ENGINEERED NANOMATERIALS: AUTHORIZATION UNDER NOVEL FOOD REGULATION (EC) NO 258/97

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In order to guarantee the public safety, the market of foods that have not been consumed to a significant degree in the European Union earlier has to undergo a premarketing authorization procedure to assess the safety for human consumption according to Regulation (EC) No 258/97 (hereafter named 'the regulation') (1).

According to the regulation, novel food and novel food ingredient that do not have a significant history of consumption before May 1997 can be divided into the following categories:

i) foods and food ingredients with a new or intentionally modified primary molecular structure (letter c in the regulation);

ii) foods and food ingredients consisting of or isolated from microorganisms, fungi or algae (letter d in the regulation);

iii) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use (letter e in the regulation);

iv) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances (letter f in the regulation).

The Regulation does not cover food for which an approval procedure is already in place, such as food additives, flavourings, extraction solvents and GMOs (Genetically Modified Organisms). If food was used exclusively in food supplements, new uses in other food require authorisation under the novel food Regulation (e.g., food fortification requires authorisation).

To market a novel food, companies must apply to the competent authority of one of the member states for authorisation, presenting a dossier, containing all the scientific information to support the safety of the product. When the competent authority decides that no additional assessment is necessary and if the Commission and EU member states do not object the product can be marketed in the EU under an authorization issued by the member state. Otherwise, an additional assessment is necessary and the approval or refusal of marketing of the product is stated in a Commission decision, approved after receiving the opinion of the Standing Committee on Food Chain and Animal Health (Figure 1).

In some cases, a novel food included in the categories ii) and/or iii) (see list above) may be marketed through a simplified procedure called "notification". The company notifies the Commission about the marketing of a novel food or ingredient based on the opinion of a food assessment body of one of the member states that has established "substantial equivalence".

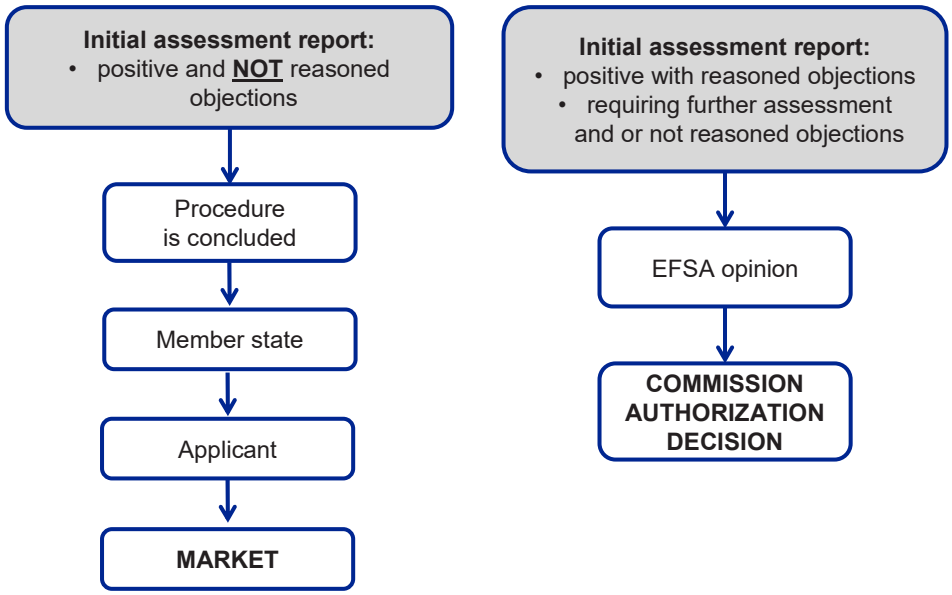

Figure 1. Main authorization procedure of a novel food under Regulation (EC) No 258/97

Foods different from additives, flavourings or enzymes that can be classified as engineered nanomaterials are considered novel in the meaning of category iv) of the above list. The authorization procedure must be followed prior to their marketing.

A proposal of a new regulation on novel food was adopted in 2008 but failed in 2011. A new proposal has been presented in December 2013 and the discussion at the Council are expected to begin in early 2014. As the former one, this new proposal explicitly makes reference to engineered nanomaterials.

References

1. European Parliament and Council, 1997. Regulation (EC) No 258/97 of 27 January 1997 concerning novel foods and novel food ingredients. *Official Journal of the European Union* L 43/1, 14/02/97.