

**Directive 2002/46/EC on food
supplements**

Came into effect on 12 July 2002

General objectives

- High level of protection of human life and health
- Free movement of good in the EU internal market
- International standards shall be taken into consideration

Definition

(For the purpose of this Directive)

““food supplements” means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities”

Scope

- Wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts
- As a first stage, the directive lays down specific rules for vitamins and minerals used as ingredients of food supplements

Key provisions of Directive 2002/46/EC

- A positive list of vitamins and minerals and of their specific chemical forms (adaptable)
- Criteria for setting maximum amounts
- Foresees setting of minimum amounts
- Specific labelling provisions
- Foresees report on other nutrients or substances in food supplements

Positive lists

Annex 1

- A list of vitamins and minerals allowed in food supplements

Annex 2

- A list of the specific chemical forms of vitamins and minerals to be used;
- Evaluated by the European Food Safety Authority (EFSA);

Maximum amount will be set concurrently for:

- Food supplements
- Foods to which vitamins and minerals are added



Establishing maximum amounts

Criteria for establishing maximum amounts of vitamins and minerals:

- **upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of 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 (PRI or RDA).

Upper safe levels

Consideration of relevant work by:

- Scientific Committee for Food (SCF)/
European Food Safety Authority (EFSA)
- US Institute of Medicine (IOM)
- UK Expert group on Vitamins and
Minerals (EVM)

Other EU legislation of relevance or applicable to food supplements

- Regulation 1924/2006 on nutrition and health claims made on foods
- Regulation 1925/2006 on addition of vitamins and minerals and of certain other substances to foods
- Directive 90/496 on nutrition labelling
- Regulation 258/1997 on novel foods