Partners in gezondheidsproducten

Position paper on other substances

NPN

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Executive summary

In this paper the viewpoint is set out that the degree of harmonisation provided under existing EU food law and case-law is sufficient to regulate free movement throughout the European Union of 'other substances' legitimately marketed in any of the member states while on the other hand a high level of protection of human health is sufficiently ensured.

Currently, substances other than the forms of vitamins and minerals listed in Annexes of the FSD and FFR, used in food supplements and fortified foods ("other substances") are only partially harmonised. For the greater part, "other substances" are regulated under national provisions and with regard to their EU-wide availability fall within the scope of the principle of free movement of goods, as formulated in Art.28 of the EU Treaty. In principle, products, which are legally marketed in one European Union (EU) member state, have to be admitted in another EU member state on the basis of the Treaty.

General and principal position of NPN
1) All "other substances" forming part of the diet and/or used as ingredients of food supplements and/or fortified foods, have to be regarded as food. They have to comply with all applicable national and European food laws and therefore should be safe for consumption and of good quality.

2) In accordance with EU law and established case-law, the only criterion that shall be used in setting quantitative limitations for "other substances", shall be the criterion of safety.

3) So as to provide consumers in al member states access to the widest possible range of safe "other substances", the EU internal market should be open to these safe ingredients and free circulation of products containing them should be realised, by way of unconditional application of the principle of free movement.

NPN Positions concerning regulation of 'other substances'
Safety of food is accounted for in other European legislation as the general European food law (Regulation EC/178/2002) and the Novel food regulation (EC/258/97). Additionally, "other substances" with well identified safety concerns can be included in one of the Parts of Annex III of the Food fortification Regulation 1925/2006/EC. This system of negative/positive listing also applies to the use of "other substances" in food supplements. This ensures the safe use of other substances in the entire EU internal market. Therefore no specific safety requirements for 'other substances' should be put in place.

Given the fact that Regulation No 178/2002 effectively approximated the differences between national levels of protection of public health, it is unlikely that Member States could still take divergent safety measures with respect to "other substances", to a degree that different levels of protection would emerge and prevent, as a possible consequence, "other substances" from moving freely within the Community.

NPN takes the position that further harmonisation of "other substances" will not noticeably lead to a higher level of protection as that which is now sufficiently ensured under the current combination of harmonized and national rules. Harmonisation should acknowledge, support and positively effect existing safe and responsible market practices and thus enhance existing economies in Member States. Within the EU a sufficient level of harmonisation exists and further harmonisation could unduly affect the internal market.

Introduction

The aim of this position paper

In this paper the viewpoint is set out that the degree of harmonisation provided under existing EU food law and case-law is sufficient to regulate free movement throughout the European Union of 'other substances' legitimately marketed in any of the member states while on the other hand a high level of protection of human health is sufficiently ensured.

This position paper wants to provide clarity regarding the legal status of substances other than vitamins and minerals as ingredients of food supplements and fortified foods, and to formulate how, in the European Community, free movement, fair competition, innovation and the unhindered EU-wide access of consumers to safe foods containing "other substances" shall be best organized.

The regulation of these so called other substances to be used in food supplements, falls within the scope of the Food Supplement Directive (2002/46/EC; "FSD"), and is also regulated by the Food Fortification Regulation (Regulation EC/1925/2006; "FFR"). Claims used for these products are harmonised under the Nutrition and Health Claims regulation (EC/1924/2006; "NHCR")

NPN is the Dutch trade association for producers, wholesalers, importers and distributors of food ingredients, natural foods and health products. NPN dedicates itself to a market for safe health products of high quality, accompanied with adequate information and supports and promotes legislation that makes these products widely available.

Definition of "other substances"

In European food legislation, "other substances" are defined in the FSD as: "categories of substances with a nutritional or physiological effect, other than vitamins and minerals. Examples of "other substances" given in the preambles of the FSD and the FFR are: amino acids, essential fatty acids, fibre and various plants and herbal extracts. Herbal extracts are explicitly mentioned, but it is logical that also extracts of other food components can fall under the definition.

The problem

Currently, "other substances" used in food supplements and fortified foods are only partially harmonised. For the greater part, "other substances" are regulated under national provisions and with regard to their EU-wide availability fall within the scope of the principle of free movement of goods, as formulated in Art.28 of the EU Treaty. In principle, products, which are legally marketed in one European Union (EU) member state, have to be admitted in another EU member state on the basis of the Treaty. This principle of free movement is also known as "mutual recognition". Due to the insufficient application of the mutual recognition principle, free trade is hampered. Many member states violate the principle by refusing products on their markets which are legitimately marketed and freely available on other member states.

Providing clarity and guidance to Dutch business operators regarding their products' entitlement to international free movement in the entire EU Community (the "internal market") forms an important aspect in their European business development. It needs to be carefully evaluated whether further regulation of "other substances" by way of supra-national European harmonisation measures should replace the currently existing system of mutual recognition. European harmonisation of "other substances" will preempt and/or delimit national authorities' sovereign positions, powers and capacities to maintain and continue to organize, a tradition of fair and liberal national rules for market entry and giving consumers access to a rich choice of safe foodstuffs.

Harmonisation will set rules for market entry on an EU-wide basis and although that will provide clarity to all European business operators, it may also mean that some national products may lose their entitlement to free movement, not only in other member states *but also in the country of origin*. The consequence being that companies will lose business, not only in other member states but also in their own member state.

Mutual recognition to open up national markets
The proper application of the principle of mutual recognition is a tool to increase the free circulation of goods in the non-harmonised area within the European Community. Recently the European Commission published a new regulation to incorporate this principle into law and to stimulate the process. This regulation no 764/2008 '*laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC*' concentrates on the burden of proof for justifying the refusal of the market entry of a product, legally marketed in another member state, by setting out the procedural requirements for member states denying mutual recognition. It also aims at reducing the risk for companies to get no access to the market of the member state of destination, enhancing free circulation of goods within the European Community, and a better functioning internal market.

General and principal position of NPN
1) All "other substances" (see definition below), forming part of the diet and/or used as ingredients of food supplements and/or fortified foods, have to be regarded as foodstuffs or food ingredients. They have to comply with all applicable national and European food laws and therefore should be safe for consumption and of good quality.

2) In accordance with EU law and established case-law, the only criterion that shall be used in setting quantitative limitations for "other substances", shall be the criterion of safety.

3) So as to provide consumers in al member states access to the widest possible range of safe "other substances", the EU internal market should be open to these safe ingredients and free circulation of products containing them should be realised, by way of unconditional application of the principle of free movement.

NPN Positions concerning regulation of "other substances"

NPN Position on Preferred Legal framework
A good, workable, balanced and synergistic combination of national and European rules has been achieved in The Netherlands. The Dutch system provides consumers free access to a broad range of safe foodstuffs so as to enable them to achieve, maintain and optimize health. The Dutch combination of national and EU regulations blends a liberal approach to market entry with the strict safety requirements now embedded in EU food law. In practice this results in a sufficiently high degree of consumer protection.

Operating with respect to the combined regulations of this Dutch-European system, Dutch food business operators should find no prohibitions or impediments in bringing their legitimately marketed Dutch products to consumers in other member states.

As stressed by the European Court of Justice (ECJ) in various judgements, the dietary or nutritional need for an ingredient may not be a standard to set maxima or determine inclusion in or exclusion from positive or negative lists.

NPN Position on Safety Aspects
Safety of food is accounted for in other European legislation as the general European food law (Regulation EC/178/2002) and the Novel food regulation (EC/258/97). “Other substances” with well identified safety concerns can be included in one of the Parts of Annex III of the Food fortification Regulation 1925/2006/EC. This system of negative/positive listing also applies to the use of “other substances” in food supplements. This ensures the safe use of other substances in the entire EU internal market. Scientifically established unsafety can be addressed and regulated in these negative list. Therefore no specific safety requirements for ‘other substances’shoud be put in place.

Distinction between foods and medicines
Within the framework of EU medicine law, criteria are defined which make a product a medicine. However if a product is presented as a food, it operates in it’s own legal frameworks and has to comply with all legal requirements set for food in Food law, there are no borderline issues with medicines.

NPN position on further harmonisation
Because harmonisation is envisioned primarily as a legislative tool to stimulate competition and the internal market, NPN holds the opinion that harmonisation should acknowledge, support and positively effect existing safe and responsible market practices and thus enhance existing economies in Member States, in casu The Netherlands. With regards to “other substances”, all further harmonisation and approximation of laws of member states should be employed only to stimulate competition and/or when serious situations of unsafety not already addressed by national authorities and/or existing EU regulations require “harmonizing” interference by EU authorities.

Current EU framework for “other substances”

National markets of Member States
There is currently a wide discrepancy between the different EU member states regarding their national legal provisions for “other substances” used as ingredients for food supplements and fortified foods. This situation has historically grown as a result of national and local customs and regulatory traditions and tends to negatively influence the access to these goods for consumers in the non-liberal member states where market-entry of these goods is prohibited or restricted e.g. by pre-market authorisation procedures.

Differences in the national rules and regulations of the Member States create different conditions for market entry within the Community. However, the principle of Mutual Recognition grants all products, legitimately brought to national Eu member states markets, equal rights to free movement throughout the entire internal EU market. Once a product is legitimately introduced in one Member State, another Member State may only prohibit such a product on grounds in conformity with Art.30 of the Treaty, that is only, when the product is unsafe or restrictions are necessary for the protection of public health.

Harmonized rules will equalize conditions for market entry/participation in all Member States. Understandably, harmonization - the European-wide permission to market entry - can sometimes quite drastically change the national conditions for market participation. Harmonization is envisioned as a tool to stimulate competition and economy in the EU. In the process of harmonization, Member States show a tendency to protect their own internal markets and defend and maintain their own conditions.

Ideally the process of harmonization objectively looks at the category to be harmonized in an organized, systematic way on the basis of standards relevant and proportionate to the goal of the matter to be harmonized. Harmonization should equalise the divergent national situations

as existing in most countries of the EU, while respecting current safe and responsible markets and practices.

The European Commission (EC) is supposed to advise on the advisability of further regulation of these ingredients as formulated in article 4.8 of Directive 2002/46/EC "…*to report to the European Parliament and Council on the advisability of establishing specific rules on categories of nutrients, other than vitamins or minerals, with a nutritional of physiological effect*."

It seems logical that this expansion of the FSD will reflect the extensive provisions already given in Art.8 of the FFR to regulate "other ingredients". Given the fact that with regard to "other substances" the FFR governs their use in the manufacture of *all* foods (including their use in the manufacture of *food supplements*), the FSD would in fact require little or no expansion, as the FFR already regulates the procedure for placing "other substances" in Parts A (prohibited), B (allowed under specified conditions) and C (under scrutiny).

Regulation 178/2002/EC also applies in the sense that food supplements and fortified foods and the "other substances" therein contained fall within the scope of general food law. With regard to "other substances", NPN takes the position that, now that Regulation No 178/2002 has been in force for more than 6 years and because the Regulation expressly stipulates that both Community and national food laws must assure a high level of protection, there currently exists an appropriate and workable balance between Community food law and the remaining non-harmonized parts of the food laws of the Member States. Given the fact that Regulation No 178/2002 effectively approximated the differences between national levels of protection of public health, it is unlikely that Member States could still take divergent safety measures with respect to "other substances", to a degree that different levels of protection would emerge and prevent, as a possible consequence, "other substances" from moving freely within the Community. Even though the FSD and the FFR do not fully harmonize "other substances", NPN sees no need for the Community legislature to intervene by adopting measures in compliance with Article 95(3) of the European Treaty.

NPN holds the firm view that for 'other substances' within the EU a sufficient level of harmonisation exists. Further harmonisation will unduly affect the internal market and will not noticeably lead to a higher level of protection as that which is now sufficiently ensured under the current combination of harmonized and national rules. There exists a workable balance between harmonised rules and the principle of free movement, providing consumers access to a broad range of safe products while guaranteeing a high level of protection.

Sense of urgency

NPN requests the Dutch authorities and the EU Commission to take into account NPN's viewpoint that the degree of harmonisation provided under existing EU food law and case-law is sufficient to regulate free movement throughout the European Union of 'other substances' legitimately marketed in any of the member states, while on the other hand a high level of protection of human health is sufficiently ensured.