

## Placing on the market of novel foods or novel ingredients in Europe “novel food procedure”

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**Abstract:** « Novel Foods » concerned foods and food ingredients that have not been used for human consumption to a significant degree within the Community before 15 May 1997. Regulation (EC) No 258/97 of 27 January 1997 lays out detailed rules for the authorisation of novel foods and novel food ingredients. In order to ensure the highest level of protection of human health, novel foods must undergo a safety assessment before being placed on the EU market. The application must be in accordance with Commission Recommendation 97/618/EC concerning the scientific information and the safety assessment. A proposal of the revision of this regulation has been adopted in order to reflect the fact that genetically modified (GM) food no longer falls under its scope, to create a more favourable legislative environment for innovation in the food industry, and to better facilitate foodstuffs trade between Europe and the rest of the world. The consumer would also benefit from a wider choice of safe novel foods.

**Key words:** novel food, regulation (EC) No 258/97, GM food, authorisation, safety

Novel foods are foods and food ingredients that have not been used for human consumption to a significant degree within the Community before 15 May 1997. Regulation (EC) No 258/97 [1] of 27 January 1997 of the European Parliament and the Council lays out detailed rules for the authorisation of novel foods and novel food ingredients.

Foods commercialised in at least one Member State before the entry into force of the Regulation on Novel Foods on 15 May 1997, are on the EU market under the “principle of mutual recognition”. In order to ensure the highest level of protection of human health, novel foods must undergo a safety assessment before being placed on the EU market. Only those products considered to be safe for human consumption are authorised for marketing.

### Legislation

Regulation (EC) No 258/97 is applying to foods and food ingredients that have not been on the EU market to a significant degree before May 1997 and that fall under the following categories:

- foods and food ingredients with a new or intentionally modified primary molecular structure;
- foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
- foods and food ingredients consisting of or are isolated from plants or isolated from animals; except for food and food ingredients

obtained by traditional propagating or breeding practices and having a history of safe food use;

- 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.

The regulation is not applicable to:

- food additives, falling within the scope of Council Directive 89/107/EEC of 21 December 1988 [2];
- flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC of 22 June 1988 [3];
- extraction solvents used in the production of foodstuffs, falling within the scope of Council Directive 88/344/EEC of 13 June 1988 [4].

### GMO's

Since 2003, most GMOs have been approved under regulation (EC) No 1829/2003 [5]. New GMO maizes, applications for the marketing of which were submitted under Regulation (EC) No 258/97, have been authorised. Their labelling is based on regulation (EC) No 1829/2003 and they are subject to the traceability requirements established by Regulation (EC) No 1830/2003 [6].

### Notified foods

Novel foods or novel food ingredients may follow a simplified procedure, only requiring notifications from the company, when they are considered by a national food assessment body as “substantially equivalent” to existing foods or food ingredients (as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein).

### Application report

Companies that want to place a novel food on the EU market need to submit their application in accordance with Commission Recommendation 97/618/EC [7] that concerns the scientific information and the safety assessment report required.

The identification of essential information for assessment is guided by *eight structured schemes* provided the information required to support the safety and nutritional evaluation of the novel food:

- I. Specification of the novel food.
- II. Effect of the production process applied to the novel food.
- III. History of the organism used as the source of the novel food.
- IX. Anticipated intake/extent of use of the novel food.
- X. Information from previous human exposure to the novel food or its source.
- XI. Nutritional information on the novel food.

XII. Microbiological information on the novel food.

XIII. Toxicological information on the novel food

## Evaluation procedure

Before being placed on the market, the foods and food ingredients referred to in the regulation must undergo Community assessment, as a result of which an authorisation decision may be taken.

Under the assessment procedure, the applicant (manufacturer, retailer...) must submit his application to the Member State which will market for the first time the Novel foods. Hence, the competent body of the Member State which receives the application must make an initial assessment and determine whether or not an additional assessment is required. If neither the Commission, assisted by the Standing Committee on the Food Chain and Animal Health<sup>1</sup> nor the Member States raise an objection, and if no additional assessment is required, the Member State informs the applicant that he may place the product on the market.

In other cases the Commission must take an authorisation decision with the assistance of the Standing Committee for Foodstuffs. Any decision or provision concerning a novel food or food ingredient which is likely to have an effect on public health must be referred to the Scientific Committee for Food.

The experience is all too aware of the length of this procedure, in average 2 to 6 years. It should be mentioned as well that the choice of the member state is important. In fact, the evaluation systems of the different authorities are not equivalent: some countries such as Belgium and UK offer a cooperative but charged approach with the applicant, around 3000 to 4000 € for a complete dossier.

## Authorisations

The authorisation decision defines the scope of the authorisation and specifies, as appropriate, the conditions of use, the designation of the food or food ingredient, its specification and the specific labelling requirements.

A total of 80 applications<sup>2</sup> have been made between May 1997 and March 2008 including the GM foods applications. Three categories of Novel foods are in practice requested:

<sup>1</sup> Health & Consumer Protection Directorate General (DG SANCO). [http://ec.europa.eu/dgs/health\\_consumer/index\\_fr.htm](http://ec.europa.eu/dgs/health_consumer/index_fr.htm).

<sup>2</sup> The list of Applications for Authorisation of novel foods. [http://ec.europa.eu/food/food/biotechnology/novelfood/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm).

Table 1. Novel food lipids: authorised and under evaluation (June 2008).

Novel food lipids authorised	Novel food lipids under evaluation (June 2008)
<ul style="list-style-type: none"><li>– Yellow fat spreads with added phytosterol-esters,</li><li>– DHA-rich oil,</li><li>– Rapeseed oil high in unsaponifiable matter,</li><li>– Maize germ oil high in unsaponifiable matter,</li><li>– ENOVA™-oil, Diacylglycerol Oil (DAG oil),</li><li>– MultOils (oil containing a diacylglycerol-rich fat component and a free phytosterol esters component).</li><li>– Diminicol, phytosterol enriched fat ingredient</li><li>– Refined Echium oil (<i>Echium plantagineum</i>),</li><li>– Allanblackia seed oil for use in yellow fat spread and cream based spreads,</li><li>– Oil enriched with phytosterols/phytostenols.</li></ul>	<ul style="list-style-type: none"><li>– Vegetable oil from Inca Inchi (<i>Plukenetia volubilis linneo</i>),</li><li>– Conjugated Linoleic Acid (CLA),</li><li>– Triterpene rich Shea Butter Unsaponifiables,</li><li>– Lipid extract from <i>Euphausia superba</i>,</li><li>– Cis-9-cetyl myristoleate</li><li>– Tomato oleoresin containing lycopene for use in foods for special medical purposes and food uses</li><li>– Synthetic lycopene in sunflower oil dispersion</li><li>– Additional uses of DHA (docahexaenoic acid)-rich oil from microalgae <i>Ulkenia sp.</i></li><li>– Fungal Oil SUN-TGA40S</li></ul>

– innovative food (e.g. phytosterols foodstuffs, threhalose, phospholipids isolated from egg yellow);

– traditional food from third countries (e.g. noni juice);

– food produced by new production techniques with possible impact on food (e.g. high-pressure pasteurised fruit juice).

For 20 products the application of the placing on the market was withdrawn or was refused (e.g. nangai nuts, *Stevia rebaudiana*); and for 140 products the notification<sup>3</sup> of the placing on the market was recognised (e.g. argan oil).

By March 2008, thereby 37% of novel foods requested have been approved to be commercialised in the Europe. Novel food lipids are representing respectively 7.5% of the total of applications and about 20% of the novel foods authorised (table 1).

## Review of Regulation (EC) No 258/97

A revision of the Novel Food Regulation is deemed necessary in order to reflect the fact that genetically modified (GM) food no longer falls under its scope, to create a more favourable legislative environment for innovation in the food industry, and to better facilitate both internal and external trade in foodstuffs.

An online consultation<sup>4</sup> on the revision of Novel Food Regulation (EC) No 258/97 was

<sup>3</sup> The list of Notifications of novel foods. [http://ec.europa.eu/food/food/biotechnology/novelfood/notified\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/notified_en.htm).

<sup>4</sup> Responses to the online consultation on the revision of novel food regulation EC 258/97, Summary report on the impact assessment for a Regulation replacing Regulation (EC) no 258/97 on novel foods and novel food ingredients, Report on impact assessment for a Regulation replacing Regulation (EC) no

launched by the European Commission, to gather input from the general public, stakeholders and Member States in order to carry out an impact assessment for a future legislative proposal to revise the current Novel Food Regulation.

From the 14th of January 2008, the European Commission has adopted a proposal (COM(2007)872)<sup>5</sup> to revise the Novel Foods Regulation (EC) No 258/97 with a view to improving the access of new and innovative foods to the EU market, while maintaining a high level of consumer protection and ensuring food safety. Under the draft regulation, novel foods would be subject to centralised authorisation procedure. The Commission will receive the application for authorisation and the European Food Safety Authority (EFSA)<sup>6</sup> will carry out the scientific assessment on the product.

The "one door – one key" approach will be taken for the approval of novel foods, just as it will be for food additives, food enzymes and food flavourings. This means that the applicant may make one application for approval covering all these possible uses of the substance in question.

The proposal also sets out data protection rules, which aim to protect newly developed foodstuffs once authorised, and encourage companies to invest in developing new types of foods and food production techniques. More-

258/97 on novel foods and novel food ingredients. [http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm).

<sup>5</sup> COM(2007)872: Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No xxx/xxx [common procedure]. [http://ec.europa.eu/food/food/biotechnology/novelfood/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm).

<sup>6</sup> Official website of the European Food Safety Authority (EFSA). [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_home.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm).

over, a notification procedure is introduced for foods which have not been traditionally sold in the EU but which have a safe history of use in third countries.

## Conclusion

In practice, novel foods are newly developed innovative foods and foods produced by new technologies with possible impact on food, as well as exotic traditional foods from outside the EU. Since 2004, GM foods are separately regulated by Regulation (EC) No 1829/2003.

The EU has since 1997 received 80 applications for approval from more than 45 companies (GM foods included). Over recent years, 7-10 applications per year have been submitted.

The consultation from 2002 to 2007 of the main stakeholders has underlined the importance of and the need to develop and update the regulation; in order to streamline the authorisation procedure, develop a more adjusted safety assessment system for traditional food from third countries, and to improve the efficiency, transparency and application of the authorisation system.

The proposal of the revision of regulation has been adopted in January 2008. Normally, the revision of this regulation shall not enter into force before 2010. Thus, the companies would benefit of a more favourable legislative environment for innovation in the food industry, and of a better foodstuffs trade between

Europe and the rest of the world. The consumer would also benefit from a wider choice of safe novel foods.

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