

REVISION OF REGULATION (EC) No 258/97 CONCERNING NOVEL FOODS AND NOVEL FOOD INGREDIENTS

PIE RESPONSE TO THE COMMISSION CONSULTATION

EXECUTIVE SUMMARY

PIE believes that a fundamental deliberation is necessary on how to regulate Novel Foods and Novel Food Ingredients in the EU. Any 'revision' should not just be a revision of the existing provisions of the text but should leave room to discuss alternative approaches. Consistent with its commitment to Better Regulation, the Commission must contemplate a completely new approach that simplifies authorization, allows innovation and free movement of goods whilst ensuring a high level of protection for the consumers.

Economic Impact

The current novel food regulation creates two major problems: legal uncertainty (is the ingredient novel or not?) and procedural burden (lengthy approval procedures). Uncertainty about the results of application, delays in returns on investment, no guarantee of return on investment if generic approval is granted and doubts about the effective functioning of the Single Market put a brake on innovation and undermine the competitiveness of the European industry. Any new proposal must be explicitly assessed with regard to these problems.

Considering a range of options, not just authorisation

Authorisation of novel foods is one and not the only option that should be subject to the Commission's impact assessment. Neither the industry, nor public health is best served by the needless reassessment of ingredients extensively evaluated by the industry. However, while potentially more burdensome to the operator, a positive ingredient approval can assist the commercialization of an ingredient.

The Commission should therefore explore an alternative approach to regulating novel foods, whereby manufacturers:

- may voluntarily submit ingredients for approval via an optional notification procedure.
- must produce documentation demonstrating the scientific basis of the safety of the new product.
- must provide additional data at the request of Member States.

Under an authorisation system:

Within the limited authorization-based framework provided for by the Consultation, the following points should be noted:

Traditional products from 3rd countries

Introducing new concepts such as 'traditional' foods or new levels of risk assessment will potentially create new discrepancies between treatment of EU and non-EU food and not address

PLATFORM FOR INGREDIENTS IN EUROPE

the core weakness of the Novel Foods Regulation, namely that it is an SPS measure based on a political compromise rather than rational science. This would therefore leave the EU vulnerable in the long term to legal challenge by WTO trading partners.

Centralized safety assessment and authorisation

A centralized procedure for safety assessment could reduce the delays currently caused by double risk assessment. A centralised procedure for authorisation would only be more efficient than the current authorisation system if Member States are prepared to place confidence in EFSA and reduce the scope for Member States to raise parochial political objections once the safety of ingredients has been established. Further reflection on the operation of this system is only possible once further details of its operation are known.

Authorisation decisions

Given the time and investment involved in developing a novel foods dossier, other companies should not be allowed to immediately profit from the work undertaken. A 2/3-year data exclusivity provision would help companies benefit from the investment made.

Submission of application for several food uses

Although avoiding the duplication of risk assessment is logical in principle, it is not yet clear what the implications of a single authorisation procedure would be, not least on ingredients with different (e.g. both nutritional and technological) functions.

Addressing legal uncertainty

The consultation does not address the problem of legal uncertainty which is as debilitating for the industry as excessive procedures. Playing with the definition of what is 'novel' may well be inadequate to encapsulate the wide range of possible technological and market innovations in the future. The creation of an optional pre-assessment procedure to assess the legal (as opposed to safety) issues related to novel foods could facilitate the effective operation of the Novel Foods Regulation.

A. ECONOMIC IMPACT

The Commission has requested information on costs related to novel foods applications. PIE members have indicated that these can vary enormously according to the type of ingredient, application and specific experience of the procedure. Aggregating this information as a Platform would therefore be of a little value to the Commission – members undertake to communicate this information, where possible, on a company basis.

Nevertheless, from the common perspective of PIE members any impact assessment of a revision of Regulation 258/97 must be considered in relation to what are currently the greatest barriers to product innovation, namely legal uncertainty and procedural burden. Legal certainty comprises not only the legal status of ingredients passing through the novel foods procedure but also those ingredients considered (by company/national authority) not to be novel foods. PIE considers that is also important to assess the economic impact of reduced innovation resulting from the procedural burden identified in the current system. It is not clear how the Commission will undertake this assessment from the data requested. To summarize the impact in qualitative terms:

Current Problem	Economic Impact
Legal uncertainty	<ul style="list-style-type: none"> • Lengthy internal and external consultation in identifying status of product in each Member State. • Costly legal assessment needed. • Negative impact on market positioning. • Uncertainty about effective functioning of Single Market operation (in case of non-novel food) about launching product on new markets. • Potential costs of recall if non-novel food status is challenged. • Potential market loss if generic approval is given.
Procedural burden	<ul style="list-style-type: none"> • Overall financial burden of minimum 2/3 year delay in return on R&D investment (i.e. 2/3 year delay in launching a new food ingredient on the EU market) + time post approval for manufacture, product marketing and sell through. • Costs of providing information that may not be necessary for assessment of specific ingredient. • Lack of predictability in procedures disrupts marketing campaign/launch of product • Administrative costs of pursuing dossiers until the whole procedure is finished.

➔ **General impact:** Legal uncertainty and burdensome procedures act as a brake on EU innovation, leading to lack of competitiveness of food ingredients industry at international level, a barrier to employment creation and a limitation on consumer choice.

B. CONSIDERING ALTERNATIVES TO MANDATORY AUTHORISATION

The Commission's consultation is constructed in a way as to permit comment on the optimization of the existing authorisation procedure. However, in particular with respect to the issue of procedural burden, it is first necessary to ask whether the authorisation procedure is the appropriate approach to regulating new food ingredients in the future. A fundamental rethink of all options is particularly valid in the light of:

1. The Commission's commitment to Better Regulation.
2. A fundamentally restructured legislative and institutional framework for food safety in 2006 when compared to 1997.
3. Concerns among WTO trading partners about the need for specific rules for novel foods.
4. The removal of GMOs from the Regulation – the principle reason for establishing the novel foods regime.

PIE believes that, consistent with its commitment to Better Regulation, all alternative options need to be considered and subjected to impact assessment by the Commission.

Fundamental question : Is the European Union best served by a system that requires all new food ingredients to undergo individual authorisation?

Food ingredient manufacturers are constantly seeking both to improve existing ingredients and develop new ones. This may imply either minor or more elaborate innovative practices, many of which would clearly not be considered 'novel' under existing legislation. Even for a 'novel' ingredient, the development may mean at the one end of the spectrum a relatively simple modification to a process or at the other a significant change in molecular structure or even a completely new molecule. The safety implications for the manufacturer remain the same regardless. Any change to an ingredient requires comprehensive safety research, not least to meet the obligations of Regulation (EC) 178/2002 that lays down that "food shall not be placed on the market if it is unsafe."¹ A food operator can be challenged at any time by national authorities to submit information justifying the safety of an individual ingredient. Depending on the nature of the ingredient and innovation undertaken, the amount of substantiating research required can vary between mere corroborative studies to complete clinical studies. It is neither useful from a consumer health perspective, nor feasible for administrators (EFSA) to re-evaluate all these changes to ingredients.

This is not to argue that an approval system is of no value to ingredients manufacturers. The commercial risk of marketing an ingredient that may subsequently be legally challenged is significant e.g. potential recall/prosecution. Increasingly, customers of ingredient suppliers are demanding confirmation of official approval before purchasing ingredients. The greater the novelty of the ingredient, the greater the risk of challenge and consequently the greater the reassurance required by the customer. The opportunity to seek approval of an ingredient is therefore sometimes a commercial necessity.

¹ Regulation (EC) N° 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety - Article 14 – Paragraph 1.

PIE

PLATFORM FOR INGREDIENTS IN EUROPE

To ensure a regulatory system that is proportionate to risk and thereby efficient both for administrators and the industry, the Commission must fully evaluate all alternatives to mandatory authorisation. In particular we ask the Commission to consider:

- **An optional notification/certification system** whereby manufacturers can submit to EFSA **on a voluntary basis**, the scientific substantiation of the safety of the new ingredient.

Where no notification is sought, there should be the following legal requirements for the company manufacturing the novel ingredient:

- To produce documentation demonstrating the scientific basis of the safety of the new product, possibly supported by publication in a peer-reviewed journal. In addition, this would help avoid the non ethical repetition of certain animal studies.²
- On request of national authorities, provide any additional information surrounding the company's scientific evaluation of the safety of these ingredients to answer specific concerns raised.

Voluntary notification would prevent unnecessary reassessment by EFSA of novel ingredients that have no significant risks. It would therefore provide a more proportionate procedure for novel foods. Moreover, introducing voluntary notification would lessen the importance of the definition of novel food, as the procedure followed would not depend on the problematic process of establishing 'novelty'. The likely concern with voluntary notification is that companies will not voluntarily undergo such procedures. However, the experience of the use of a voluntary system in the UK demonstrates that rather than launching a product without assessment, companies - for the reasons outlined above - are very much prepared to make use of such a system.³

² E.g. in the case of the development of similar ingredients for which results of similar animal studies might be needed, and which would consequently benefit from the results already available to serve as basis of a corroborative study.

³ In the first seven years of the operation of the UK Advisory Committee on Novel Foods and Processes, 61 cases were considered, with 35 approved and 1 rejected. This compares with 53 cases considered, 14 approved and 2 rejected during the first 7 years of the Novel Foods Regulation.

C. SPECIFIC ISSUES

Within the limited authorization-based framework provided for by the Consultation, the following points should be noted:

1. Traditional food from 3rd countries

Traditional food from 3rd countries has not been a central concern for food ingredient manufacturers. However, the Commission is correct to address the issue of 3rd country exports. Prohibiting, in the absence of authorisation, the import of food sold in other markets prior to 1997 is clearly discriminatory.

However, creating a specific procedure for 'traditional' or exotic foods would not address this fundamental discrimination. It is because the '1997 rule' reflects an internal political compromise rather than being based on any rational scientific underpinning, that the EU is vulnerable to challenge from its partners under SPS rules. Creating a procedure for exotic foods may address in the short term the immediate concerns of certain trading partners, but it changes the nature of the discrimination rather than addressing it at its core.

To prevent further discrimination, the same rules should apply for all products from third countries as EU Member States. If there are concerns about the general safety of the food in question, a Member State may under existing SPS rules challenge an exporting State to demonstrate that the domestic rules in place meet the level of protection required by the Community.

2. Centralized procedure

There has been only one case (tagatose) where the authorisation of a substance on the EU market proceeded without challenge from Member States, reflecting a regrettable lack of trust between the national safety authorities. An effective centralized procedure for safety assessment would hopefully reduce the risk of 'double' risk assessments and could therefore be significant in reducing time delay and increasing confidence in the operation of the system.

PIE would like to comment further on the specific authorisation procedures being considered by the Commission (referred to on page 5 of the Consultation Explanatory Document) when this document is published.

However, it should be noted that a centralized procedure may not *per se* improve the efficiency of processing novel food applications. If maintained in future legislation, the current authorisation system could be more efficient. Authorisation is currently automatically granted in the absence of a reasoned objection by a Member States within 60 days of the completion of the risk assessment. Procedurally, this offers clear advantages over a mandatory formal centralized authorisation procedure, which would undoubtedly exceed 60 days and could – taking account of similar procedures in other legislation – take between 3 and 9 months.

A centralised procedure for authorisation would only be more efficient than the current authorisation system if Member States are prepared to place confidence in EFSA and reduce the scope for Member States to raise parochial political objections once the safety of ingredients has been established. Reform must therefore be focused on these points.

3. Authorisation decision

PIE recognizes that any rules adopted under a revised Novel Foods Regulation can only provide limited protection for those companies or consortium of companies that have invested time and money in a novel foods dossier. Other legal measures e.g. patents are likely to be more effective in this respect. However, given the investment made, and that such legal measures may not be accessible to smaller companies, some form of protection should be provided to the first petitioner within the Novel Foods Regulation to ensure that other companies cannot match or even beat the novel food's entry on the market. A data exclusivity provision of 2-3 years is therefore proposed to allow some additional advantage to petitioners.

4. Submission of application for several food uses

The need to undertake parallel risk assessments on the same ingredient would appear to be unnecessarily burdensome for both industry and administration and does need to be addressed. However, it is as yet unclear what the broader implications would be of a single authorization procedure and a fuller understanding is needed of how this procedure would work. For example, there is potentially a danger that centralized authorization would lead to a *de facto* positive list, thereby hindering either the new use of ingredients or those ingredients considered not strictly falling within existing Community 'positive' categories of food e.g. additives, colours, food supplement ingredient etc., This is a danger that has been noted by the Community in the past⁴ and should be maintained.

Developing a new use for an existing ingredient may potentially have risk implications, e.g. increasing general intake of that substance. However we maintain that **the novel food procedure is not the most appropriate way of addressing this issue, as the substance itself is not novel, having been previously used/authorised e.g. as additives or in food supplements.** In the context of the development of its central authorization procedure, the Commission therefore needs to consider, for example, the option of a proportionate procedure when 'extending' existing uses, whether this is from one category to another or for additional uses within already approved categories.

⁴ For example, it is recognised that certain substances, even if able to play a technological role, should not be considered as food additives. European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners – Article 5.

D. ADDITIONAL ISSUES

Although it is noted that 'clarifying the definition of novel' will be one of the objectives of the new proposal (Explanatory Note, page 1), the consultation focuses on only one of the difficulties facing the ingredient industry, namely procedural burden and not on legal uncertainty. While the rationalization and streamlining considered is extremely important, PIE would like to emphasize that **the question of legal certainty is equally crucial to the effective operation of the novel foods procedure**. In short, without confidence about whether a product needs to undergo a novel foods procedure or not, changes to procedures alone will not give industry the necessary confidence in the legal framework.

As new products and market opportunities are explored, the definition of a novel food has naturally come under strain. The Commission and Member States appear to be forming new interpretations of the Novel Foods Regulation, which are difficult to reconcile with any common reading of the text. Moreover, these interpretations remain opaque even for those larger companies who are most involved with regulatory affairs. Among the uncertainties experienced are:

- Ingredients authorised and with established use as additives, but to be used as an ingredient are considered novel.
- Ingredients used in supplements prior to 1997, are not food ingredients within the meaning of Regulation 258/97.
- A process once authorised as novel is not considered to be novel in the case of a second applicant.

Such decisions, however justified from a policy perspective, have questionable legal textual support. These issues must be clarified in the revision of the Regulation. At the same time, it is recognised that any (even new) definitions may soon be challenged in the light of technological advances.

Ideally, a system could be put in place where the definition of the novel food does not dictate the procedure to be undertaken (see section B above).

Failing that, PIE proposes the introduction of a voluntary pre-assessment of the legal status of a substance. This could have the following advantages:

1. Separate more clearly the scientific and legal aspects of an application.
2. Provide greater certainty to operators on the correct procedure to follow.
3. Provide a forum for assessing the more complex legal aspects of third country exports.
4. Avoid unnecessary novel food applications and possible 'blockage' of EFSA risk assessment.

The clear disadvantage to such a procedure is that there is a danger of complicating the existing procedure and thereby extending rather than reducing the timeline for accepting products. However, it is proposed that this procedure should be voluntary, therefore allowing the applicant to choose greater certainty at the potential cost of further delay.

PIE calls on the Commission to take full account of problems relating to legal uncertainty in its impact assessment.

13 July 2006