

**DISCUSSION PAPER : IMPLEMENTATION OF REGULATION (EC) No  
258/97 ON NOVEL FOODS AND NOVEL FOOD INGREDIENTS**

**ERNA COMMENTS**

ERNA very much welcomes the European Commission's review of Regulation 258/97 and the opportunity to comment on its Discussion Paper.

ERNA members, many of whom have had direct experience of assessing ingredients with reference to the novel foods Regulation, would like to draw the European Commission's attention to the following points:

1. Member State approach to novel food dossiers

In general, ERNA welcomes the involvement of Member States in the initial assessment of whether foods are novel or not. A national ministry will often provide informal advice which assists the company in an initial assessment of a food. However, in the experience of our members there are two ways in which this system could be improved., :

a. Member States should not refer cases to the Novel Foods Working Group (as described in the Discussion Paper 1.4.1) in a way that could be detrimental to the case of the applicant. Dossiers should in the future be forwarded to other Member States in the original format submitted by the applicant in order not to prejudice the Working Group's assessment.

b. Foods should be subjected by Member State to an objective assessment. The ejection of foods for consideration as novel foods on the premise that they are 'not needed' or 'not welcome' in a particular Member State is not consistent with the aims or the letter of the regulation and may act as a barrier innovation.

We would recommend that stricter guidelines are introduced as to the process by which Member States should deal with data submitted for consideration.

## 2. Transparency

In addition and concomitant to point 1, where Member States have referred cases to the Novel Foods Working Group, companies submitting dossiers for consideration do not always get substantiated explanation as to how or why the Novel Foods Working Group reaches its decision. On occasions, this raises questions as to whether further dialogue between applicants and the Working Group could resolve the issues that are being discussed e.g. by providing additional data or explanations.

Public access to the opinions of the Working Group would result in a clearer picture of the practice of approvals. Furthermore, we would suggest that the outcome of discussions of the Novel Food Working Group is declared as legally binding even for those Member States that have not initially been approached in order to guarantee uniform understanding of the legal status of a product within the Union.

While ERNA is sympathetic to the need for objective assessments, it would ask the Commission to review Working Group process to see how greater flexibility and dialogue can be built into the process.

## 3. Significant consumption

One of the greatest problems for companies in assessing potential novel foods is to assess to what extent they have been consumed "to a significant degree". The Discussion Paper gives, for the first time, an insight into the Commission's expectations in this respect, but further clarity is required both to the common understanding of 'significant consumption' and to the level of evidence required in support of the application.

Experience has shown that there is no mutual recognition of what constitutes 'significant use' and that Member States will sometimes reject supporting evidence of significant use if it does not include use in their own Member State. This is contrary to the spirit of the Directive and leads to 'ministry hopping' by food companies. In many cases, clarity over this one point would reduce the need for referral to the Working Group on Novel Foods and would therefore be beneficial to all.

## 4. Production processes

The application of known processes to foods that have previously not undergone that process is an important motor of innovation. Our understanding is that GMOs specifically, rather than production processes in general, inspired the inclusion of the 'production process' novel food category. Given the development of specific GMO legislation, this category would now seem to be redundant.

Food manufacturers are constantly striving to improve processes e.g. to enhance yields, but these technological improvements do not necessarily have safety or ethical implications. General food safety regulations should be sufficient to counter to address such problems as the presence of undesirable substances. Subjecting production processes to the kind of scrutiny currently established by the novel foods Regulation, even to foods that are not significantly different in their final form, would lead to the stagnation of food technology. We would therefore support Option 1 proposed by the Commission in paragraph 3.1.2. to remove the category from the Novel Food Regulation.