

**Evaluation of Regulation (EC) No 258/97 of the European Parliament and of the Council
of 27 January 1997 concerning novel foods and novel food ingredients
(Novel Food Regulation)¹**

Executive Summary

Article 14 of the Novel Food Regulation requires, in the light of the experience gained, to review the implementation of the Novel Food Regulation.

It appeared necessary and appropriate to establish a common Regulatory framework concerning GM food and GM feed apart from the Novel Food Regulation. To this end, a major step in fulfilling the obligations to review and possibly amend Regulation (EC) No. 258/97 was the Commission proposal for a Regulation concerning GM food and feed this Regulation (EC) No 1829/2003² of the European Parliament and of the Council, which was adopted on 22 September 2003 and was applicable since 18 April 2004. Another parallel step in reviewing the implementation of the Novel Food Regulation by the Commission was the elaboration of a *Discussion Paper* in 2002 and its circulation, in order to offer the opportunity to interested parties to comment on the current legal situation regarding Novel Foods.

With regard to the *Discussion Paper*, the Commission received a large number of written comments. In addition, the Commission organised a stakeholder meeting in January 2003. All comments were summarized by the *Summary Report – Revision of the Novel Food Regulation – Stakeholder Submissions* ('*Summary Report*') 17 June 2003 and based on this report an *Evaluation Report on the Novel Food Regulation 258/97 Concerning Novel Foods and Novel Food Ingredients* ('*Evaluation Report*') 22 January 2004 was prepared. Further revision of Regulation (EC) No 258/97 will be undertaken in consideration of the *Evaluation Report* and the *Summary Report*.

Having taken into account the stakeholders' comments, the *Evaluation Report* and the *Summary Report* offer several recommendations regarding the revision of the Novel Food Regulation, focussing on the following:

- Definition of Novel Foods according to article 1 of the Novel Food Regulation (1.4.1/5.1 of the *Evaluation Report*; VII. 1 of the *Summary Report*.; 3.1 of the *Discussion Paper*.),
- Authorisation procedure (1.4.2, 1.4.3/5.2, 5.3 of the *Evaluation Report*; VII. 2., VII. 5. of the *Summary Report*; 3.3 of the *Discussion Paper*),
- Simplified procedure (1.4.2/5.2 of the *Evaluation Report*; VII. 2 of the *Summary Report*.; 3.3 of the *Discussion Paper*),
- Resolution process (VII. 3 of the *Summary Report*),
- Authorisations under the Novel Food Regulation (1.4.2/5.2 of the *Evaluation Report*; VII. 4.b of the *Summary Report*; 3.2 of the *Discussion Paper*),
- Transparency and public consultation (1.4.2/5.2 of the *Evaluation Report*; 3.3.3 of the *Discussion Paper*),
- Labelling of Novel Foods (1.4.2/5.2 of the *Evaluation Report*; 3.4 of the *Discussion Paper*).

¹ Official Journal 43, 14 February 1997, p. 1.

² OJ 268, 18 October 2003, p. 1.

Definition of Novel Foods

The main objectives of the Novel Food Regulation were to facilitate the functioning of the internal market within the Community and to protect human health. Therefore the Regulation foresees a pre-market assessment of foods and food ingredients which have not been used for human consumption to a significant degree before the Regulation entered into force (15 May 1997). However, foods legally on the market in at least one Member State would not require a specific safety assessment.

Furthermore, the Novel Food Regulation also lists categories of foods that are subject to the Regulation. As practice has shown and stakeholders stated in their comments on the *Discussion Paper*, the novel food categories listed in article 1 of the Novel Food Regulation have in some cases been perceived to cause difficulties in interpretation and applicability of the Regulation. Therefore it seems to be appropriate to provide for more clarity regarding the scope of the Regulation in order to avoid further misunderstanding. The procedure to classify whether or not a food or food ingredient is novel should be easy to implement and transparent, thus providing clear guidance on the application of the Regulation.

The safety of foods for which there was no history of safe consumption in the European Union needs to be verified before such foods may be placed on EU market.

Stakeholders' comments also focussed on category f of Article 1(2) concerning new production procedures. The *Discussion Paper* suggests different options to deal with this category. The discussion revealed that most of the stakeholders support the current approach, i.e. not to regulate food production processes as such but to check whether a food would be significantly changed when a new production process was applied. However, it appears useful to reword that category in order to avoid misunderstandings.

Apart from that, the *Evaluation Report* shows that the applicability of the Novel Food Regulation to food supplements, food additives and flavourings would have to be verified and clearly pointed out. In particular, it would have to be considered how to proceed with regard to novel foods and food ingredients with multiple purposes, e.g. technological, nutritional or physiological uses. One solution might be to authorise all uses requested under the scope of the Novel Food Regulation in order to avoid multiple application and assessment, e.g. concerning uses as food additive, as/in food supplements or in other foods. If only technological uses are concerned authorisation might be still granted under the specific provisions regarding food additives. In this context it has to be emphasised that even the current Novel Food Regulation would be applicable to food additives if the safety levels laid down for the assessment of food additives does not correspond to the safety level of the Novel Food Regulation.

Authorisation procedure

Stakeholders' comments also focussed on the authorisation procedure and different opinions on how the authorisation procedure might look were presented. Nearly all stakeholders commenting on this issue pointed out that the authorisation procedure should be accelerated and provide for more reliability for applicants, in order to be able to better schedule the launching of novel foods and novel food ingredients.

In consideration of the *Evaluation Report* and the *Summary Report* it seems to be justifiable to amend the current procedure with the objectives of acceleration and simplification. At the same time high quality food safety assessment has to be assured. Several stakeholders emphasised that different types of novel food categories would require different authorisation procedures and different documentations regarding safety assessment. For example, novel foods and novel food ingredients as a result of an innovative production process and/or exotic fruits might have to be assessed and authorised differently.

On the other hand, the establishment of many different authorisation procedures under the scope of one Regulation would possibly create more confusion than achieve clarity. Therefore it seems to be reasonable to establish only one frame authorisation procedure but to fix particular requirements depending on the novel food category. In any case these requirements would have to be well considered in order to assure high quality safety assessment. It might even be appropriate to clearly specify the data which have to be submitted in order to give advice to potential applicants.

Furthermore, if the authorisation procedure is amended as described above the current simplified procedure would surely have to be abolished. However, this item also has to be considered within the context of future forms of authorisations under the Novel Food Regulation (e.g. general or exclusive authorisation).

It should be emphasised that the establishment of the European Food Safety Authority (EFSA) has to be taken into account. The *Evaluation Report* and the *Summary Report* clearly pointed, out and stakeholders were also mainly of this opinion, that EFSA should play a decisive role within the authorisation procedure. Since in practice most of the applications under the Novel Food Regulation were assessed twice – initially by a Member State and afterwards by the former Scientific Committee on Food (SCF) and EFSA respectively – a suitable solution for an accelerated and tightened authorisation procedure might therefore be exclusive safety assessment by EFSA.

Determination of novelty

Apart from the amendment of the authorisation procedure, the *Summary Report* addresses the possibility to establish an ‘advanced ruling procedure’ to decide whether a food/food ingredient has to be classified as novel according to the Novel Food Regulation in order to achieve certainty about its status within the European Community.

In order to increase acceptance of the status of a food/food ingredient according to the Novel Food Regulation by all affected parties and to make available as much information as possible, some kind of ‘advanced ruling procedure’ could probably improve the current situation. One would have to well consider how such a procedure might look like - e.g. offering the opportunity to interested parties to comment on the status of a food or food ingredient within a fixed period - while assuring that the authorisation procedure would not be delayed since this was one of the points highly criticised by stakeholders. Acceptance of a final food/food ingredient status would probably be higher, should more parties be in the position to submit information about a potential use of a product within the Community.

The form of such a decision about the final status of a food or a food ingredient would also have to be considered in order to assure that it is approved by all the parties involved.

Authorisation under the Novel Food Regulation

As concerns authorisations made under the Novel Food Regulation different approaches about the addressee of the novel food authorisation and the forms of the authorisation were suggested.

The *Evaluation Report* and the *Summary Report* show that different options should probably be established depending on the nature of the novel food/novel food ingredient. Especially foods/food ingredients resulting from an innovative process might require other forms, since in some cases post market surveillance might be necessary or interests of the applicants have to be warranted, in contrast to other novel food types, e.g. exotic plants. Therefore it might be in some cases adequate to exclusively address an authorisation to the applicant while in other cases, a general authorisation could be granted.

It also has to be considered whether novel foods/novel food ingredients should be still authorised via a Commission Decision or if any other forms, e.g. a Regulation, might be preferable. In the context of the above remarks about the addressee of a novel food authorisation, one might also consider whether different forms of authorisation depending on the novel food category and even the addressee should be established.

Apart from that the question of potential applicants for novel food authorisation would also have to be taken into account. It has to be considered whether persons others than those placing the novel food/food ingredient on the Community market might be entitled to apply for novel food authorisation, e.g. non-profit organisations, consortia, the public sector. However, it has to be assured that the applicant attends legal responsibility for the novel food/food ingredient authorised.

Transparency and public consultation

The *Evaluation Report* shows that more transparency with regard to novel food authorisations might be required and that interested parties should be enabled to submit comments while a delay of the authorisation procedure would have to be avoided.

In fact, it seems to be valuable to inform interested parties at an early stage of the procedure so that effected parties would be able to submit relevant information about individual foods and food ingredients which might contribute to improve the acceptance of the final status and the authorisation granted under the Novel Food Regulation. There are several options how to involve the public whereas one possibility would be the above mentioned advanced ruling procedure.

Labelling of Novel Foods

Labelling of novel foods and novel food ingredients must be in conformity with existing general labelling provisions. However, novel foods and novel food ingredient may in some cases require additional labelling in comparison to existing foods in order to inform consumers sufficiently. Since the specific labelling provisions of the Novel Food Regulation were established with particular emphasis on GM-food and food ingredients, it would have to be verified which provisions need to be retained after having separated GM-food related provisions from the scope of the Novel Food Regulation.

The *Evaluation Report* pointed out that stakeholders were mostly in favour of having more general and therefore more flexible requirements. Thus, it should be considered whether this option might provide for adequate information regarding the characteristics of novel food/food ingredients, including particular conditions of use and its possible impact on health or safety of individual consumer groups.

Naturally, the amendment of the novel food labelling provisions would also have to take into account current labelling policy and legislative approaches, e.g. on nutrition and health claims. Therefore, it would have to be clearly determined which additional labelling information might have to be ruled under the scope of the Novel Food Regulation and what information would be reserved to other existing or future labelling provisions.