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ROADMAP TO REVIEW THE NUTRITION AND HEALTH CLAIMS REGULATION 1924/2006

Food Supplements Europe Comments

1. Food Supplements Europe

Food Supplements Europe represents the interests of the EU food supplement industry as a trusted partner for solutions on regulatory, scientific, and technical matters based on knowledge, dialogue and transparency. Our membership includes national associations and companies, committed to ensuring that future EU legislation and policy reflects the important role that this sector plays in the health of consumers.

Food Supplements Europe represents companies manufacturing botanical preparations and food supplements. This comprises both large and small and medium sized enterprises that are directly primary affected of the activities covered by this roadmap and would like to share its comments.

Our members have very welcomed the decision that the Commission took in 2010 to put the assessments of botanicals on hold. We have worked constructively with the Commission and Member States since then to find solutions and aim to continue this work. Given our in-depth knowledge of the sector, we would appreciate if we would be able to provide our input at the various stages of the process, which we believe will be useful when defining the aims, objectives and briefings of the consultants that will be carrying out the work.

2. Nutrient profiles

Food supplements should be exempted from nutrient profiles

As Food supplements are concentrated sources of nutrients and other substances that contribute insignificantly to the amounts of energy, fats, sugars and salt in the diet, we believe that nutrient profiles should not apply to food supplements and that the questions related to that part of the REFIT exercise are not relevant for our products.

Therefore, our comments to the EU road map on the Nutrition and Health Claims Regulation is limited to the aspect that covers botanicals.

3. Plants and their preparations (further referred to as Botanicals)

The Nutrition and Health Claims Regulation is not the right instrument for harmonisation all aspects of botanicals

As a general comment, we strongly question if the Nutrition and Health Claims Regulation is the right instrument for the harmonization of botanicals in the EU. The European Commission has already published in 2013 a

discussion paper for the Member States proposing several options. Only option 1 dealt with covering the claims aspect of botanicals under the Nutrition and Health Claims Regulation. The paper noted however rightfully that it is expected that most (if not all) of the health claims on botanicals that were put 'on hold' would obtain a negative assessment and that therefore they would ultimately be prohibited while in parallel, therapeutic indications on the basis of 'traditional use' for the same botanical ingredients would continue to be given under the THMPs Directive.

Option 2 proposed to explore the opportunity of changes to the existing legal framework applying to botanicals, which could be extended to further aspects, including quality and safety. This option proposes a more comprehensive approach than addressing only claims. Although the responses of the specific Member States have not been reported, the Commission has indicated at several occasions that most Member States would accept option 2 provided safety and quality are also addressed. In this respect, addressing the specificities of botanicals under a REFIT of the Nutrition and Health Claims Regulation is a step back. If this is nevertheless pursued, the questions already put forward in the 2013 discussion paper should also be part of this consultation.

The issues relating to botanicals cannot be addressed in isolation

In addition, we strongly doubt if addressing the complex aspects of botanicals under REFIT of the Nutrition and Health Claims Regulation in isolation is appropriate, in particular since the other provisions of that legislation are not open for consideration and the general regulatory framework already applicable to botanicals is also not taken into consideration.

If a REFIT of the Nutrition and Health Claims Regulation is undertaken, it should cover all aspects of that legislation to address if its objectives have been met and at what cost. Since the botanicals issue under consideration is very complex and intrinsically linked to other aspects of Regulation 1924/2006, in our eyes it is not coherent that these other aspects are not open for consideration.

Addressing the effectiveness, efficiency, coherency, relevance and EU added value of those parts that have not been implemented yet can only be done on theoretic assumptions. We believe that in this context a number of questions are put in a way that they lead to obvious answers and should be rephrased. We have included suggestions in detailed comments below.

Botanical food supplements are subject to the whole food law framework, with specific rules on additives, contaminants, etc. However, specific provisions only exist at national level, with detailed national laws in a number of Member States. This is part of the current regulatory framework and should also be covered. Addressing only the EU legislation is bound to give a biased picture or reality.

Barriers to trade between the Member States should be considered

The area of botanical food supplements is not harmonized. While these products are regulated under food law and need to be in conformity with the general principles of food law, the requirements of the Food Supplements Directive 2002/46 and provisions already harmonized (such as additives, contaminants, etc), specific legislation covering composition exists at national level. Botanical food supplements therefore should be traded in accordance with the rules governing the internal market and benefit from the so-called principle of mutual recognition. This is in reality mostly not the case, with Member States refusing imports of products lawfully marketed as food supplements in other Member States. The provisions of Regulation 764/2008 are often not respected and justification for refusing the acceptance of products not provided. In other cases products are refused because the botanical is reserved for use in medicinal products only. Also in such cases justification for considering the botanical as medicinal for individual products is not provided despite the Court of Justice of the EU having extensive case law to that effect.

Addressing the legal framework for botanicals in the EU will need to consider these aspects, which is not possible under the umbrella of the Nutrition and Health Claims Regulation. The recently review of the Mutual Recognition Regulation 674/2008 in the framework of the single market initiative announced on 28 October 2015, should be an integral part of the consultation on the future legal framework for botanicals.

Food Supplements Europe as directly affected sector requests to be actively involved in this consultation

Food Supplements Europe is the primary affected stakeholder in this debate, with any decision affecting our companies and people. We would request that comments received from stakeholders that are not directly impacted or not part of the sector are put into perspective. Because of our in-depth knowledge of the sector we would also appreciate if we could be involved in the briefing of the consultants that will be contracted to carry out the subsequent consultations, as has been the case with other sectors in other consultations.

4. Information about the sector

Food Supplements Europe

Food Supplements Europe is the European Association of the food supplements sector. Created in 2013, it gathers European national food supplements associations, leading companies in the area of food supplements and functional ingredients and the former members of the European Botanical Forum.

Food Supplements Europe therefore represents the companies, both large and small that will be directly affected by any decision that the European

Commission will take on future regulations on botanicals.

We would request that we are involved in all discussions on this issue. We would like to note that Food Supplements Europe is not a member of the Advisory Group on the Food Chains and Animal and Plant Health because Food Supplements Europe did not formally exist when the last composition was appointed. We would strongly request the European Commission opens up its consultative platforms with stakeholders to all stakeholders in an equal capacity.

The botanicals market

Any decision on further harmonization of botanicals in food supplements will affect a well-established market and will have consequences. We would strongly support that any measure is taken solely on the basis of a thorough impact assessment and not only on political considerations. The importance of the botanicals market in the European Union is high:

Botanicals are widely used in foods

Botanicals are used in various product categories, including food, tea, food supplements, traditional medicines, cosmetics, etc. They are also a major source of food ingredients, either isolated or extracted, such as bioactive substances (e.g. lutein, lycopene, flavanols, isoflavones, etc) and compounds with flavouring or coloring properties. While the issue under consideration is limited to the use of botanicals for health purposes, the Nutrition and Health Claims Regulation is likely not to be able to discriminate and any decision on botanicals may therefore have implications far outside the food supplements sector.

The botanical food supplements market is worth over 4 Billion Euros

The botanical food supplements market is estimate to be over 4 Billion Euro (Euromonitor 2015 and own data). The market is again growing since 2013 and is expected to reach 5 Billion Euros in 2020.

The market is highly innovative with thousands of new products every year

The market is highly dynamic and innovative. In a small country like Belgium, over 3,000 new products are notified every year. In Italy, the number of new products notified is over 4,500 per year. This is at least partly thanks to clear and detailed legislation covering these products in these countries. In contrast, the total number of traditional herbal medicinal product registrations since 2004 is 1438 (EMA 2015).

Over 80% of companies are SMEs and over 100,000 direct jobs are affected

The employment in the sector has been estimated to be over 100,000 people in the supply chain (EBF, 2013). Herb growers account for over 21,000 jobs (Europam 2005), while it is estimated that 40-50,000 people are directly involved in manufacturing of products and another 75-100,000 people in sales and distribution.

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Botanical food supplements are sold through all distribution channels

Botanical food supplements represent a substantial part of the business of: pharmacies (over 120,000 pharmacies EU-wide) and health shops and drug stores (over 50,000 outlets EU-wide). They are sold also in groceries and supermarkets. About 400 Million Euros is covered by direct sales, involving over 800,000 direct sellers.

The impact of the Nutrition and Health Claims Regulation on the sector could have been dramatic

Because of the lack of consideration of the specificities of botanicals, the approach adopted by EFSA is likely to result in the rejection of all claims for botanicals. Had the European Commission not taken the decision to put the assessments of these claims on hold, the consequences would have been disastrous, as an independent impact assessment commissioned by the sector has shown (Brooks 2013, attached):

- Considerable economic impact by loss of profitability and competitiveness: loss of sales of 25%
- Increased costs for clinical trials (4-500,000 € / product)
- Loss of employment: 30-50% of employment threatened

How we see the future

We do not believe that regulating botanicals under the Nutrition and Health Claims Regulation is possible. Botanicals used in food supplements should have their own framework, addressing benefit, safety and quality, based on what has already been accomplished at national level in Member States with vast experience and detailed legislation in place for decades.

Botanicals and botanical extracts are not chemicals but products with a long history of use and experience. They are part of the cultural heritages of many Member States. Harmonisation of these various traditions is difficult, but feasible when based on national experience.

Many aspects of botanicals are already covered by the EU harmonized food law framework (such as additives, contaminants, hygiene, …). This should remain and in addition further aspects should be considered for harmonization in the future. Food Supplements Europe has developed tools for its members to help them understand and apply this legal framework, e.g. quality guide for botanicals and botanical preparations.

Food Supplements Europe sees the following four elements as appropriate to complement this EU level framework:

1. A positive list of botanicals including claims outlining their benefit based on tradition of use and conditions of use to ensure their safe use. This can be based on national experience (e.g. the common list established by Belgium, France and Italy, with additional work to identify the traditional benefits of the plants included).

2. An effective notification system enabling Member States to monitor the products on their market and identify priorities for control. Some Member States have very efficient systems in place that could serve as example.
3. Addressing quality by applying appropriate quality requirements (such as included in our quality guide for botanicals and botanical preparations) and organising effective control.
4. Setting up a system of nutrivigilence to monitor the use of botanicals in the market. Also here, certain Member States already have such systems in place.

It is clear that these elements can only be part of a comprehensive framework and cannot be incorporated in a limited legislation such as the Nutrition and Health Claims Regulation.

5. Comments on the roadmap

It is our view that many questions included in the roadmap cannot be answered in an objective manner because the application of the Nutrition and Health Claims Regulation has stopped and not proceeded. Logically therefore, with regard to botanicals the Nutrition and Health Claims Regulation it is difficult to say that and to which extent this legislation has been effective, efficient, or has had added value. The issue is far more complex and should best be addressed outside of the Nutrition and Health Claims Regulation given the specificities of botanicals that are not shared with other food components

Also, botanicals are not covered by a specific harmonised law at EU level, but extensive legislation is in place at national level in many Member States. These national aspects are not covered in this REFIT exercise. The outcome is therefore likely not to represent the whole picture.

Effectiveness

Q. *What progress has been made over time towards achieving the objectives of the legislative framework introduced by Regulation (EC) No 1924/2006? Is this progress in line with the initial expectations?*

The answer to this question cannot be answered for botanicals, as the process has been put on hold. However, we agree this is a very pertinent question relating to the other provisions of the Nutrition and Health Claims Regulation.

Q. *Did the absence of a decision on the authorisation or rejection of health claims on plants and their preparations used in foods prevent the realisation of the objectives of the Regulation, and if so how?*

This question can only be answered in the context of the Nutrition and Health Claims Regulation, and thus can only be “yes”, as the assessments have been put on hold and have not proceeded and

therefore the objectives of the Regulation have not been met. Still, the decision by the European Commission to put the assessments of botanicals on hold was very appropriate (and even found justified by the Court of Justice of the EU (Case T-296/12). The matter is therefore far more complex and should be addressed outside the Nutrition and Health Claims Regulation. If maintained, this question should be rephrased as: "*Would decisions on the authorisation or rejection of health claims on plants and their preparations used in foods have met the objectives of the Regulation, and if so how?*"

Q. *What are the objectives that are not met and to what extent?*

Also this question cannot be answered in an objective way as no objectives could have been met given the assessments have been put on hold. This question therefore does not make sense and should be removed.

Q. *To what extent the legislative framework applicable to plants and their preparations used in foods has allowed achieving its objectives with respect to placing of safe food on the EU market and facilitating free movement of goods?*

This question is not sufficiently precise. It seems to refer to all legislation and not only to the Nutrition and Health Claims Regulation, so its scope would need to be clarified. In addition, the objectives of the Nutrition and Health Claims Regulation do not include safety and only addresses the internal market in terms of the use of nutrition and health claims. It should also be noted that although specific aspects of botanicals are not subject of harmonized EU legislation, botanicals are subject to the whole food law framework, with many aspect that have been harmonised (e.g. additives, contaminants, etc). In addition, very specific national legislation exists on botanical food supplements covering safety and quality aspects. It should therefore be specified that the 'legislative framework' referred to above covers both EU and national legislation.

Efficiency

Q. *What are the costs and benefits (monetary and non-monetary) associated with the absence of a final decision on the authorisation of health claims on plants and their preparations used in foods in the context of the application of Regulation (EC) No 1924/2006?*

The way this question is formulated addresses only one element: Costs of not taking a decision. What is not addressed if what the costs would have been if a decision had been taken. Both elements need to be considered in the balance to avoid that costs incurred outweigh costs avoided, the latter not being addressed. We would propose this question to be rephrased as follows: "*What are the costs and benefits (monetary and non-monetary) associated with the absence of a final*

decision on the authorisation of health claims on plants and their preparations used in foods in the context of the application of Regulation (EC) No 1924/2006 or in case all claims for such products would have been rejected?"

Q. *What is the specific cost impact of authorisation procedures required for health claims on micro-, small and medium sized enterprises?*

This is a pertinent question that is not only relevant for micro-, small and medium sized enterprises. It is also not specific for botanicals but of a general nature. We would therefore propose that this question is rephrased: "*What is the specific cost impact of authorisation procedures required for health claims, in particular on micro-, small and medium sized enterprises?*"

Q. *What are the alternatives, to the current provisions for regulating health claims on plants and their preparations used in foods, which could achieve similar objectives to the objectives of the Regulation, but with less burdensome requirements?*

This is a pertinent question. However, it only covers nutrition and health claims and not the other aspects that are relevant for dealing with botanicals.

Q *What are the costs and benefits of the legislative framework applicable to plants and their preparations used in foods?*

This question is not sufficiently precise. It seems to refer to all legislation and not only to the Nutrition and Health Claims Regulation, so its scope would need to be clarified. It should also be noted that although specific aspects of botanicals are not subject of harmonized EU legislation, botanicals are subject to the whole food law framework, with many aspect that have been harmonised (e.g. additives, contaminants, etc). In addition, very specific national legislation exists on botanical food supplements covering safety and quality aspects. It should therefore be specified that the 'legislative framework' referred to above covers both EU and national legislation. Part of the costs will also be related to the lack of harmonization and the effect of different national attitudes on the internal market. These aspects should also be covered to be able to assess the whole picture.

Relevance

Q. *To what extent is the legislative framework introduced by Regulation (EC) No 1924/2006 still relevant to address current needs and trends in relation to health claims made on plants and their preparations used in foods? Are there any other objectives that should be considered?*

This is a pertinent question.

Q. *To what extent is the legislative framework applicable to plants and their preparations used in foods still relevant to deal with issues related to the evolution of the market with regard to plants and their preparations used in foods?*

This question is not sufficiently precise. It seems to refer to all legislation and not only to the Nutrition and Health Claims Regulation, so its scope would need to be clarified. It also indicates that there is a legal framework in place today and questions if it is 'still' relevant. As a number of Member States have very specific, but differing legislation to deal with botanicals in food, the question should be better defined to ensure comparability of answers depending on the local situation.

Coherence

Q. *To what extent are the requirements set out in Regulation (EC) No 1924/2006 coherent with EU legislation applicable to plants and their preparations, including the part of the legislation on medicines for human use dealing with traditional herbal medicinal products?*

This is a pertinent question.

Q. *How and to what extent does the regulatory framework for the use of nutrition and health claims affect the trade of foods bearing claims?*

This is a general question that covers a broader scope than only claims for botanicals. It is a pertinent question addressing one of the objectives of the Nutrition and Health Claims Regulation.

Q. *How coherent is it to have a positive list at EU level of permitted health claims for plants and their preparations while there is no positive list at EU level of permitted plants and plant preparations for use in food?*

This is a pertinent question and not only for botanicals, as experience with other substances has shown. It should be noted however that reference to a positive list of permitted plants and plant preparations at EU level refers to a specific risk management measure. It would be better to rephrase the question: "*How coherent is it to have a positive list at EU level of permitted health claims for plants and their preparations while the there is no harmonisation at EU level of the use of plants and plant preparations in food?"*

In addition, the coherence of measures relating to safety and quality with the already applicable EU legal framework and with national legislation needs to be addressed. In particular the coherency with the Novel Foods legislation Regulation 258/97 and the probably soon adopted new Regulation on Novel Foods is of particular relevance, as the definition of novel food is changed and Member States have diverging interpretations as to what should be covered and what not in the area of botanical preparations. Also coherency with Article 8 of

Regulation 1925/2006 is of relevance as this procedure has already been applied for botanicals and botanical preparations.

EU added value

Q. *What are the merits and disadvantages in terms of the EU added value of the current governance of health claims on plants and their preparations used in foods?*

This is a pertinent question

Q. *What would be the merits and disadvantages in terms of the EU added value of a positive list of plants and their preparations for use in foods?*

This is explicitly referring to a specific risk management measure that could be the basis of future harmonization. There may be other measures also feasible. The question should therefore be extended to ask for any alternatives.

It is also noted that other ingredients in food supplements are in the same situation, meaning that claims are harmonized while the use of the compounds is not. This is one element that would fit in a general review of the Nutrition and Health Claims Regulation.

6. Comments on the REFIT exercise relating to the Nutrition and Health Claims Regulation

REFIT of Regulation 1924/2006 has limitation

REFIT envisages a revision of applicable legislation, to see if and to what extent that legislation is fit for purpose and in particular to assess the effectiveness, efficiency, relevance, coherency and EU added value of its provisions. The two elements that are subject of this revision are precisely the two elements that have not been implemented. It is therefore impossible to assess if these provisions have been effective, efficient, relevant, coherent and have had added value, unless on the basis of purely theoretic assumptions.

In addition, this REFIT exercise deals with the nutrition and health claims part of botanicals, while many other aspects need to be considered. This is impossible under this legislation given its scope. A future regulatory framework for botanicals needs an assessment of its own, in which the specificities of botanicals can be fully addressed, while the principles of the Nutrition and Health Claims Regulation apply to all other foods for some of which additional legislation is already in place. We therefore wonder how tradition of use, quality and safety of botanicals can be addressed appropriately in such context.

Finally, the specificities of botanicals and the scope of the discussion (tradition of use, quality and safety) would require specific provisions or exemptions to be included in the Nutrition and Health Claims Regulation for

this product category that may also be relevant or be not relevant at all for other groups of food ingredients, given their nature and extent of already harmonized specific provisions.

Not all objectives of the Nutrition and Health Claims Regulation are being addressed, not even with regard to botanicals

The various objectives of the Nutrition and Health Claims Regulation are mentioned in the roadmap:

1. To ensure a high level of consumer protection and to facilitate healthier food choices;
2. To improve the free movement of foods with nutrition and health claims within the internal market;
3. To increase legal certainty for economic operators;
4. To ensure fair competition when nutrition and health claims are being used;
5. To promote innovation in the area of foods.

We note that in the roadmap only the aspects relating to free movement of foods and fair competition are mentioned explicitly but not the other aspects. We consider that a number of specific questions would enhance the quality of the input that will be received. Examples of such questions are listed in the annex to these comments.

If REFIT of the Nutrition and Health Claims Regulation is undertaken, all provisions of that legislation should be part of the revision.

In addition, the Nutrition and Health Claims Regulation has been particularly difficult to implement and some aspects clearly have not been implemented as they were intended. An extensive overview of the impact of this legislation and the extent to which it has been capable of meeting its objectives has been undertaken and published by the European Responsible Nutrition Alliance in 2011. A copy of this report is attached for information.

It clearly shows that a full fitness check of this legislation would certainly have added value, as this legislation has been claimed not to meet its objectives and has resulted in considerable economic consequences for certain sectors. This full assessment would also satisfy that evaluation that is foreseen by Article 27 of the Regulation.

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Annex. Suggested additional questions for the REFIT assessment of the Nutrition and Health Claims Regulation

Also, the questions already put into the 2013 discussion paper by the European Commission on the various options, should be part of the consultation. These include:

1. Do you consider that the current different legal treatment of botanicals in foods and medicines legislation with respect to health claims / therapeutic indications is justified and should be maintained?

   If yes,

   a. Do you agree that the criteria and standards that have been applied to the scientific evaluation and subsequent decisions on the authorisation of all health claims should be applied in the same way to health claims for botanicals used in foods, including food supplements?

2. If you consider that the different treatment with respect of health claims I therapeutic indications for botanicals used in foods or medicinal products is not justified, would you agree that a specific legislation regarding the use of botanicals in foods, including food supplements, should be adopted?

   If yes,

   a. Should such legislation be confined only to the use and substantiation of health claims for botanicals?

   b. Should such legislation include other elements of harmonisation for the use of botanicals in foods, including food supplements? If so which other elements?

   If not, but you still consider that the different treatment with respect to health claims / therapeutic indications for botanicals used in foods or medicinal products is not justified,

   c. Do you have any suggestion as to how this different treatment and its consequences can be rectified with an action that would be equally legally robust?

3. Can you provide any quantitative and qualitative data on the botanicals sector in your territory that you consider relevant in the context of this reflection?

In addition, questions should be more direct and targeted at the companies affected by the legislation. We welcome the focus on SMEs but the broad questions mentioned in the road map are not adapted to companies. The following questions should be added to the consultation:

1. To what extent have claims for botanicals been regulated prior to the NHCR? What criteria have been used to substantiate claims before the NHCR?

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2. What are the main difficulties encountered with the application of the NHCR?
3. What has been the main impact of the NHCR on your products?
4. What will be the likely consequences of the application of the NHCR in future?
5. To what extent has the NHCR contributed to:
    - Consumer protection and trust?
    - Free movement of products/internal market?
    - Legal certainty?
    - Fair competition?
    - Promotion of innovation?
6. To what extent has the NHCR been adequate to address:
    - Innovation potential of the food chain?
    - Avoidance of misleading claims for consumers?
    - Consumption of healthier food or diet in the population?
    - Competitiveness of the food industry?
    - Globalisation of trade and e-commerce?
    - Safety of the products concerned
    - Quality of the products concerned
    - Others?
7. To what extent have the provisions of the NHCR been relevant to meet the various objectives?
    - Definitions?
    - General principles?
    - Procedures?
    - Data protection?
    - Others?
8. What aspects have not been (adequately) addressed by the NHCR?
9. To what extent has the NHCR led to reduced or increased administrative burden?
10. What have been the costs for your company for implementing the NHCR and in particular:
    - Costs for product label changes
    - Costs for product reformulation
    - Costs of research and studies
    - Costs of procedures
    - Costs of regulatory support
    - Other costs
11. Have the costs outweigh the benefit?
12. What sectors have been impacted the most?

13. To what extent have differences between Member States appeared, relating to:
    - Interpretation of provisions?
    - Ease of putting products on the market?
    - Application of the procedures?
    - Degree and effectiveness of enforcement?
    - Others
14. To what extent have the different procedures been adequate and effective in relation to?
    - Scope
    - Timing
    - Decision making
    - Other
15. Has the NHCR helped
    - Facilitate access to the market in the EU?
    - Facilitate export?
16. What have been the overall benefits of this legislation?
17. Which benefits have not been achieved? What have been the major restraints for achieving the benefits?

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