisaged that this level of detail will be introduced through accompanying guidance. We also note that many of the issues concerning definitions are also apply in the current regulation and have to be considered case-by-case
2.02	9	Definition of novel food may need some careful thought.	(see 2.01 above)
2.03	21	No clarity is given on what is considered a significant history of consumption.	(see 2.01 above)
2.04	24	Definitions of novel food must be clarified especially 'significant degree' and 'significant change'.	(see 2.01 above)
2.05	18	(definition of novel food): Article 3(2)b and c should be reworded. There is no mention of safety in definition b, it is therefore not clear if assumptions are made that any safety risks posed by foods in this category are acceptable. It is not clear why compositional data is required to prove safety in foods that fall under definition c.	(see 2.01 above)
2.06	23	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.	This is implicit in the definition of "food" in general food law (regulation 178/2002)
2.07	2	<p>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.</p> <p>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</p>	<p>Point noted. However this part of the proposal does not differ significantly from the current regulatory requirements</p> <p>The Agency has requested additional information from stakeholders as to the current and future implications of this issue to the plant breeding sector.</p>

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		<p>in the plant breeding sector.</p> <p>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.</p>	
2.08	17	Proposed regulation would require all products developed through new breeding techniques and techniques developed since 97 to be considered as novel even if product does not differ from similar products from plants bred by using older breeding techniques. Essential that this aspect is implemented in a pragmatic manner, proportional to the risks involved otherwise this could be a barrier to breeders developing new technologies in the future.	(see 2.07 above)
2.09	24	Inclusion of all breeding techniques will lead to confusion for industry and difficulties for breeding industries. Considers that 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.	(see 2.07 above)
2.10	8	<p><u>Cloning:</u> Non-traditional breeding techniques need to be defined. To avoid confusion, the regulations should include definitions of non-traditional breeding techniques, those techniques not considered to be non-traditional and non-traditional techniques which are excluded from the regulation.</p> <p>The inclusion of cloning in the proposal needs legal clarification, if cloning technologies are to be allowed they should be explicitly stated as a non-traditional breeding technique within Article 3.2.</p>	<p>It is envisaged that this level of detail would be introduced through implementing measures.</p> <p>Animal cloning is considered to be a non-traditional breeding technique.</p>
2.11	8	<u>Offspring of clones:</u> It is unclear whether proposed regulations would cover food products from the offspring of cloned animals. Offspring of cloned animals are likely to be produced	We agree that this should be clarified.

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		<p>through traditional breeding techniques and therefore fall outside the scope of the proposed regulation.</p> <p>It is necessary that products from the offspring of cloned animals be included within this regulation given the concerns that have been raised regarding the health and welfare of the offspring of clones and the substantial public concern surrounding the issue of cloning and its implications for the food chain. The definition of a novel food should therefore be expanded to include those animals that are derived from an animal to which a non-traditional breeding technique has been applied.</p>	
2.12	23	Article 3 (2) (a) (ii) should specify that the products of the progeny of cloned animals are also included as a novel food.	(see 2.11 above)
2.13	25	In principle believe [the existing] definition should be clarified to include new technology.	Noted
2.14	23	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.	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.
2.15	6	Undesirable substances should be defined when considering whether an ingredient produced using a novel technique is novel or not. There would be a need to look for unknown undesirable substances however how can you look for something if you do not know it exists?	It is not possible to define undesirable substances if the nature of the novel technologies to be employed is not known.
2.16	7	The scope of the proposal includes nanotechnology and nanosciences as examples of “foods modified by new production processes” however does not define these terms and GMA is not aware of any universally agreed upon definitions for these terms.	The legislation does not define these terms as they are not part of the legal text. (They are mentioned in the preamble as examples of new processing methods that could result in

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			substantive changes in the properties of a food)
2.17	7	Foods with a history of safe consumption in food supplements could be considered novel if the mode of consumption is changed. The GMA questions the existence of a scientific justification for such a distinction.	The classification of ingredients that have a history of consumption solely in food supplements was established at a Standing Committee meeting in 14 February 2005
2.18	13	Unsure of the scientific justification regarding intake of food supplements versus normal food use as exposure for purposes of risk assessment is usually calculated as a worst case scenario in which highest intake of “all users” is taken.	(see 2.17 above)
2.19	20	Recital 7 states that food ingredients used in food supplements are not excluded from the regulation when their use is broadened out to other types of foods. The same requirement is not specified for traditional food from third countries.	It seems unlikely that a product with a history of use only in food supplements would meet the definition of a traditional food, which refers e.g. to use "as a normal part of the diet"
2.20	20	Proposal does not include a procedure to clarify if a “borderline product” is novel or not.	The status of products on the borderline between food and medicines depends on the application of legislation on medicinal products. (In the UK, this is the responsibility of the MHRA). An additional recital has been proposed to explain the relationship between legislation on food and medicines.
2.21	20	Focus should be on establishing on the comitology procedure to help clarify if a food/ingredient is novel/or not. The current system where individual countries evaluate ingredients and communicates this to other countries is not transparent, consistent or efficient.	Noted. The Commission has recently published a catalogue that records the outcome of previous enquiries that have been considered by Member States http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/index.cfm
2.22	21	The evidence that an ingredient was on the market before	Noted

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		May 97 becomes more difficult with the passing of time, it is therefore taking longer to gather evidence and the proposed 3-month time limit defined in Article 4(2) is too short. We would request this period is doubled to 6 months.	The 3 month time limit is to ensure that there is not an overly long delay at this stage. Evidence of history of consumption found after this period can still be taken into account
2.23	19	May be difficult to maintain access to informal advice from EFSA on novel status of foods.	EFSA will not have responsibility for advising whether a food is novel; enquirers would continue to contact their national competent authority [or the Commission?] and the procedure in Article 4 could also be invoked by the Commission. (see also the preceding comment)
2.24	18	<u>Collection of information</u> Article 4, 1: Information should be collected in a harmonised way by each Member State such that history of significant consumption in one/several Member States can be recognised as such throughout the Community. Recital 13: In the process of transparent collection of data, products competitive position should not be negatively affected by incorrect inferences of novel status. It is not clear who will be responsible for collecting this information and what would happen if a comparable product is shown not to be novel	We agree that this should be clarified, however we note that this is an operational issue to formalise current procedures.
2.25	23	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.	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

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No	Respondent	Comment	FSA Response
			EU-wide definition of "food"

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3. Foods that are traditional in third countries

No	Respondent	Comment	FSA Response
3.01	1	Supports proportionate approach taken in introducing a simplified authorisation process for traditional foods from third countries. 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.	Noted
3.02	4	Proposals for a simplified safety assessment for traditional foods from countries outside the EU are welcome and highly desirable to protect choice of EU citizens.	Noted
3.03	17	Introduction of simplified procedure should allow EU access to foods consumed in non-EU countries in a way that is proportional to the risks. There needs to be some flexibility in the compositional data required to demonstrate “history of safe food use”.	Noted. Detailed guidance on the definitions and data requirements are to be established through implementing measures.
3.04	12	Guidelines on the new simplified procedures and data required for approval of traditional foods from third countries would be helpful.	(see 3.03 above)
3.05	16	Unclear what compositional data is required and why it is required to prove the safety of these foods.	(see 3.03 above)
3.06	23	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.	(see 3.03 above)
3.07	22	More detailed definitions are required for “significant history of consumption”, “one generation” and “large part of the population”.	(see 3.03 above)
3.08	7	Further criteria should be elaborated for assessing the currently subjective term “significant degree”. Concerned that only traditional food that continues to be a	(see 3.07 above) It seems appropriate that foods that have "declined from favour" should be

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		<p>part of the normal diet would not be novel, therefore some foods which have been declined from favour but have been consumed for centuries would be considered novel under the proposal.</p> <p>Considers that designating a specific regulatory process for these foods may be deemed discriminatory and inconsistent with the provisions described within the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement). In particular it notes that “additional labelling information” may be required.</p>	<p>excluded from the simplified procedure, as it will be difficult to base an assessment of safety on the history of safe use.</p> <p>The Commission has notified this proposal under TBT rules and will respond to any comments that are received.</p>
3.09	16	Concerned that Member States are invited to raise safety objections independently of EFSA. Should be accepted that EFSA decisions are final	The proposed role of EFSA in the simplified procedure is under discussion
3.10	18	Concerned that only one Member State needs to raise an objection to block the procedure. It must be acceptable that EFSA decisions are final unless relevant new scientific evidence becomes available	(see 3.09 above)
3.11	20	Confirmation of safety from ‘experience of use and continued use’ can be highly disputed. What efforts need to be made in order to demonstrate this?	(see 3.07 above – implementing measures)
3.12	20	Article 8 paragraph 1 should clarify what triggers re-notification of a traditional food. Current text suggests re-notification is necessary if an already notified traditional food is imported from a different country/region.	The ambiguity is noted – this is not the intention
3.13	21	Welcome a simplified notification system however there seems to be no provision for appeal if a notification is rejected.	Noted
3.14	22	In order to maximise the opportunities for developing countries, applications should be accepted from a wide range of applicants not only food business operators.	Agree; we consider that notifications could also be made by others, such as government bodies and trade associations

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3.15	22	Important that traditional food with a history of safe food use is not restricted to low value raw materials and that the proposal encourages value addition by food processing operators in developing countries.	Agree, provided that there is a history of safe use that is relevant to the processed product
3.16	22	Rather than introduce different terminology for traditional foods, it would be more consistent to use similar terminology to that used to define a novel food.	We agree that the definitions for traditional food require additional clarification, but use of the existing wording in a different context may be confusing.
3.17	23	Concerned that a less robust process is proposed for 'traditional food from a third country' by relying on a 'history of safe food use'. 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.	Noted. 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
3.18	23	There should be clear criteria of how a 'history of safe use' for traditional foods is to be determined.	The proposal provides for implementing measures that will provide additional guidance on this point.
3.19	23	Believe that novel foods which are traditional foods from third countries should also be included in the Community list.	Agree –there should be a single list of novel foods that can legally be marketed
3.20	23	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.	Agree – there may be occasions where special conditions should apply to foods that are unfamiliar to European consumers
3.21	23	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.	Noted. If there are safety concerns then this would require a full application.
3.22	24	Concerned by lack of clarity of terminology. Is there a workable definition for a 'traditional food'? Simplified assessment should only apply when sufficient and accurate	(see 3.16 above)

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		data are available for clearly defined 'traditional foods'.	
3.23	24	Reasoned safety objections from Member States should also be accepted if scientific evidence is not sufficient.	We agree that the text as proposed is unduly restrictive
3.24	18	Absence of a simplified procedure offers little scope to SME's to market innovative products which might include, for example, processed versions of the traditional foods or extracts, or a new process for an existing product. Would like a more proportionate procedure which would stimulate innovation in the EU and offer greater access to SMEs to develop and market novel foods.	The criteria and procedures for authorisation of a novel food are independent of the size of the applicant company. However, Article 9 of the Commission proposal recognises the need to provide support for SMEs.
3.23	24	Would be wise to extend simplified assessment to new foods and ingredients that are significantly similar to existing products on the market in order to avoid duplication of unnecessary safety assessments.	(see point 1.15 above)

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4. Scope in relation to other EC legislation

No	Respondent	Comment	FSA Response
4.01	4	Proposals to simplify application for and assessment of foods falling in more than one legislative category are sensible and welcome.	Noted
4.02	21	Welcome removal of need for parallel authorisations. This will result in lower costs for applicant companies.	Noted
4.05	24	Update scope of regulation in relation to parallel legislation is welcomed but must be workable.	Noted

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5. Data protection

No	Respondent	Comment	FSA Response
5.01	16	<p><u>Protection of innovation</u> In order to achieve the objective of encouraging innovation, there is a need for improvement to the provisions for innovation protection. More information is required in Article 12 of the proposal to offer protection for applicants.</p> <p>In view of the large investment required to develop and bring to market an innovative food, a period of only 5 years protection for the novel food is inadequate.</p> <p>Authorisation should remain exclusively to the applicant during the period of data protection unless another applicant provides their own data sufficient for an authorisation. Suggest the mechanism and text used is same as that used in Article 21(2) of Regulation 1924/2006/EC (Nutrition and Health Claims Reg.)</p> <p>The re-introduction of applicant-linked procedures for applicants where protection is required would be welcomed.</p>	<p>We agree that the Commission's proposal is unclear and the text should specify clearly when and how the data protection system should apply.</p> <p>The request for a longer period of data protection is noted. However, the period of 5 years is consistent with the period agreed for health claims.</p>
5.02	9	<p>Not happy with the safeguard that may be put in place for businesses that have spent large sums in gaining approval not having the monopoly of that approval.</p> <p>Suggest approval process is closely aligned with that for health and nutrition claims so that small enterprises can understand more easily and this would lead to greater compliance</p>	(see 5.01 above)
5.03	10	<p><u>Data protection and Animal testing</u> While protection of commercial investment in development of a novel food is clearly desirable, the proposal could lead to</p>	<p>Noted. In practice, we do not anticipate that there will be significant duplication of</p>

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		<p>duplication of animal tests to provide safety data. A mechanism should be introduced to compel the sharing or re-use of any safety data generated using animals, with appropriate compensation to the company providing the original data. A specific prohibition on the repetition of animal tests should be introduced. Recital 20 and Article 12 should be amended accordingly.</p>	<p>animal studies. In some cases the second company may enter into agreement with the original applicant to use their safety studies.</p>
5.04	12	<p>Protection should be given to applicants regarding traditional foods in addition to those for novel foods and technologies.</p>	<p>Noted. The purpose of the simplified assessment for traditional foods is to enable staple foods that have not hitherto been marketed in the EU to be approved quickly. In such cases emphasis would be placed on evidence demonstrating that as part of the normal diet it is widely available in the third country, and the lack of any known adverse reactions, which could not be considered for data protection. We anticipate that data protection could only be sought for proprietary scientific studies carried out to determine the safety of individual novel foods.</p>
5.05	13	<p>Generic approvals are not acceptable. Community list must name the company to whom the approval applies. Limiting this aspect to only those based on proprietary data is not acceptable and will limit innovation in the Community.</p>	<p>(see 5.01 above)</p>
5.06	20	<p>Support generic approval process with the possibility of protecting proprietary data for at least 5 years to justify company investments made to bring a novel food on the market. It should be clarified in the text how the 5 years data exclusivity will be enforced and practically managed from the</p>	<p>(see 5.01 above)</p>

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		Commission's side.	
5.07	20	Unclear if any producer can produce a novel food as long as they comply with approved specification of the novel food.	It is intended that approvals for novel foods will be generic, in line with other areas such as food supplements and food additives, except where data protection applies.
5.08	21	The 5yr data protection is welcomed.	Noted
5.09	18	<p>The mechanism for data protection should be the same as in Article 21(2) of Regulation 1924/2006/EC.</p> <p>The data protection provisions as drafted would not include protection of the authorisation decision as such. Industry would like to see applicant linked procedures reintroduced specifically in respect of applications containing a justified designation of proprietary data and covering the period of limited data protection as defined by Article 12.</p> <p>Whilst there is provision under Article 12 for data protection, the proposal does not allow for exclusivity in marketing of the approved novel food by the first applicant. In order to protect the investment of the original applicant, we would like to see a provision similar to that in the nutrition and health claims regulation, 1924/2006. In addition, protection of the authorisation itself and exclusivity for the initial applicant could be introduced via text of Article 5, establishing the community list of novel foods.</p>	(see 5.01 above)
5.10	22	<p>All novel foods authorised need to have automatic protection.</p> <p>a) For at least 3 years regardless of protected innovation b) 5 years in the case of newly developed scientific evidence c) up to the maximum number of years as defined by applicable legislation for patentable processes.</p>	<p>Noted</p> <p>Patent protection is independent of data protection.</p> <p>Data protection is not being proposed for traditional foods submitted under the simplified procedure (see 5.03 above)</p>

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No	Respondent	Comment	FSA Response
			The Agency agrees that this issue requires additional clarification (see 5.01 above)
5.11	23	Concerned that Article 12 regarding data protection could be too limiting and would like its intention to be clarified.	(see 5.01 above)
5.12	24	Suggest data protection is for 10 years to be consistent with GM Food and Feed regulation. Public access to data should not be at the expense of innovation.	(see 5.01 above) Each authorisation under Regulation 1829/2003 on GM food and feed is addressed to the individual applicant and expires after 10 years, after which a new application must be made for renewal. Regulation 1829/2003 does not include any provisions for data protection.
5.13	17	Support the period of data protection however due to extreme costs involved in developing a product, believe a period of 10 years compatible with Regulation (EC) 1829/2003 is more appropriate.	(see 5.11 above)
5.14	18	Industry would like data protection periods of related authorisations to be aligned if requested by the applicant.	As at present the timing of the final authorisation Decision, once agreed by the Standing Committee, is controlled by the Commission. If an applicant wished, the Commission could delay until it is in a position to adopt a second, related, Decision e.g, the approval of a novel food and a related health claim
5.15	18	Concerned that once regulations are in force, prior authorisations will become generic. Additional text is needed under Article 17 to allow existing authorisations to remain applicant linked.	Noted The Commission has explained that data protection is not a feature of the existing procedures and it is therefore unnecessary to apply it retrospectively when authorisations are transferred to the future regulation.

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6. Draft Impact Assessment

No	Respondent	Comment	FSA Response
6.01	4	The proposals are likely to have a significant and positive financial impact on ATA members depending on the interpretation of 'significant' use.	This information will be used when updating the draft Impact Assessment
6.02	5	<p>Welcomes the more realistic costs for Enforcement Authorities to implement any new provisions in the Regulatory Impact Assessment (RIA) and appreciates realistic time allocation for cascading the information to other enforcement staff within local authorities.</p> <p>The resources in the RIA do not take account of the time taken by local authorities to deal with enquiries from businesses, but it is anticipated that the volume of these will be quite small.</p>	<p>Noted</p> <p>This information about business enquiries will be used when updating the draft Impact Assessment</p>
6.03	17	<p>New costs: Believe the number of staff hours has been greatly under estimated and believe a value close to 100 hours is more appropriate. The cost allocation of £11.24 per hour is extremely low, especially if external consultants are required to assess the regulations.</p> <p>New benefits: Cost of the compositional analysis appears to be under-estimated and would be closer to £100 000.</p> <p>Should be noted that a centralised procedure has potential to reduce regulatory burden (and cost) but for this to occur the Member States would need to fully support the approach and not request additional studies after EFSA have given their opinion.</p>	This information will be used when updating the draft Impact Assessment
6.04	3	Does not envisage any significant environmental impacts arising from the proposal.	Noted

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7. Other comments

No	Respondent	Comment	FSA Response
7.01	1	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.	Noted
7.02	21	The removal of the substantial equivalence simplified procedure may lead to higher-level scientific scrutiny to be applied to each application, even when applying to almost identical materials.	<p>If the detailed assessment of a novel food reveals a risk to consumers, Member States and the Commission are able to consider appropriate measures to manage the risks associated with equivalent (non-novel) foods that are already on the market.</p> <p>This provides a higher degree of consumer protection than the existing "substantial equivalence" procedure, which permits all new foods that are judged equivalent to existing products, without assessing potential risk.</p>
7.03	7	<p>GMA supports the agreed voluntary industry moratorium on the use of animal clones in the food supply until preparations have been made to allow for a seamless transition into the marketplace.</p> <p>GMA underscores the scientific views of the FDA and EFSA that food products from clones and their progeny are as safe as food products of livestock derived from conventional breeding and believes that cloning is a process and products derived from clones do not need to be labelled.</p>	As noted above, we are seeking clarification on the role of this proposal in the assessment of food obtained from cloned animals and their progeny
7.04	7	Believes that regulations mandating labelling at this early stage are likely to discourage technology development and	Noted. However, the current EC regulation on novel foods includes

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No	Respondent	Comment	FSA Response
		may pose technical barriers to trade. Supports mandatory labelling requirements only when material to the composition, nutrition and safe use of the products but strongly opposes labelling based on production and processing methods.	additional criteria for labelling e.g. ethical concerns, and the food labelling directive 2001/18/EC refers to the need in certain cases to indicate processing methods.
7.05	8	<p><u>Labelling</u></p> <p>The provision in the draft regulation for labelling of novel foods is not adequately covered highlighting only that labelling should not mislead the consumer and fails to impose that labelling should enable the consumer to make an informed choice. Labelling requirements should enable full traceability of product from clones and their offspring throughout the food chain and enable the ‘final users’ to make an informed choice.</p> <p>Food products derived from animals which have been produced using non-traditional breeding technologies, as well as the offspring of such animals, should be clearly labelled with the origin so that consumers can identify the product. The Commission should impose specific labelling requirements for products from cloned animals and their offspring. Given the animal welfare issues and the concern the general public has regarding food safety and animal health can welfare, the omission of such information would inhibit the ‘final user’ from making an informed choice.</p>	See 7.04 above
7.06	9	Strongly object to any charges being levied by EFSA for gaining approvals. This stifles initiative and enterprise by small businesses to explore markets for niche products, particularly those from Asian and African sources.	The possibility of fees is a generic issue falling under general food law (see Article 45 of Regulation 178/2002)
7.07	21	There is no indication of fees for authorisation or for notification and any such fees should be resisted so that SMEs are not disadvantaged.	(see 7.06 above)
7.08	8	<p><u>Safety Assessment</u></p> <p>Use of animals in scientific procedures designed to assess</p>	The FSA (and EFSA) recognise the need to minimise the use of animals for testing

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No	Respondent	Comment	FSA Response
		food safety is not explicitly required by the legislation. Given the commitment of the UK Government and EU Commission to replacing animal studies to humane alternatives, it is important to cross-reference this regulation with Directive 86/609, which, in Article 7.2, requires alternatives to living animals to be used if these are available.	purposes. Insofar as a reference to Directive 86/609 is required, this would be more appropriate in the later implementing legislation that will set out the detailed data requirements for novel foods dossiers.
7.09	10	<u>Minimising Animal Testing for Safety Evaluation</u> PETA is opposed to the use of animals in toxicological evaluation of novel foods on ethical and scientific grounds and recognises this regulation does not specify the use of animal tests. The regulation should therefore make clear that the use of animals in determining safety of novel foods must be viewed as a last resort only. Specific justification must be provided for any animal study undertaken and intelligent testing strategies applied. An appropriate model can be found in the REACH regulation (1907/2006) Recital 47 and Articles 13 and 25.	(see 7.08 above)
7.10	23	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.	Agree – risk assessment should take account of "high level" consumption and "at-risk" groups.
7.11	23	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.	Agree – Article 10 should be amended to make clear that this is not the sole endpoint of the assessment.
7.12	23	Would like to see post market monitoring (PMM) made a requirement in all cases.	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

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No	Respondent	Comment	FSA Response
			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.
7.13	13	In terms of harmonisation of submissions, note that post-market monitoring is not a current requirement for food improvement agents.	(see 7.12 above) We are not aware of any suggestion that application dossiers should include plans for post market monitoring.
7.14	18	<u>Obligations on the food business operators</u> Post-market-monitoring should be done on a case-by-case basis where it is justified. There is no requirement for PMM in the Nutrition and Health Claims Regulation and it is also not clear who will be responsible for PMM when authorisation becomes generic. Any obligation for a food business operator to report restrictions of third countries should be limited to instances which are relevant to the conditions for inclusion of a novel food on the Community list as defined by Article 6.	(see 7.12 above)
7.15	20	Food operators should only be obliged to inform about prohibitions or restrictions in non-EU countries if only they are based on scientific risk and not because of technical barriers to trade or precautionary reasons.	Noted
7.16	24	Question the procedures that will be put in place to review decisions made under this new centralised regulation.	The proposal allows for post market monitoring where this is justified by the risk assessment of individual novel foods and this implies that the use of the novel food will be reviewed in the light of the monitoring data.
7.17	18	Article 13 should refer to Regulation 178/2002 which sets clear rules as regards penalties.	This is implicit and does not need to be formally stated.

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No	Respondent	Comment	FSA Response
7.18	13	Penalties should be in place at the time the regulation is adopted and they should be harmonised as much as possible.	The setting of penalties for offences under EU law is a matter for each Member State.
7.19	23	Concerned that the conditions of inclusion in the 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>The proposed criteria are unchanged from 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.</p> <p>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. (See also 7.33 below)</p>
7.20	13	The statement that foods “should not differ from the food that they are to replace in a way that would be nutritionally disadvantageous for the consumer” requires further clarification in the text to avoid confusion.	The wording of this criterion is carried over from the existing regulation 258/97 and has not proved to be problematic, based on the 90+ dossiers submitted so far.
7.21	13	Purity criteria should also be inducted from existing approvals to clearly define these products (Preamble 25 and Article 4(2)).	Agree – this should be done as part of the transitional arrangements under Article 18.
7.22	13	In line with additives legislation we agree that specifications should be laid down for novel foods on the list. This could allow “fast-track” approvals based on notifications of purity criteria/specification changes.	Our understanding is that minor amendments to the list of approved novel foods, including purity criteria, could be handled by comitology without reference to EFSA (see Article 3.2 of the Common Authorisation Procedure)
7.23	13	Question whether substances on sale in a new Member State will become illegal if not consumed before 15 th May 97	In principle, such a substance would require novel food approval. The

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No	Respondent	Comment	FSA Response
			Commission will discuss this possibility with each candidate country as part of the normal pre-accession procedures (as it did with the 12 Member States who have already joined the EU after regulation 258/97 came into force)
7.24	15	<p>Legislation should strengthen provisions to allow local authorities to obtain information from businesses and to take appropriate action.</p> <p>Legislation should be amended to provide a clear legal onus on a food business to demonstrate that a novel food was on the market prior to May 97 and powers to enable enforcement authorities to require this information to be produced by food businesses.</p>	<p>Enforcement bodies already have general powers to obtain information from businesses.</p> <p>Member States are considering amendments to Article 4 that will clarify that it is the operator's responsibility to provide evidence of a history of consumption!</p>
7.25	17	Important the regulation does not discriminate against certain types of technology without having thorough understanding of the risks and adverse effects involved. The regulation should not be used as a means to hinder processes such as nanotechnology and cloning based on ideological opposition to innovation, but each process should be assessed on a case by case basis in a stringent scientific manner.	Agree that regulation should be on the basis of the scientific evidence, while safeguarding the consumer's right to make informed choices about the foods that they eat.
7.26	13	Very clear procedures must be laid down for novel foods/vitamins and minerals currently in the application process when the regulation is adopted.	Agree. Applications that are well advanced in the current system should be completed under the old framework (cf Article 46 of regulation 1829/2003 on GM food and feed)
7.27	13	More information is needed regarding applications still awaiting approval when the new regulation is in place. Detailed guidance is required for Member States.	(see 7.26 above)
7.28	18	Would like to see changes in the transitional measures to give applicants options whether to complete pending applications	It does not seem necessary to provide this option in the legislation, as any

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No	Respondent	Comment	FSA Response
		under the existing requirements of Regulation 258/97 or under new procedure. The proposed text disadvantages applications for which an initial assessment has already been forwarded to the Commission, since it may be possible to authorise an application without redirection of the application.	application can always be withdrawn by the applicant and re-submitted at a later date.
7.29	12	A list of approved and pending applications for novel technologies, novel foods and traditional foods on the Commission's website would be useful for potential applicants.	Agree – the procedures for handling and assessing applications should be open and transparent and a single list would benefit operators and enforcement bodies.
7.30	20	Supports a single 'community' list of notified foods and foods authorised as 'novel foods'. Transparency will be more important than before.	(see 7.29 above)
7.31	23	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.	Agree
7.32	13	Additional labelling must be proportionate to the identified risks from the safety assessment	It is a general principle of food law that risk management should be proportionate. However, we consider that labelling of novel foods may also be necessary to allow consumers to exercise informed choice about the products, not solely for risk reduction.
7.33	23	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.	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

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No	Respondent	Comment	FSA Response
			consulted on fundamental issues related to novel foods and processes, as recently happened for animal cloning
7.34	13	Clear guidelines must be laid down as to the scope of the European Group on Ethics' intervention. (Preamble 24)	(see 7.33 above)
7.35	20	There is doubt regarding the contribution of ethical advice since none of the existing novel food applications have caused ethical controversy but may be useful in future. Why should novel foods be treated any different to other materials approved under harmonised legislation?	(see 7.33 above)

List of Respondents:

- 1 National Farmers Union, Scotland
- 2 British Society of Plant Breeders Ltd
- 3 Countryside Council for Wales
- 4 Ayurvedic Trade Association
- 5 Trading Standards South East
- 6 Intertek Labtest UK Ltd
- 7 The Grocery Manufacturers Association [USA]
- 8 RSPCA
- 9 Food Solutions
- 10 PETA
- 11 The Nutrition Society
- 12 The British Soft Drinks Association (BSDA)
- 13 Food Additives and Ingredients
- 14 The Anaphylaxis Campaign
- 15 LACORS
- 16 Premier Foods
- 17 Syngenta
- 18 The Food and Drink Federation
- 19 Margaret Anderson
- 20 Nutricia Ltd
- 21 HFMA (Health Food Manufacturers' Association)
- 22 Fair Venture Consulting Ltd.
- 23 Which?
- 24 Royal Society of Chemists
- 25 British Retail Consortium
- 26 East Ayrshire Council