European Economic and Social Committee

NAT/809
How to implement harmonisation of market entry for food supplements in the EU

OPINION

European Economic and Social Committee

How to implement harmonisation of market entry for food supplements in the EU: Solutions and best practice
(Exploratory opinion)

Rapporteur: **Veselin MITOV**

Referral	Portuguese EU Presidency, 26/10/2020
Legal basis	Article 304 of the Treaty on the Functioning of the European Union
Section responsible	Agriculture, Rural Development and the Environment
Adopted in section	15/04/2021
Adopted at plenary	27/04/2021
Plenary session No	560
Outcome of vote (for/against/abstentions)	245/0/5

1. Conclusions and recommendations

1.1 The food supplements market is growing in Europe. Food supplements are regulated by Directive 2002/46/EC[1], which is not applied uniformly across the EU. However, if the EU internal market is to function properly it is essential for the legislation to be applied in a uniform way to enable safe products to circulate freely.

1.2 The EESC advocates **revising this legislation**, in particular by updating the definition of food supplements, including a requirement of notification and scrutiny of administrative dossiers and setting up a **food monitoring** system that collects adverse reactions, thereby increasing protection of public health.

1.3 Product and ingredient **safety** must be the top requirement and should therefore be determined on a scientific basis. The EESC recommends that **maximum levels** be set for vitamins and minerals and that lists of authorised and unauthorised ingredients, including plants, be drawn up.

1.4 The **information** provided to consumers must enable them to consume the products safely. The EESC recommends that communication and consumer education measures be put in place, particularly for e-commerce.

1.5 The EESC encourages the authorities to step up **monitoring, testing and surveillance** of products in order to protect consumers by ordering non-compliant products to be withdrawn. This monitoring should also prevent **unfair competition** between operators (e.g. use of unauthorised claims, non-compliant products from third countries, in particular).

1.6 The EESC therefore calls on all the relevant parties to **harmonise** the regulatory framework for food supplements and its implementation, in the interests of a fairer economy and greater product safety.

2. Introduction

2.1 This opinion has been drawn up at the request of the Portuguese Council Presidency, in order to find methods and best practice for implementing harmonised market entry of food supplements within the EU. The EESC opinion could feed into the presidency's work on this subject, in particular through a conference to be organised in the first half of the year and Council working groups. The EESC has welcomed this request, which concerns a part of the food sector which is seldom studied.

2.2 The EESC believes that this topic fits well with the World Health Organisation's One Health approach and the EU Farm to Fork Strategy, which calls for healthy, sustainable diets and better consumer information, while ensuring fair trade between operators[2]. The EESC considers that

1 OJ L 183, 12.7.2002, p. 51.

2 OJ C 429, 11.12.2020, p. 268https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/farm-fork-sustainable-food-strategy

healthy and sustainable diets represent a key "pillar" of a comprehensive EU food policy, as we urgently need to orient our diets to improve – not damage – the health of both ecosystems and the public[3].

2.3 The EESC has always been supporting an EU policy to protect health throughout the food chain, with a view to promoting safety and hygiene and clear, transparent and safe product information[4]. The Committee also maintains that food safety must continue to be based on a robust system and a European Food Safety Agency (EFSA), with transparent procedures for assessing the safety of new products entering the food chain, full traceability and appropriate risk communication[5].

3. Towards harmonisation in the area of food supplements

3.1 A regulatory framework that needs to be improved

3.1.1 Food supplements are specifically regulated by Directive 2002/46/EC, which has hardly been amended at all since it was adopted.

3.1.2 The **definition** of food supplements has not changed despite innovation in the sector and new consumption patterns. It is not sufficiently precise and is subject to different interpretations. Examples include the concept of "measured small unit quantities", which differs from country to country (no defined quantity). These interpretations may lead to disparities between Member States as regards the status of food supplements and the results of checks. The definition needs to be made broader and more precise.

3.1.3 The EESC proposes **updating the rules** in order to better harmonise the market for food supplements and to take account of new developments.

3.2 Making notification more effective

3.2.1 **Notification** is a possibility provided for by the directive. The declaration serves as administrative registration of products before they are placed on the market. It is not a marketing authorisation or proof of compliance or safety. Each Member State (24/27) may decide on the content of the notification and on the procedure for processing the data (ranging from simple submission of data to thorough scrutiny).

3.2.2 The information contained in the notification gives the authorities in question a better knowledge of their market, and processing the data prevents non-compliant products (national and European legislation) circulating and facilitates checks.

3.2.3 The EESC proposes better harmonisation of national systems and recommends including in the legislation the minimum information (quality and quantity of ingredients, labelling, etc.) to be

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3 OJ C 190, 5.6.2019, p. 9.

4 OJ C 440, 6.12.2018, p. 158.

5 OJ C 268, 14.8.2015, p.1.

provided, preferably in digital form, in order to cut red tape for the operator while ensuring the highest possible standards. If feasible, the EESC suggests setting up a European multilingual portal, with its contents left to the discretion of the Member States. Indeed, given that composition is poorly harmonised (see below), this issue can only be addressed at national level.

3.2.4 In order to protect the consumer, the EESC believes that notification should be made mandatory. This practice allows safer products to be placed on the market and also facilitates market surveillance and monitoring. The list of notified products and the related conclusions should be made available to the consumer. Consumers should not hesitate to inform themselves and to file a complaint to the control authorities in the event of the discovery of a violation.

3.3 Setting maximum levels for nutrients – a priority for legislation

3.3.1 **Vitamins and minerals** are the ingredients in food supplements which are most well-known. Nutrients and their chemical forms were first regulated and listed by Regulation (EC) No 1170/2009[6], following safety assessments carried out by the European Food Safety Authority (EFSA). Currently, maximum doses are set at national level either on the basis of the useful dose or on the basis of toxicity[7]. Some countries have not set legal limits. EFSA has specified toxicity thresholds in its various opinions. These values relate to total dietary exposure[8] and cannot be extrapolated to food supplements alone.

3.3.2 The EESC recommends that the Commission swiftly instruct EFSA to set maximum amounts for nutrients in food supplements, along with purity criteria. Given the size of the European Union and different eating habits (consumption of vegetables, fish or meat, composition of tap water, etc.), a single maximum level may not be possible, but limits may be set by region/group of countries. It would also be preferable to establish limits for vulnerable sections of the population: children, pregnant women, and so on.

3.3.3 Harmonisation across the European Union would benefit all stakeholders: consumer safety would be increased and the risk of overdose reduced, and the free movement of products would benefit both operators – which could sell their products on more markets –and consumers, who would have access to a wider choice.

3.3.4 Although nutrients take priority, **other ingredients** used in products should also be harmonised. This would make it easier for them to circulate and enable a scientific assessment to be carried out to prove they are safe. In particular, some countries have tried to approximate their legislation on herbal products by compiling joint lists: Belgium, France and Italy, and recently Germany, Switzerland and Austria. Bioengineered ingredients such as micro-organisms (probiotics, yeast) also deserve special attention.

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6 OJ L 314, 1.12.2009, p. 36.

7 Judgment of the European Court of Justice, Case C-672/15.

8 Under Article 6 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals, the Commission should have set maximum amounts for nutrients in foods (excluding food supplements) by 19 January 2009.

3.3.5 The EESC also recommends that the Commission look into compiling lists of authorised and unauthorised other substances, in terms of both identity and quantity and of conditions of use, as provided for by Regulation (EU) No 2015/2283[9] on novel foods.

3.4 Claims as a tool for consumer choice

3.4.1 Consumer information is generally provided by product labelling – list of ingredients, allergens, etc. – and is covered by Regulation (EU) No 1169/2011[10][11]. However, labelling accounted for 58% of the infringements revealed during checks in 2018[12]. The EESC welcomes the EU's efforts in the context of the Council's work on food labelling, but notes that some issues remain.

3.4.2 The properties of the product are described in claims on labelling, but also in advertisements in magazines and on television or the internet, etc. Advertising can encourage people to buy certain products. Regulation (EC) No 1924/2006[13] provided for lists of permitted nutrition and health claims. The claims regarding vitamins and minerals have already been evaluated by EFSA and published, but claims concerning botanicals and other substances have yet to be examined. These claims are therefore subject to national rules, where they exist, and the **market** contains all kinds of unverified claims and is thus **distorted**.

3.4.3 The EESC therefore calls for the Commission to find the best working option so that EFSA can continue to assess nutrition and health claims on pending substances – first and foremost claims regarding botanicals – and establish the conditions to ensure that ingredients are safe.

3.5 Borderline products – products which are not without risk

3.5.1 The way food supplements are presented and advertised may also give rise to confusion as to the **status of the products**. Some operators do not hesitate to attribute to products therapeutic or prophylactic properties, making them substitutes for medicines and calling them "nutraceuticals" (a contraction of the words "nutrient" and "pharmaceutical"). A specific monitoring campaign revealed that such **misleading** claims were being used in the prevention or control of COVID-19[14]. Consumers can be influenced by these false promises.

3.5.2 These products whose status is unclear[15] are referred to as "borderline products". The grey area is due to their place of sale, the form of the products, and the fact that certain ingredients may be used in both foods and medicines, but in different doses.

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9 OJ L 327, 11.12.2015, p. 1.

10 OJ L 304, 22.11.2011, p. 18.

11 The Council is currently discussing a roadmap, with limited impact on food supplements, on the revision of the rules on consumer information on the origin of ingredients and expiry dates.

12 EU Food Fraud Network and Administrative Assistance and Cooperation System – 2018 Annual report.

13 OJ L 404, 30.12.2006, p. 9.

14 The results of the checks are available here.

15 According to a judgment of the European Court of Justice, the status of products falls within the remit of national authorities, and a food supplement may have different status depending on the country: Joined cases C-211/03, C-299/03, C-316/03, C-317/03 and C-318/03.

3.5.3 The EESC advises the Commission to set up a working group on borderline products, for example as part of the Standing Committee on Plants, Animals, Food and Feed (PAFF) expert group, as exists for medicines, medical devices, cosmetics and biocides. This would publish documents that help authorities and operators clarify the status of products. Creating a European working group is no hindrance to the establishment of national joint committees that would determine the status of products.

3.5.4 The EESC strongly advises the authorities to carry out specific checks on these products in order to withdraw them from the market. Their presence on the market constitutes **unfair competition** for pharmaceutical companies, which have to obtain marketing authorisations for medicinal products. Publishing these checks would also make consumers aware of the risks of these products.

3.6 The emergence of e-commerce – providing choice but also giving rise to inequality

3.6.1 **Distance selling** of food products has increased as a result of the COVID-19 pandemic. Food supplements are products which generally have a long expiry date and transporting them is simple.

3.6.2 Regrettably, the composition of a number of these products and the claims made for them – especially products from outside Europe – are not compliant, creating **unfair competition** for European operators which follow the rules. In addition, Member States have detected the presence of banned and dangerous substances (amphetamines in sports supplements, medicines, etc.) in certain products, making them a danger to the consumer.

3.6.3 The EESC calls on the Commission and the Member States to step up **surveillance** and monitoring of e-commerce platforms and websites, to carry out sampling and testing and to report non-compliant products in the Rapid Alert System for Food and Feed (RASFF).

3.6.4 The EESC also considers that **communication** and **education** of consumers and health professionals should be increased to make products purchased on the internet safer. While food must be safe to be sold, consumers should be aware that some products offered online may pose a risk to their health.

3.7 Food monitoring as a warning tool

3.7.1 Some ingredients may cause **adverse reactions**, even if the products comply with the legislation. Safety is not assessed for each product or ingredient, nor is how they might interact with other products such as medicines.

3.7.2 Very few Member States have an organised system for collecting adverse reactions and monitoring them (**food monitoring**). The countries which do have such a system are Italy, France, Denmark, Portugal, the Czech Republic, Slovenia and Croatia.

3.7.3 The EESC encourages the introduction of national **food monitoring** systems to promote product safety and ensure a high level of **public health protection** by detecting signs early and so

preventing health problems. This system should enable adverse reactions to be collected, regardless of how serious they are, in order to support product safety assessments, allow emergency measures to be taken or legislation adapted where necessary, and to enable operators to incorporate the information into their **quality control** and thus develop safer products. With regard to production, food supplements follow the same safety rules as other agri-food products (HACCP[16], etc.) and no specific risks for workers in the sector have been identified.

3.7.4 The EESC also suggests that a working group be set up at European level for the Member States, under the supervision of EFSA, which would allow information to be exchanged between countries, best practice to be shared with a view to uniform assessments, and scientific knowledge to be exchanged and incorporated into European legislation if necessary.

Brussels, 27 April 2021

Christa SCHWENG
The president of the European Economic and Social Committee

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16 Hazard Analysis and Critical Control Points.