Food supplements explained

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Background information on the rules on selling food supplements in the EU, including requirements regarding permitted ingredients, maximum levels, labelling and notification requirements

Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

Update

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Background

Under EU law, food supplements are considered to be food and therefore must comply with general food law (Regulation 178/2002) and rules on food information to consumers (Regulation 1169/2011).

Food supplements are a specific category of foods for which certain specific requirements are set out in Directive 2002/46/EC.

Scope

This Directive only governs the use of vitamins and minerals in food supplements. As the use of other ingredients in supplements on the EU market is not covered by Directive 2002/46/EC, Member States may adopt national rules determining what ingredients may be used in supplements, in addition to vitamins and minerals.

The European Commission (2008) has stated that, given the wide diversity of practices across EU Member States, developing EU legislation on other substances used in food supplements is not feasible.

Which vitamins and minerals may be used?

Annex I of Directive 2002/46/EC lists the minerals which may be used in food supplements.

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Annex II sets out the mineral sources (chemical substances) that have been assessed as safe and available to the body. The latest list can be found in the consolidated version of the Directive. Requests for additions to this list can be made in accordance with published guidance (European Commission 2004/2020).

Maximum limits

Although the Directive foresees the establishment of maximum and minimum amounts of vitamins (Art. 5), the setting of harmonised EU maximum levels is controversial, given different practices among EU Member States. Maximum and minimum levels are therefore subject to national rules. The Commission has produced a discussion paper on maximum levels (European Commission 2006), but has not yet produced a proposal. Further public consultation on maximum levels is expected in 2023.

Labelling

Labelling and advertising of food supplements must not claim that supplements prevent, treat or cure a human disease. In addition, they must include:

- names of the nutrients or substances that characterise the product
- portion of the product recommended for daily consumption
- warning not to exceed the stated recommended daily dose
- statement that supplements should not be used as a substitute for a varied diet
- statement that supplements should be stored out of the reach of young children.

Notification

The Directive allows Member States to implement a notification procedure to facilitate the monitoring of food supplements. This requires operators placing food supplements on the market to notify the competent authority (see European Commission 2022) by forwarding a model of the product label.

As of 2022, all Member States, except Austria, the Netherlands, Slovenia and Sweden, have implemented a notification procedure.

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Mutual recognition

Under the principle of mutual recognition (Regulation (EU) 2019/515), food supplements lawfully marketed in one Member State should be permitted access to another Member State market, provided the necessary procedures (e.g. notification) have been completed. However, another Member State is permitted to refuse placement on the market to protect the health and life of humans, for example where levels of vitamins and minerals exceed those permitted by that Member State. Such decisions can be contested and brought to the attention of the Commission (Food Supplements Europe 2021).

Impacted products

food supplements

Timeline

The European Commission intends to set maximum levels of vitamins and minerals that may be included in food supplements (and foods). A public consultation on this initiative is expected in the second quarter of 2023.

Resources

European Commission (2004/2020) Administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacturer of foods (revised 2020).

European Commission (2006) Discussion paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs.

European Commission (2008) Report from the Commission to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements.

European Commission (2022) List of competent authorities of the Member States within the meaning of Article 4(6) of Directive 2002/46 on food supplements.

Food Supplements Europe (2014) Good manufacturing practice for manufacturers of food supplements.

Food Supplements Europe (2021) Guidelines on how to apply the new Mutual Recognition Regulation (EU) 2019/515 to food supplements in the EU.

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Sources

Directive 2002/46/EC

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