

## **FLEP Proposals for the EU concerning food supplements**

### **Members of the Working Party “Food Supplements”:**

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# **FLEP Proposals for the EU concerning food supplements**

## **Why do we need a regulation**

- The consumer assumes that the nutrition with normal food is not sufficient. The consumer is influenced through public educational campaigns, promotional activities of manufacturers, mail-order business, the mass media and the internet. Misleading advertising causes anxiety. Just in Germany there is an increase in turnover to about 2 billions of marks.
- European regulations exist only for food additives and dietary products and no regulation on food supplements.
- Food supplements may contain physiological active substances from plants and animals, which may cause serious health problems. Other food supplements are vitamins and minerals. The overdosing of vitamins and minerals may lead to health defects as well. The long term consequences of the accumulation of vitamins and minerals are not known in every case. This kind of products are to be found on the market.
- Many food supplements are in a pharmaceutical form like capsules, drops or tablets with health-related advertising. There is a difference in national legislation with regard to regulations for food and pharmaceuticals. Therefore supplements are permissible in some member states while prohibited in others. Therefore we need definitions for supplements for avoiding obstacles to trade. The Member States were evoking reasons of protecting public health for not allowing the marketing of these products. Obviously the mutual recognition cannot solve the problems since there is an increasing number of complaints from economic operators concerning obstacles to trade with food supplements.
- Many food supplements have misleading or deceptive presentations claiming effects which have not been sufficiently justified by scientific research. Therefore it is necessary to bring about a uniform regulation.
- In its Green Paper on Food Law the commission announced to identify and debate the points that need to be considered für harmonizing Community legislation on the subjects in question. FLEP should give an opinion to the subject.

## **What should a regulation contain**

### **1. Definitions**

#### **Definitions for food supplements**

There does not exist a definition for food supplements. Nevertheless the term is used in Community papers. A definition of food supplements is required.

#### **Proposal**

**Food supplements are considered as foodstuffs and not as drugs. In case of not being not considered or registered as drugs the products have to be considered as foodstuffs also in a pharmaceutical form like capsules, drops, tablets, which is not typical for foodstuffs. They must contain essential nutrients like vitamins, mineral salts or other substances for a nutritional purpose. The aim and purpose of specific food have to be declared explicitly. The purpose for nutrition or positive health effects must be scientifically proved.**

The definition "food supplements" does not include the restoration, standardisation, fortification and enrichment of essential nutrients in so called "Functional Food"(food to which vitamins, minerals, nutrients like as fat, sugar, protein have been added or reduced persuming a positive effect on health, performance or wellness). The definition for the addition of essential nutrients to food (functional food) corresponding to the Codex Alimentarius General Principles for the addition of essential nutrients to food include the following definitions:

- **restoration**: addition to food of essential nutrient which are lost during the course of Good Manufacturing Practice, normal storage, handling procedures etc.
- **standardisation**: compensation for natural deviations in nutrient level
- **fortification or enrichment**: addition of essential nutrient whether or not it is normally contained in the food for the purpose of preventing or correcting deficiency in the population.

### Proposal

**FLEP agrees with the codex definitions for the addition to food. FLEP also agrees, that restoration, standardisation and fortification or enrichment do not come under the definition for supplements.**

### Proposal

**A general addition of minerals and vitamins to basic foodstuff has to be done only on nutritional purpose and on scientific basis.**

## 2. Composition considerations

### Proposal

**A community regulation should contain:**

- **a negative list containing all substances which are bad for the health and should not be used as food supplements (germanium salts, drugs, hormones, undefined plant extracts, extracts from human organs etc.)**
- **a negative list with substances with a narrow range of the correct dosage (for instance selenium, fluoride, vitamin A and D etc.)**
- **a general limit for dosage. For instance the daily intake should not exceed one (vitamin A, D, selenium and fluoride) or a few (the other vitamins) multiples of the Recommended Daily Allowance RDA = Population Reference Intake PRI. Otherwise the products are no foodstuffs but drugs.**
- **a minimum limit for dosage of the RDA of about 15 - 20 %**
- **where no RDA exists, the safety and the effect of the dosis has to be scientifically proved**

An alternative could be positive lists containing all substances and their range of dosage which would be allowed.

## 3. Labelling issues

### **Proposal:**

**Mandatory regulations for labelling must contain:**

- **mandatory labelling for foodstuffs**
- **a clear description of the aim and the purpose of the food supplements**
- **the recommended daily dosage by tablets, capsules, drops and the percentage of the RDA if available; it would be helpful for the consumer to declare the average recommended daily portion in 100 g or ml.**
- **a warning declaration if the consumption of certain food supplements could be a problem for the very young, the very old, the pregnant etc. (for instance high dosage of vitamin A to pregnant is considered as a serious problem)**
- **no claims evoking directly or indirectly the prevention, curing or eliminating of illness**
- **no misleading claims**
- **warnings to keep out of sight and reach of children**
- **warnings not to exceed the recommended dosage**

### **4. Purity criteria**

Manufacturers claim that vitamins and minerals used in food supplements are purchased in pharmacopoeia standards. However opinions are expressed that the purity criteria for substances used in food manufacture should be even stricter than the ones applicable to substances used in making drugs which are used in the majority of cases occasionally and for a limited period of time.

### **Proposal**

**Special purity criteria for vitamins and minerals do exist for additives. They should be applied to food supplements. When purity criteria are lacking the minimum purity of pharmacopoeia standards should be reached. It should be scientifically proved if they should be stricter than the ones used in making drugs.**

**The purity criteria concerning by-products and contaminants should be issued by legislation.**

### **5. Packaging**

### **Proposal**

**In general the child resistant closure CRC is recommended. The requirement may be limited to products containing specific nutrients which are possibly dangerous for children (for instance iron, fat soluble vitamins, alcohol).**

### **References**

1. Discussion paper on "Addition of Vitamins and Minerals to Food and Food supplements", Pharmaceutical committee, Dokument III/5934/97, prepared by DG III of the European Commission
2. Richtlinienentwurf über Vitamin- und Mineralstoffergänzungsmittel, Alinorm 97/26 Anhang VI, Stufe 5, vom 20.12.1996

3. Green Paper on Food Law
4. Avant-projet de directives pour l'emploi des allégations relatives à la nutrition, Alinorm 97/22, Annexe II (Porté à l'étape 8 de la procédure)