

Health & Consumer Protection

Food Safety Directorate

Food Law, nutrition and labelling unit



Nutrition related legislation

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Framework legislation

- Council Directive 89/398/EEC on foodstuffs intended for particular nutritional uses
- Directive 2002/46/EC of the European Parliament and of the Council on food supplements
- Commission proposal for a regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods



Foods for particular nutritional uses

Other descriptions:

Dietetic foods

Dietary foods

Foods for particular nutritional uses (Dietetic foods)

- [Council Directive 89/398/EEC](#) on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses
(as amended by [Council Directive 96/84/EC](#) and [Council Directive 1999/41/EC](#))
- Provides framework of rules for the composition, marketing and labelling requirements, including measures to ensure the appropriate use and to exclude any risk to human health

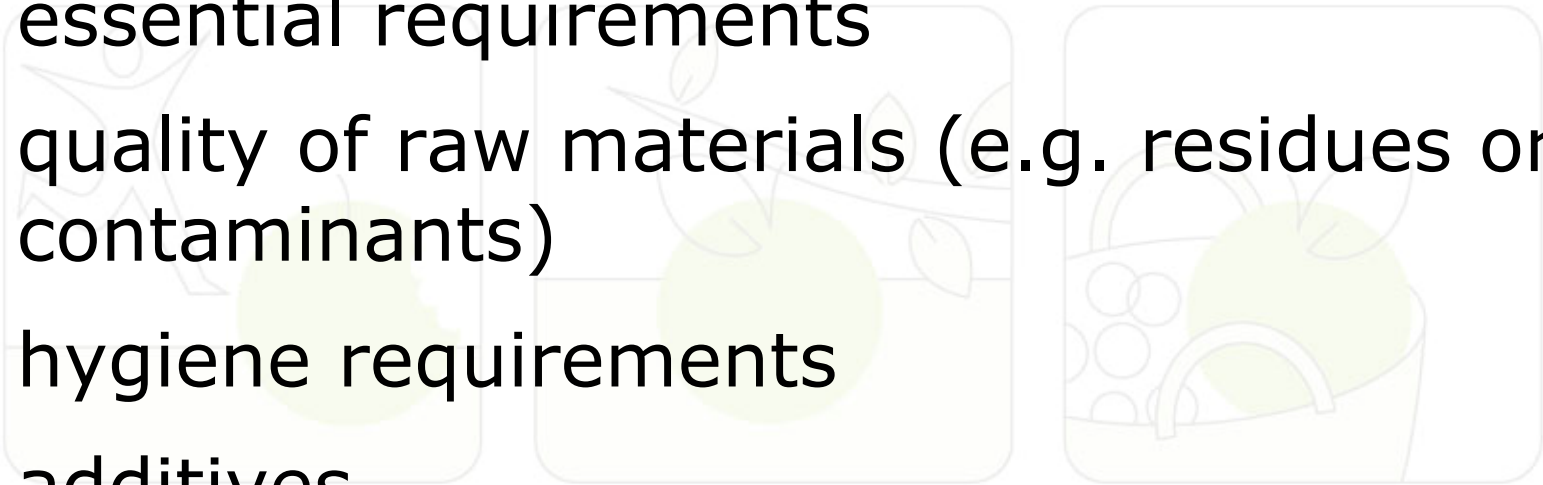
Dietetic foods - Definition

- owing to their special composition or manufacturing process,
- are distinguishable from foods for normal consumption,
- are suitable for their claimed nutritional purposes, and
- are marketed to indicate such suitability

A dietetic food must fulfil the particular nutritional requirements of:

- certain categories of person whose digestive processes or metabolism is disturbed
- certain categories of person in a special physiological
- infants or young children condition

Specific directives may cover:

- essential requirements
 - quality of raw materials (e.g. residues or contaminants)
 - hygiene requirements
 - additives
 - labelling presentation and advertising
 - sampling procedures and methods of analysis
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Dietetic foods

Framework Directive : 89/398/EEC



Specific Directives for 4 categories adopted



Foods for infants
& young children:

Formulae

Weaning Foods

Foods for weight
control

Dietary foods
for special
medical
purposes

Dietetic foods

Other categories mentioned in the Annex to Directive 89/398/EEC:

- Foods for sports people
- Foods for diabetics

Dietetic foods

- Notification procedure for dietetic foods not listed in the Annex
 - manufacturer or importer notifies competent authority when product is first placed on the market
 - not a prior authorisation procedure

Specific Directives for Certain Dietetic Foods



Specific Directives on Dietetic Foods

- Infant formulae and follow-on formulae
- Processed cereal-based foods and baby foods for infants and young children
- Foods intended for use in energy-restricted diets for weight reduction
- Dietary foods for special medical purposes
- Substances that may be added for specific nutritional purposes in foods for particular nutritional uses

Infant formulae and follow-on formulae

■ Directive 91/321/EEC (essential composition and labelling)

Amended by:

- 96/4/EC – revision of essential composition
- 1999/50/EC and 2003/14/EC provisions on pesticide residues

■ Council Directive 92/52/EEC (products intended for export to 3rd countries)

Infant formulae and follow-on formulae

- products intended for infants
- infant formula is suitable as the sole source of nutrition from birth
- follow-on formula is suitable for use as main liquid part of an increasing diversified diet

Scope of legislation

- essential composition (nutrients)
- positive lists for nutritional substances
- specific labelling requirements
- restrictions on the promotion and advertising of infant formula
- limits on the pesticide residues

Processed cereal-based foods and baby foods for infants and young children

■ Directive 96/5/EC (essential composition and labelling)

Amended by:

- 98/36/EC – inclusion of maximum levels for vitamins and minerals, if added
- 1999/39/EC and 2003/13/EC provisions on pesticide residues

Scope of legislation

- products intended as part of a diversified diet of infants and young children – defined categories
- essential composition (nutrients)
- positive lists for nutritional substances
- specific labelling requirements
- limits on the pesticide residues

Foods intended for energy-restricted diets for weight reduction

- **Directive 96/8/EC**
 - products intended to replace all or part of the diet
 - defines the essential composition
 - includes specific labelling requirements

Dietary foods for special medical purposes

■ Directive 1999/21/EC

- covers products intended for persons with impaired or disturbed metabolism
- for use under medical supervision
- intended to replace all or part of the diet
- defines essential composition for vitamins and minerals
- includes specific labelling requirements

Substances added for specific nutritional purposes

■ Directive 2001/15/EC

Amended by:

- 2004/5/EC - positive lists updated

■ Positive lists for certain categories of nutrients

(vitamin and minerals, nitrogen containing substances)

Directive 2002/46/EC on Food Supplements



Food supplements are:

- intended to supplement the normal diet
- not intended to prevent, treat or cure a disease or make a diagnosis
- concentrated sources of vitamins, minerals and/or other substances (such as amino acids, essential fatty acids, fibre and various plant and herbal extracts)
- sold as pills, tablets and other dose forms

Food supplements legislation

- harmonises legislation on vitamins and minerals
- regulates compositional aspects (positive lists of vitamins and minerals) in view of ensuring the safety of the products
- establishes specific rules on labelling

Food supplements legislation

The maximum levels for vitamins and minerals to be established according to following criteria:

- upper safe levels established by scientific risk assessment taking into account the sensitivity of different consumer groups
- intake of vitamins and minerals from other dietary sources
- due account taken of reference intakes of vitamins and minerals for the population

Food supplements - labelling

- recommended daily consumption and a warning not to exceed it
- statement that food supplements should not be used as a substitute to a varied diet
- amount of vitamins and minerals present in the absolute amount and as a percentage of the Recommended Daily Allowances



Thank you
for your attention