

Brussels, 27 September 2001

Safety of food supplements - Commissioner Byrne welcomes political agreement in Council

Commissioner David Byrne today welcomed the political agreement reached by the Council on the proposed Directive on Food Supplements. The Internal Market, Tourism and Consumer Affairs Council this morning agreed a compromise text of the Belgian Presidency, substantially based on the Commission's original proposal, that would harmonise the substantially diverging national rules on the sale of food supplements in the form of pills and capsules. The proposed legislation sets out harmonised safety rules for food supplements that contain vitamins and minerals. It requires that maximum limits for vitamins and minerals intake will be set based on scientific risk assessment and data on vitamin and minerals intake from other foods, while also taking due account of what is considered an adequate vitamin and mineral intake for an average person. The labels will give consumers detailed information on vitamin and mineral content and on daily use, including a warning about exceeding the intake as set out in the manufacturer's instructions. The Council is expected to adopt a Common Position shortly, and to proceed with its final adoption once the European Parliament will have completed its second hearing.

"I am very pleased with the compromise reached today". David Byrne, the Commissioner for Health and Consumer Protection said today. "It puts consumer safety and informed consumer choice first, and will solve the problems manufacturers face in marketing their products due to the current differences in national legislation. Some people find they need food supplements to compensate for their inadequate intake of essential vitamins and minerals. Labels must give them clear information about how to use and how not to use them. We also must make sure that the chemical substances used to produce vitamins and mineral supplements are safe and subject to independent scientific assessment. These principles of food safety and transparent information as outlined in the White Paper on Food Safety apply here as they do to all other food products. It must however be clear that a varied diet remains the best approach to achieving good health. "

The Commission presented its proposal for this Directive in May 2000 in response to an increase in the use of pills and capsules as diet supplements and to varying national rules on and attitudes to the proliferation of these products. The objective of the proposal is two-fold. First, to set out a general framework and safety rules for food supplements. As a first step detailed rules on vitamins and minerals are laid down. The Commission will within the next five years come forward with a report and appropriate measures on other types of ingredients used in food supplements. . The second objective is to give the consumer detailed information on the label to ensure consumers can make an informed choice. Under the text as agreed today labels on, for example, bottles of vitamin pills will have to include clear instructions for daily dosage, a warning about possible health risk in case of excess use, and a statement that the pills should not be used as a substitute for a varied diet. Claims that the product can prevent, treat or cure illness are prohibited.

Any language suggesting that a varied diet does not provide the necessary amounts of essential nutrients is equally prohibited.

The proposed Directive establishes a positive list of chemical substances authorised for the production of vitamins and minerals following their scientific assessment by the Scientific Committee for Food (see Annex I and II). The proposal also foresees that maximum and minimum levels of vitamin and mineral content in the daily dose of food supplements will be set by the competent regulatory committee, the Standing Committee on Food. These maximum limits are to be determined on the basis of science-based risk analysis, taking into account the intake of vitamins and minerals from other foods, as well as the 'population reference intake'. The population reference intake is the total intake of vitamins and minerals that the competent scientific committee, the Scientific Committee on Food, considers as adequate for an average person.

The Directive defines as food supplements all foodstuffs that are concentrated sources of nutrients, alone or in combination, marketed in dose form, whose purpose is to supplement the intake of those nutrients in the normal diet.. Food supplements can be sold in different 'dose forms', such as capsules, tablets, pills and other similar forms, sachets of powder, ampoules of liquids and drop dispensing bottles. The full text of the original Commission proposal of May 2000 is available at http://europa.eu.int/comm/food/fs/sfp/df_index_en.html

The proposed Directive on Food Supplements is part of the package of measures announced in the Commission's White Paper on Food safety. It is based on article 95 and has to be agreed by the European Parliament and the Council of Ministers in co-decision. It is intended to enter into force on 31 May 2002, allowing the marketing of products complying with the directive as of June 2002 and prohibiting the marketing of products which do not respect its rules by June 2004 at the latest.

ANNEX I

Vitamins and minerals which may be used in the manufacture of food supplements

1. *Vitamins*

Vitamin A ($\mu\text{g RE}$)
Vitamin D (μg)
Vitamin E (mg α -TE)
Vitamin K (μg)
Vitamin B1(mg)
Vitamin B2(mg)
Niacin (mg NE)
Pantothenic acid (mg)
Vitamin B6 (μg)
Folic acid(μg)
Vitamin B12 (μg)
Biotin (μg)
Vitamin C (mg)

2. *Minerals*

Calcium (mg)
Magnesium (mg)
Iron (mg)
Copper (μg)
Iodine (μg)
Zinc (mg)
Manganese (mg)
Sodium (mg)
Potassium (mg)
Selenium (μg)
Chromium (μg)
Molybdenum (μg)
Fluoride (mg)
Chloride (mg)
Phosphorus (mg)

ANNEX II

Chemical substances in Vitamin and mineral substances which may be used in the manufacture of food supplements

1. *Vitamins*

VITAMIN A

- retinol
- retinyl acetate
- retinyl palmitate
- beta-carotene

VITAMIN D

- cholecalciferol
- ergocalciferol

VITAMIN E

- D-alpha-tocopherol
- DL-alpha-tocopherol
- D-alpha-tocopheryl acetate
- DL-alpha-tocopheryl acetate
- D-alpha-tocopheryl acid succinate

VITAMIN K

- phylloquinone (phytomenadione)

VITAMIN B1

- thiamin hydrochloride
- thiamin mononitrate

VITAMIN B2

- riboflavin
- riboflavin 5'-phosphate, sodium

NIACIN

- nicotinic acid
- nicotinamide

PANTOTHENIC ACID

- D-pantothenate, calcium
- D-pantothenate, sodium
- dexpanthenol

VITAMIN B6

- pyridoxine hydrochloride
- pyridoxine 5'-phosphate

FOLIC ACID

- pteroylmonoglutamic acid

VITAMIN B12

- cyanocobalamin
- hydroxocobalamin

BIOTIN

- D-biotin

VITAMIN C

- L-ascorbic acid
- sodium-L-ascorbate
- calcium-L-ascorbate
- potassium-L-ascorbate
- L-ascorbyl 6-palmitate

2. Minerals

calcium carbonate
calcium chloride
calcium salts of citric acid
calcium gluconate
calcium glycerophosphate
calcium lactate
calcium salts of orthophosphoric acid
calcium hydroxide
calcium oxide
magnesium acetate
magnesium carbonate
magnesium chloride
magnesium salts of citric acid
magnesium gluconate
magnesium glycerophosphate
magnesium salts of orthophosphoric acid
magnesium lactate
magnesium hydroxide
magnesium oxide
magnesium sulphate
ferrous carbonate
ferrous citrate
ferric ammonium citrate
ferrous gluconate
ferrous fumarate
ferric sodium diphosphate
ferrous lactate
ferrous sulphate
ferric diphosphate (ferric pyrophosphate)
ferric saccharate
elemental iron (carbonyl+electrolytic+hydrogen reduced)
cupric carbonate
cupric citrate
cupric gluconate
cupric sulphate
copper lysine complex
sodium iodide
sodium iodate
potassium iodide
potassium iodate
zinc acetate
zinc chloride
zinc citrate
Zinc gluconate
zinc lactate
zinc oxide
zinc carbonate

zinc sulphate
manganese carbonate
manganese chloride
manganese citrate
manganese gluconate
manganese glycerophosphate
manganese sulphate
sodium bicarbonate
sodium carbonate
sodium chloride
sodium citrate
sodium gluconate
sodium lactate
sodium hydroxide
sodium salts of orthophosphoric acid
potassium bicarbonate
potassium carbonate
potassium chloride
potassium citrate
potassium gluconate
potassium glycerophosphate
potassium lactate
potassium hydroxide
potassium salts of orthophosphoric acid
sodium selenate
sodium hydrogen selenite
sodium selenite
chromium (III) chloride
chromium (III) sulphate
ammonium molybdate (molybdenum (VI))
potassium molybdate (molybdenum (VI))
potassium fluoride
sodium fluoride