L.N. 346 of 2002

FOOD SAFETY ACT
(CAP. 448)

Novel Foods Regulations, 2002

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister of Health has made the following regulations:

Citation and commencement.

1.1 These Regulations may be cited as the Novel Foods Regulations, 2002.

1.2 These Regulations shall come into force on the 1st January, 2003.

Applicability of these regulations.

2.1 These regulations concern the placing on the market of novel foods or novel food ingredients.

2.2 These regulations shall apply to the placing on the market of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the European Community and which fall under the following categories:

(a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC;

(b) foods and food ingredients produced from, but not containing, genetically modified organisms;

(c) foods and food ingredients with a new or intentionally modified primary molecular structure;

(d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;

(e) 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;

(f) food 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.

2.3 These regulations shall not apply to:

(a) food additives falling within the scope of the Additives in Foods Regulations (L.N. 89 of 1994);

(b) flavourings for use in foodstuffs, falling within the scope of the Flavourings for Use in Foodstuffs & Source Materials for their Production Regulations (L.N. 257 of 1998);

(c) extraction solvents used in the production of foodstuffs, falling within the scope of the Extraction Solvents for Foodstuffs Regulations, 1999 (L.N. 25 of 1999),

provided that the safety levels laid down in the Regulations referred to in points (a), (b) and (c) above correspond to the safety level of these regulations.

2.4 These regulations shall not apply to novel foods falling within the scope of regulation 2.2 but which had already been placed on the market within the European Community prior to 28th April 1997.

Interpretation.

3.1 In these regulations, unless the context otherwise requires:

'EC Regulation' shall mean Regulation (EC) No. 258/97 of the European Parliament and of the Council.[1]

General safety requirement.

4.1 Foods and food ingredients falling within the scope of these regulations must not:

- present a danger for the consumer;
- mislead the consumer;
- differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer

Marketing of novel foods.

5.1 Foods and food ingredients falling within the scope of regulation 2.2 may not be placed on the market unless they have already been marketed within the European Community following assessment and, where necessary, authorization by the competent authorities within the European Community, according to the procedures laid down in Articles 4, 6, 7 and 8 of Regulation (EC) No. 258/97 of the European Parliament and of the Council.[2] However, in the case of foods or food ingredients referred to in these Regulations derived from plant varieties subject to Directives 70/457/EEC and 70/458/EEC, the authorization

[1] OJ L 43, 14.2..1997, p.1
[2] OJ L 43, 14.2..1997, p.1

decision referred to in Article 7 of the EC Regulation shall be taken in accordance with the procedures provided for in those Directives, provided they take account of the assessment principles laid down in the EC Regulation and the criteria set out in regulation 4.1, with the exception of the provisions relating to the labelling of such foods or food ingredients.

5.2 Regulation 5.1 shall not apply to the foods and food ingredients referred to in regulation 2.2(b) where the genetically modified organism used in the production of the food or food ingredient has been placed on the market within the European Community in accordance with the EC Regulation.

5.3 Regulation 5.1 shall not apply to foods or food ingredients referred to in regulation 2.2(b), (d) and (e) and which, on the basis of the scientific evidence available and generally recognized, or on the basis of an opinion delivered by one of the competent bodies referred to in Article 4(3) of the EC Regulation, are 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. Such foods or food ingredients must have been duly notified to the European Commission according to the procedure laid down in Article 5 of the EC Regulation.

5.4 In the case of foods or food ingredients which have been authorized in terms of Article 7 of the EC Regulation, any conditions of use, designation, specification or specific labelling requirements established pursuant to such authorization, shall also be applicable to the marketing of the food or food ingredient in Malta.

Labelling of novel foods.

6.1 Without prejudice to other requirements concerning the labelling of foodstuffs, the following additional specific labelling requirements shall apply to foodstuffs in order to ensure that the final consumer is informed of:

(a) any characteristic or food property such as:

- composition,
- nutritional value or nutritional effects,
- intended use of the food,

which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient. A novel food or food ingredient shall be deemed to be longer equivalent for the purpose of this regulation if scientific assessment, based upon an appropriate analysis of existing

data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics. In this case, the labelling must indicate the characteristics or properties modified, together with the method by which that characteristic or property was obtained;

(b) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;

(c) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns;

(d) the presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in Annex I A, Part 1 of Directive 90/220/EEC.

6.2 In the absence of an existing equivalent food or food ingredient, appropriate measures shall be taken to ensure that consumers are adequately informed of the nature of the food or food ingredient.

Genetically modified organisms.

7.1 Article 9 of the EC Regulation shall apply in the case of foods or food ingredients which contain or which consist of a genetically modified organism within the meaning of article 2 (1) and (2) of Directive 90/220/EEC.

Safeguard measures.

8.1. The Superintendent of Public Health, acting on the advice of the Directorate responsible for foodstuffs within the Malta Standards Authority, may temporarily restrict or suspend trade in and use of any novel food or food ingredient complying with these regulations if, as a result of new information or a reassessment of existing information, he has detailed grounds to believe that the use of the food or food ingredient in question endangers human health or the environment.