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From:	General Secretariat of the Council
To:	Council
Subject:	Presidency report on *"Food supplements in the Union market - a way forward"* – *Information from the Presidency*

Delegations will find in Annex a report by the Portuguese Presidency on the above-mentioned subject to be presented under "Any other business" items at the meeting of the Council ("Agriculture and Fisheries") on 28-29 June 2021.

ANNEX

Food supplements in the Union market - a way forward

Report by the Portuguese Presidency

INTRODUCTION

1. Directive 2002/46 /EC[1], in force since 2003, aims to guarantee that food supplements placed on the Union market are safe and bear adequate and appropriate labelling. The purpose is to ensure a high level of health protection for consumers and facilitate their choice, while safeguarding the smooth functioning of the internal market.

2. The Directive defines food supplements as "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"*. Food supplements can contain a wide range of ingredients, including vitamins and minerals, herbals (“ botanicals”) and their extracts, fatty acids, amino acids and others.

3. In the past two decades, an increasing number of products, aimed at supplementing normal diets, have been placed on the market to meet growing consumer interest and demand. At the same time, food habits have changed during this period and consumers have become increasingly aware of the importance of a balanced diet and of the possible benefits and risks of food supplements.

[1] 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.

4. Aware of a number of difficulties encountered by Member States in applying the Union's legal framework to food supplements sold in their territory, the Portuguese Presidency considered it important to launch an informal discussion on this subject within the Working Party on Foodstuffs. The Presidency invited the delegations to contribute to the state of play, to identify the major constraints that authorities and food business operators encounter and to suggest priority actions to improve the current situation.

5. On 21 April 2021, the Presidency held a High Level Conference on Food Supplements. This provided representatives of competent authorities and stakeholders the opportunity to share their views on the state of play and on possible ways of improving the legislative framework applicable to food supplements marketed in the Union.

6. On 27 April 2021, the European Economic and Social Committee (EESC) adopted an opinion on *How to implement harmonisation of market entry for food supplements in the EU: Solutions and best practice*[2]. In its opinion, the EESC calls on all relevant parties to harmonise the regulatory framework on food supplements and its implementation so as to ensure a fairer economy and greater product safety. In particular, the EESC advocates revising the legislation on food supplements especially by: updating the definition of such supplements; setting maximum levels for vitamins and minerals; introducing a requirement for the notification and scrutiny of these products before they enter the EU market; setting up a food monitoring system that records any adverse effects. Moreover, the EESC recommends that communication and consumer education measures be put in place, particularly for e-commerce, to enable consumers to use such products safely. In addition, the EESC encourages the authorities to step up the monitoring, testing and surveillance of these products.

7. With the current report, the Presidency intends to inform the Council on the outcome of the initiatives organised together with the relevant stakeholders and of the conclusions of the discussions held with Member States on food supplements placed on the Union market.

[2] NAT/809-EESC-2021-00521.

STATE OF PLAY AND PRIORITY CONSTRAINTS

8. Despite the nearly twenty years that the Directive on food supplements has been in force, the Union's legislative framework has only been partially harmonised: Member States still have a wide margin of decision on the applicable procedures and on the implementation measures. Moreover, the role of competent authorities varies between Member States.

9. In order to facilitate efficient monitoring of food supplements, Member States may require the manufacturer, or the person placing a food supplement on the market in their territory to notify their national competent authority of their intention. The notification must be accompanied by a model of the label that will be used for the product[3].

   However, each Member State can require additional information or impose other procedural steps.

10. Accordingly, national competent authorities may impose different requirements for placing food supplements on the Union market: while in some Member States national authorities carry out detailed assessments of the product characteristics, in other Member States, national authorities only require a simple set of data or, indeed, no notification at all.

    Following a notification, national authorities may then list the food supplements on a national register. However, no common Union information-sharing system has been put in place to ensure that information is systematically shared between national competent authorities. The availability of the information collected by any of the Member States is particularly relevant when food business operators request the (mutual) recognition by other Member States of a food supplement placed on the Union market, under the conditions established by Regulation (EU) 2019/515[4].

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3 See Article 10 of Directive 2002/46/EC (consolidated version here).

4 Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008.

11. Nevertheless, it should be noted that Regulation (EU) 2019/515, which applies to all types of goods, does not provide appropriate technical specifications to support food business operators in their requests and to prevent divergent interpretations by national competent authorities[5]. In this respect, the Presidency welcomes the Commission Guidance document on the application of the Mutual Recognition Regulation to food supplements.

12. As regards the legal definition of food supplements, certain technical requirements[6] are not sufficiently accurate or have become obsolete and may lead to misinterpretations. It is, for instance, the case for the wording '*concentrated sources of nutrients and other substances*' and '*small unit quantities*'. The meaning and interpretation of such wording might differ from country to country[7].

13. Furthermore, the expression '*physiological effect*', which is similar to the expression '*physiological functions*' used in the definition of medicinal product[8], leads to uncertainty in the distinction between these different categories of products and to different classifications of the same type of products in different Member States.

14. In addition, this lack of clarity is increased by the fact that some of the ingredients with a nutritional or physiological effect used in food supplements[9] are substances that are usually also present in medicines and regarding which Union law does not establish clear (minimum and maximum) quantitative limits for their inclusion in food supplements or maximum limits for (daily) intake when they are ingested from different sources.

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5 This is the case in terms of the mutual recognition declaration or the burden of proof. In addition, the Regulation does not provide enough guidance for business operators or for an adequate information exchange system between Member States.

6 Article 2 of Directive 2002/46/EC defines food supplements as "*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*".

7 For instance, the maximum for liquids means a spoon, in certain Member States, or a glass, in others.

8 Under Article 1(2)(b) of Directive 2001/83/EC, "*any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis*." should be considered a medicinal product.

9 See Article 2 of Directive 2002/46/EC.

15. Currently, Directive 2002/46/EC lists the vitamins and minerals that can be used in food supplements. Under its Article 5, the Directive confers powers on the Commission to set the maximum limits for the presence of such vitamins and minerals in food supplements. The Presidency welcomes the Commission's recent initiative to resume its work in this respect.

16. As regards the use of substances other than vitamins and minerals as ingredients in food supplements, Union law foresees that specific rules would only be established when appropriate scientific data is available. Until then, national rules could apply[10]. Maximum quantities could be also be indicated for substances other than vitamins and minerals in order to guarantee consumer safety.

17. Another concern relates to the fact that the ingredients used in food supplements are often concentrated forms of substances that are considered safe because they had been consumed to a significant degree in the Union before 15 May 1997, or are included in the list of authorised novel foods. However, it might not be a reliable assumption that those concentrated forms are substantially equivalent to the safe base ingredients, and that they should thus be subject to a specific risk assessment under the Novel Food Regulation. Accordingly, certain food supplements placed on the Union market may not have been subject to an appropriate risk assessment.

18. Owing to their composition or the advertising used, some products marketed as food supplements may also fall under another status – they are also known as 'borderline products'.

19. Views on whether it is appropriate to include recommendations for nutrients contained in food supplements in national health promotion and disease prevention recommendations may differ amongst Member States[11].

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[10] In 2008, in its report to the Council and the European Parliament, the Commission concluded that '*laying down specific rules applicable to substances other than vitamins and minerals for use in food supplements is not justified* and *in any case, is not necessary in the short term*'. This cast doubt on the feasibility of such a measure. See Recital 8 of Directive 2002/46/EC (initial legal act here).

[11] Most Member States recommend that adequate nutrient intake for the general public be achieved solely from foods, and reserve recommendations of specific nutrient supplements targeted for specific subgroups).

20. Several of the questions included in the evaluation[12] of Regulation (EC) Nº 1924/2006[13] with regard health claims made in relation to plants and their preparations – also known as 'botanicals' – and of the general regulatory framework for their use in foods, cannot yet be answered in an objective manner. The application of Regulation (EC) Nº 1924/2006 to botanicals has been suspended since 2012, as almost 50% of all health claims (1958 out of 4600, known as "on hold claims") still have to be assessed. In addition, such claims made in relation to plants and their preparations have not yet been substantiated and backed by scientific evidence. However, in line with Article 28(5) of Regulation 1924/2006, they can be used in relation to foods placed on the Union market, including in relation to food supplements, which are made available to consumers in the same form as medicines (e.g. pills, tablets). Moreover, strong advertising strategies, commonly used in food supplements, make claims to offering potential health benefits which are not scientifically based nor approved.

21. Food supplements can contain substances with a nutritional or physiological effect[14]. Claims used on packaging, or advertised in the media, often present those products as having a therapeutic or prophylactic effect. In addition, the composition of food supplements is insufficiently regulated and food supplements may contain ingredients identical to the active substances used in medicines. The similarities with the properties and composition of medicines can lead to confusion between food supplements and medicines[15] and, as a consequence, consumers often confuse food supplements with medicines in terms of effects and characteristics.

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12 The *Commission's Evaluation of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods.*

13 Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9).

14 See Union legal definition in Article 4 of Directive 2002/46/EC which defines food supplements as "foods, (…) which are concentrated sources of nutrients or other substances with a nutritional or *physiological effect*, (…)".

15 In the Union, medicinal products can consist of: "Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying *physiological functions* by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.". See Article 1(2)(b) of Directive 2001/83/EC.

22. In accordance with European Court of Justice case-law[16], the legal status of each product is to be established by the competent national authorities. As a result, the same product can be classified as a food supplement in a Member State and as a medicinal product (for instance, as a herbal medicine[17]) in another. Accordingly, there may be differences between Member States in the level of requirements imposed on the same product in the context of placing it on the Union market.

23. The Rapid Alert System for Food and Feed (RASFF) establishes a network involving the Member States, the Commission and the European Food Safety Authority for the notification of direct and indirect risks to human health from food or feed. Furthermore, only a few Member States have a structured system to collect data related to possible adverse reactions from food supplements (Nutrivigilance System).

24. Some consumers tend to see food supplements as a 'natural' replacement of medicines. This suggests that the perception of the safety of food supplements may vary as regards the different types of products available on the market, and that a "natural source" is sufficient for the purpose. Consumers' wrongly perceive food supplements as "natural" products that pose less of a risk than medicines. For most consumers, advertisements are the key source of information about food supplements.

25. It is the responsibility of Member States to ensure that only food supplements complying with the applicable Union rules[18] may be marketed within the Union. However, the lack of legal requirements concerning many of the ingredients used in food supplements[19] makes it difficult to establish a harmonised official control system in this sector.

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16 The Court of Justice ruled that the definition of medicinal product by function should be interpreted restrictively, since it is designed to cover only products whose pharmacological properties have been scientifically observed, and not substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions (see paragraphs 60 to 65 of case C-319/05).

17 Herbal medicinal products are defined as medicinal products containing, as active ingredients dried, fresh or treated (parts of) plants, alone or combined. See Article 1(29) to (32) of Directive 2001/83/EC.

18 Article 3 of Directive 2002/46/EC.

19 Only the presence of vitamins and minerals in food supplements is (partially) regulated by Union law. Legal maximum levels for their inclusion in food supplements are, however, not yet established. Maximum quantities for other ingredients (such as melatonin) present in food supplements are not defined at Union level either.

26. The number and range of products sold on the internet (e-commerce) has increased considerably in recent years. This is due to new forms of consumption and, more recently, to the impact of the COVID-19 pandemic. Furthermore, the use of unauthorised, unverified and unsubstantiated health and medicinal claims for supplements on websites and associated social media platforms has also increased. The convenience and availability of internet sales, with often an unknown source of origin and unknown composition of many of these products, remains a considerable challenge to authorities and a challenge in terms of consumer protection. In addition, this entails a source of unfair competition among food business operators within the Union market.

27. As the general regulatory framework governing health claims made on plants and their preparations for the use in foods has not been implemented yet[20] it is, at this stage, impossible to assess whether the legal provisions are effective, efficient and have an added value.

28. In the absence of a harmonised notification procedure, the legal conformity of food supplements placed on the Union market (e.g. compliance with labelling requirements) is not systematically checked in the same way at national level.

29. Despite the existing common list of vitamins and minerals, in the absence of harmonisation of the other aspects (other substances, quantitative limits), it is difficult to carry out a common approach in official controls performed at national level.

30. Moreover, the different interpretations of the definition of food supplements and the lack of legal support to take appropriate measures to ensure compliance with specific requirements, can lead to divergence in product classification. Against this background, the application of the mutual recognition principle could undermine the protection of public health and compromise consumer safety.

31. Challenges in evaluating and monitoring food supplements persist, owing to the use of multiple ingredients and changes in composition over time.

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20 See paragraph 19.

32. Since the new legislation governing food intended for special purposes no longer includes sports food (protein and / or carbohydrate powders, exercise drinks, etc.), some food business operators tend to place these products on the market as food supplements. This practice could raise public health concerns. At the same time, some Member States reject this practice on the grounds that these products do not meet the definition of food supplement in terms of their macronutrients and energy content.

33. Currently, Union law[21] does not specifically address the placing on the market of food supplements for infants and young children (ages 0-3). By definition[22], food supplements are meant to supplement a normal diet (for anyone 3 years of age and older). Equally, it is clear that the 0-3 age group has specific nutritional requirements that are different from those in a normal diet: this raises the question of whether it is even appropriate to allow the existence of food supplements for this particularly vulnerable age group.

PROPOSED SOLUTIONS

34. Given the above, several specific requirements were identified as requiring priority attention:

a) Marketing procedures (legal framework)

– put in place harmonised national notification procedures and requirements in the context of market placement following an application by a food business operator. Such procedures and requirements should be based on sufficient data allowing for the risk assessment of food supplements, in accordance with the established harmonised criteria (legislative initiative required).

– provide for an optional centralised notification procedure and a single register (European portal). Registered food supplements could be placed anywhere on the Union market, without any further "mutual recognition" request (legislative initiative required).

[21] Directive 2002/46/EC, Regulation (EC) No 1333/2008 on food additives or Delegated Regulation (EU) 2016/127 applicable to infant formulas and follow-on formulas)

[22] Directive 2002/46/EC: "food supplements' means foodstuffs the purpose of which is to supplement the normal diet (…)"

– revise and update the definition of "food supplement" and the scope of the legislation, accordingly (legislative initiative required).

– establish a Union list of authorised ingredients and conditions of use, including quantitative limits, where applicable.

– require Member States to systematically check requests for mutual recognition, to detect fraudulent requests for products that are not legally marketed in another Member State (the “original” market).

– develop a centralised database making available information on national notifications and product specifications.

b) Safety and Public Health Impact

– make data collected by national authorities (including scientific data and the monitoring of undesirable effects) available to all other national competent authorities to allow appropriate evaluation of food supplements. A working group led by EFSA could centralise, share information between Member States and propose assessment methodologies and procedures.

– establish a list of authorised claims for plants and their preparations (botanicals) to ensure a higher level of public health protection and certainty for food business operators.

– exclude food supplements intended for infants and young children from the scope of Union legislation governing food supplements and subject such products to Regulation (EU) No 609/2013[23]**.** Alternatively, these products should be governed by specific criteria applicable to the specific 0-3 age group under food supplements’ legislation.

– establish an EU Nutrivigilance System to monitor consumption patterns and register undesirable effects/ adverse reactions to food supplements.

[23] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control or under Directive 2002/46/EC (OJ L 181, 29.06.2013, p.35).

– increase the level of awareness among healthcare professionals so as to help them assess possible adverse reactions to food supplements and promote increased awareness among consumers of the importance of reporting adverse reactions.

– ensure that the EFSA and the Commission, in close cooperation with Member States, continue/complete safety assessments on plants and other substances and to investigate associated medicinal and health claims, in particular in relation to botanicals, in order to harmonise their use in food supplements.

– provide consumers with better communication on the composition of, quality of and the risks associated with the consumption of food supplements, particularly in relation to supplements purchased on the internet and/or in third countries.

– promote education programmes and health campaigns aimed at reducing the consumption of food supplements or, at least, at proposing informed choices.

– revise and update the definition of food supplement in order to harmonise product characteristics, without jeopardising innovation.

– improve EU coordinated control plans, particularly in relation to 'borderline products'.

– foresee legislative quality requirements applicable to purity criteria and the bioavailability of the nutrient sources.

– define at Union level the performance criteria for the analytical methods used in controls and guidance for interpretation results.

– relaunch the Commission's Working Group on food supplements, with a view to establishing guidance for a harmonised approach. The aim would be to provide support to the competent authorities responsible for enforcement, to establish guidelines for 'borderline products' and to achieve a better exchange of information between sectors (e.g. food, medicines) at Union level.

– establish a harmonised list of plants and other substances with physiological effects used in food supplements[24] . This would increase legal certainty for food business operators and authorities.

CONCLUSIONS

35. The current lack of harmonisation on the general legal framework applicable to food supplements can give rise to differences in its implementation in each of the Member States. This situation can compromise the protection of public health and consumer safety. It can also undermine fair competition and compromise the smooth functioning of the internal market.

36. The Union's legislative framework needs to be adapted to scientific and technological progress in the creation of innovative formulas and new marketing techniques. This can increase consumer protection and provide authorities with sufficient and appropriate control tools.

37. The implementation of Union legislation should ensure that the safety of food supplements, including its ingredients and information provided for consumers, is science-based.

38. It is thus widely recognised that the way forward should envisage, first and foremost, a revision of the current legislation. This should include clear and enforceable legal provisions facilitating the implementation of common requirements and the harmonisation of market conditions throughout the Union.

24 The results of the work carried out by MS Food Safety Agencies, notably in creating a negative list of botanical substances in food supplements should constitute a good working basis.

39. In this regard, a large majority of the Member States would welcome a study by the Commission on the areas which need legal clarity. This should take into account the experience acquired since the implementation of the Directive, especially in terms of the definition, classification, scope (notably for infants and young children), market notifications procedures, labelling and surveillance of food supplements.

40. Furthermore, it is generally agreed that an impact assessment to evaluate the legal framework applicable to food supplements and the market situation would help identify further steps and the best way(s) forward.