

SUBSIDIARY LEGISLATION 231.29**ADDITIVES IN FOOD REGULATIONS**

17th August, 1994

Legal Notice 89 of 1994.

1. The title of these Regulations is Additives in Food Regulations. Title.

2. (1) These regulations shall apply to food additives the various categories of which are listed in the First Schedule, and which are used, or intended to be used, as ingredients during the manufacture or preparation of food and are still present in the final product, even if in altered form. Applicability.

(2) For the purposes of these regulations, "food additive" means any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods.

(3) These regulations shall not apply to:

- (a) processing aids, which means any substance, not consumed as a food ingredient by itself, which is intentionally used in the processing of raw materials, foods or their ingredients to fulfill a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, always provided that such residues do not present any health risk and do not have any technological effect on the finished product;
- (b) substances used in the protection of plants and plant products in conformity with the European Community rules relating to plant health;
- (c) flavourings for use in foodstuffs, falling within the scope of Council Directive 88/388/EEC of the European Community;
- (d) substances added to foodstuffs as nutrients.

3. (1) Only food additives listed under regulations as may from time to time be published in respect of any categories of additives listed additives in the First Schedule may be used in the manufacture or preparation of food, and such use shall be subject to the conditions of use specified in any such other regulations to be made. Permitted additives.

(2) The inclusion of a food additive in one of the categories in

such Schedule shall be on the basis of the principal function normally associated with the food additive in question. However, the allocation of an additive to a particular category does not exclude the possibility of such additive being authorised for several functions.

(3) Food additives shall satisfy general criteria laid down in the Second Schedule.

Labelling of food additives not intended for sale to ultimate consumer.

4. (1) Food additives not intended for sale to the ultimate consumer may be marketed only if their packaging or container bears the following information, which must be conspicuous, clearly legible and indelible:

- (a) for food additives sold singly or mixed with each other, for each additive, the name of such additive as may be laid down by any applicable European Community provisions and its EEC number or serial number, or, in the absence of any such provision, a description of the additive that is sufficiently precise to enable it to be distinguished from additives with which it could be confused, in descending order of the proportion by weight in the total:

Provided that when other substances or materials or food ingredients are incorporated in any food additive or additives, to facilitate storage, sale, standardization, dilution or dissolution of such additive or additives, there shall be included the name of the additive and an indication of each component in descending order of the proportion by weight in the total;

- (b) - either the statement "for use in food";
- or the statement "restricted use in food";
- or a more specific reference to its intended food use;
- (c) the special conditions of storage and use if omission thereof would preclude appropriate use of the additive;
- (d) the directions for use, if the omission thereof would preclude appropriate use of the additive;
- (e) a mark identifying the batch or lot;
- (f) the name or business name and address of the manufacturer or packager, or of a seller;
- (g) an indication of the percentage of any component which is subject to a quantitative limitation in a food or adequate compositional information to enable the purchaser to comply with any European Community provision applicable to the food. Where the same quantitative limitation applies to a group of components used singly or in combination, the combined percentage may be given as a single figure;
- (h) the net quantity; and
- (i) any other information as may be requested under regulations published in respect of specific food

additives.

(2) Notwithstanding the provisions of sub-regulation (1), the information required under the proviso to paragraph (a), and under paragraphs (d), (e), (f) and (g) of the said sub-regulation may appear merely on the documents relating to the consignment which are to be supplied with or prior to the delivery, provided that the indication "intended for the manufacture of foodstuffs and not for retail sale" appears on a conspicuous part of the packaging or container of the product in question.

5. Food additives intended for sale to the ultimate consumer may be marketed only if their packaging or containers bear the following information, which must be conspicuous, clearly legible and indelible:

Labelling of food additives intended for sale to ultimate consumer.

- (a) the name under which the product is sold. Such name shall be constituted by the name laid down by any European Community provisions applying to the product in question plus its EEC number or serial number, or, in the absence of such provisions, by a description of the product that is sufficiently precise to enable it to be distinguished from products with which it could be confused; and
- (b) the date of minimum durability within the meaning given in the Labelling, Presentation and Advertising of Foodstuffs Regulations; and
- (c) the information required under regulation 4(1)(a) to (f), (h) and (i).

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6. The particulars referred to in regulations 4 and 5 shall at least appear in one of the official languages of Malta, and the provisions of regulation 10 of the Labelling, Presentation and Advertising of Foodstuffs Regulations in respect of exemptions shall likewise apply.

Language to be used.

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7. No person may import, sell, keep for sale, or supply by way of compensation or otherwise, any food additive or any food containing such additive in either case unless in compliance with the provisions of these regulations.

Prohibition of sale, etc., of additives not complying with regulations.

FIRST SCHEDULE

Regulation 2 (1)

CATEGORIES OF FOOD ADDITIVES

Colour

Preservative

Anti-oxidant

Emulsifier

Emulsifying salt

Thickener

Gelling Agent
Stabiliser ⁽¹⁾
Flavour enhancer
Acid
Acidity regulator ⁽²⁾
Anti-caking agent
Modified starch
Sweetener
Raising agent
Anti-foaming agent
Glazing agent ⁽³⁾
Flour treatment agent
Firming agent
Humectant
Sequestrant ⁽⁴⁾
Enzyme ^{(4) (5)}
Bulking agent
Propellant gas and packaging gas

(1) This category also comprises foam stabilisers.

(2) These can act as two-way acidity regulators.

(3) These substances include lubricants.

(4) Inclusion of these terms in this list is without prejudice to any future decision or mention thereof in the labelling of foodstuffs intended for the final consumer.

(5) Only those used as additives.

SECOND SCHEDULE

Regulation 3 (3)

GENERAL CRITERIA FOR THE USE OF FOOD ADDITIVES

1. Food additives may be approved only provided that:
 - there may be demonstrated a reasonable technological need and the purpose cannot be achieved by other means which are economically and technologically practicable,
 - they present no hazard to the health of the consumer at the level of use proposed, so far as can be judged on

the scientific evidence available,

- they do not mislead the consumer.

2. The use of food additives may be considered only where there is evidence that the proposed use of the additive could have demonstrable advantages of benefit to the consumer, in other words it is necessary to establish the case for what is commonly referred to as "need". The use of food additives should serve one or more of the purposes set out from points (a) to (d) below, and only where those purposes cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to the health of the consumer:

- (a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified only where the food does not constitute a significant item in a normal diet or where the additive is necessary for the production of foods for groups of consumers having special dietary needs;
- (b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
- (c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer;
- (d) to provide aids in manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

3. Food additives shall at all times comply with the approved criteria of purity.

4. Approval for food additives shall -

- (a) specify the foodstuffs to which these additives may be added and the conditions under which they may be added;
- (b) be limited to the lowest level of use necessary to achieve the desired effect;
- (c) take into account any acceptable daily intake, or equivalent assessment established for the food additive and the probable daily intake of it from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account should be taken of the possible daily intake of the food additive by consumers in those groups.

5. Any food additive or any derivatives thereof, which are used in food must have been fully subjected to appropriate toxicological testing and evaluation with a view to assessing any possible harmful effects.

Such evaluation must also take into account any cumulative, synergistic or potentiating effect of its use and the phenomenon of human intolerance to substances foreign to the human body.
