L.N. 257 of 1998

FOOD, DRUGS AND DRINKING WATER ACT (CAP. 231)

Flavourings for Use in Foodstuffs and Source Materials for their Production Regulations, 1998

IN exercise of the powers conferred by section 12 of the Food, Drugs and Drinking Water Act, the Minister of Health, on the advice of the Malta Standardisation Authority, has made the following regulations:–

Citation and commencement.

1. (1). These regulations may be cited as the Flavourings for Use in Foodstuffs and Source Materials for their Production Regulations, 1998.

(2) These regulations shall come into force on the 1st January, 1999.

Interpretation.

2. In these regulations, unless the context otherwise requires–

(a) "flavouring" means flavouring substances, flavouring preparations, process flavourings, smoke flavourings or mixtures thereof;

(b) "flavouring substance" means a defined chemical substance with flavouring properties which is obtained:

(i) by appropriate physical processes (including distillation and solvent extraction) or by enzymatic or microbiological processes from material of vegetable or animal origin either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation),

(ii) by chemical synthesis or isolated by chemical processes and which is chemically identical to a substance naturally present in material of vegetable or animal origin as described in subparagraph (i) above,

(iii) by chemical synthesis but which is not chemically identical to a substance naturally present in material present in material of vegetable or animal origin as described in subparagraph (i) above;

(c) "flavouring preparation" means a product, other than the substances defined in paragraph (b)(i) above, whether concentrated or not, with flavouring properties, which is obtained by appropriate physical processes (including distillation and solvent extraction) or by enzymatic or microbiological processes from material of vegetable or animal origin, either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation);

(d) "process flavouring" means a product which is obtained according to good manufacturing practices by heating to a temperature not exceeding 180 degrees Celsius for a period not exceeding 15 minutes a mixture of ingredients, not necessarily themselves having flavouring properties, of which at least one contains nitrogen (amino) and another is a reducing sugar;

(e) "smoke flavouring" means a smoke extract used in traditional foodstuffs smoking processes.

Ingredients of flavourings.

3. Flavourings may contain foodstuffs as well as :-

-additives necessary for the storage and use of flavourings,
-products used for dissolving and diluting flavourings,
-additives necessary for the production of flavourings (processing aids) where such additives are not covered by any other provisions.

Applicability.

4. These regulations shall apply to flavourings, imported into Malta or manufactured in Malta, used or intended for use in or on foodstuffs to impart odour and/or taste and to source materials, imported into Malta or manufactured in Malta, used for the production of flavourings. These regulations, however, shall not apply to:

(a) edible substances and products intended to be consumed as such, with or without reconstitution,

(b) substances which have exclusively a sweet, sour or salt taste,

(c) material of vegetable or animal origin, having inherent flavourings properties, where they are not used as flavouring sources.

5. (1) No flavouring may contain any element or substance in a toxicologically dangerous quantity. Criteria of purity.

(2) Subject to any exceptions provided for in any specific criteria of purity prescribed under these regulations or otherwise by any other law, flavourings may not contain more than:-

- 3 mg/kg of arsenic,
- 10 mg/kg of lead,
- 1 mg/kg of cadmium, and
- 1 mg/kg of mercury.

(3) The use of flavourings must not result in the presence in foodstuffs as consumed, of undesirable substances listed in the First Schedule to these regulations in quantities greater than those specified therein,.

(4) The use of flavourings and of other food ingredients with flavouring properties must not result in the presence in foodstuffs as consumed, of substances listed in the Second Schedule to these regulations in quantities greater than those specified therein.

6. (1) No person shall, for the purpose of a food business import, keep or sell any food in which or on which there is any flavouring which does not comply with the requirements of these regulations. Sale of flavouring etc. and source materials.

(2) No person shall keep or suffer to be kept on, or use in, any food premises used for the preparation, or for the preparation for sale, of food, any flavouring or source material for its production, not being respectively a flavouring or source material for the production of such food which complies with the requirements of these regulations.

7. Flavourings not intended for sale to the final consumer may not be marketed unless their packagings or containers bear in at least one of the official languages of Malta the following information, which should be easily visible, clearly legible and indelible: Labelling of flavourings not intended for sale to the final consumer.

(a) the name or business name and address of the manufacturer, or packer, or of a seller established in Malta;

(b) the sales description: either the word '"flavouring" or a more specific name or description of the flavouring;

(c) either the statement '"for foodstuffs" or a more specific reference to the foodstuff for which the flavouring is intended;

(d) a list in descending order of weight, of categories of flavouring substances, and flavouring preparations present classified as follows:

- natural flavouring substances in the case of flavouring substances defined in regulation 2, paragraph (b) (i),
- flavouring substances identical to natural substances in the case of flavouring substances defined in regulation 2, paragraph (b) (ii),
- artificial flavouring substances in the case of flavouring substances defined in regulation 2, paragraph (b) (iii),
- flavouring preparations in the case of preparations defined in regulation 2, paragraph (c),
- process flavourings in the case of flavourings defined in regulation 2, paragraph (d),
- smoke flavourings in the case of flavourings defined in regulation 3, paragraph (e);

(e) in the case of a mixture of flavourings with additives necessary for the storage and use of flavourings or with products used for dissolving and diluting flavourings, a list in descending order of weight in the mixture of:

- the categories of flavourings classified as in paragraph (d) of this regulation,
- the names of each of the other substances or materials or, where appropriate, their EEC numbers;

(f) an indication of the maximum quantity of each component or group of components subject to quantitative limitation in a foodstuff, or appropriate information;

(g) an indication identifying the consignment;

(h) the nominal quantity expressed in units of mass or volume:

Provided that the information required in paragraphs (d), (e) and (f) of this regulation may appear merely on the trade documents relating to the consignment which are to be supplied with or prior to delivery, sohowever that the indication "intended for the manufacture of foodstuffs and not for retail" appears in a conspicuous part of the packaging or container of the products in question.

8. Flavourings intended for sale to the final consumer may not be marketed unless their labels indicate in at least one of the official languages of Malta, the following obligatory information, which should be easily visible, clearly legible and indelible: Labelling of flavourings intended for sale to the final consumer.

(a) either the word "flavouring" or a more specific name or description of the flavouring;

(b) either the words "for foodstuffs" or a more specific reference to the foodstuff for which the flavouring is intended;

(c) the date of minimum durability as provided for in the Labelling and Presentation of Foodstuffs Regulations, 1992; L.N. 65 of 1992.

(d) where necessary, the special conditions for storage and use;

(e) the instructions for use if omission thereof would prevent appropriate use of the flavouring;

(f) the nominal quantity expressed in units of mass or volume;

(g) the name or business name and address of the manufacturer, or packer, or of a seller established in Malta;

(h) an indication or mark identifying the batch as provided for in the Labelling and Presentation of Foodstuffs Regulations, 1992;

(i) in the case of a mixture of flavouring(s) with other substances, a list in descending order of weight in the mixture of:

- the categories of flavourings classified as in regulation 7, paragraph (d);

- the names of each of the other substances or materials or, where appropriate, their EEC numbers.

9. (1) The word "natural", or any other word having substantially the same meaning, may be used only for flavourings in which the flavouring component contains exclusively flavouring substances as defined in paragraph (b) (i) of regulation 2 of these regulations, or flavouring preparations as defined in regulation 2 of these regulations. Use of the word "natural".

(2) If the sales description of the flavourings contains a reference to a foodstuff or a flavouring source, the word "natural", or any other word having substantially the same meaning, may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the foodstuff or the flavouring source concerned.

(3) The provisions of paragraphs (1) and (2) of this regulation shall apply to the labelling of flavourings referred to in regulations 7 and 8 of these regulations.

FIRST SCHEDULE

(Regulation 5(3))

Maximum limits for certain undesirable substances present in foodstuffs as consumed as a result of the use of flavourings.

SUBSTANCE	FOODSTUFFS	BEVERAGES
3,4 benzopyrene	0.03 µg/kg	0.03 µg/kg

SECOND SCHEDULE

(Regulation 5(4))

Maximum limits for certain substances obtained from flavourings and other food ingredients with flavouring properties present in foodstuffs as consumed in which flavourings have been used.

Substances	**Foodstuffs mg/kg**	**Beverages mg/kg**	**Exceptions and or special restrictions**
Agaric acid *	20	20	100 mg/kg in alcoholic beverages and foodstuffs containing mushrooms.
Aloin *	0.1	0.1	50 mg/kg in alcoholic beverages.
Beta asarone *	0.1	0.1	1 mg/kg in alcoholic beverages and seasonings used in snack foods.
Berberine *	0.1	0.1	10 mg/kg in alcoholic beverages.
Coumarin *	2	2	10 mg/kg in certain types of caramel confectionery. 50 mg/kg in chewing gum. 10 mg/kg in alcoholic beverages.
Hydrocyanic acid *	1	1	50 mg/kg in nougat, marzipan or its substitutes or similar products. 1 mg/% volume of alcohol in alcoholic beverages. 5 mg/kg in canned stone fruit.
Hypericine *	0.1	0.1	10 mg/kg in alcoholic beverages. 1 mg/kg in confectionery.
Pulegone *	25	100	250 mg/kg in mint or peppermint-flavoured beverages. 350 mg/kg in mint confectionery.

* May not be added as such to foodstuffs or to flavourings. May be present in a foodstuff either naturally or following the addition of flavourings prepared from natural raw materials.

Substances	Foodstuffs mg/kg	Beverages mg/kg	Exceptions and/or special restrictions
Quassine *	5	5	10 mg/kg in confectionery in pastille form. 50 mg/kg in alcoholic beverages.
Safrole and isosafrol *	1	1	2 mg/kg in alcoholic beverages with not more than 25% volume of alcohol. 5 mg/kg in alcoholic beverages with more than 25% volume of alcohol. 15 mg/kg in foodstuffs containing mace and nutmeg.
Santonin *	0.1	0.1	1 mg/kg in alcoholic beverages with more than 25% volume of alcohol.
Thuyone (α and β) *	0.5	0.5	5 mg/kg in alcoholic beverages with not more than 25% volume of alcohol. 10 mg/kg in alcoholic beverages with more than 25% volume of alcohol. 25 mg/kg in foodstuffs containing preparations based on sage. 35 mg/kg in bitters.

* May not be added as such to foodstuffs or to flavourings. May be present in a foodstuff either naturally or following the addition of flavourings prepared from natural raw materials.