SUBSIDIARY LEGISLATION 449.46

LABELLING, PRESENTATION AND ADVERTISING OF FOODSTUFFS REGULATIONS

25th November, 2004

LEGAL NOTICE 483 of 2004, as amended by Legal Notices 114 and 339 of 2005, 70 of 2006, 64, 242 and 436 of 2007, 136 of 2008 and 278 of 2013.

Title and implementation. *Amended by: L.N. 114 of 2005.*

1.1. The title of these regulations is the Labelling, Presentation and Advertising of Foodstuffs Regulations.

1.1.1 Products which do not comply with the provisions of these regulations, but which comply with the provisions of the Labelling, Presentation and Advertising of Foodstuffs Regulations, 2002*, and which have been placed on the market or labelled prior to the 25th November, 2005 may continue to be sold while stocks last;

1.1.2 the provisions of subregulation 1.1.1 shall not apply to the provisions of regulation 17.1, and points 6, 7 and 8 of the Sixth Schedule;

1.1.3 **t**he provisions of regulation 17.1, and points 6, 7 and 8 of the sixth Schedule, shall apply as from the 20th May, 2006, however products which do not comply with regulation 17.1, and points 6, 7 and 8 of the Sixth Schedule, but which were labelled before the 20th May, 2006 may be sold while stocks last.

1.2 These regulations implement the provisions of:

(*a*) Directive 2000/13/EC of the European Parliament and of the Council of the 20th March, 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, as amended by:

- Commission Directive 2001/101/EC of the 26th November, 2001,
- Commission Directive 2002/67/EC of the 18th July, 2002,
- Directive 2003/89/EC of the European Parliament and of the Council of the 10th November, 2003;

(*b*) Council Directive 89/398/EEC of the 3rd May, 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, as amended by:

- Directive 96/84/EC of the European Parliament and of the Council of the 19th December, 1996,

*Revoked by these regulations.

- Directive 1999/41/EC of the European Parliament and of the Council of the 7th June, 1999;

(*c*) Commission Directive 87/250/EEC of the 15th April, 1987 on the indication of alcoholic strength by volume in the labelling of alcoholic beverages for sale to the ultimate consumer;

(*d*) Commission Directive 94/54/EC of the 18th November, 1994 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Council Directive 79/112/EEC, as amended by:

- Council Directive 96/21/EC of the 29th March, 1996,
- Commission Directive 2004/77/EC of the 29th April , 2004;

(*e*) Commission Directive 2001/15/EC of the 15th February, 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, as amended by:

- Commission Directive 2004/5/EC of the 20th January, 2004;

(*f*) Commission Directive 2013/20/EU of 13 May 2013 adapting certain directives in the field of food safety, veterinary and phytosanitary policy, by reason of the accession of Croatia.

Scope and applicability.

2.1. These regulations concern the labelling of foodstuffs to be delivered as such to the ultimate consumer and certain aspects relating to the presentation and advertising thereof.

2.2 These regulations shall apply also to foodstuffs intended for supply to hotels, restaurants, hospitals, canteens and other similar mass caterers (thereinafter referred to as "mass caterers").

Definitions and interpretation. *Amended by: L.N. 114 of 2005.*

3.1. In these regulations, unless the context otherwise requires, the following definitions shall apply:

(*a*) "labelling" means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuff;

(*b*) "pre-packaged foodstuff" shall mean any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and the packaging i.nto which it was put before being offered for sale, whether such packaging encloses the foodstuff completely or only partially, but in any case in such a way that the contents cannot be altered without opening or changing thc packaging;

(*c*) "ingredient" shall mean any substance, including additives, used in the manufacture or preparation of a

foodstuff and still present in the finished product, even if in altered form;

(*d*) "edible ice" includes ice cream, water ice and fruit ice, whether alone or in combination, and any similar food;

(*e*) "confectionery product" means any item of chocolate confectionery or sugar confectionery;

(*f*) "fancy confectionery product" means any confectionery product in the form of a figure, animal, cigarette or egg or in any other fancy form;

(*g*) "biscuits" includes wafers, rusks, oatcakes and matzos;

(*h*) "catering establishment" means any restaurant, canteen, club, public house, school, hospital or similar establishment (including a vehicle or a fixed or mobile stall) where, in the course of business, food is prepared for delivery to the ultimate consumer, and is ready for consumption without further preparation;

(*i*) "cheese" means the fresh or matured product intended for sale for human consumption, which is obtained as follows:

(i) in the case of any cheese other than whey cheese, by the combining, by coagulation or by any technique involving coagulation, of any of the following substances: milk, cream, skimmed milk, partly skimmed milk, concentrated skimmed milk, reconstituted dried milk, butter milk, materials obtained from milk, other ingredients necessary for the manufacture of cheese provided that those are not used for replacing, in whole or in part, any milk constituent, with or without partially draining the whey resulting from coagulation;

(ii) in the case of whey cheese -

- by concentrating whey with or without the addition of milk and milk fat, and moulding such concentrated whey, or
- by coagulating whey with or without the addition of milk and milk fat;

(*j*) "cream" means that part of milk rich in fat which has been separated by skimming or otherwise and which is intended for human consumption;

(*k*) "disease" includes any injury, ailment or adverse condition, whether of body or mind;

(*l*) "flour confectionery" means any cooked food which is ready for consumption without further preparation (other than reheating), of which a characterising ingredient is ground cereal, including shortbread, sponges, crumpets, muffins, macaroons, ratafias, pastry and pastry cases, and also includes meringues, petits fours and uncooked pastry and pastry cases, but does not include bread, pizzas, biscuits, crispbread,

extruded flat bread or any food containing a filling which has as an ingredient any cheese, meat, offal, fish, shellfish, vegetable protein material or microbial protein material;

(*m*) "ionising radiation" means any gamma rays, X-rays or corpuscular radiations which are capable of producing ions either directly or indirectly other than those rays or radiations which are emitted by measuring or inspection devices, provided that the dose absorbed is not greater than 0.01 Gy for inspection devices which utilise neutrons and 0.5 Gy in other cases, at a maximum radiation energy level of 10 MeV in the case of X-rays, 14 MeV in the case of neutrons and 5 MeV in other cases;

(*n*) "irradiated" means subjected to treatment by ionising radiation;

(*o*) "lot" means a batch of sales units of food produced, manufactured or packaged under similar conditions;

(*p*) "lot marking indication" means an indication that allows identification of the lot to which a sales unit of food belongs;

(*q*) "milk" means the milk intended for sale, or sold, for human consumption of -

(i) one or more cows, and includes skimmed milk, semi-skimmed milk and whole milk, or

(ii) one or more ewes, goats or buffaloes;

(*r*) "prepacked for direct sale" means -

(i) in relation to a food other than flour confectionery, bread, and edible ices, prepacked by a retailer for sale by him on the premises where the food is packed or from a vehicle or stall used by him, and

(ii) in relation to flour confectionery, bread and edible ices, prepacked by a retailer for sale as in sub-paragraph (i) of this definition, or prepacked by the producer of the food for sale by him either on the premises where the food is produced or on other premises from which he conducts business under the same name as the business conducted on the premises where the food is produced;

(*s*) "preparation", in relation to food, includes manufacture and any form of processing or treatment, and "prepared" shall be construed accordingly;

(*t*) "seasonal selection pack" means a pack consisting of two or more different items of food which are wholly or partly enclosed in outer packaging decorated with seasonal designs;

(*u*) "treating", in relation to disease, includes doing or

providing anything for alleviating the effects of the disease, whether it is done or provided by way of cure or not;

(*v*) "'food for particular nutritional use" means a food intended for human consumption which -

(i) owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal human consumption is suitable for its claimed particular nutritional purpose, and

(ii) is sold in such a way as to indicate that suitability;

(*w*) "community" means the European Community;

(*x*) "Member State" shall mean a Member State of the European Community;

(*y*) "Directive" means Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs;

(*z*) "Foodstuffs Directorate" shall mean the Directorate responsible for foodstuffs within the Malta Standards Authority;

(*aa*) "meat" shall mean the flesh of bovines, porcines, ovines, caprines, poultry or lepines, and presented as such for sale, but shall exclude prepared products containing meat as an ingredient.

Misleading claims.

4.1. The labelling and methods used must not:

(*a*) be such as could mislead the purchaser to a material degree, particularly:

(i) as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production;

(ii) by attributing to the foodstuff effects or properties which it does not possess;

(iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics;

(*b*) subject to other provisions applicable to natural mineral waters and foodstuffs for particular nutritional uses, attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties.

4.2 The prohibitions or restrictions referred to in regulation 4.1 shall also apply to:

(*a*) the presentation of foodstuffs, in particular their shape,

appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;

(*b*) advertising.

Compulsory particulars.

5.1. In accordance with regulations 6 to 18 and subject to the exceptions contained therein, indication of the following particulars shall be compulsory on the labelling of foodstuffs:

(*a*) the name under which the product is sold;

(*b*) the list of ingredients;

(*c*) the quantity of certain ingredients or categories of ingredients as provided for in regulation 9;

(*d*) the date of minimum durability or, in the case of foodstuffs which, from the microbiological point of view, are highly perishable, the "use by" date;

(*e*) any special storage conditions or conditions of use;

(*f*) the name or business name and address of the manufacturer or packager, or of a seller established in Malta or within the European Community, provided that a post office box shall not be considered to be a valid address for the purposes of these regulations;

(*g*) particulars of the place of origin or provenance where failure to give such particulars might mislead the consumer to a material degree as to the true origin orprovenance of the foodstuff;

(*h*) instructions for use when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions;

(*i*) with respect to beverages containing more than 1.2% by volume of alcohol, the actual alcoholic strength by volume.

5.2 The provisions of regulation 5.1 shall be without prejudice to other provisions regarding weights and measures.

Other provisions applicable to specified foodstuffs.

6.1. Other provisions applicable to specified foodstuffs and not to foodstuffs in general may provide for derogations, in exceptional cases, from the requirements laid down in regulation 5.1(*b*) and (*d*), provided that this does not result in the purchaser being inadequately informed.

6.2 Other provisions applicable to specified foodstuffs and not to foodstuffs in general may provide that other particulars in addition to those listed in regulation 5.1 must appear on the labelling.

Name under which the productis sold. *Amended by: L.N. 242 of 2007.*

7.1. The name under which a foodstuff is sold shall be the name provided for in the specific Community provisions applicable to it, provided that -

(*a*) in the absence of Community provisions, the name under which a product is sold shall be the name provided for in the laws, regulations and

administrative provisions applicable in Malta;

(*b*) failing this, the name under which a product is sold shall be the name customary in Malta, or a description of the foodstuff, and if necessary of its use, which is clear enough to let the purchaser know its true nature and distinguish it from other products with which it might be confused;

(*c*) the use in Malta of the sales name under which the product is legally manufactured and marketed in the Member State of production shall also be allowed. However, where the application of the other provisions of these regulations, in particular those set out in regulation 5.1, would not enable consumers in Malta to know the true nature of the foodstuff and to distinguish it from foodstuffs with which they could confuse it, the sales name shall be accompanied by other descriptive information which shall appear in proximity to the sales name;

(*d*) in exceptional cases, the sales name of the Member State of production shall not be used in Malta when the foodstuff which it designates is so different, as regards its composition or manufacture, from the foodstuff known under that name that the provisions of paragraph (*c*) are not sufficient to ensure correct information for consumers in Malta

7.2 No trade mark, brand name or fancy name may be substituted for the name under which the product is sold.

7.3 The name under which the product is sold shall include or be accompanied by particulars as to the physical condition of the foodstuff or the specific treatment which it has undergone (e.g. powdered, freeze-dried, deep-frozen, tenderized, concentrated, smoked) in all cases where omission of such information could create confusion in the mind of the purchaser.

7.4 (*a*) Any foodstuff which has been treated with ionizing radiation shall bear one of the following indications:

in Maltese:

"ittrattat bir-radjazzjoni" or "ittrattat b'radjazzjoni jonizzanti",

in English:

"irradiated" or "treated with ionizing radiation",

in Italian:

"irradiato" or "trattato con radiazioni ionizzanti".

(*b*) Without prejudice to paragraph (*a*), the list provided for in the Eighth Schedule specifies the names under which foodstuff which have been treated with ionizing radiation are sold in all the European Community languages.

Listing of ingredients.

8.1. Ingredients shall be listed in accordance with this regulation and the First, Second and Third (Parts A and B) Schedules.

8.2 Ingredients need not be listed in the case of:

(*a*) - fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated,

- carbonated water, the description of which indicates that it has been carbonated and to which no other ingredient has been added,
- any drink with an a1coholic strength by volume of more than 1.2%,
- fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added;

(*b*) - cheese,

- butter,
- fermented milk and cream,
- provided that no ingredient has been added other than lactic products, enzyrnes and micro-organism cultures essential to manufacture, or the salt needed for the manufacture of cheese other than fresh cheese and processed cheese;

(*c*) products comprising a single ingredient, where:

- the trade name is identical with the ingredient name, or
- the trade name enables the nature of the ingredient to be clearly identified.

Provided that any ingredient, as defined in regulation 3.1(*c*) and listed in Part B of the Third Schedule, shall be indicated on the labelling where it is present in beverages referred to in paragraph (*a*). This indication shall comprise the word "contains" followed by the name of the ingredient(s) concerned. However, an indication is not necessary when the ingredient is already included under its specific name in the list of ingredients or in the name under which the beverage is sold.

8.3 Where an ingredient of the foodstuff is itself the product of several ingredients, the latter shall be regarded as ingredients of the foodstuff in question.

8.4 The following shall not be regarded as ingredients:

(i) the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions;

(ii) additives:

- whose presence in a given foodstuff is solely due to the fact that they were contained in one or more ingredients of that foodstuff, provided that

they serve no technological function in the finished product,

- which are used as processing aids;

(iii) substances used in the quantities strictly necessary as solvents or media for additives or flavouring;

(iv) substances which are not additives but are used in the same way and with the same purpose as processing aids and are still present in the finished product, even if in altered form.

8.5 The list of ingredients shall include all the ingredients of the foodstuff, in descending order of weight, as recorded at the time of their use in the manufacture of the foodstuff. It shall appear preceded by a suitable heading which includes the word "ingredients".

However:

- added water and volatile products shall be listed in order of their weight in the finished product; the amount of water added as an ingredient in a foodstuff shall be calculated by deducting from the total amount of the finished product the total amount of the other ingredients used. This amount need not be taken into consideration if it does not exceed 5% by weight of the finished product,
- ingredients used in concentrated or dehydrated form and reconstituted at the time of manufacture may be listed in order of weight as recorded before their concentration or dehydration,
- in the case of concentrated or dehydrated foods which are intended to be reconstituted by the addition of water, the ingredients may be listed in order of proportion in the reconstituted product provided that the list of ingredients is accompanied by an expression such as "ingredients of the reconstituted product", or "ingredients of the ready-to-use product",
- where fruit, vegetables or mushrooms, none of which significantly predominates in terms of weight and which are used in proportions that are likely to vary, are used in a mixture as ingredients of a foodstuff, they may be grouped together in the list of ingredients under the designation "fruit", "vegetables" or "mushrooms" followed by the phrase "in varying proportions", immediately followed by a list of the fruit, vegetables or mushrooms present; in such cases, the mixture shall be included in the list of ingredients in accordance with the first subparagraph, on the basis of the total weight of the fruit, vegetables or mushrooms present;
- in the case of mixtures of spices or herbs, where none significantly predominates in proportion by weight, those ingredients may be listed in another order

provided that that list of ingredients is accompanied by an expression such as "in variable proportion",

- ingredients constituting less than 2% of the finished product may be listed in a different order after the other ingredients,
- where ingredients which are similar or mutually substitutable are likely to be used in the manufacture or preparation of a foodstuff without altering its composition, its nature or its perceived value. and in so far as they constitute less than 2% of the finished product, they may be referred to in the list of ingredients by means of the phrase "contains ..... and/ or .....", where at least one of no more than two ingredients is present in the finished product. This provision shall not apply to additives or to ingredients listed in Part B of the Third Schedule.

8.6 Ingredients shall be designated by their specific name, where applicable, in accordance with the rules laid down in regulations 7.1 to 7.4.

However:

- ingredients which belong to one of the categories listed in the First Schedule and are constituents of another foodstuff need only be designated by the name of that category; however, the designation "starch" listed in the First Schedule must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,
- ingredients belonging to one of the categories listed in the Second Schedule must be designated by the name of that category, followed by their specific name or EC number; if an ingredient belongs to more than one of the categories, the category appropriate to the principal function in the case of the foodstuff in question shall be indicated; however, the designation "modified starch" listed in the Second Schedule must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,
- flavourings shall be designated in accordance with Part A of the Third Schedule, provided that quinine and/or caffeine used as a flavouring in the production or preparation of a foodstuff must be mentioned by name in the list of ingredients indicated in regulation 5.1 , immediately after the term "flavouring".

8.7 Other provisions may lay down that the name under which a specific foodstuff is sold is to be accompanied by mention of a particular ingredient or ingredients.

8.8 In the case referred to in regulation 8.3, a compound ingredient may be included in the list of ingredients, under its own

designation in so far as this is laid down by law or established by custom, in terms of its overall weight, provided that it is immediately followed by a list of its ingredients.

Such a list, however, shall not be compulsory:

(*a*) where the composition of the compound ingredient is defined in current Community legislation, and in so far as the compound ingredient constitutes less than 2% of the finished product; however, this provision shall not apply to additives, subject to regulation 8.4,

(*b*) for compound ingredients consisting of mixtures of spices and/or herbs that constitute less than 2% of the finished product, with the exception of additives, subject to regulation 8.4,

(*c*) where the compound ingredient is a foodstuff for which a list of ingredients is not required under Community legislation.

8.9 Notwithstanding regulation 8.5 the water content need not be specified:

(*a*) where the water is used during the manufacturing process solely for the reconstitution of an ingredient used in concentrated or dehydrated form;

(*b*) in the case of a liquid medium which is not normally consumed.

8.10 Notwithstanding regulation 8.2, the second subparagraph of regulation 8.6 and the second subparagraph of regulation 8.8, any ingredient used in the production of a foodstuff and still present in the finished product, even if in altered form, and listed in Part B of the Third Schedule or originating from an ingredient listed in Part B of the Third Schedule shall be indicated on the label with a clear reference to the name of this ingredient.

Provided that,

- the indication referred to in the first subparagraph shall not be requ.ired if the name under which the foodstuff is sold clearly refers to the ingredient concerned;
- notwithstanding regulation 8.4 (ii), (iii) and (iv), any substance used in production of a foodstuff and still present in the finished product, even if in altered form, and originating from ingredients listed in Part B of the Third Schedule shall be considered as an ingredient and shall be indicated on the label with a clear reference to the name of the ingredient from which it originates;
- in the case of foodstuffs delivered to the ultimate consumer by mass caterers, the provisions of this subregulation shall be deemed to have been complied with if the mass caterer informs the consumer, upon request, of the presence or absence of any ingredient(s) listed in Part B of the Third Schedule.

Quantity of ingredients.

9.1. The quantity of an ingredient or category of ingredients used in the manufacture or preparation of a foodstuff shall be stated.

9.2 The indication referred to in regulation 9.1 shall be compulsory:

(a) where the ingredient or category of ingredients concerned appears in the name under which the foodstuff is sold or is usually associated with that name by the consumer; or

(*b*) where the ingredient or category of ingredients concerned is emphasised on the labelling in words, pictures or graphics; or

(*c*) where the ingredient or category of ingredients concerned is essential to characterise a foodstuff and to distinguish it from products with which it might be confused because of its name or appearance; or

(*d*) in the cases determined in accordance with the procedure laid down in Article 20(2) of the Directive.

9.3 Regulation 9.2 shall not apply:

(*a*) to an ingredient or category of ingredients:

- the drained net weight of which is indicated in accordance with regulation 10.4, or
- the quantities of which are already required to be given on the labelling under Community provisions, or
- which is used in small quantities for the purposes of flavouring, or
- which, while appearing in the name under which the food is sold, is not such as to govern the choice of the consumer in Malta because the variation in quantity is not essential to characterise the foodstuff or does not distinguish it from similar foods;
- where specific Community provisions stipulate precisely the quantity of an ingredient or of a category of ingredients without providing for the indication thereof on the labelling;

(*b*) in the cases referred to in the fourth and fifth indents of regulation 8.5;

(*c*) in the cases determined in accordance with the procedure laid down in Article 20(2) of the Directive.

9.4 The quantity indicated, expressed as a percentage, shall correspond to the quantity of the ingredient or ingredients at the time of its/their use. However, other provisions, adopted in accordance with the procedure laid down in Article 20(2) of the Directive, may allow for derogations from this principle for certain foodstuffs.

9.5 The indication referred to in regulation 9.1 shall appear

either in or immediately next to the name under which the foodstuff is sold or in the list of ingredients in connection with the ingredient or category of ingredients in question.

9.6 The provisions of regulations 9.1 to 9.5 shall apply without prejudice to the Nutrition Labelling for Foodstuffs Regulations. S.L. 449.20

10.1. The date of minimum durability of a foodstuff shall be the date until which the foodstuff retains its specific properties when properly stored. It shall be indicated in accordance with regulations 10.2 to 10.5. Date of minimum durability.

10.2 The date shall be preceded by the words:

- "Best before ....." when the date includes an indication of the day,
- "Best before end ....." in other cases.

10.3 The words referred to in regulation 10.2 shall be accompanied by:

- either the date itself, or
- a reference to where the date is given on the labelling.

If need be, these particulars shall be followed by a description of the storage conditions which must be observed if the product is to keep for the specified period.

10.4 The date shall consist of the day, month and year in uncoded chronological form.

However, in the case of foodstuffs:

- which will not keep for more than three months, an indication of the day and the month will suffice,
- which will keep for more than three months but not more than eighteen months, an indication of the month and year will suffice,
- which will keep for more than eighteen months, an indication of the year will suffice.

10.5 Subject to other provisions imposing other types of date indication, an indication of the durability date shall not be required for:

- fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated. This derogation shall not apply to sprouting seeds and similar products such as legume sprouts,
- wines, liqueur wines, sparkling wines, aromatised wines and similar products obtained from fruits other than grapes, and beverages falling within CN Guidelines 2206 00 91, 2206 00 93 and 2206 00 99 and manufactured from grapes or grape musts,
- beverages containing 10 ølo or more by volume of alcohol,
- soft drinks, fruit juices, fruit nectars and alcoholic beverages in individual containers of more than five

litres, intended for supply to mass caterers,

- bakers' or pastry cooks' wares which, given the nature of their content, are normally consumed within twenty-four hours of their manufacture,
- vinegar,
- cooking salt,
- solid sugar,
- confectionery products consisting almost solely of flavoured and/or coloured sugars,
- chewing gums and similar chewing products,
- individual portions of ice-cream.

"Use by" date. *Amended by: L.N. 242 of 2007.*

11.1. In the case of foodstuffs which, from the microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the "use by" date.

11.2 (*a*) The date shall be preceded by the words:

in Maltese:

"uża sa",

in English:

"use by",

in Italian:

"da consumare entro".

(*b*) These words shall be accompanied by:

(i) either the date itself, or

(ii) a reference to where the date is given on the labelling.

(*c*) These particulars shall be followed by a description of the storage conditions which must be observed.

(*d*) Without prejudice to paragraph (*a*), the list provided for in the Ninth Schedule specifies the term of the 'use by' date in all the European Community languages.

11.3 The date shall consist of the day, the month and, possibly, the year, in that order and in uncoded form.

11.4 The 'use by' date or minimum durability date, as the case may be, shall be deterrnined by the manufacturer or packer of the product.

11.5 No person may sell any food after the date shown in a 'use by' date relating to it.

Instructions for use.

12.1. The instructions for use of a foodstuff shall be indicated in such a way as to enable appropriate use to be made thereof.

12.2 Other provisions may, in the case of certain foodstuffs, specify the way in which the instructions for use should be indicated.

Indication of alcoholic strength.

13.1. The rules concerning indication of the alcoholic strength by volume shall, in the case of products covered by tariff heading Nos 22.04 and 22.05, be those laid down in the specific provisions applicabie to such products.

13.2 In the case of other beveragcs containing more than 1.2% by volume of alcohol, these rules shall be those laid down in the Fifth Schedule.

Indications of particulars on prepackaged products.

14.1. When the foodstuffs are prepackaged, the particulars provided for in regulations 5.1 and 6.2 shall appear on the prepackaging or on a label attached thereto.

14.2 Notwithstanding regulation 14.1 and without prejudice to other provisions on nominal quantities, where prepackaged foodstuffs are -

- intended for the ultimate consumer but marketed at a stage prior to sale to the ultimate consumer and where sale to a mass caterer is not involved at that stage,
- intended for supply to mass caterers for preparation, processing, splitting or cutting up,

the particulars required under regulations 5.1 and 6.2 need appear only on the commercial documents referring to the foodstuffs where it can be guaranteed that such documents, containing all the labelling information, either accompany the foodstuffs to which they refer or were sent before or at the same time as delivery.

14.3 In the case referred to in regulation 14.2, the particulars referred to in regulation 5.1(*a*), (*d*) and (*f*) and, where appropriate, that referred to in regulations 11.1 to 11.3, shall also appear on the external packaging in which the foodstuffs are presented for marketing.

14.4 The particulars mentioned in regulations 5.1 and 6.2 shall be easy to understand and marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible. They shall not in any way be hidden, obscured or interrupted by other written or pictorial matter.

14.5 The particulars listed in regulation 5.1(*a*), (*d*) and (*i*) shall appear in the same field of vision.

14.6 In the case of the glass bottles intended for re-use which are indelibly marked and which therefore bear no label, ring or collar and packaging or containers the largest surface of which has an area of less than 10 cm^2 only the particulars listed in regulation 5.1(*a*) and (*d*) need be given. In this case, regulation 14.5 shall not apply.

14.7 Where a beverage which is intended for consumption without modification, or after reconstitution of the concentrated or dried product, contains caffeine, from whatever source, in a proportion in excess of 150 mg/l, the following message must appear on the label in the same field of vision as the name under which the product is sold: ‘High caffeine content’. This message shall be followed, in brackets and in accordance with regulation 14.4, by the caffeine content expressed in mg/100 ml, provided

that:

14.7.1 this regulation shall not apply to beverages based on coffee, tea or coffee or tea extract where the name under which the product is sold includes the term 'coffee' or 'tea' .

Provided that products which do not comply with this regulation and which were labelled before 1 July 2004 may be marketed until stocks last.

Omission of certain particulars. *Amended by: L.N. 114 of 2005.*

15.1. The provisions of this regulation shall apply without prejudice to the requirements of regulation 8.10.

15.2 The following foods need not be marked or labelled with any of the particulars specified in regulation 5.1 except the name of the food:

(*a*) food which is:

(i) not prepacked, or

(ii) prepacked for direct sale,

other than any such food to which paragraphs 15.13, 15.14, 15.15 or 15.17 apply;

(*b*) any flour confectionery which is packed in a crimp case only or in wholly transparent packaging which is either unmarked or marked only with an indication of the price of the food and any lot marking indication given in accordance with regulation 16.1, if there is not attached to the flour confectionery or its packaging any document, notice, label, ring or collar (other than a label or labels on which only the price of the food and any lot marking indications are marked); and

(*c*) individually wrapped sugar or chocolate confectionery products, including boiled sweets and chocolates weihing less than 50g per item, which are not enclosed in any further packaging when sold to the ultimate consumer and which are intended for sale as single items or by number.

15.3 Food which has not been irradiated and which is -

(*a*) not intended for sale, or

(*b*) white bread or flour confectionery, or

(*c*) carcasses and parts of carcasses which are not intended for sale in one piece,

need not be marked or labelled with any of the particulars specified in regulation 5.1.

15.4 Any food which -

(*a*) by virtue of regulations 15.2 or 15.3 alone is not marked or labelled with a list of ingredients, and

(*b*) contains any additive which -

(i) but for regulations 15.2 or 15.3, would be required to be named in the list of ingredients of

the food, and

(ii) was added to or used in the food or an ingredient of the food to serve the function of an antioxidant, colour, flavouring, flavour enhancer, preservative or sweetener,

shall be marked or labelled with an indication of every such category of additive that is contained in the food.

15.5 Any edible ice or flour confectionery which, but for this regulation, would be required to be marked or labelled in accordance with regulation 15.4 need not be marked or labelled if there is displayed in a prominent position near the edible ice or flour confectionery a notice stating, subject to regulation 15.6, that edible ices or flour confectionery, as the case may be, sold at the establishment where the notice is displayed may contain such categories of additives.

15.6 Where, in the circumstances described in regulations 15.4 or 15.5, an additive serves more than one of the functions specified in the said regulation 15.4, it shall only be necessary to indicate that category which represents the principal function served by the additive in the food or ingredient to which it was added or in which it was used.

15.7 Regulations 15.4, 15.5 and 15.6 do not apply to food which is not intended for sale.

15.8 Subject to regulation 15.9, any food which -

(*a*) by virtue of regulations 15.4, 15.5, 15.6 or 15.7 alone is exempted from the requirement to be marked or labelled with a list of ingredients, and

(*b*) contains any ingredient which has been irradiated (and which comprises a particular with which, had that food not been subject to that exemption, the food would have been required by these regulations to be marked or labelled),

shall be marked or labelled with an indication that it contains that ingredient, and in such a case the reference within that indication to that ingredient shall include or be accompanied by the word "irradiated" or the words "treated with ionising radiation".

15.9 Regulation 15.8 does not apply to food which is not intended for sale.

15.10 Subject to regulations 15.11 or 15.12, any pre-packed food, either contained in an indelibly marked glass bottle intended for re-use and having no label, ring or collar, or the largest surface of whose packaging has an area of less than ten square centimetres, need not by virtue of thcse regulations be marked or labelled with any of the particulars specified in regulation 5.1 except the name of the food and, unless the food is not required to be marked or labelled with such an indication, the appropriate durability indication.

15.11 Subject to regulation 15.12, any pre-packed food which -

(*a*) is sold or supplied as an individual portion, and

(*b*) is intended as a minor accompaniment to either -

(i) another food, or

(ii) another service,

need not be marked or labelled with any of the particulars specified in regulation 5.1 except the name of the food. Such pre-packed food shall include butter and other fat spreads, milk, cream and cheeses, jams and marmalades, mustards, sauces, tea, coffee and sugar, and such other service shall include the provision of sleeping accommodation at an hotel or other establishment at which such accommodation is provided by way of trade or business.

15.12 Regulations 15.10 and 15.11 do not apply to any food to which regulations 15.2, 15.3, 15.13, 15.14 or 15.15 apply.

15.13 Subject to regulations 15.14 and 15.15, any food which is sold at a catering establishment and is either -

(*a*) not pre-packed, or

(*b*) pre-packed for direct sale,

need not be marked or labelled with any of the particulars specified in regulation 5.1.

15.14 In the case of any such food which has been irradiated that food shall be marked or labelled with an indication of such treatment, which indication shall include or be accompanied by the word "irradiated" or the words "treated with ionising radiation".

15.15 In the case of any such food which contains an ingredient which has been irradiated, that food shall be marked or labelled with an indication that it contains that ingredient and reference within that indication to that ingredient shall include or be accompanied by the word "irradiated" or the words "treated with ionising radiation".

15.16 The outer packaging of a seasonal selection pack need not be marked or labelled with any of the particulars specified by these regulations, provided that each item contained in the pack is individually pre-packed and is marked or labelled in accordance with the provisions of these regulations or any other regulations applying to such items.

15.17. Meat that is:

(i) not prepacked, or

(ii) prepacked for direct sale,

shall be marked or labelled at the point of sale with the following particulars in addition to those specified in regulation 15.2:

(*a*) a statement stating the presence of added water or other ingredients, if such water or other ingredients have been added to the meat at any stage prior to sale to the ultimate consumer;

(*b*) a declaration stating the amount of added water, if applicable, expressed as a percentage by weight of the product as offered for sale to the ultimate consumer.

15.18 Regulation 15.17 shall not apply where the only other ingredients added to meat are salt, spices or herbs in small quantities exclusively for the purposes of flavouring.

Lot marking indication.

16.1. Subject to the provisions of paragraph 16.6, no person may sell or offer for sale any food which forms part of a lot unless it is accompanied by a lot marking indication.

16.2 The lot to which the food in the sales unit belongs shall be determined by the producer, manufacturer, packager or the first seller in Malta of the food.

16.3 A lot marking indication must be determined and affixed under the responsibility of one of the operators specified in regulation 16.2.

16.4 The lot marking indication must be preceded by the letter 'L', except where the indication is clearly distinguishable from other indications on the packaging of the food or on an attached label.

16.5 In the case of prepacked food, the lot marking indication must appear on the packaging of the food or on a label attached to it. For non-pre-packaged food the indication must appear on the container of the food or on a commercial document that accompanies the food. The indication must be easily visible, clearly legible and indelible.

16.6 The following foodstuffs need not be marked with a lot marking indication:

(*a*) agricultural products which, on leaving the production holding, are -

(i) sold or delivered to a temporary storage, preparation or packaging station or to a producer's organisation, or

(ii) collected for immediate integration into an operational preparation or processing system;

(*b*) food which is intended to be sold to the ultimate consumer and which is not prepacked, is packed at the request of the purchaser or is prepacked for immediate sale;

(*c*) food in a container where the area of the largest side is less than 10 square centimetres;

(*d*) prepacked food which is sold as an individual portion for immediate consumption and which is intended as a minor accompaniment to another food or another service;

(*e*) individual portions of edible ices supplied to the seller in bulk packaging which contains more than one such portion, provided that the bulk packaging must bear the lot marking indication;

(*f*) food which is marked or labelled with the minimum durability or ‘use by’ date where this consists of at least an uncoded indication of the day and month in that order, whether or not this is required by these

regulations.

Indication of other particulars.

17.1. The labelling of foodstuffs falling within one of the categories given in the Sixth Schedule must contain the additional particulars as set out in that Schedule.

Permitted languages.

18.1. Subject to the provisions of regulations 18.2, 18.3 and 18.6, the particulars given according to the provisions of these regulations shall appear in at least one of the following languages: Maltese, English, Italian.

18.2 Regulation 18.1 shall not apply in the case of the following products:

(*a*) foodstuffs registered in terms of Council Regulation 2081/92 regarding the protection of origin and geographical indications for agricultural products and foodstuffs;

(*b*) foodstuffs registered in terms of Council Regulation 2082/92 regarding certificates of specific character for agricultural products and foodstuffs;

(*c*) foodstuffs for which specific permitted languages are prescribed by other provisions.

18.3 The Food Safety Commission may, on the advice of the Malta Standards Authority, exempt specific categories of foodstuffs from the language requirement prescribed by regulation 18.1, provided that such exemptions may only be given to categories of foodstuffs and not to individual products.

18.4 Any exemptions issued by virtue of regulation 18.3 shall ensure that consumers are adequately informed.

18.5 Exemptions issued by virtue of regulation 18.3 may permit the use of other languages other than the ones prescribed by regulation 18.1 as well as the use of other measures as regards one or more labelling particulars.

18.6 The Food Safety Commission may, on the advice of the Malta Standards Authority, require that the labelling of specific categories of foodstuffs or the provision of specified information must be given in at least one of the official languages of Malta, provided that -

(*a*) such requirements shall apply to all products falling within their scope and not to individual products;

(*b*) such requirements are justified by the need to protect human health.

18.7 Nothing in these regulations shall be construed as precluding the labelling particulars from being indicated in other languages in addition to those prescribed by regulations 18.1 and 18.6.

Claims relating to foods for particular nutritional uses.

19.1. The nature or composition of products being described as being intended for particular nutritional uses must be such that the products are appropriate for the particular nutritional use intended.

19.2 The products referred to in regulation 19.1 must also

comply with any mandatory provisions applicable to foodstuffs for normal consumption, save as regards changes made to them to ensure their conformity with the definitions given in regulation 3.1(*v*).

19.3 The specific provisions applicable to the groups of foods for particular nutritional uses appearing in Part A of the Fourth Schedule shall be those laid down by rneans of the specific regulations given in that Schedule.

19.4 Subject to any derogations given by other provisions, the labelling and the labelling methods used, the presentation and the advertising of the products referred to in regulation 3.1(*v*) must not attribute properties for the prevention, treatment or cure of human disease to such products or imply such properties.

19.5 Nothing in regulation 19.4 shall be construed as preventing the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

19.6 Only the products referred to in regulation 3.1(*v*) may be characterized as "dietetic" or "dietary".

19.7 In the labelling, presentation and advertising of foodstuffs for normal consumption the following shall be prohibited:

(*a*) the use of the adjectives "dietetic" or "dietary" either alone or in conjunction with other words, to designate these foodstuffs;

(*b*) all other markings or any presentation likely to give the impression that one of the products referred to in regulation 3.1(*v*) is involved.

19.8 However, in accordance with other provisions which may be adopted, it shall be possible for foodstuffs for norrrial consumption which are suitable for a particular nutritional use to indicate such suitability. The aforesaid provisions may also lay down the arrangements for indicating this suitability:

Provided that -

19.8.1 where no Community provisions have been adopted for the purposes of this subregulation, appropriate provisions may be adopted by the Food Safety Commission.

19.9 The designation under which such a product is sold shall be accompanied by an indication of its particular nutritional characteristics; however, in the case of products intended to fulfil the particular nutritional requirements of infants and young children in good health, thi.s reference shall be replaced by a reference to the purpose for which they are intended.

19.10 The labelling of products for which no specific provisions have been adopted must also include:

(*a*) the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular

nutritional characteristics;

(*b*) the available energy value expressed in kilojoules and kilocalories and the carbohydrate, protein and fat content per 100 grams or 100 millilitres of the product as marketed and, where appropriate, per specified quantity of the product as proposed for consumption:

Provided that if, however, the energy value is less than 50 kilojoules (12 kilocalories) per 100 grams or 100 millilitres of the product as marketed, these particulars may be replaced either by the words "energy value less than 50 kilojoules (12 kilocalories) per 100 grams" or by the words "energy value less than 50 kilojoules (l2 kilocalories) per 100 millilitres".

19.11 The labelling of products for which specific provisions have been adopted must comply with the requirements laid down in those provisions.

19.12 Products intended for particular nutritional uses shall only be allowed on the retail market in pre-packaged form, and the packaging shall completely cover the products.

19.13 To permit efficient official monitoring of foodstuffs intended for a particular nutritional use which do not belong to one of the groups listed in the Fourth Schedule, the following specific provisions shall apply:

(*a*) when a product as referred to above is placed on the market for the first time, the manufacturer or the importer shall notify the Superintendent of Public Health by forwarding a model of the label used for the product;

(*b*) in the case of products which have already been placed on the market within the European Community, the manufacturer or importer shall, in addition to the model required by paragraph (*a*), provide the Superintendent of Public Health with an indication of the recipient of the first notification to the competent authorities of a Member State of the European Community.

19.14 Where necessary, the Superintendent of Public Health may require the manufacturer or the importer to produce the scientific work and the data establishing the product's compliance with the provisions of these regulations relating to foodstuffs for particular nutritional uses as defined in regulation 3.1(*v*) together with the information provided for in regulation 19.10(*a*). If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

19.15 The Superintendent of Public Health may prohibit, restrict or subject to specified conditions the marketing of products intended for particular nutritional uses if he considers that such products do not comply with paragraph 3.1(*v*) or endanger human health, provided that any such prohibition or restriction shall be notified to the Malta Standards Authority at least three months before being brought into effect, subject to the provisions of

regulation 19.18.

19.16 The Foodstuffs Directorate shall, within three months, issue an opinion regarding the proposed measures.

19.17 In issuing any prohibition or restriction by virtue of regulation 19.15, the Superintendent of Public Health shall take into account the opinion of the Foodstuffs Directorate.

19.18 Where the Superintendent of Public Health considers the imposition of a prohibition or restriction to be an urgent requirement for the protection of public health, he may impose such prohibition or restriction with immediate effect provided the Foodstuffs Directorate is immediately notified of such measures. The Foodstuffs Directorate shall, within three months, issue an opinion regarding the proposed measures.

Substances which may be added to foods for particular nutritional uses.

19.19 For the categories of substances added for specific nutritional purposes in foods for particular nutritional uses listed in the Seventh Schedule, only the chemical substances mentioned under each category may be used in the manufacture of foodstuffs for particular nutritional uses covered by this regulation.

19.20 The use of the substances mentioned in regulation 19.19 shall be in conformity with any specific provisions concerning those substances that may be laid down in applicable specific provisions.

19.21 Without prejudice to European Parliament and Council Regulation (EC) No 258/97 or equivalent measures, other substances added for specific nutritional purposes, not belonging to one of the categories listed in the Seventh Schedule, may be used in the manufacture of foods for particular nutritional uses.

19.22 The use of nutritional substances in foods for particular nutritional uses shall result in the manufacture of safe products that fulfil the particular nutritional requirements of the persons for whom they are intended as established by generally accepted scientific data.

19.23 The Superintendent of Public Health may require the manufacturer or, where appropriate, the importer to produce the scientific work and the data establishing the use of substances added for specific nutritional purposes in compliance with regulation 19.22. If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

19.24 Any purity criteria for substances listed in the Seventh Schedule, specified by legislation for their use in the manufacture of foodstuffs for pmposes other than those covered by this regulation, shall apply.

19.25 For those substances listed in the Seventh Schedule for which purity criteria are not specified by Maltese or European Community legislation, and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall apply.

FIRST SCHEDULE

Categories of Ingredients which may be designated by the Name of the Category rather than the Specific Name

Definition	Designation
Refined oils other than olive oil	"Oil", together with - either the adjective "vegetable" or "animal", as appropriate, or - an indication of their specific vegetable or animal origin The adjective "hydrogenated" must accompany the indication of a hydrogenated oil.
Refined fats	"Fat", together with - either the adjective "vegetable" or "animal", as appropriate, or - an indication of their specific vegetable or animal origin The adjective "hydrogenated" must accompany the indication of a hydrogenated fat.
Mixtures of flour obtained from two or more cereal species	"Flour", followed by a list of the cereals from which it has been obtained, in descending order by weight.
Starches, and starches modified by physical means or by enzymes	"Starch"
All species of fish where the fish constitutes an ingredient of another foodstuff and provided that the name and presentation of such foodstuff does not refer to a specific species of fish	"Fish"
All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another foodstuff and provided that the name and presentation of such foodstuff does not refer to a specific type of cheese	"Cheese"
All spices not exceeding 2% by weight of the foodstuff	"Spice(s)" or "mixed spices"
All herbs or parts of herbs not exceeding 2% by weight of the foodstuff	"Herb(s)" or "mixed herbs"
All types of gum preparations used in the manufacture of gum base for chewing gum	"Gum base"
All types of crumbed baked cereal products	"Crumbs" or "rusks" as appropriate
All types of sucrose	"Sugar"
Anhydrous dextrose or dextrose monohydrate	"Dextrose"
Glucose syrup and anhydrous glucose syrup	"Glucose syrup"
All types of milk protein (caseins, caseinates and whey proteins) and mixtures thereof	"Milk proteins"
Press, expeller or refined cocoa butter	"Cocoa butter"
All types of wine as defined in Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine ([1])	"Wine"

<table>
<tr><th>Definition</th><th>Designation</th></tr>
<tr><td>Skeletal muscles ([2]) of mammalian and bird species recognized as fit for human consumption with naturally included or adherent tissue, where the total fat and connective tissue content does not exceed the values indicated below and where the meat constitutes an ingredient of another foodstuff. The products covered by the European Community definition of "mechanically recovered meat" are excluded from this definition.

Maximum fat and connective tissue contents for ingredients designated by the term "..... meat".

<table>
<tr><th>Species</th><th>Fat (%)</th><th>Connective tissue ([3]) (%)</th></tr>
<tr><td>Mammals (other than rabbits and porcines) and mixtures of species with mammals predominating</td><td>25</td><td>25</td></tr>
<tr><td>Porcines</td><td>30</td><td>25</td></tr>
<tr><td>Birds and rabbits</td><td>15</td><td>10</td></tr>
</table>
If these maximum limits are exceeded, but all other criteria for the definition of "meat" are satisfied, the "..... meat" content must be adjusted downwards accordingly and the list of ineredients must mention, in addition to the term "..... meat", the presence of fat and/or connective tissue.</td><td>"..... meat" and the name(s) ([4]) of the animal species from which it comes.</td></tr>
</table>

[1] OJ L 179, 14.7.1999, p.l.

[2] The diaphragm and the masseters are part of the skeletal muscles, while the heart, tongue, the muscles of the head (other than the masseters), the muscles of the carpus, the tarsus and the tail are excluded.

[3] The connective tissue content is calculated on the basis of the ratio between collagen content and meat protein content. The collagen content means the hydroxyproline content multiplied by a factor of 8.

[4] For labeling in English, this designation may be replaced by the generic name of the ingredient for the animal species concemed.

SECOND SCHEDULE

Categories of Ingredients which must be designated by the Name of their Category followed by their Specific Name or EC Number

Colour

Preservative

Antioxidant

Emulsifier

Thickener

Gelling agent

Stabiliser

Flavour enhancer

Acid

Acidity regulator

Anti-caking agent

Modified starch *

Sweetener

Raising agent

Anti-foaming agent

Glazing agent

Emulsifying salts †

Flour treatment agent

Firming agent

Humectant

Bulking agent

Propellent gas

---

*The specific name or EC number need not be indicated.
†Only for processed cheeses and products based on processed cheeses.

THIRD SCHEDULE

Amended by: L.N. 339 of 2005; L.N. 70 of 2006; L.N. 436 of 2007. Substituted by: L.N. 136 of 2008.

PART A

Designation of Flavourings in the List of Ingredients

1. Flavourings shall be designated either by the word "flavouring(s)" or by a more specific name or description of the flavouring.

2. 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 Article 1(2)(b)(i) of Council Directive 88/388/EEC of the 22nd June, 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production* and/or flavouring preparations as defined in Article 1(2)(c) of the said Directive.

3. If the name of the flavouring contains a reference to the vegetable or animal nature or origin of the incorporated substances, 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.

PART B

Ingredients referred to in regulation 8

1. Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof, except:

   (*a*) wheat-based glucose syrups including dextrose†;

   (*b*) wheat-based maltodextrins†;

   (*c*) glucose syrups based on barley;

   (*d*) cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

2. Crustaceans and products thereof.

3. Eggs and products thereof.

4. Fish and products thereof, except:

   (*a*) fish gelatine used as carrier for vitamin or carotenoid preparations;

   (*b*) fish gelatine or Isinglass used as fining agent in beer and wine.

5. Peanuts and products thereof.

6. Soybeans and products thereof, except:

   (*a*) fully refined soybean oil and fat†;

   (*b*) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources;

---

*OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

†And products thereof, insofar as the process that they have undergone is not likely to increase the level of allergenicity assessed by the EFSA for the relevant product from which they originated.

(*c*) vegetable oils derived phytosterols and phytosterol esters from soybean sources;

(*d*) plant stanol ester produced from vegetable oil sterols from soybean sources.

7. Milk and products thereof (including lactose), except:

(*a*) whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

(*b*) lactitol.

8. Nuts, i.e. almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoiesis* (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (*Pistacia vera*), macadamia nuts and Queensland nuts (*Macadamia ternifolia*), and products thereof, except:

(*a*) nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

9. Celery and products thereof.

10. Mustard and products thereof.

11. Sesame seeds and products thereof.

12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO_2.

13. Lupin and products thereof.

14. Molluscs and products thereof.

FOURTH SCHEDULE

Categories of Foodstuffs for Particular Nutritional Uses

Part A

Groups of foodstuffs for particular nutritional uses for which specific provisions are or will be laid down

	Group	Relevant Provisions
1.	Infant Formulae and Follow-on Formulae	Infant Formulae and Follow-on Formulae Regulations
2.	Processed Cereal-based Foods and Baby Foods for Infants and Young Children	Processed Cereal-based Foods and Other Foods for Infants and Young Children Regulations
3.	Food intended for Use in Energy-Restricted Diets for Weight Reduction	Foods Intended for Use in Energy-Restricted Diets for Weight Reduction Regulations
4.	Dietary Foods for Special Medical Purposes	Dietary Foods for Special Medical Purposes Regulations
5.	Foods intended to meet the Expenditure of Intense Muscular Effort, especially for Sportsmen	To be adopted

Part B

Groups of foodstuffs for particular nutritional uses for which no specific provisions will be adopted and in respect of which the notification procedure prescribed by regulation 19.13 is not reguired

1. Foods with a reduced or negligible content of sodium or salt (sodium chloride, table salt)

2. Gluten-free foods

FIFTH SCHEDULE

Rules for the Indication of Alcoholic Strength by Volume in the Labelling of Alcoholic Beverages for Sale to the Ultimate Consumer

1. Alcoholic strength shall be determined at 20ºC.

2. The figure for alcoholic strength shall be given to not more than one decimal place. It shall be followed by the symbol "% vol." and may be preceded by the word "alcohol" or the abbreviation "alc.".

3. The positive and negative tolerances allowed in respect of the indication of the alcoholic strength by volume shall be as follows expressed in absolute values:

(*a*) Beverages not specified below:

0.3% vol.;

(*b*) Beers having an alcoholic strength not exceeding 5.5% vol.; beverages classified under subheading 22.07 B II of the Common Customs Tariff and made from grapes:

0.5% vol.;

(*c*) Beers having an alcoholic strength exceeding 5.5% vol.; beverages classified under subheading 22.07 B I of the Common Customs Tariff and made from grapes; ciders, perries, fruit wines and the like, obtained from fiuits other than grapes, whether or not semi-sparkling or sparkling; beverages based on fermented honey:

1% vol.;

(*d*) Beverages containing macerated fruit or parts of plants:

1.5% vol.

4. The tolerances set out in paragraph 3 shall apply without prejudice to the tolerances deriving from the method of analysis used for determining the alcoholic strength.

SIXTH SCHEDULE

Compulsory Indication on the Labelling of Certain Foodstnffs of Particulars as required by regulation 17.1

	Type or category of foodstuff	Particulars
1.	Foodstuffs whose durability has been extended by means of packaging gases authorized pursuant to the Additives in Food Regulations	"Packaged in a protective atmosphere"
2.	Foodstuffs containinga sweetener or sweeteners as authorized by the Sweeteners for Use in Foodstuffs Regulations	"with sweetener/s" This particular shall accompany the name under which the product is sold.
3.	Foodstuffs containing both an added sugar or sugars and a sweetener or sweeteners as authorized by the Sweeteners for Use in Foodstuffs Regulations	"with sugar/s and sweetener/s" This particular shall accompany the name under which the product is sold.
4.	Foodstuffs containing aspartame	"contains a source of phenylalanine"
5.	Foodstuffs containing more than 10% added polyols	"excessive consumption may produce laxative effects"
6.	Confectionery or beverages containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant *Glycyrrhiza glabra*, at concentration of 100 mg/kg or 10 mg/1 or above	The terms "contains liquorice" shall be added immediately after the list of ingredients, unless the term "liquorice" is already included in the list of ingredients or in the name under which the product is sold. In the absence of a list of ingredients, the particular shall take place nearby the name under which the product is sold.
7.	Confectionery containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant *Glycyrrhiza glabra*, at concentrations of 4 g/kg or above	The following message must be added after the list of ingredients: "contains liquorice - people suffering from hypertension should avoid excessive consumption". In the absence of a list of ingredients, the particular shall take place nearby the name under which the product is sold.
8.	Beverages containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant *Glycyrrhiza glabra*, at concentrations of 50 mg/l or above, or of 300 mg/l or above in the case of beverages containing more than 1.2% by volume of alcohol*.	The following message must be added after the list of ingredients: "contains liquorice - people suffering from hypertension should avoid excessive consumption". In the absence of a list of ingedients, the particular shall take place nearby the name under which the product is sold.

* The level shall apply to the products as proposed ready for consurnption or as reconstituted according to the instructions of the manufacturers.

SEVENTH SCHEDULE

Amended by: L.N. 64 of 2007.

Substances that may be added for specific nutritional purposes in foods for particular nutritional uses

For the purposes of this table:

"FSMP" means foods for particular nutritional uses intended for special medical purposes,

"All FPNU" means dietary foods for particular nutritional uses including FSMPs but excluding infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children.

Substance	Condition of use	
	All FPNU	FSMP
Category 1 - Vitamins		
VITAMIN A		
retinol	x	
retinyl acetate	x	
retinyl palmitate	x	
beta-carotene	x	
VITAMIN D		
cholecalciferol	x	
ergocalciferol	x	
VITAMIN E		
D-alpha-tocopherol	x	
DL-alpha-tocopherol	x	
D-alpha-tocopheryl acetate	x	
DL-alpha-tocopheryl acetate	x	
D-alpha-tocopheryl acid succinate	x	
VITAMIN K		
phylloquinone (phytomenadione)	x	
VITAMIN B1		
thiamin hydrochloride	x	
thiamin monoitrate	x	
VITAMIN B2		
riboflavin	x	
riboflavin 5'-phosphate, sodium	x	
NIACIN		

Substance	Condition of use	
	All FPNU	FSMP
nicotinic acid	x	
nicotinamide	x	
PANTOTHENIC ACID		
D-pantothenate, calcium	x	
D-pantothenate, sodium	x	
dexpanthenol	x	
VITAMIN B6		
pyridoxine hydrochloride	x	
pyridoxine 5'-phosphate	x	
pyridoxine dipalmitate	x	
FOLATE		
calcium-L-methylfolate	x	
pteroylmonoglutamic acid	x	
VITAMIN B 12		
cyanocobalamin	x	
hydroxocobalarmin	x	
BIOTIN		
D-biotin	x	
VITAMIN C		
L-ascorbic acid	x	
sodium L-ascorbate	x	
calcium L-ascorbate	x	
potassium L-ascorbate	x	
L-ascorbyl 6-palmitate	x	
Category 2 - Minerals		
CALCIUM		
carbonate	x	
chloride	x	
salts of citric acid	x	
gluconate	x	
glycerophosphate	x	
lactate	x	
salts of orthophosphoric acid	x	

Substance	Condition of use	
	All FPNU	FSMP
hydroxide	x	
oxide	x	
sulphate	x	
MAGNESIUM		
magnesium L-aspartate	x	
acetate	x	
carbonate	x	
chloride	x	
salts of citric acid	x	
gluconate	x	
glycerophosphate	x	
salts of orthophosphoric acid	x	
lactate	x	
hydroxide	x	
oxide	x	
sulphate	x	
IRON		
ferrous bisglycinate	x	
ferrous carbonate	x	
ferrous citrate	x	
ferric ammonium citrate	x	
ferrous gluconate	x	
ferrous fumarate	x	
ferric sodium diphosphate	x	
ferrous lactate	x	
ferrous sulphate	x	
ferric diphosphate (ferric pyrophosphate)	x	
ferric saccharate	x	
elemental iron (carbonyl + electrolytic + hydrogen reduced)	x	
COPPER		
cupric carbonate	x	
cupric citrate	x	
cupric gluconate	x	
cupric sulphate	x	
copper lysine complex	x	
IODINE		

Substance	Condition of use	
	All FPNU	FSMP
potassium iodide	x	
potassium iodate	x	
sodium iodide	x	
sodium iodate	x	
ZINC		
acetate	x	
chloride	x	
citrate	x	
gluconate	x	
lactate	x	
oxide	x	
carbonate	x	
sulphate	x	
MANGANESE		
carbonate	x	
chloride	x	
citrate	x	
gluconate	x	
glycerophosphate	x	
sulphate	x	
SODIUM		
bicarbonate	x	
carbonate	x	
chloride	x	
citrate	x	
gluconate	x	
lactate	x	
hydroxide	x	
salts of orthophosphoric acid	x	
POTASSIUM		
bicarbonate	x	
carbonate	x	
chloride	x	
citrate	x	
gluconate	x	
glycerophosphate	x	

Substance	Condition of use	
	All FPNU	FSMP
lactate	x	
hydroxide	x	
salts of orthophosphoric acid	x	
SELENIUM		
sodium selenate	x	
sodium hydrogen selenate	x	
sodium selenite	x	
CHROMIUM (III) and their hexahydrates		
chloride	x	
sulphate	x	
MOLYBDENUM (VI)		
ammonium molybdate	x	
sodium molybdate	x	
FLUORINE		
potassium fluoride	x	
sodium fluoride	x	
Category 3 - Amino acids		
L-alanine	x	
L-arginine	x	
L-aspartic acid		x
L-citrulline		x
L-cysteine	x	
Cystine	x	
L-histidine	x	
L-glutamic acid	x	
L-glutamine	x	
glycine		x
L-isoleucine	x	
L-leucine	x	
L-lysine	x	
L-lysine acetate	x	
L-methionine	x	
L-ornithine	x	
L-phenylalanine	x	
L-proline		x

Substance	Condition of use	
	All FPNU	FSMP
L-threonine	x	
L-trytophan	x	
L-tyrosine	x	
L-valine	x	
L-serine		x
L-arginine-L-aspartate		x
L-lysine-L-aspartate		x
L-lysine-L-glutamate		x
N-acetyl-L-cysteine		x
N-acetyl-L-methionine		x in products intended for persons over 1 year of age
For amino acids, as far as applicable, also the sodium, potassium, calcium and magnesium salts as well as their hydrochlorides may be used		
Category 4 - Carnitine and taurine		
L-carnitine	x	
L-carnitine hydrochloride	x	
taurine	x	
L-camitine-L-tartrate	x	
Category 5 - Nucleotides		
adenosine 5'-phosphoric acid (AMP)	x	
sodium salts of AMP	x	
cytidine 5'-monophosphoric acid (CMP)	x	
sodium salts of CMP	x	
guanosine 5'-phosphoric acid (GMP)	x	
sodium salts of GMP	x	
inosine 5'-phosphoric acid (IMP)	x	
sodium salts of IMP	x	
uridine 5'-phosphoric acid (UMP)	x	
sodium salts of UMP	x	
Category 6 - Choline and inositol		
choline	x	
choline chloride	x	
choline bitartrate	x	
choline citrate	x	

Substance	Condition of use	
	All FPNU	FSMP
inositol	x	

EIGHTH SCHEDULE

Added by: L.N. 242 of 2007. Substituted by: L.N. 278 of 2013.

Names under which foodstuff which have been treated with ionizing radiation are sold in all the European Community languages:

– 'in Bulgarian:
'облъчено' or 'обработено с йонизиращо лъчение',

– in Spanish:
'irradiado' or 'tratado con radiación ionizante',

– in Czech:
'ozářeno' or 'ošetřeno ionizujícím zářením',

– in Danish:
'bestrålet/…' or 'strålekonserveret' or 'behandlet med ioniserende stråling' or 'konserveret med ioniserende stråling',

– in German:
'bestrahlt' or 'mit ionisierenden Strahlen behandelt',

– in Estonian:
'kiiritatud' or 'töödeldud ioniseeriva kiirgusega',

– in Greek:
'επεξεργασμένο με ιονίζουσα ακτινοβολία' or 'ακτινοβοληµένο',

– in English:
'irradiated' or 'treated with ionising radiation',

– in French:
'traité par rayonnements ionisants' or 'traité par ionisation',

– in Croatian:
'konzervirano zračenjem' or 'podvrgnuto ionizirajućem zračenju',

– in Italian:
'irradiato' or 'trattato con radiazioni ionizzanti',

– in Latvian:
'apstarots' or 'apstrādāts ar jonizējošo starojumu',

– in Lithuanian:
'apšvitinta' or 'apdorota jonizuojančiąja spinduliuote',

– in Hungarian:
'sugárkezelt'or 'ionizáló energiával kezelt',

– in Maltese:
'ittrattat bir-radjazzjoni' or 'ittrattat b'radjazzjoni jonizzanti',

– in Dutch:

'doorstraald' or 'door bestraling behandeld' oder 'met ioniserende stralen behandeld',

– in Polish:
'napromieniony' or 'poddany działaniu promieniowania jonizującego',

– in Portuguese:
'irradiado' or 'tratado por irradiação' or 'tratado por radiação ionizante',

– in Romanian:
'iradiate' or 'tratate cu radiaţii ionizate',

– in Slovak:
'ošetrené ionizujúcim žiarením',

– in Slovenian:
'obsevano' or 'obdelano z ionizirajočim sevanjem',

– in Finnish:
'säteilytetty' or 'käsitelty ionisoivalla säteilyllä',

– in Swedish:
'bestrålad' or 'behandlad med joniserande strålning'.

Added by:
L.N. 242 of 2007.
Substituted by:
L.N. 278 of 2013.

NINTH SCHEDULE

Term of the ‘use by’ date in all the European Community languages:

– 'in Bulgarian: 'използвай преди',

– in Spanish: 'fecha de caducidad',

– in Czech: 'spotřebujte do',

– in Danish: 'sidste anvendelsesdato',

– in German: 'verbrauchen bis',

– in Estonian: 'kõlblik kuni',

– in Greek: 'ανάλωση μέχρι',

– in English: 'use by',

– in French: 'à consommer jusqu'au',

– in Croatian: 'upotrijebiti do',

– in Italian: 'da consumare entro',

– in Latvian: 'izlietot līdz',

– in Lithuanian: 'tinka vartoti iki',

– in Hungarian: 'fogyasztható',

– in Maltese: 'uża sa',

– in Dutch: 'te gebruiken tot',

– in Polish: 'należy spożyć do',

– in Portuguese: 'a consumir até',
– in Romanian: 'expiră la data de',
– in Slovak: 'spotrebujte do',
– in Slovenian: 'porabiti do',
– in Finnish: 'viimeinen käyttöajankohta',
– in Swedish: 'sista förbrukningsdag'.