FOOD SUPPLEMENTS (FS) AND FORTIFIED FOODS (FF): GENERAL PROVISIONS AND INFORMATION TO CONSUMERS

Vittorio Silano
Medical School, II University of Rome
Tor Vergata
SPECIFIC LEGISLATION ON FOOD SUPPLEMENTS (FS) (1)

• Directive 2002/46/EC relating to food supplements
• Directive 2006/37/EC amending Annex II to Directive 2002/46/EC as regards the inclusion of certain substances
• Regulation (EC) 1170/2009 amending Directive 2002/46/EC and Regulation (EC) No 1925/2006 as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements
SPECIFIC LEGISLATION ON FOOD SUPPLEMENTS (FS) (2)


• Regulation (EC)1137/2008 with regard to the regulatory procedure with scrutiny.
DIR. 2002/46: DEFINITION OF FS

- the purpose of which is to supplement the normal diet and
- which are concentrated sources of nutrients (vitamins and minerals) or other substances with a nutritional or physiological effect, alone or in combination
- marketed in dose form...designed to be taken in measured small unit quantities.
Vitamins and minerals in food supplements

2002/46: VITAMINS AND MINERALS ALLOWED IN FS

ANNEX I

REGULATION (EC) No 1170/2009
FORMS OF VITAMINS AND MINERALS IN FOOD SUPPLEMENTS

LIST OF PERMITTED SOURCES OF VITAMIN OR MINERAL THAT MAY BE USED IN FS (1)

ANNEX II Dir. 2002/46
amended by:
Directive 2006/37/EC
REGULATION (EC) No 1170/2009
REGULATION (EU) No 1161/2011
SPECIFIC LEGISLATION ON FORTIFIED FOOD (FF) (1)

- REGULATION (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods
- Commission Regulation (EC) 1170/2009 and by Commission Regulation (EU) No 1161/2011 which amended Annex I and Annex II to include additional vitamin or mineral formulations
SPECIFIC LEGISLATION ON fortified FOOD (FF) (2)

The Regulation applies without prejudice to Community legislation regarding:
• Foods for particular nutritional uses
• Novel foods and novel food ingredients
  • Genetically modified food
• Food additives and flavourings
• Authorised oenological practices and processes
1925/2006: ADDITION OF VITAMINS AND MINERALS TO FORTIFIED FOODS (1)

Purposes

• restoration
  the final product has the amount of nutrient(s) lost during the various stages of the storage, handling and manufacturing of food

• fortification
  Vitamins and minerals are added to foods irrespective of whether the nutrients are originally present in the food
1925/2006: Addition of vitamins and minerals to fortified foods (2)

The provisions of the Regulation regarding vitamins and minerals food supplements in do not apply to fortified foods

• Vitamin and minerals listed in Annex I,

• The forms of vitamins and minerals listed in Annex II.
1925/2006: Addition of vitamins and minerals to fortified foods (2)

• Vitamins and minerals may be added to foods, taking into account:
  ➢ deficiency of one or more vitamins and/or minerals in the population or specific population groups, or
  ➢ the potential to improve nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins and minerals due to changes in dietary habits, or
  ➢ evolving generally acceptable scientific knowledge on the role of vitamins and minerals in nutrition and on health
Vitamins and minerals should be in a bioavailable form to the human body

-The identification of permitted preparations of vitamins and minerals to be used in food supplements was made possible by the work carried out by EFSA who evaluated the safety and bioavailability of nutrient sources proposed for addition to the list of permitted substances in Annex II of the food supplements Directive.

-Between 2005 and 2009 EFSA examined a total of 533 applications. Of these, 186 applications were withdrawn during the evaluation process, and EFSA received insufficient scientific evidence to be able to assess around half of the remaining applications. Possible safety concerns were identified in relation to 39 applications.
INCLUSION OF SUBSTANCES IN THE ANNEXES OF REGULATIONS APPLICABLE TO FOOD SUPPLEMENTS AND FORTIFIED FOODS

Vitamin and mineral substances may be considered for inclusion in the lists following the evaluation of an appropriate scientific dossier concerning the safety and bioavailability of the individual substance by the European Food Safety Agency (EFSA).
PURITY CRITERIA OF VITAMINS AND MINERALS

Purity criteria, specified by Community legislation for the use of these substances in the manufacture of foodstuffs for purposes other than food supplements, shall apply. If purity criteria are not specified, generally acceptable purity criteria recommended by international bodies shall be applicable and national rules setting stricter purity criteria may be maintained.
the maximum and minimum amounts of vitamins and minerals shall be adopted in food supplements and fortified foods
In doing so the following elements should be considered:

• (a) 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;

• (b) intake of vitamins and minerals from other dietary sources.

• (c) reference intakes of vitamins and minerals for the population.
SETTING MAXIMUM AMOUNTS OF VITAMINS AND MINERALS (NOT ESTABLISHED) (3)

PENDING THE SETTING OF SUCH MAXIMUM AND MINIMUM AMOUNTS AT THE EU LEVEL, MEMBER STATES ARE ALLOWED TO MAINTAIN OR SET SUCH RULES AT NATIONAL LEVEL, WITHOUT PREJUDICE TO THE PROVISIONS OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION.
Since 1998, the Commission has requested a review from the Scientific Committee on Food (SCF) (1)

- to review the upper levels of daily intakes of individual vitamins and minerals that are unlikely to pose a risk of adverse health effects;
- to provide the basis for the establishment of safety factors, where necessary, for individual vitamins and minerals which would ensure the safety of fortified foods and food supplements containing these nutrients.
(SINCE 1998) COMMISSION REQUEST TO THE SCIENTIFIC COMMITTEE ON FOOD (SCF) (2):

A GUIDANCE DOCUMENT (SCF/CS/ADD/NUT/21) GAVE INFORMATION ON THE DATA TO BE PROVIDED IN THE DOSSIER SUPPORTING THE APPLICATION FOR A NEW SUBSTANCE (11 JULY 2001)
EFSA WORK ON TOLERABLE UPPER INTAKE LEVELS (ULS) FOR VITAMINS AND MINERALS (1)

In 2003, the terms of reference previously attributed to the SCF were handed over to EFSA with respect to 12 outstanding vitamins and minerals
In 2006 the EFSA’s NDA Panel performed a comprehensive evaluation of the possible adverse health effects of individual micro-nutrients at intakes exceeding the dietary requirements and, where possible, established Tolerable Upper Intake Levels (ULs) for different population groups.
EFSA WORK ON TOLERABLE UPPER INTAKE LEVELS (ULS) FOR VITAMINS AND MINERALS (3)

- The ULS defined by EFSA represent the highest level of chronic daily intake of a nutrient that is not likely to pose a risk of adverse health effects to humans.
- Throughout this work EFSA is providing support to the European Commission to make possible the establishment of maximum limits for vitamins and minerals in food supplements (and fortified foods) harmonized at an European level.
SETTING MINIMUM AMOUNTS OF VITAMINS AND MINERALS

According to Reg.1925/2006, the addition of vitamins and minerals to foodstuffs shall result in the presence of at least a significant amount as defined by Directive 90/496/EEC
SETTING MINIMUM AMOUNTS OF VITAMINS AND MINERALS

Directive 90/496/EEC

SIGNIFICANT AMOUNT OF VITAMINS AND MINERALS

15% of the recommended allowance in 100 g or 100 ml
Discussion Paper

According to Reg.1924/2006, 15% of the recommended allowance has to be present if a nutrition claim is made that the food is a “source” of a vitamin or a mineral.
SETTING MINIMUM AMOUNTS OF VITAMINS AND MINERALS

Reg. 1169/2011

• 15% of NRVs by 100g or 100 ml for products other than beverages
  • 7.5% of NRVs by 100ml for beverages
• 15% of NRV per portion if the package contains only a single portion
OTHER NUTRIENTS OR SUBSTANCES WITH A NUTRITIONAL OR PHYSIOLOGICAL EFFECT (1)

According to Art 4(8) a report was transmitted to Council and European Parliament on 05 December 2008 "on the use of substances other than vitamins and minerals in food supplements"
THE REPORT ON “THE USE OF SUBSTANCES WITH NUTRITIONAL OR PHYSIOLOGICAL EFFECT OTHER THAN VITAMINS AND MINERALS IN FS» (EAS, 5 December 2008) (1)

• Categories of substances other than vitamins and minerals identified in the study:
  (i) aminoacids; (ii) enzymes; (iii) pre- and probiotics; (iv) essential fatty acids; (v) botanicals and botanical extracts; (vi) miscellaneous bioactive substances.

• The total size of the EU food supplement market and its segments was: 50% vitamin and mineral fs, 43% fs containing other substances 7% fs tonics and bottled nutritive drinks
THE REPORT ON “THE USE OF SUBSTANCES WITH NUTRITIONAL OR PHYSIOLOGICAL EFFECT OTHER THAN VITAMINS AND MINERALS IN FS» (EAS, , 5 December 2008) (3)

The regulatory status of a representative sample of substances was provided for 26 member states showing that:
- the majority of substances were permitted for use in food supplements:
  (i) under national law or internal guidelines;
  (ii) maximum level or specific conditions established;
  (iii) Or on a case by case basis following evaluation.

- the minority of substances require either authorisation or are regarded as medicinal substances
Other substances used in fortified foods include:

(i) amino acids; (ii) enzymes; (iii) pre- and probiotics; (iv) essential fatty acids; (v) miscellaneous bioactive substances.
SAFETY PROVISIONS ACCORDING TO REGULATION 178/2002

Art. 14

Food shall not be placed on the market if it is unsafe
Unsafe = injurious to health or unfit for human consumption.

Art. 17:

Food business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.
ADDITION OF CERTAIN «OTHER» SUBSTANCES TO FOOD: POTENTIAL RISK (1)

The procedure shall be followed if the ingestion of the substance or the ingredient containing the substance used in food:

- would result in the ingestion of amounts of this substance that greatly exceed those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or
- would represent a potential risk to consumers (general adult population or other specified population group)

These conditions shall occur under actual circumstances and shall be assessed on a case-by-case basis in comparison with the average intake of the concerned substance by the general adult population or other specified population group.
Where the use of a substance other than vitamins and minerals may represent a potential risk to consumers.

Inclusion in annex III: procedure for prohibition, restriction or under Community scrutiny applies according to art. 8 of Reg. 1925/2006 and implementing Reg. 307/2012, establishing implementing rules for the application of art.8
ART.8: PROCEDURE (2)
SUBSTANCES PROHIBITED, RESTRICTED OR UNDER COMMUNITY SCRUTINY (ANNEX III)

Decision to include, if necessary, the substance or ingredient containing the substance in Annex III

PART A -> Has a harmful effect and its addition shall be prohibited
PART B -> Has a harmful effect and its addition to food shall be allowed under specified conditions
PART C -> A possible harmful effect has been identified but scientific uncertainty persists
Substances under Community scrutiny

Substance “X” listed in Part C

efsa

FILE
18 months
scientific data on safety
Supplementary information

Food Business Operators

Opinion

Decision by Commission + MS

4 years

9 months (+ 3 months)
CURRENT REQUESTS FROM MS

1. Ephedra species (Ephedra spp.) ephedra alkaloid-containing Ephedra haulm to be classified in Part A of Annex III

2. Yohimbe (Pausinystalia yohimbe (K. Schum.) Pierre ex Beille) bark, and preparations made from it, yohimbine HCl. To be classified in Part C of Annex III

Both are substances used in food supplements and their consumption may pose a health risk
CONSUMER’S INFORMATION ON FOOD SUPPLEMENTS (FS) AND FORTIFIED FOODS (FF)

Dir. 2002/46/EC (FS)
Reg. (EC) 1925/2006 (FF)

Dir. 2000/13/EC until 13/12/2014 and
Reg. (UE) 1169/2011 (FS) + (FF)

Reg. (EC) 1924/2006 (FS) + (FF)
1169/2011: COMPULSORY LABELLING (FS and FF)

(1) the name under which the product is sold;
(2) the list of ingredients;
(3) the quantity of certain ingredients or categories of ingredients
(4) the net quantity;
(5) 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;
1169/2011: COMPULSORY LABELLING (FF and FS)

(6) any special storage conditions or conditions of use;

(7) the name or business name and address of the manufacturer or packager, or of a seller established within the Community.

(8) 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 or provenance of the foodstuff;
1169/2011: COMPULSORY LABELLING (FF) and (FF)

(9) instructions for use when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions;
(10) with respect to beverages containing more than 1,2 % by volume of alcohol, the actual alcoholic strength by volume.

The mandatory nutrition declaration does not apply to FS
2002/46/EC: MANDATORY LABELLING REQUIREMENTS FOR FS (1)

- The name under which FS are sold shall be ‘food supplement’
- The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties
(a) the names of the categories of nutrients or substances that characterize the product or an indication of the nature of those nutrients or substances;

(b) the portion of the product recommended for daily consumption;

(c) a warning not to exceed the stated recommended daily dose;

(d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;

(e) a statement to the effect that the products should be stored out of the reach of young children.
The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.
1. The amount of the nutrients or substances with a nutritional or physiological effect present in the product shall be declared on the labelling in numerical form.

2. The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.

3. Information on vitamins and minerals shall also be expressed as a percentage of the reference values mentioned, as the case may be, in the Annex to Directive 90/496/EEC as updated in Annex XIII of Reg. EU 1169/2011.
LABELLING OF NOVEL FOOD INGREDIENTS IN FOOD SUPPLEMENTS AND FORTIFIED FOODS

(1)

Requirements for labelling of novel food and ingredients are additional to the general EU requirements on food labelling. Where necessary, labelling of novel food and novel food ingredients may mention:

• Characteristics - composition, nutritional value, intended use;
• Materials which may affect the health of some individuals;
• Materials that give rise to ethical concerns
LABELLING OF NOVEL FOOD INGREDIENTS IN FOOD SUPPLEMENTS AND FORTIFIED FOODS (2)

(AN EXAMPLE)
TREHALOSE.

The designation "trehalose" shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs containing it. In a prominently displayed footnote related to the designation trehalose by means of an asterisk (*) the words "trehalose is a source of glucose" shall be displayed. The words shall have a typeface of at least the same size as the list of ingredients itself.

(Commission Decision 2001/721/EC)."
1925/2006: LABELLING, PRESENTATION AND ADVERTISING FOR FORTIFIED FOODS

• Shall not state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients

• Shall not mislead or deceive the consumer as to the nutritional merit of a food that may result from the addition of these nutrients
1925/2006: NUTRITION LABELLING OF FORTIFIED FOODS

• NUTRITION LABELLING IS COMPULSORY
  ○ Information in Group 2 of Dir. 90/496 (until 13/12/2014)
  ○ Information specified in Article 30(1) of Reg 1169/2011 (FROM 13/12/2014)
1925/2006 FOOD WITH ADDED VITAMINS AND MINERALS: COMPULSORY NUTRITION LABELLING Dir. 90/496 (Reg. 1169/2011) (1)

<table>
<thead>
<tr>
<th>Nutrition information</th>
<th>per 100g or ml or per serving / portion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>Kj/Kcal</td>
</tr>
<tr>
<td>Protein</td>
<td>g</td>
</tr>
<tr>
<td>Carbohydrate</td>
<td>g</td>
</tr>
<tr>
<td>sugars</td>
<td>g</td>
</tr>
<tr>
<td>Fat</td>
<td>g</td>
</tr>
<tr>
<td>saturates</td>
<td>g</td>
</tr>
<tr>
<td>fibre</td>
<td>g</td>
</tr>
<tr>
<td>sodium</td>
<td>g</td>
</tr>
<tr>
<td>Vit. and Min.</td>
<td>mg/μg + %RDA</td>
</tr>
</tbody>
</table>

**Group 2, (dir. 90/496) until 13/12/2014**
1925/2006 FOOD WITH ADDED VITAMINS AND MINERALS: COMPULSORY NUTRITION LABELLING Dir. 90/496 (Reg. 1169/2011) (2)

<table>
<thead>
<tr>
<th>Nutrition information</th>
<th>per 100g or ml or per serving / portion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>Kj/Kcal</td>
</tr>
<tr>
<td>Fat</td>
<td>g</td>
</tr>
<tr>
<td>saturates</td>
<td>g</td>
</tr>
<tr>
<td>Carbohydrate</td>
<td>g</td>
</tr>
<tr>
<td>sugars</td>
<td>g</td>
</tr>
<tr>
<td>Protein</td>
<td>g</td>
</tr>
<tr>
<td>salt</td>
<td>g</td>
</tr>
<tr>
<td>Vit. and Min.</td>
<td>mg/µg + %NRV</td>
</tr>
</tbody>
</table>

**Art. 30(1) Reg. 1169/2011 after 13/12/2014**
1925/2006 FOOD WITH ADDED VITAMINS AND MINERALS: OPTIONAL NUTRITION LABELLING Reg. 1169/2011 (2)

<table>
<thead>
<tr>
<th>Nutrition information</th>
<th>MANDATORY</th>
<th>OPTIONAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>per 100g/ml</td>
<td>% of reference intakes per 100g/ml</td>
<td>per serving or consumption unit</td>
</tr>
<tr>
<td>Vit. and Min.</td>
<td>mg or μg</td>
<td>%</td>
</tr>
</tbody>
</table>

Reg. 1169/2011 (2)
NUTRITION CLAIMS APPLICABLE TO FOOD SUPPLEMENTS AND TO0 FORTIFIED FOODS

- Nutrition claims include any claim that states, suggests or implies that a food has particular beneficial nutritional properties due to the energy content and/or the nutrients or other substances
- it contains
- it contains in reduced or increased proportions, or
- it does not contain

http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/nutrition_claims_en.htm
Nutrition claims

• Energy
• Fats and saturated fatty acids
• Salt
• Sugar
• 
• Proteins
• Carbohydrates
• Unsaturated and omega-3 fatty acids
• Vitamins and minerals
AUTHORISED HEALTH CLAIMS

• Article 13.1 222 +6
• ‘general function’ health claims
• Article 13.5: 1 + 3
• New scientific evidence and/or proprietary data
• Article 14(1a): 9
• Reduction of disease risk health claims
• Article 14(1b): 11
• Claims referring to children’s development and health
• Generic versus authorized health claims
EU REGISTER OF NUTRITION AND HEALTH CLAIMS

EU Register of nutrition and health claims made on foods

The EU Register is for information only, showing:
- Permitted nutrition claims and their conditions of use
- Authorised health claims, their conditions of use and applicable restrictions, if any;
- Non-authorised health claims and the reasons for their non-authorisation;
- EU legal acts for the specific health claims;
- National measures mentioned in Art. 23(3) of Regulation EC 1924/2006

The Commission will update the EU Register when required, namely upon adoption of EU decisions on applications for claims or on changes to conditions of use and restrictions.