European Commission

Explanatory meeting on the EU acquis

Legislation for specific categories of food

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

DG SANTE E1

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Health and Food Safety

European Commission

Content

- Fortified Foods
- Food Supplements
- Natural Mineral Waters and Spring Waters

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Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

- Harmonises the provisions laid down in the Member States relating to the addition of vitamins and minerals and of certain other substances to foods (such as amino acids, essential fatty acids and botanicals).
- The provisions of the Regulation regarding vitamins and minerals do not apply to food supplements (covered by Directive 2002/46/EC).

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Addition of Vitamins and Minerals

Key provisions of Regulation (EC) No 1925/2006:

- regulates compositional aspects (positive list of vitamins and minerals in Annexes) in view of ensuring safety of products;
- establishes specific rules on labelling, presentation and advertising of foods to which vitamins and minerals have been added;
- envisages setting of maximum amounts;
- envisages report on effects of implementation of the Regulation (implementing rules adopted).

Addition of Vitamins and Minerals

Labelling requirements:

- shall not include any mention stating or implying 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 the food as a result of fortification;
- nutrition labelling is mandatory (Regulation (EU) No 1169/2011 on provision of food information to consumers);
- may bear a statement indicating addition of vitamin/mineral according to Regulation (EC) No 1924/2006 on nutrition and health claims.

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Addition of certain other substances

Procedure under Article 8 of the Regulation:

On its own initiative or on the basis of information provided by Member States, the Commission may take a decision to include substances other than vitamins or minerals for which a harmful effect on health has been identified, in **Annex III** of the Regulation (**Part A** – prohibition, **Part B** – restriction of use, **Part C** – Union scrutiny);

Implementing rules:

Commission Implementing Regulation (EU) No 307/2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006

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Addition of certain other substances

Conditions that must be met to initiate procedure under Article 8:

- substance shall be added to foods or used in the manufacture of foods AND;
- substance presents a potential risk to consumers because of intake that greatly exceeds normal intake of a balanced and varied diet OR;
- substance presents a potential risk to consumers for reasons other than a great excess of its normal intake.

Addition of certain other substances

Substances assessed under Article 8 procedure following request by a Member State:

- *Ephedra* species: placed in Part A (prohibited use in foods, including food supplements);
- Yohimbe (*Pausinystalia yohimbe (K. Schum) Pierre ex Beille*): placed in Part C (Union scrutiny); Commission has taken decision at end of scrutiny period to place it in Part A (prohibited use).

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Addition of certain other substances

Substances being assessed under Article 8 procedure:

Hydroxyanthracene derivatives and Monacolins from red yeast rice

- During discussions on authorisation of health claims, Member States raised safety concerns with the use of these substances in food.
- The Commission, on its own initiative started Article 8 procedure.
- EFSA adopted opinion on the safety of hydroxyanthracene derivatives on 22 November 2017.
- EFSA adopted an opinion on safety of monacolins from red yeast rice on 25 June 2018.

Green tea catechins

- Article 8 procedure initiated following a request by Member States. Possible safety concerns were associated with the use of green tea catechins in foods including food supplements. EFSA adopted an opinion on the safety of green tea catechins on 25 June 2018.

A risk management decision for the use of the above-mentioned substances in foods will be taken by the Commission.

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Addition of vitamins and minerals and of certain other substances to foods

Community Register (Article 9) with information on:

- vitamins and minerals and their forms which may be added to foods as listed in Annexes I and II;
- maximum and minimum amounts of vitamins and minerals which may be added to foods;
- information on national provisions on the mandatory addition of vitamins and minerals;
- restrictions on the addition of vitamins and minerals;
- substances under derogation (Article 17);
- information about the substances listed in Annex III.

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Directive 2002/46/EC on food supplements

General objectives

- High level of protection of human life and health;
- Free movement of foods in the EU internal market.

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.
- Directive 2002/46/EC lays down specific rules for vitamins and minerals used as ingredients of food supplements, as a first stage.
- Commission has prepared a report to the Council and European Parliament on the use of substances other than vitamins and minerals in food supplements (Article 4(8) of Directive 2002/46/EC).
- https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-supplements-comm_2008_0824_en.pdf

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Directive 2002/46/EC on food supplements

Food supplements are regulated as food in the EU and are subject to:

- EU horizontal rules applicable to foods in general
- EU specific rules applicable to food supplements
- National specific rules of Member States in the absence of relevant EU rules

For the purpose of this Directive, food supplements are defined as:

- "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"

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Directive 2002/46/EC on food supplements

Key provisions of Directive 2002/46/EC:

- A positive list of vitamins and minerals and of their specific chemical forms (can be modified following a request by a petitioner)
- Criteria for setting of maximum amounts for vitamins and minerals
- Envisages setting of minimum amounts of vitamins and minerals
- Specific rules on labelling, presentation and advertising of food supplements.

Other EU legislation of relevance or applicable to food supplements:

- Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.
- Regulation (EU) 2015/2283 on novel foods.
- Regulation (EC) No 1924/2006 on nutrition and health claims
- Regulation (EU) No 1169/2011 on food information to consumers

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Directive 2009/54/EC on the exploitation and marketing of natural mineral waters (NMW)

Definition of NMW (Annex I):

- microbiologically wholesome water, originating in an underground water table or deposit and emerging from a spring tapped at one or more natural or bore exits.
- Understanding of 'spring' clarified by European Court of Justice ruling (C-207/14)

NMW can be clearly distinguished from ordinary drinking water by its:

- Nature, characterised by a stable mineral content (and other constituents);
- Original purity (microbiologically safe; free from all risks of pollution)

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Directive 2009/54/EC on the exploitation and marketing of natural mineral waters (NMW)

Official recognition of NMW:

- Competent authorities of Member States grant official recognition for NMW extracted on their territory and from third countries.

Publication of lists of officially recognised NMW:

- Regular update of lists of officially recognised NMW on Europa website;
- Annual publication of lists on Official Journal of European Union.

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Directive 2009/54/EC on the exploitation and marketing of natural mineral waters (NMW)

Constituents of NMW:

- Commission Directive 2003/40/EC lays down maximum limits for certain constituents naturally present in NMW.

Separation of undesirable constituents:

- Only certain separation techniques are permitted according to Article 4 of the Directive.
- Commission Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters.

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Directive 2009/54/EC on the exploitation and marketing of natural mineral waters (NMW)

Spring waters are included in the scope of Directive:

- Defined as *"water which is intended for human consumption in its natural state, and bottled at source".*

Specific provisions of Directive applicable to spring water:

- Conditions of exploitation (Annex II);
- Permitted separation techniques (Article 4);
- Microbiological criteria (Article 5);
- Labelling requirements (Articles 7 and 8).

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Thank you for your attention

More information may be found on the Europa website:

https://ec.europa.eu/food/safety

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