

Position Paper

# Solving the current different legal treatment of health claims and medical claims based on traditional use

NPN

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**Position Paper**

**15 June 2016**

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claims and medical claims based on traditional use**

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In this Position Paper, NPN provides the legal grounds for the following propositions:

1) legislative measures that regulate the market entry of foods/foodstuff and the market entry of health claims used in commercial speech must remain strictly separated.

2) the current “Article 8” procedure laid down in Regulation 1925/2006/EC and Commission Implementing Regulation 307/2012 is the least onerous and least restrictive harmonized measure required to sufficiently secure and procure public safety in the field of “other substances” in the European Union. There is no need to change this procedure.

3) the least onerous and least restrictive legislative measure to resolve the problems arising from the “different treatment” of traditional health claims and traditional therapeutic/medicinal claims should be found in the creation of:

- a separate Union Regulation that organizes the market entry of traditional health claims via a simplified procedure, in ways equivalent and similar to those which, in Article 16 of Directive 2001/83/EC, have regard specifically to information regarding traditional medicinal use, or

- an amendment of Regulation 1924/2006/EC that specifically addresses the market entry of traditional health claims via a simplified procedure, in ways equivalent and similar to those which, in Article 16 of Directive 2001/83/EC, have regard specifically to information regarding traditional medicinal use.

In the Annex to this Paper (page 51), NPN presents a *Simplified Procedure for the Application, Evaluation and Authorization of Health Claims based on Traditional Use* as the elaboration of its position that the least onerous and least restrictive legislative measure to resolve the problems arising from the “different treatment” of traditional health claims and traditional therapeutic/medicinal claims can be found in the creation of either a separate Union Regulation or an Amendment of Regulation 1924/2006/EC.

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### **The Roadmap**

In October of 2015, the European Commission came forward with an “EVALUATION AND FITNESS CHECK (FC) ROADMAP” entitled “Evaluation of a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of b) the general regulatory framework for their use in foods.”

In its introductory sections the Commission sets the stage for a Union Regulation that deals with what it defines as “[h]ealth claims on plants and their preparations,” so that, “in this context,” it will be able to “extend” its evaluation to “other regulatory aspects, such as safety requirements for the use of plants and their preparations in food.” According to the Commission, “the more general regulatory framework for the use of such substances [plants and their preparations] in foods ... is closely related to the use of health claims.”

To lend support to this opinion, the Commission redefines Regulation [1924/2006/EC] as a Union rule that was designed to somehow apply to “plants and their preparations,” in that the Regulation would “ensure that consumers are correctly informed on nutritional/health value of plants and their preparations contained in food and to allow them to make an informed choice on a healthy diet.”

The wording chosen by the Commission in the Roadmap’s introduction is not in alignment with the stated subject matter and scope of the Nutrition and Health Claims Regulation (NHCR). In Article 1 of the NHCR, it is clearly stated that:

- “1. This Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection.
2. This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.” (emphasis added)

Nothing in the NHCR suggests or implies that the Regulation would specifically cover health claims on plants and their preparations. Unfortunately, the FC Roadmap misinforms the readers concerning elementary aspects of the current legislative frameworks that deal, on the one hand, with health claims made in commercial communications, and, on the other hand, with the safety aspects of “other substances.” At the end of this Paper, on pages 39- 49, NPN presents a detailed textual analysis of the introductory sections of the FC.

### **NPN’s Propositions**

Before analyzing the FC Roadmap, NPN will trace the “roadmap” that led to the FC Roadmap. It will do so on the basis of 2 Explanatory Notes which it sent to the Commission to substantiate propositions made in letters sent on 11 November 2014 and on 13 April 2015. Thus, this Paper will shed light not only on the current FC Roadmap, but on the entire

roadmap, that began on 27 September 2010, when the Commission sent out a press release in which it announced its “progressive adoption of the list of permitted health claims.”<sup>(i)</sup> In 2012, the Commission sent a *Discussion Paper* to the Member States concerning “Health Claims on Botanicals used in Foods.” In this Paper, the Commission informed the MS’s of “the current different legal treatment of botanicals in foods and medicines legislation with respect to health claims / therapeutic indications.” In this context, it asked the MS’s whether this “different treatment” is or isn’t justified and should be maintained or rectified.

In 2014, NPN took the liberty of submitting views that might assist the Commission in finding a solution for the problem concerning the different treatment of information concerning traditional use in the adjoining markets of foods and medicines. In the aforementioned *Discussion Paper*, the Commission presented a non-exhaustive list of questions dealing with the issues caused by the “different treatment.” It was in the context of “Option 2,” that NPN respectfully submitted to the Commission the following propositions:

1) legislative measures that regulate the market entry of foods/foodstuff and the market entry of health claims used in commercial speech must remain strictly separated.

2) the current “Article 8” procedure laid down in Regulation 1925/2006/EC and Commission Implementing Regulation 307/2012 is the least onerous and least restrictive harmonized measure required to sufficiently secure and procure public safety in the field of “other substances” in the European Union. There is no need to change this procedure.

3) the least onerous and least restrictive legislative measure to resolve the problems arising from the “different treatment” of traditional health claims and traditional therapeutic/medicinal claims should be found in the creation of:

- a separate Union Regulation that organizes the market entry of traditional health claims via a simplified procedure, in ways equivalent and similar to those which, in Article 16 of Directive 2001/83/EC, have regard specifically to information regarding traditional medicinal use, or

- an amendment of Regulation 1924/2006/EC that specifically addresses the market entry of traditional health claims via a simplified procedure, in ways equivalent and similar to those which, in Article 16 of Directive 2001/83/EC, have regard specifically to information regarding traditional medicinal use.

### **Proportionality and burden**

In formulating its propositions, NPN took account of Article 5 of the Protocol on the Application of the Principles of Subsidiarity and Proportionality, which refers to Article 5 of the Treaty on European Union. There, it is stated *inter alia* that: “Draft legislative acts shall take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved.”

On many occasions, the European Court of Justice (ECJ) has held that the principle of proportionality requires that, for a legislative act to be proportionate, its objective - *in casu* the protection of consumers against misleading health claims - should not be achievable by less restrictive and/or less onerous means. <sup>(ii)</sup> In addition to this requirement, a legislative act must be proportionate to the seriousness of what it seeks to regulate. In this regard, the risk that consumers incur when being exposed to misleading health claims was qualified by the Court as “residual.” <sup>(iii)</sup>

It is against these backdrops of proportionality and residual risk that NPN proffers its propositions.

### **Regulating foods and health claims**

In general, NPN is of the opinion that legislative measures and regulatory frameworks that regulate the market entry of foods/foodstuff and the market entry of health claims used in commercial speech must remain strictly separated. This separation is in line with the existing policies consistently applied by the Union legislature in regulating food safety and health claims. Health claims are accompanied by claim-specific conditions of use. Practically all conditions of use concern ingredients (foodstuffs). According to NPN, a rejection of a claim does not and should not imply or produce a rejection (prohibition) of the accompanying foodstuff.

### **Market entry of “other” substances / safety and bioavailability**

With regard to regulating the market entry of foods/foodstuffs, NPN holds the view that (at least for vitamins, minerals and other physiologically active substances), in accordance with the 11<sup>th</sup> Recital provided in Directive 2002/46/EC, the only relevant criteria that should regulate market entry/exit of foods/foodstuffs are those relating to the safety and bioavailability of the substances in question. This view is in conformity with the Judgment made by the ECJ in the Joined Cases C-154/04 and C-155/04. <sup>(iv)</sup>

In line with the determinations made by the Court, NPN submits that the only criteria for regulating market entry/exit of foods and foodstuffs (ingredients) must be safety and bioavailability, to the exclusion of criteria of nutritional, physiological or medicinal function.

### **The Article 8 procedure and “botanicals”**

Arguably, Directive 2002/46/EC does not itself regulate market entry or “market exit” of physiologically active substances other than vitamins and minerals. Market entry/exit of these “other substances” is regulated under the adjoining Regulation 1925/2006/EC, which provides, under Article 8, a fully harmonized procedure for monitoring the safety of these “other” substances used as or in foods. In Commission Implementing Regulation 307/2012, <sup>(v)</sup> this procedure is explicated in greater detail.

NPN holds the view that this “Article 8” procedure is the least onerous and least restrictive harmonized measure required to achieve the objective of sufficiently securing and procuring public safety and the elimination of potentially harmful effects in the field of “other substances” in the European Union. With this harmonized procedure in place, any regulatory framework that would entail financial and administrative burdens in excess of those that may arise in the application of the “Article 8” procedure are unnecessarily restrictive and onerous.

In addition, the procedure provides a sufficient level of legal certainty and clarity required for such procedures.

The “Article 8” procedure procures the highest - precautionary - level of protection set in Article 7 of Regulation 178/2002/EC. <sup>(vi)</sup> In accordance with the precautionary principle, Article 8.2.c provides the option to place under scrutiny certain “other substances” (including “botanicals” <sup>(vii)</sup>) in case “the possibility of harmful effects on health is identified but scientific uncertainty persists.”

Since “botanicals” do not pose a greater potential risk than other “other substances,” NPN holds the view that the unconditional and loyal application of the “Article 8” procedure sufficiently and therefore proportionately safeguards the highest level of public health and public safety.

### **Traditional health claims**

In its *Discussion Paper*, the Commission formulated the “Roadmap” problem as “the current different legal treatment of botanicals in foods and medicines legislation with respect to health claims / therapeutic indications.” More precisely, the “different treatment” concerns the different treatment with respect to “traditional health claims / traditional medical claims.” NPN considers that the problems arising from the “different treatment” can and must only be solved in the least onerous and least restrictive way by precisely stating that the different treatment does not concern - botanical - products/ingredients, but traditional health claims used in commercial communication.

In the view of NPN, this different treatment, if upheld, would enforce a discriminatory constraint, by unconditionally prohibiting the use of truthful traditional health claims in the market for foods, while strictly reserving entitlement to practically unhindered market entry for *technically and legally equivalent* traditional medical claims in the adjacent and competing market for medicinal products. In this case, the competitive disadvantage would arise as a result of what the Commission has clearly qualified as the “different treatment” of traditional health claims in commercial speech.

### **The NHCR and the THMPD**

This “different treatment” came into being with the enactment of the NHCR, which explicitly and unconditionally denies food business operators entitlement to an unhindered market entry for traditional health claims that are technically and legally equivalent to traditional medicinal claims. The Commission formulated the problem as follows:

“As regards botanical substances, Member States and stakeholders expressed concerns as regards the difference in consideration given to the evidence based on ‘traditional use’ on the one hand under Regulation (EC) No 1924/2006 in relation to health claims and on the other hand under Directive 2001/83/EC [...] relating to medicinal products for human use concerning the use as traditional herbal medicinal products. Since the Commission considers that these concerns are relevant and require further reflection and consultation, a decision on claims relating to botanical substances should only be taken once those steps have been completed.” <sup>(viii)</sup>

In the *Discussion Paper*, the Commission also observes that “[b]ecause of the consideration given by EFSA to the evidence related to ‘traditional use’, no claim on botanicals based on this kind of evidence alone has obtained a positive assessment so far. On the contrary, [...], evidence of traditional use is given a different consideration in the case of THMPs [Traditional Herbal Medicinal Products].” The Commission concludes: “Considering that the different requirements in these two areas of EU law can lead to important differences in the level of information that is provided to consumers on products apparently similar, the Commission decided to launch a reflection on whether this difference should be maintained or not.”

### **Simplified procedure for traditional health claims**

In the context of this reflection, NPN holds the view that the least onerous and least restrictive legislative measure to resolve the problems arising from the “different treatment” of traditional health claims and traditional therapeutic/medicinal claims should be found in the creation of a separate Union Regulation or an amendment of the NHCR that organizes the market entry of traditional health claims via a simplified procedure, in ways equivalent and similar to those which, in Article 16 of Directive 2001/83/EC, have regard specifically to information regarding traditional medicinal use.

More in particular, with regard to establishing and procuring the truthfulness of health claims based on or referring to the traditional use of foods/foodstuffs, the legal criteria for truthfulness shall be equivalent to those laid down in Article 16 of Directive 2001/83/EC. In this regard, criteria of truthfulness (non-misleadingness) are met when bibliographical evidence describing the tradition and/or evidence written by recognized experts in the field of a particular tradition meet the standard of biological plausibility. The claim that a relationship exists between a putative cause and an effect on health or a disease-risk-factor must be consistent with existing biological and medical knowledge. See in this regard in the ANNEX to this Paper NPN’s *Simplified Procedure for the Application, Evaluation and Authorization of Health Claims based on Traditional Use*.

What matters here is that the evidence shall also be unbiased and based on adequate facts. This brings into play the integrity of the authors and publishers of the bibliographical data and/or of the experts who write reports or monographs about a certain tradition. An inquiry into the authors/experts’ beliefs, opinions and interests and possibly a “cross examination” may be relevant in case of doubt.

### **Another Letter and Additional Explanatory Note**

On 13 April 2015, NPN sent a second letter to the Commission, as a follow-up to its letter of 11 November 2014, the Explanatory Note that accompanied that letter and a meeting with representatives of the Commission that took place at 11 March 2015. The 2<sup>nd</sup> letter was accompanied by an Additional Explanatory Note, in which NPN explained that the problem of the differences between the legal treatment of traditional health claims and that of traditional therapeutic claims cannot be solved by a harmonizing measure that is predicated on obstacles to trade that are the result of heterogenous national regulations. The fields of the aforementioned claims have been fully harmonised, so that no obstacles to trade remain. When framed as a problem that concerns “botanicals,” the situation is equally well harmonised.

As the Commission observed in its *Discussion Paper*, any harmonized legal framework, if it is to be “legally robust,” is *per se* predicated on the existence of obstacles to the free circulation of goods (*in casu* foods or food supplements) and/or free circulation of health claims used in commercial communication. Indeed, in various Judgments, <sup>(ix)</sup> the European Court of Justice (ECJ) has held that the existence of obstacles to free movement form, in words used by the Commission in the *Discussion Paper*, a “pre-condition to justify harmonisation at EU level on grounds of proportionality and subsidiarity.” Absent such obstacles, the approximation of laws and/or regulations of the Member States under Article 114 TFEU to achieve the objectives laid down in Article 26 TFEU (a well functioning internal market) is unwarranted. <sup>(x)</sup>

### **Obstacles cannot arise in a fully harmonized regulatory environment**

The problem of the “different treatment” of traditional claims does not specifically concern or create obstacles to the free movement of food products and/or the health claims used in commercial communication concerning them. The NHCR prohibits the use of “traditional health claims” in commercial communication concerning food-products. Evidently, this is a pre-market-entry issue, which, in terms of the *ex ante* prohibition laid down in the NHCR, cannot possibly result in an obstacle to the free movement of such claims, because free movement of such claims is barred *ab initio*. Furthermore, the health claims that are authorized by the European Union, following a positive assessment by the European Food and Safety Authority, cannot produce an obstacle to free movement either, since their use is authorized throughout the EU.

No “heterogeneous development of national laws” could cause obstacles to the free movement of health claims, since the NHCR fully and exhaustively approximated all provisions laid down by law, regulation or administrative action in Member States concerning nutrition and health claims. In addition, since the NHCR does not concern or regulate foods, this Regulation cannot possibly lead to obstacles to their (the foods’) free movement.

In the market of medicinal products, the Medicines Directive (under Article 16) permits the use of “traditional therapeutic claims.” <sup>(xi)</sup> This Directive fully and exhaustively harmonized the conditions for market entry of such traditional claims and for the medicinal products carrying them. All the differences between laws, regulations or administrative provisions of Member States that could have led to obstacles to the free movement of traditional medicines bearing traditional therapeutic claims, were fully approximated by the enactment of Directive 2004/24/EC of 31 March 2004. In this approximated situation, obstacles to free movement no longer exist.

Both situations – traditional health claims and traditional therapeutic claims – are fully harmonised, be it that in the case of “traditional health claims,” the harmonised measures prohibit market entry of such claims, while in the case of “traditional therapeutic claims” the harmonised measures allow for market entry of such claims.

NPN stresses that in addition to European law, European case law has a strong and complementary harmonising effect in cases where European regulations might still give rise to different outcomes in the classification and evaluation of products and/or health claims.

More in particular, the Court has provided clear-cut criteria that must be applied when distinguishing food-products from medicinal products. In various Judgments regarding the subject at hand, the European Court of Justice's provided specific criteria which, when correctly applied, should make it possible for any competent "classifier" or evaluator to reach outcomes that should not have the effect of hindering or obstructing trade on the internal market.

### **The hypothetical "botanicals" market**

Still, in Section I of the *Discussion Paper*, entitled "Background: two legal regimes for botanicals," the Commission stated:

"The use of botanicals for health-related effects has a long tradition in Europe and the rest of the world. In the last decades, building on such tradition, products have developed on the market which contain such botanicals and which claim to have a variety of beneficial physiological effects. In the EU, such products have been marketed in various ways and legislation has developed in parallel, both at national and at EU level. Regulation of the market is, however, only partly harmonised."

The idea that "the market" for "botanicals" is "only partly harmonised" begs for a more precise analysis. The Commission defines this market as a market for "products which contain botanicals [used for health-related effects] and which claim to have a variety of beneficial physiological effects." On this market, according to the Commission, "products have been marketed in various ways," and to regulate this market, "legislation has developed in parallel, both at national and at EU level." NPN understands the Commission's words as meaning that legislation has developed in parallel with the various ways in which these products have been marketed. <sup>(xii)</sup>

This market, as defined by the Commission, is a hypothetical one. First of all, in the absence of a legal definition of the term "botanical," any definition of a market for "products containing 'botanicals'" is imprecise and will lead to further debate and confusion. In the context of this Paper, NPN will not try to solve this lack of proper definition, especially not because, in NPN's opinion, the problem of the "different treatment" does not concern "botanicals." However, NPN stresses that if the problem of the "different treatment" is going to be dealt with by a solution predicated on "botanicals," the term "botanical" must be precisely and unequivocally defined. Pending the formulation of such a legal definition, NPN uses the term "botanicals" under the proviso that without proper legal definition the term isn't meaningful.

Secondly, European measures aimed at regulating the internal market are primarily based on the ordering principle of products' Intended Normal Use (INU), as unambiguously clarified and presented by the manufacturer on a finished product's packaging and in the accompanying information. <sup>(xiii)</sup> This is how markets are legally defined and distinguished per the definitions provided for different categories of finished products, ready to be delivered to the ultimate consumer. EU policies do not seek to regulate the internal market *in vacuo*, but, primarily, in the interest of EU's consumers, on the actual market-floor where consumers are exposed to finished products and services marketed *in various ways* in accordance with the applicable regulations.

This is how “botanicals,” depending on the INU of the products containing them, may end up in *different* markets, *in casu* in the markets of medicinal products, food supplements, fortified foods, foods for special medical purposes, cosmetic products, condiments, etc. Evidently, the Commission is aware of this state of affairs. In Section I of the *Discussion Paper*, which concerns the Paper’s Background, the Commission notes that “products containing botanicals can, because of the physiological effects on the functions of the body, be considered and marketed either as medicinal products or as foods (in particular food supplements). Depending on how a product is marketed, different legal frameworks apply.” This state of affairs has been noted by the European Food Safety Authority (EFSA) as well, when it observed in its Discussion Paper on “botanicals” that “this heterogeneous group of commodities ..., mainly depending on their intended uses and presentations, fall under different Community regulatory frameworks.”<sup>(xiv)</sup>

In general, but especially when it comes to “botanicals” and other “physiologically active substances,” harmonisation is often misunderstood as meaning or implying the *positive* listing (authorisation) of permitted substances. Positive listing of authorized foodstuffs concerns their market entry. However, harmonisation can also take place by way of the *negative* listing of (unauthorised) substances. In this case, harmonisation takes place by harmonising heterogenous or heterogenously developing procedures applied by Member States to “negatively” regulate certain markets. Negative listing of foodstuffs concerns their market exit. When harmonisation is understood in this broader meaning, the various markets for products containing “botanicals” are sufficiently regulated by harmonised measures.

In light of this, and in addition to the fact that all food-products are regulated under EU’s General Food Law (Regulation 178/2002/EC), the use of “other substances” (including “botanicals”) as or in foods, is well harmonised. Market entry/exit of these “other substances” is well regulated under Regulation 1925/2006/EC, which provides, under Article 8, a *fully harmonised* procedure for monitoring the safety of these “other” substances used as or in foods. In Commission Implementing Regulation 307/2012,<sup>(xv)</sup> this procedure is explicated in greater detail.

The “Article 8” procedure comprehensively approximated the relevant procedures of the Member States which were or might have been obstructing the functioning of the internal market for food-products containing “other substances”, including “botanicals.” When the harmonised “Article 8” procedure is correctly and unconditionally applied, it is unlikely that outcomes would arise that would pose an obstacle to trade, especially not since the application of the harmonised procedure will eventually lead to an equally harmonised outcome, *in casu* to a measure that will have effect in the entire internal market, allowing, permitting under certain conditions or prohibiting the use of an “other substance” as or in foods. Since Regulation 1925/2006/EC and Commission Implementing Regulation 307/2012 also apply to “other substances” used in food supplements, said Regulations have a harmonising effect on food supplements and foods to which such “other substances” are added.

In the various markets for products containing “botanicals,” there are no remaining national measures laid down by law, regulation or administrative action, which could obstruct the free movement of said products and thus have a direct effect on the functioning of the internal

market. Even if, *arguendo*, a market for a certain category of products containing “botanicals” would not be fully harmonised, such a lacuna can only exist on the “food-side” of these markets. Such a lacuna no longer exists at the “medicines-side” of this market.

NPN reiterates that the problem in the market for “products which contain such botanicals and which claim to have a variety of beneficial physiological effects” does not really concern the market entry/exit of the “other – botanical – substances” embodied in said products. The problem, as stated by the Commission in the *Discussion Paper*, concerns “the current different legal treatment of botanicals in foods and medicines legislation with respect to health claims / therapeutic indications.” (emphasis added) Any further – in the view of NPN unnecessary – harmonisation of measures regulating the market entry/exit of “other substances” will not resolve that problem, especially not since the stated problem cannot arise in the fully harmonised part of the market that concerns health and therapeutic claims.

### **The three problems**

In Section II of the *Discussion Paper* entitled “Problem Description,” the Commission describes not one but three – altogether different – problems. In the first paragraph of this section, the Commission describes the problem of the “different treatment” as follows:

“Because of the consideration given by EFSA to the evidence related to 'traditional use', no claim on botanicals based on this kind of evidence alone has obtained a positive assessment so far. On the contrary, as explained in Section I.1, evidence of traditional use is given a different consideration in the case of THMPs.”

This is a problem indeed, but, this problem does not only concern traditional health claims accompanying products containing “botanicals.” The problem concerns all food-products that have been traditionally used for their health benefits. Moreover, this problem cannot lead to obstacles to the free movement of products containing “botanicals.” Therefore, this problem cannot and should not be solved by approximating laws of Member States, simply because no national laws remain in the fully harmonized regulatory frameworks dealing with (traditional) health and therapeutic claims.

Describing the second problem, the Commission observes that “[t]he same botanicals are sometimes used in both foods and medicines and consumers may sometimes struggle to perceive the difference between certain claims/indications of their physiological effect (e.g. “*relief of minor articular pain*” vs. “*maintenance of normal joints*”. “*Treatment of common cold*” vs. “*supports immune system*”).” Indeed, most consumers don’t understand the *difference* between a health claim (especially not when such a health claim concerns disease risk reduction) and a therapeutic claim, but for consumers the problem of not understanding the difference between such claims is irrelevant. Said difference is only relevant in the structure of the *acquis communautaire*, in which this difference distinguishes *de facto* and *de jure* the separate though adjoining markets of certain categories of food- and medicinal products. Consumers don’t “struggle” with this legal difference. Even at the level of the *average* consumer, (<sup>xvi</sup>) this problem does not exist and, even if it did, it cannot possibly lead to obstacles to free movement.

The third problem described by the Commission in Section II, concerns the Background of the *Discussion Paper*, presented in Section I, where the Commission notes that “products containing botanicals can, because of the physiological effects on the functions of the body, be considered and marketed either as medicinal products or as foods (in particular food supplements). Depending on how a product is marketed, different legal frameworks apply.”

On this note, the Commission elaborated in Section II: “Furthermore, since Member States have the right to classify, on a case-by-case basis, a product as food or as medicine, it is possible, as stated on several occasions by the Court of Justice of the EU, that differences exist between Member States in the classification of products. In other words, as EU law stands, it is possible that the same product is classified as a foodstuff in one Member State and as a medicinal product in another, if the national authority considers, taking account of all the characteristics of the product, that this complies with the definition of foodstuff or of medicinal product.”

### **Distinguishing food-products from medicines**

Indeed, determining the status of an individual product (food-product or medicinal product), falls under the discretion of the Member States. However, such determinations must be made by applying *harmonized* legal definitions. In this regard, NPN notes that all the relevant definitions are provided in fully harmonized European regulations, to the effect that no heterogenous definitions remain in the Member States. Although the jurisdictions are national, the “*ius*” that must be applied is one and the same in all jurisdictions.

The fact that the Member States have the right to classify products does not in itself produce differences, provided of course that the Member States correctly exercise this right and apply the relevant European rules and regulations. Irrespective of their position (Member State) all “classifiers” must apply the same legal criteria, that apply throughout the Union. These criteria exclude that different outcomes will be produced by different “classifiers” residing in different Member States. Should different outcomes arise, the “classifiers” either misinterpreted, misunderstood or failed to apply the criteria.

Still, the Commission does not exclude the possibility that different outcomes might be the result of lacunas in EU’s rules and regulations. It ends the abovementioned paragraph by stating: “In other words, as EU law stands, it is possible that the same product is classified as a foodstuff in one Member State and as a medicinal product in another, if the national authority considers, taking account of all the characteristics of the product, that this complies with the definition of foodstuff or of medicinal product.” (emphasis added) Here, the Commission contends that, as EU law stands, the fully approximated definitions of foodstuff and medicinal product would not be exclusionary, in other words, that the definitions would be deficient, overlap or contain lacunas.

In this regard, NPN holds the view that, as EU law and case law stand, it will rarely occur that the same finished product could be classified in one Member State as a food-product and in another Member State as a medicinal product. When correctly applied, hardly any heterogenous decisions will arise in different Member States. Should heterogenous decisions arise nevertheless, they are most likely the result of cultural differences. However, such cultural heterogeneity cannot and should not lead to more regulatory measures. According to

NPN, the *legal* definitions provided in EU's food law and the legal definitions provided in EU's Medicinal Products law are clear enough for any expert "classifier." The following examples highlight the fact that in recent years, the European legislature has provided more and more precise legal definitions to help clarify and prevent conflicts concerning the "borderline" that separates food-products from medicines.

In Recital 7 of Directive 2004/27/EC of 31 March 2004, which amended Directive 2001/83/EC on the Community code relating to medicinal products for human use, the European legislature explained:

*"(7) Particularly as a result of scientific and technical progress, the definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products for human use. In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, the definition of 'medicinal product' should be modified so as to avoid any doubt as to the applicable legislation when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products. This definition should specify the type of action that the medicinal product may exert on physiological functions. This enumeration of actions will also make it possible to cover medicinal products such as gene therapy, radiopharmaceutical products as well as certain medicinal products for topical use. Also, in view of the characteristics of pharmaceutical legislation, provision should be made for such legislation to apply. With the same objective of clarifying situations, where a given product comes under the definition of a medicinal product but could also fall within the definition of other regulated products, it is necessary, in case of doubt and in order to ensure legal certainty, to state explicitly which provisions have to be complied with. Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics, this Directive should not apply. It is also appropriate to improve the consistency of the terminology of pharmaceutical legislation."* (emphases added)

In Directive 2004/27/EC, the legislature upgraded the definitions of medicinal products as follows:

- "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*
- (b) 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."* (emphasis added)

By adding the words "... by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" to the old "by function" definition of medicinal product, <sup>(xvii)</sup> the EU legislature clarified that use of a product to restore, correct or modify physiological functions in itself no longer makes that product a medicinal product. The type of action must clearly and objectively be pharmacological, immunological or metabolic,

meaning that the action must be unambiguously qualified as capable of treating or preventing disease in human beings. By clarifying the “by function” definition, the legislature distinctly kept vitamins, minerals and other nutritionally or physiologically active substances <sup>(xviii)</sup> outside the scope and field of application of the European Medicines Directive. Since the enactment of the new “pharmacological” definition of medicine by function, the ECJ has constantly applied this criterion in adjudicating “food-or-medicine” cases.

In 2002, food supplements containing nutritionally or physiologically active substances were defined in Article 2.a of Directive 2002/46/EC 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.”

### **As EU case law stands**

Whatever the reason for potentially different outcomes of the classification process may be, it is precisely on such occasions, i.e. when different outcomes result in obstacles to the free movement of a finished product, that the Court of Justice of the EU is asked to give advice as to how the criteria laid down in EU’s rules and regulations must be understood and interpreted. With respect to the problem of distinguishing food-products from medicines, the Court has provided explicit criteria in several judgments. In the context of this Position Paper, NPN will not address the Court’s explications concerning the definition of a “medicine by presentation,” since we are concerned with the problems that arise when substances may be sold as ingredients in food-products as well as medicines. In resolving such problems, the definition of “medicine by function” is the relevant one.

NPN will provide a non-exhaustive yet detailed exposé of the ECJ’s “medicine by function” case law, to demonstrate that not only the EU’s regulations, but especially the Court’s case law provides extensive and sufficiently precise criteria to exclude that national authorities, acting under the supervision of the courts, may reach different outcomes when applying harmonised measures, definitions, criteria and/or procedures to resolve disputes. When correctly applied, the Court’s case law as it stands today seeks to prevent that heterogenous decisions will arise in different Member States.

In various Judgments, the European Court of Justice has constantly held that, in establishing the status of a product, no less than 6 criteria must be checked when evaluating the status - food or medicine - of a product:

“For the purposes of determining whether a product falls within the definition of a medicinal product by function within the meaning of Directive 2001/83, the national authorities, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular [1] its composition, [2] its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, [3] the manner in which it is used, [4] the extent of its distribution, [5] its familiarity to consumers and [6] the risks which its use may entail.” (numeration added) <sup>(xix)</sup>

Emphasis is often laid on the 2<sup>nd</sup> criterion, the pharmacological effect, as if this criterion, when fulfilled, would suffice for the national authorities and/or courts to conclusively affirm the medicinal status of a product. In Case C-140/07 (Hecht-Pharma / “Red Rice”), this issue was brought before the Court in the form of the following question:

“In its third question, [...], the national court seeks to ascertain whether, following the amendment of the definition of a medicinal product by Directive 2004/27, Article 1(2)(b) of Directive 2001/83 [definition of medicine by function] must be interpreted as meaning that the characteristics of the manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail, laid down in the case-law of the Court, are still relevant in determining whether that product comes within the definition of a medicinal product by function.”<sup>(xx)</sup>

In point 2 of its Judgment, the Court explicitly and unambiguously confirmed that in all cases all criteria must be checked:

“Article 1(2)(b) of Directive 2001/83, as amended by Directive 2004/27, must be interpreted as meaning that the characteristics of the manner in which a product is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail are still relevant to determining whether that product falls within the definition of a medicinal product by function.”

Should heterogenous decisions arise nevertheless, they are most likely the result of cultural differences and/or different consumer habits. With regard to the practice of using cultural differences to create barriers to the free movement of goods, NPN refers to the argument brought forward by the Commission in the context of the complaint it filed in 2000 at the European Court of Justice to stop the Republic of Austria from applying an NHCR-type “*Verbotssystem mit Erlaubnisvorbehalt*.”<sup>(xxi)</sup> In point 37 of its Complaint, the Commission stated:

“Finally, it should be pointed out with respect to the Federal Government’s argument regarding consumer perceptions in Austria that according to the Court, (\*) the right of a Member State may not serve to cement the given consumer habits in order to preserve an advantage for a domestic industry acquired in satisfying these habits, when other measures exist for protecting consumers from being misled. This finding by the ECJ can - against the opinion of the Federal Government in the response to the reasoned opinion - also be applied to this case. *With this case law, as well as in other Judgments, (\*\*) the Court emphasised that it is impermissible to base State regulations concerning health or consumer protection solely on circumstances prevailing in the respective Member State.*

\* Vgl. Rs. 178/84, Kommission/Deutschland, Slg. 1987, S.1227, Rz. 32.

\*\* Vgl. Rs. C-51/94, Kommission/Deutschland, Slg. 1995, S. 3599; Rs. C-290/90, Kommission/Deutschland, Slg. 1992, S. I-3317, Rz. 11 und Rs. C-210/96, Gut Springenheide, Slg. 1998, S. I-4657.”<sup>(xxiii)</sup> (emphasis added)

In addition to the Commission's argument and the relevant ECJ case law, NPN holds the view that any negative effects on the free movement of goods between Member States caused by decisions made on the basis of cultural and/or "consumer habits" heterogeneity must not be "harmonized away" by installing more Union measures. Under ECJ case law, such barriers are impermissible in the first place and, as such, their negative effects shall not serve as a convenient argument for more legislation.

### **Case-by-case, product-by-product**

Another important aspect of the Court's instructions, is that the evaluation of the 6 criteria must take place on a case-by-case basis, i.e. per each individual - industrially prepared – finished product. In this regard, the Court's case-law precludes the "food or medicine" type regulation (determination of status) of ("botanical") ingredients that are not embodied in a finished product.

Evidently, ("botanical") ingredients may be and are regulated, but such regulations exclusively concern their safety, not their function. In its Judgment made in the Joined Cases C-154/04 and C-155/04, <sup>(xxiii)</sup> the Court explicated in precise terms that the criteria for regulating ingredients (*in casu* forms of vitamins and minerals not embodied in products) are safety and bioavailability, to the exclusion of criteria of function, such as nutritional or medicinal needs. <sup>(xxiv)</sup> Apart from the fact that regulating ingredients on the basis of their nutritional (physiological) and/or medicinal (pharmacological) function is precluded by the Union's legislation and the Court's case law, an evaluation of the nature of the function (physiological or pharmacological) of an active ingredient can only have legal and classificatory consequences when performed in the context of evaluating an industrially prepared/processed finished product that embodies it, when that product is on the market and when it is readily available to consumers. The Court's 4<sup>th</sup> criterion ("the extent of its distribution) and the 5<sup>th</sup> criterion ("its familiarity to consumers") clearly concern ingredients embodied in finished products.

The Scope of the Medicines Directive is explicitly limited to finished products, defined in Article 2.1 as "products for human use intended to be placed on the market in Member States." Although both definitions of medicinal products concern substances, the limited Scope of the Directive excludes application of the Medicines Directive in the regulation of "substances" not yet incorporated in finished products. The Medicines Directive cannot cross the "product" borderline behind which we find ("botanical") "substances."

This makes that the "by function" test may not be applied to "herbal substances," i.e. to "botanicals" not yet embodied in a finished product, and/or to non-industrially prepared botanical products. This limitation provision also makes that the precedence of the legal provisions governing medicinal products law over the legal provisions governing foods, laid down in Article 2.2. of the Medicines Directive, does not apply in the case of substances not yet embodied in finished products. The precedence clause applies only in the case of products intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.

Likewise, Article 1.1 of the Food Supplements Directive 2002/46/EC states that this Directive “concerns food supplements marketed as foodstuffs and presented as such. These products shall be delivered to the ultimate consumer only in a pre-packaged form.”

In any case, Union regulations and the Court’s case law preclude regulating - by way of positive or negative lists - the use of (“botanical”) ingredients on the basis of their potential function. In this regard, it is illustrative that Article 8 of Regulation 1925/2006/EC on the addition of “other substances” to foods and/or the use of “other substances” as foods, exclusively and delimitatively concerns the safety of these “other substances,” to the inclusion of “botanicals.”

Arguably, the “positive list” approach applied in the Nutrition and Health Claims Regulation is based on function. But this is not a list-approach that concerns ingredients. The Community Register of Health Claims provides lists with authorised claims, not lists with authorised foodstuffs. The Claims Regulation aims at prohibiting misleading claims. It is not a legal instrument constructed to prohibit or otherwise regulated unsafe foods/foodstuffs.

In this regard, it is unhelpful and confusing that the “traditional health claims” problem has been framed as a “botanicals” and not as a “traditional health claims” problem. The regulatory instruments to regulate claims (“commercial information”) and those that regulate “botanicals” (“other substances”) are essentially different. One cannot regulate claims by applying regulatory instruments (criteria) that concern ingredients (safety and bioavailability). *Vice versa*, one cannot regulate ingredients (“botanicals” / safety) by applying - essentially different - regulatory instruments (criteria) that concern function (“claims” / misleading commercial information / scientific substantiation).

### **The Borderline drawn by the Court regarding the application of the pharmacological properties criterion**

In paragraph 52 of its Judgment made in the *Warenvertriebs-Orthica v Germany* case, <sup>(xxv)</sup> the Court held that:

“The pharmacological properties of a product are the factor on the basis of which the authorities of the Member States must ascertain, in the light of the potential capacities of the product, whether it may, for the purposes of the second subparagraph of Article 1(2) of Directive 2001/83, be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.”

“Pharmacological properties to the extent to which they can be established in the present state of scientific knowledge” is the 2<sup>nd</sup> of the Court’s 6 criteria that must be evaluated when determining the status - food or medicine - of a finished product. It is quite evident why the pharmacological properties of a product are the factor on the basis of which it may be administered to human beings as a medicinal product. However, this criterion is not absolute, in the sense that each and every product that has a pharmacological effect must be classified as a medicinal product. Should a product lack pharmacological properties, no further evaluation is necessary to establish whether other characteristics would prevent its classification as a medicinal product. In fact, the finding that a certain finished product is

capable of producing a medicinal effect obligates the classifier to inspect, in accordance with the ECJ's "corrective" criteria, whether that product's other characteristics determine whether it classifies as a medicinal product. <sup>(xxvi)</sup>

In addition, in paragraph 36 of the Opinion delivered in this case, <sup>(xxvii)</sup> Advocate General Geelhoed observed that the subordination of foods to the Medicines Directive – application of the precedence clause laid down in Article 2.2. of the Medicines Directive – must not cross a certain borderline:

“In my opinion, there are three objections to too broad an interpretation and application of the definition of medicinal product. First of all, the concept of ‘medicinal product’ would cease to have any differentiating effect if it were to include products whose properties and action did not justify their being classified as such. This would harm rather than serve the interests of human health. Secondly, it could result in the specific Community regulations for certain categories of food – containing provisions relating to the particular risks of the products – losing their regulatory object. I am thinking, *inter alia*, of Regulation No 258/97 concerning novel foods and novel food ingredients and Directive 2002/46 on food supplements. Thirdly, a ‘stealthy’ extension of the scope of Directive 2001/83 to include extraneous products would be detrimental to the free movement of goods.”

In line with these concerns, the Court has drawn a clear borderline across which the pharmacological effect no longer co-influences the status of a food-product. This borderline was developed in the “Garlic” case (C-319/05), in which the Commission went against the decision – made by the Federal Republic of Germany – that a food supplement containing a garlic extract should be classified as a medicine. <sup>(xxviii)</sup> <sup>(xxix)</sup> In paragraphs 63-65 of this Judgment, the Court determined:

“63. Furthermore, although only the provisions of Community law specific to medicinal products apply to a product which satisfies the conditions for classification as a medicinal product, even if it comes within the scope of other, less stringent Community rules (see, to that effect, *Delattre*, paragraph 22, *Monteil and Samanni*, paragraph 17, *Ter Voort*, paragraph 19, and *HLH Warenvertrieb and Orthica*, paragraph 43 ), it must be stated, as is shown by a reading of Article 1(2) of Directive 2001/83 in conjunction with Article 2 of Directive 2002/46, that the physiological effect is not specific to medicinal products but is also among the criteria used for the definition of food supplements.

64. In those circumstances, and in order to preserve the effectiveness of that criterion, it is not sufficient that product has properties beneficial to health in general, but it must strictly speaking have the function of treating or preventing disease

65. That statement is even more relevant in the case of products which, in addition to being food supplements, are recognised as having beneficial effects on health. *As the Advocate General observed, in point 60 of her Opinion, there are many products generally recognised as foodstuffs which may also serve therapeutic purposes. That*

*fact is not sufficient however to confer on them the status of medicinal product within the meaning of Directive 2001/83. (Emphasis in paragraph 65 added)*

### **Any remaining heterogenicity is residual**

Regarding the subject at hand, the Court's case law has reached a very high level of clarity, unambiguity and completeness. NPN holds the view that under the present regulatory and judicial circumstances, obstacles to trade can only arise when national authorities fail to apply the Union's regulations and the Court's case law. Any heterogenicity cannot and must not be solved by harmonising it, because it is the result of irregular digressions from an already harmonised situation. Deviations from European law and case law deserve to be challenged before the European Court of Justice.

Still, NPN does not exclude the possibility that, in spite of the overwhelming clarity provided by the Court, the *same* product is classified as a foodstuff in one Member State and as a medicinal product in another, if the national authority considers, taking account of all the characteristics of the product, that this complies with the definition of foodstuff or of medicinal product. But such a problem cannot arise in the regulation of ingredients. It can only arise in individual cases (*case-by-case*) concerning finished products and only in the unlikely event that national authorities, after having unconditionally applied all the Court's criteria, would nevertheless reach disparate conclusions. NPN contends that in most cases, the authorities will – should – reach identical conclusions. In the broad context of European law and case law the problem that Member States might reach disparate conclusions is residual, negligible, and most certainly does not merit a complete overhaul of existing harmonised regulations concerning “botanicals.”

### **New developments**

Since NPN presented its views to the Commission, developments took place that merit discussion in the context of the Commission's Roadmap. On the 11<sup>th</sup> of June of this year, the *Verwaltungsgericht Braunschweig* lodged a Request for a Preliminary Ruling at the European Court of Justice (ECJ). <sup>(xxx)</sup> The questions referred are as follows:

#### “Questions referred

1. Are Articles 34, 35 and 36 of the Treaty on the Functioning of the European Union (“the TFEU”) in conjunction with Article 14 of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, <sup>(xxxi)</sup> to be interpreted as precluding national statutory provisions which prohibit the manufacture or processing and/or marketing of a food supplement with amino acids (here: L-histidine), unless a temporary derogation has been issued at the discretion of the national authority subject to specific additional factual requirements ?
2. Does the scheme of Articles 14, 6, 7, 53 and 55 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety mean that

national bans on individual foods or food ingredients may only be issued under the conditions set out therein, and does this preclude a national statutory provision as set out at 1 above ?

3. Is Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (<sup>xxxii</sup>) to be interpreted as precluding a national statutory provision as set out at 1 above ?”

NPN holds the view that the “Article 8” procedure laid down in Regulation 1925/2006/EC conclusively harmonizes the national provisions regulating the way national authorities must deal with physiologically active substances (foodstuffs) other than vitamins and minerals (the “other substances”). Apparently, the *Verwaltungsgericht Braunschweig* agrees with NPN’s qualification of Regulation 1925/2006/EC as “conclusive” (“*abschliessend*”) and leaving no room for deviating national measures. In the “Grounds” that accompany its Request, the German Court provides the following considerations with respect to the 3<sup>rd</sup> question:

“To question 3:

79. The consideration must be made, that the procedure according to Article 8 of Regulation (EG) Nr. 1925/2006 in connection with the Implementing Rules laid down in Regulation Nr. 307/2012 conclusively regulates the legality of the addition of amino acids to food supplements and does not allow any possibility for a deviating national Regulation and that therefore the national legal provisions laid down in the LFGB [*“Lebensmittel - und Futtermittelgesetzbuch”* / German Food and Feed Law] [...] are inapplicable.

80. With regard to that procedure, the European legislature has established a procedure that concerns the use of nutritionally or physiologically active substances other than vitamins or minerals, in case their use may pose a potential risk to consumers. The use of amino acids in food supplements, such as the L-histidin in the product of the plaintiff, might fall within the field of application of the Regulation, in particular since Article 1 Section 2 of Regulation 1925/2006 only excludes food supplements from its field of application with regard to vitamins and minerals, while amino acids are explicitly mentioned in sentence 1 of Recital 1.

81. In accordance with this Regulation, the use of amino acids is prohibited by listing them in Annex III Part A or allowed under certain conditions by listing them in Annex III Part B, only when in a specific single case on the basis of a scientific evaluation of the risks for the consumer it is demonstrated that use of the amino acid in a food supplement has adverse effects on human health. Inasmuch as, on the basis of the available scientific evidence concerning a single case, a potential risk for consumers has been demonstrated, the substance can be listed in Annex III Part C. According to Article 8 Section 5 of Regulation 1925/2006, it shall be determined within a period of 4 years after the listing of the substance in Annex III Part C whether its use is generally allowed or whether it needs to be listed in Annex III Part A or B.

82. That this procedure conclusively regulates the legality of the use of amino acids in food supplements, may be concluded from the fact that, according Article 1 paragraph 1, the subject matter and goal of the Regulation is to harmonize the regulations of the Member States with regard to the addition of e.g. such “other substances” to food supplements, in order to guarantee the functioning of the internal market and to ensure a high level of consumer protection. Moreover, Recital 1 of Regulation 1925/2006, which explicitly mentions amino acids, evokes the necessity to establish Community measures in order to harmonize national regulations concerning the addition of “other” substances. On the one hand, it appears that, so far, no decisions were made within the context of the procedure laid down in Article 8 of Regulation 1925/2006; on the other hand, the procedure is open for the Member States.

83. Apart from this, it needs to be considered - as an autonomous ground - that by way of the procedure laid down in Article 8 EG No. 1925/2006, the European legislature has standardized a system, closed in and of itself [*“in sich geschlossenes”*], how to deal with other substances - *inter alia* amino acids -. This could have the consequence that Member States, even when, for the time being, there is fundamentally room for national regulations, may not take a position that is in principal contradiction with the aforementioned system. The national Regulation in question might diametrically oppose the regulatory principle of Article 8 of Regulation (EG) No. 1925/2006, in that it prohibits the use of amino acids in foods or as foodstuffs across the board - independently of the issue whether there is, in a single case, a substantiated suspicion of a threat to human health, and in that it forms the basis for the possibility to maintain, in accordance with national rules, an exemption clause [(vgl. *Möstl*, ...)]. Therefore, the national provision could be inapplicable.”<sup>(xxxiii)</sup>

Indeed, in Recital 1 of Regulation 1925/2006/EC, the European legislature determined that the Regulation shall apply to “a wide range of nutrients and other ingredients that might be used in food manufacturing, including, but not limited to, vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts.” This leaves no doubt that the considerations made by the German Court with regard to the use of the amino acid L-histidin can also be made with regard to the use of “botanicals.”

“Botanicals” were somewhat defined by the EU legislature in Recital 10 of Commission Regulation 432/2012/EU as “plant or herbal substances, commonly known as ‘botanical’ substances.” By the addition of the words “commonly known,” the EU legislature avoided making the definition a conclusive legal one. In the Union’s Food Law, “botanicals” remain an undefined category of “other substances.” In Recital 1 of Regulation 1925/2006/EC, the legislature speaks of “plants and herbal extracts.” In Article 8(1) of that Regulation, “plants and herbal extracts” are categorized as “certain other substances or ingredients containing substances other than vitamins or minerals.” Hence, “plant or herbal substances, commonly known as ‘botanical’ substances” fall within the scope of the European measure that conclusively regulates the use of these “other substances” in or as foods/foodstuffs. As the German Court observes, the “Article 8” procedure leaves no room for national provisions, simply because those national provisions were conclusively harmonized by that very procedure.

In Ground #83 of its Request, the German Court qualifies the “Article 8” procedure as an “*in sich geschlossenes System zum Umgang mit sonstigen Stoffe*.” (...a system, closed in and of itself, how to deal with other substances.) In Ground #79 of its Request, the German Court affirmatively explains: “The consideration must be made, that the procedure according to Article 8 of Regulation (EG) Nr. 1925/2006 in connection with the Implementing Rules laid down in Regulation Nr. 307/2012 conclusively regulates the legality of the addition of amino acids [and “botanicals”] to food supplements and does not allow any possibility for a deviating national Regulation and that therefore the national legal provisions laid down in the LFGB [“*Lebensmittel - und Futtermittelgesetzbuch*” / Food and Feed Law] [...] are inapplicable.”

In Ground 82 of its Request, the German Court considers: “That this procedure conclusively regulates the legality of the use of amino acids [and “botanicals”] in food supplements, may be concluded from the fact that according Article 1 paragraph 1 the subject matter and goal of the Regulation is to harmonize the regulations of the Member States with regard to the addition of e.g. such “other substances” to food supplements, in order to guarantee the functioning of the internal market and to ensure a high level of consumer protection. Moreover, Recital 1 of Regulation 1925/2006, which explicitly mentions amino acids [and “botanicals”], evokes the necessity to establish Community measures in order to harmonize national regulations concerning the addition of “other substances.” On the one hand, it appears that, so far, no decisions were made within the context of the procedure laid down in Article 8 of Regulation 1925/2006; on the other hand, the procedure is open for the Member States.”

### **Prohibition with a Permission Proviso**

In its Request, the German Court makes reference to an article written by Prof.Dr. Markus Möstl: *Rechtliche Anforderungen für den Einsatz funktioneller Inhaltsstoffe im Lebensmittelbereich*, which was published in the June 2013 issue of the *German Zeitschrift für das gesamte Lebensmittelrecht (ZLG)*.<sup>(xxxiv)</sup> In this article, Möstl qualifies the German system which is the object of the Request for a Preliminary Ruling as a “*Verbot mit Erlaubnisvorbehalt*” (Prohibition with a Permission Proviso / a prohibition *ex ante* evaluation). Under such a system, market entry of an entire category of substances (*in casu* “*Zusatzstoffe*” or “other substances”) or information (e.g. health claims) is prohibited “across the board,” *ex ante* the explicit permission or authorisation by the authorities following a case-by-case evaluation of each individual substance or health claim.

In Germany, “*Zusatzstoffe*” comprise not only food additives, but also physiologically active substances other than vitamins or minerals (“other substances”). Absent an explicit authorization, none of these substances may be used in or as foods/foodstuffs. The European Nutrition and Health Claims Regulation also qualifies as a *Prohibition with a Permission Proviso* in that it prohibits all nutrition and health claims “across the board” (“*pauschal*”), *ex ante* their individual evaluation and authorisation.

Möstl argues that, with regard to “other substances,” such a system is not compatible with the *Prohibition Proviso* applied in the “Article 8” procedure. According to Möstl, in the regulation of “other substances,” the *Prohibition Proviso* (prohibition *ex post* evaluation) is

the normative paradigm in Union Law. “German Law,” so he writes, “must orient itself to this normative paradigm.”

“This means that so far, under European Union law, other substances - be it with full responsibility of the food business operator for the safety of his product - are not subjected to any particular restrictions, since Article 8 of Regulation 1925/2006/EC (in sharp contradiction to German law) does not lay down a prohibition with an approval proviso, but only a bare prohibition proviso; it is not up to the food business operator to make the effort of obtaining an approval to legitimately market his product, but, the other way around, the Commission must take action in case marketability must be restricted.”<sup>(xxxv)</sup>

That the “Article 8” *Prohibition Proviso* procedure is not an exception in European Food Law finds confirmation in the fact that, in Regulation 609/2013/EU on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control, the normative regulatory paradigm was also followed.<sup>(xxxvi)</sup> Even though this Regulation concerns food/foodstuffs intended to be used by vulnerable consumers (patients, children), it follows the fundamental regulatory principle that in European Food Law the market entry of (“non-novel”) foods/foodstuffs may take place without *a priori* restrictions or prohibitions, i.e. without any “permission proviso.”<sup>(xxxvii)</sup>

In this regard, Article 15(7) of Regulation 609/2013 provides: “Substances belonging to categories not listed in paragraph 1 of this Article [<sup>xxxviii</sup>] may be added to food referred to in Article 1(1), provided that they satisfy the general requirements set out in Articles 6 and 9 and, where applicable, the specific requirements established in accordance with Article 11.” Since “botanicals” are not listed in Article 15(1), they enjoy unhindered market entry status also granted to them under the “Article 8” procedure.

Möstl observes that “[t]he question, whether the German principle of prohibition with the permission proviso or the European abuse principle with the prohibition proviso applies, is of great practical importance: it determines who - authority or food business operator - carries the burden to take action and, principally, who carries the burden of proof.”<sup>(xxxix)</sup> He then raises the question that was also raised by the *Verwaltungsgericht Braunschweig*. Does Union Law that organizes and regulates the marketability of “other substances” leave room for additional or special national provisions or does the applicable Union law, *in casu* Article 8 of Regulation 19265/2006/EC, have the effect of completely obstructing them.<sup>(xl)</sup>

Möstl holds the opinion that the current “across the board” prohibition with a permission proviso as it is applied in German Law is not compatible with Union Law and that for this reason such a system is no longer applicable. In case Member States would insist on maintaining or developing national measures, they “must comply with the principle of proportionality, which means that they must restrict themselves to measures which are genuinely needed and proportionate in the context of the protection of health; in precisely this context the BGH (*Bundesgerichtshof* / Federal Court of Justice) has convincingly held that with reference to the case law of the ECJ (European Court of Justice), the current German version of the prohibition with a permission proviso and more in particular the insufficient possibilities for permission of § 68 of German Food Law do not comply with the requirements

which European Union Law imposes with regard to an easily accessible procedure that can be concluded within an appropriate period - meaning a procedure that is proportionate to its stated purpose -, by way of which a substance can be listed in a national national list of permitted substances.”<sup>(xli)</sup>

In line with the *Verwaltungsgericht Braunschweig*, Möstl qualifies Article 8 of Regulation 1925/2006/EC as a regulatory system that is closed in and of itself (“*in sich geschlossenes*”). He explains that this system brings to expression the Prohibition Proviso that is the fundamental normative paradigm followed in European Food Law. According to Möstl, in the field of regulating the marketability of “other substances,” the “Article 8” procedure precludes that Member States may maintain and/or develop national measures which are not compatible with the normative paradigm which the European legislature laid down as binding.<sup>(xlii)</sup>

In this regard, Member States must also respect ECJ’s case law by giving expression to Europe’s regulatory concept in the execution of their national provisions.<sup>(xliii)</sup> Möstl reiterates that a general (“*pauschales*”) prohibition with an approval proviso, as it is applied in German law, cannot be reconciled with the regulatory concept that underlies Article 8 of Regulation 1925/2006/EC, which, according to Möstl, “is based on a principal market entry permissability by laying down no more than a prohibition proviso.”<sup>(xliiv)</sup>

### **The Pharmacological Activity Proviso - the German *Stoffliste***

In September 2014, the German *Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* (BVL / Federal Office of Consumer Protection and Food Safety) published a "*Stoffliste - Kategorie "Pflanzen und Pflanzenteile"* (List of Substances of the Competent Federal Government and Federal State Authorities - Category “Plants and plant parts”)<sup>(xlv)</sup> The list is “*nicht rechtsverbindlich*” (“not legally binding”). The *Stoffliste* constitutes a hybrid system of Negative and Positive Lists loosely organized on the basis of the template of Article 8 of Regulation 1925/2006/EC. The *Stoffliste* presents 3 categories of “botanicals.” The BVL explains:

“To understand the List of Substances in the category of “plants and plant parts”, the following should additionally be noted:

1. The sub lists have the following meanings:

List A: Substances not recommended for use in foods

List B: Substances for which restricted use in foods is recommended

List C: Substances which cannot yet be completely assessed due to lack of sufficient data”<sup>(xlvi)</sup>

However, where the “Article 8” system strictly concerns the regulation of “other substances” exclusively on the basis of their safety, by prohibiting or allowing under certain specified conditions the safe use in or as foods of “other substances” and by taking account of their “potential risk to consumers” and/or identified “harmful effects on health,” the BVL applies the additional criterion of “pharmacological activity” to regulate by way of a restriction (“*Beschränkung*”) the use of “botanicals” in or as foods. As articulated heretofore in this Paper, the pharmacological criterion is alien to the “Article 8” procedure and, in fact, it is alien to Food Law in general. This criterion has nothing to do with food safety.

The fact that, in various Regulations and Directives, European Food Law provides that foods/foodstuffs may not be recommended for medicinal use, does not constitute a Pharmacological Proviso *per se*. This prohibition corresponds to the definition of medicine by presentation laid down in Article 1.2(a) of the Medicinal Products Directive as: “Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.” The pharmacological activity criterion corresponds to the definition of medicine by function in Article 1.2(b) of that Directive: “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.”

As explained hereabove, even here, as part of the 2<sup>nd</sup> definition of medicinal product, the Proviso does not *per se* have the force of law as a stand alone legal instrument. Nevertheless, the German Consumer Protection and Food Safety Office (BVL) deemed it opportune to apply the pharmacological activity proviso in a *Stoffliste* that concerns the use of “botanicals” in or as foods. By-passing relevant Union measures and ECJ case law, and lacking legal ground or relevance, the BVL determined:

“5. If any restrictions of use as a food or food ingredient are recommended for a substance (List B) due to evidence of a pharmacological effect (No. 4 in the explanatory notes on the decision tree), such a restriction always refers to the substance described in that evidence (e.g. dried plant or dried plant part). Evidence of a pharmacological effect that leads to a classification as a medicinal product in accordance with Section 2 Clause 1 No. 2a AMG included court-approved sources such as monographs, marketing authorisations or classifications of competent authorities. Other evidence (e.g. results of clinical studies) may additionally be relevant to the classification of a substance as a medicinal product.

6. Substances for which a pharmacological effect or efficacy as a medicinal product is plausible based on use and experience over many years (“traditional evidence”) in accordance with Sections 39a ff. of the Medicinal Products Act will not be placed on List B based on that traditional evidence alone. For a substance to be placed on List B, pharmacological effects, as specified above in item 5, or risks must be reported due to which restricted use in foods is recommended.”<sup>(xlvi)</sup>

In the Decision Tree presented in BVL’s *Stoffliste*, the *Pharmacological Proviso* leads to the following situation.

“The decision tree serves as the basis for the classification of substances in the category of ‘plants and plant parts’ as ‘food (F)’, ‘medicinal product (MP)’ and/or ‘novel food/novel food ingredient (NF)’ as well as possible combinations thereof (ambivalent substances). It also provides instructions for the classification of the substances in the Lists A, B and C.

Classification as a medicinal product - except for ambivalent substances (see No. 3 below) - is made based on the definition of medicinal products by function set out in Section 2 Clause 1 No. 2a of the Medicinal Products Act (AMG). These are characterised by their pharmacological, metabolic or immunological effect. For the

sake of clarity, the term ‘pharmacological effect’ is used in the decision tree for this definition. Classification as a medicinal product by presentation as defined in Section 2 Clause 2 No. 1 AMG is not taken into account.

Based on the answers to the questions in the decision tree, plants and plant parts are classified as follows:

**No. 1: Food**

**(Decision tree I - via question 3)**

Common foods without any known use as medicinal products. Based on their previous use, any restrictions of use are not required.

**No. 2: Food - List B**

**(Decision tree III - via question 3)**

Common foods without any known use as medicinal products. Dose restrictions and restrictions of use are required due to risks posed by the constituents of the plant or plant part. Such restrictions are expressed by placing the substance on List B.

**No. 3: Food - traditional medicinal product**

**(Decision tree II – via question 5)**

For traditional herbal medicinal products, a pharmacological effect is plausible based on use and experience over many years in accordance with Sections 39a ff. of the Medicinal Products Act (AMG). At present, processing monographs for plants/plant parts that can be contained in traditional medicinal products are being created or revised by the European Medicines Agency (EMA).

Where these monographs have been adopted and published, they are taken into account accordingly. Some of the plants/plant parts used therein have also long since been used in food. A restriction (List B) was not recommended in individual cases where it would have been done exclusively on the basis of traditional evidence of pharmacological effect. Despite such evidence of pharmacological effect, classification as ambivalent substance (F/MP) without any restrictions is therefore made **in this case only**.

**No. 4: Food - medicinal product - List B**

**(Decision tree III/IV – via question 5)**

Common foods that are also used as medicinal products. Pharmacological effects are reported above a certain dose. If no significant pharmacological effects are identified, the substance can be classified as food. When reaching the pharmacologically effective dose, it is defined as a medicinal product by function. This is expressed by placing the substance on List B.

**No. 5: Novel food**

**(Decision tree VIII - via question 9)**

The substance is not known to be used as either food or a medicinal product. The substance is also not known to be associated with any risks that would restrict its use in food. The further assessment takes place in accordance with the Novel Food Regulation.

**No. 6: Novel food - medicinal product  
(Decision tree IV/V – via question 8)**

The substance has so far been known as a medicinal product only. However, it is not associated with any risks that would restrict its use in food. Its use in food would therefore be conceivable after assessment in accordance with the Novel Food Regulation. Medicinal products and novel foods are distinguished on the basis of the pharmacologically effective dose (by analogy with No. 4). The substance cannot be placed on List B as it is no common food.

**No. 7: Novel food (Not NFS) - List C  
(Decision tree VIII – via question 9)**

A number of substances are classified as not novel exclusively when used in food supplements. When used in foods other than food supplements, these substances are usually placed on List C, since no sufficient information is available for their conclusive assessment.

**No. 8: Novel food (Not NFS) - List B - medicinal product  
(Decision tree IV/V - via question 8)**

The substance is known as a medicinal product. It is additionally used in food supplements and is classified as not novel in this case only. The necessary restriction of use in FS due to the pharmacological effect is expressed by placing the substance on List B.

**No. 9: Medicinal product - List A  
(Decision tree VI – via question 7)**

The substance has so far been known as a medicinal product only. Due to the associated risks, its use in food is not recommended, irrespective of the dose.

**No. 10: List A substance  
(Decision tree VII – via question 9)**

The substance, which is not a medicinal product, is associated with risks. Its use in food is therefore not recommended, irrespective of the dose.”

The incorporation of the Pharmacological Proviso at practically every step of the Decision Tree turns the BVL Lists into Positive Lists. No “botanical” is placed on any of the Lists prior to or independent of its “pharmacological” evaluation. Only Steps 2, 5, 7, 9 and 10 (also) address safety as a secondary criterion that needs to be evaluated during the assessment of the “botanical” substance. The approach applied by the BVL must be qualified as a Prohibition with a Permission Proviso system in that it stealthily but steadily and unconditionally has the effect of an implied prohibition of all “botanical” substances *ex ante* the evaluation of their pharmacological effect.

Only when, upon examination, a pharmacological activity appears to be absent, does a “botanical” fall under Food Law. This is quite explicitly confirmed in point 4 of the *Stoffliste*’s Decision Tree, where it is stated: “If no significant pharmacological effects are identified, the substance can be classified as food. When reaching the pharmacologically

effective dose, it is defined as a medicinal product by function. This is expressed by placing the substance on List B.” This proviso applies to all steps in the Decision Tree.

In the *Stoffliste*, the Pharmacological Proviso functions as a prohibitive criterion in that the absence of a pharmacological effect is the condition for classifying a “botanical” substance as a food. The prohibition hinges on the assumption that all “botanical” substances must be classified as medicinal substances to begin with. At the end of the Decision Tree, the Pharmacological Proviso finds its expression in List B:

“List B

Substances that are only used in food and for which a dose restriction is required due to certain constituents (No. 2) are placed on List B.

Furthermore, substances that are known as both foods and medicinal products with a pharmacological effect demonstrated on the basis of clinical data are placed on this list. This is also done by strict application of the decision tree in respect of basic foods in usual amounts of intake (No. 4).

Finally, substances that are used as food exclusively in food supplements (but are otherwise novel foods) and are known as medicinal products with a demonstrable pharmacological effect are placed on list B (No. 8).

Substances that are known as both foods and medicinal products with exclusively traditional evidence of pharmacological effect (No. 3) are not placed on List B.”

Arguably, the *Stoffliste* does not have the force of law and (for that reason) it does not contain any clause establishing a derogation period during which “prohibited” “botanical” substances already on the market may be marketed without interference from the BVL or other relevant and competent authorities. Still, the effect of the *Liste* is comparable to that of a national legal provision, since food business operators will take the BVL’s classification approach into consideration, especially when they’re situated in Germany. Absence of a derogation clause and the force of law do not diminish or cripple the *Stoffliste*’s effect.

In this regard, it is quite telling that the BVL ends its explanatory web-page concerning its *Stoffliste* with the following disclaimer:

“Federal and State List of Substances - Category Plants and Plants parts

Federal and State representatives established a *Stoffliste*, which shall serve as an orientation aid [“*Orientierungshilfe*”] in the use of plants and plant parts (hereafter: substances) as food/foodstuff or as food-additives.

The procedure concerning the categorization of the substances was visualized in the form of a decision tree.

The List of Substances is not legally binding, does not claim completeness and is open to updating so as to reflect new scientific insights and the development of the market.

A conclusive appraisal of products that embody plants and plant parts, must always take place case-by-case and by taking account of all criteria relevant in the assessment. These include *inter alia* the preparation and the dosage of the embodied substance. For example, extracts can show significant differences in terms of their composition or nutritional/physiological, pharmacological or toxicological properties, due to the used extraction agents or the method of manufacturing. During the appraisal of the

individual case, account must also be taken of presentation [“*Aufmachung*”], advertising [“*Bewerbung*”], identification [“*Kennlichmachung*”] and recommendation [“*Auslobung*”].” (xlviiii)

This is precisely what the Court determined in the *Hecht-Pharma* case. In spite of it, the BVL erected a *Stoffliste* suggesting that ingredients can be pre-regulated by applying no more than the pharmacological proviso.

### **The Pharmacological Proviso in the “Belfrit” approach**

The national systems applied by the Italian, French and Belgian (“Belfrit”) authorities to regulate “botanicals” also fit the definition of a *Prohibition with a Permission Proviso* system, in that they provide “positive” lists with “botanicals” that may be used in or as foods/foodstuffs. Positive Lists form part and parcel of any *Prohibition with a Permission Proviso* system. The “Belfrit” approach rests on a prohibition of all “botanicals” not permitted. This prohibition antecedes the placing of “botanicals” in a Positive List.

Differently put, the enactment of the Positive “Belfrit” List(s) activates the general prohibition that antecedes the Lists’ enactment, even when such a general prohibition has not been explicitly laid down in a legal provision. Every positive list implies, confirms and activates the existence of an *ex ante* prohibition. Like the German approach applied in the “*Zusatzstoffe*” regulation and the *Stoffliste*, the “Belfrit” systems are not compatible with the normative legal paradigm followed *inter alia* in the Article 8 procedure laid down in Regulation 1925/2006/EC. (See Möstl *supra*)

In 2 articles, published in the journal *European Food and Feed Law*, (xlix) the “Belfrit” approach is presented as the approach that must first install a Positive List of “botanicals” as a way to then add traditional health claims to this list. As praiseworthy as this may be, what remains underexposed is the fact that the “Belfrit” approach includes an exclusionary cut-off point for the use of “botanical” substances and “botanical” preparations, that permits for use in or as foods only the “botanicals” that are ...

“... not characterized by a pharmacological activity capable of restoring, correcting or modifying physiological function (although the boundary between physiological and pharmacological activities is sometimes difficult to establish), ...” (l)

This introduces a “Borderline”-type market-entry-condition in the Positive List system for “botanical” compounds (raw materials) that has nothing to do with safety. The approach found expression in the French *Arrêté du 24 juin 2014 établissant la liste des plantes, autres que les champignons, autorisées dans les compléments alimentaires et les conditions de leur emploi* (NOR: ERNC1406332A). (Decree of 24 June 2014 establishing a list of plants, other than mushrooms, authorized in food supplements and the conditions of their use.) Other than merely establishing a positive list of “botanicals” that may be used as or in foods, the *Arrêté* also determines in Article 11(3) that:

“L'utilisation de préparations issues des parties de plantes [“botanicals”] figurant sur la liste de l'annexe I dans la fabrication d'un complément alimentaire ne doit pas conduire à ce que celui-ci constitue un médicament par fonction tel que défini par l'article L.

5111-1 du code de la santé publique [concerning medicinal products], notamment en exerçant une activité pharmacologique.

A ce titre, ne peuvent pas entrer, dans la fabrication des compléments alimentaires, les préparations de plantes pour lesquelles un usage médical bien établi a été identifié par le comité des médicaments à base de plantes de l'Agence européenne des médicaments, dans les conditions de cet usage.”

(The use of preparations isolated from plant particles [“botanicals”] presented in annex 1 in the manufacturing of a food supplement should not lead to this product constituting a medicinal product by function defined in article L.5111-1 of the public health code [concerning medicinal products], notably by exercising a pharmacological activity.

In this regard, the use of plant preparations for which a well established medicinal use has been identified by the European Medicines Agency’s committee responsible for medicines based on plants is prohibited in the manufacturing of food supplements under the conditions similar to that use.)

In the 1<sup>st</sup> paragraph of Art.11.(3), the french authorities clearly indicate that a “botanical’s” pharmacological activity alone will lead to a product that embodies it constituting a medicinal product by function. In the Article’s 2<sup>nd</sup> paragraph, the French authorities determined that “botanical” preparations (“préparations de plantes”) for which the European Medicines Agency identified a well established medicinal use, may not be used in dietary supplements for conditions of use similar to the medicinal ones. Evidently, dosage is the most critical condition of use. The French *Arrêté* expresses precisely what the authors of the “Belfrit” approach had and have in mind: positive list + Pharmacological Proviso.

The Pharmacological Activity Proviso now runs through positive as well as semi-negative lists of physiologically active substances (foodstuffs). The application of the proviso is justified on the basis of the narrow view that medicinal products may be classified on the basis of no more than the “by function” definition, provided in Article 1(2)(b) of the European Medicines Directive as: “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.” Moreover, this view is not reconcilable with European law and case law and it produces a serious transgression of the Food-Medicine Borderline established in European Regulations and Directives and in the relevant case law formulated by the European Court of Justice.

### **The Food-Medicine Borderline**

Hereabove, NPN provided an extensive review of the ECJ’s case law, in which, by now, the Court has patiently and steadfastly confirmed and reconfirmed <sup>(1)</sup> that when national authorities, acting under the supervision of the courts, apply the ECJ’s instructions concerning the classification of medicines by function, they must do so by taking account of all characteristics on a case-by-case basis, i.e. per each individual - industrially prepared – finished product. This precludes the “food or medicine” type regulation (determination of status) of (“botanical”) ingredients that are not embodied in a finished product. It also

precludes that finished products may be classified by merely applying the Pharmacological Proviso, i.e. by 1 of all characteristics.

NPN reiterates that (“botanical”) ingredients may be and are regulated, but that such regulations must exclusively concern their safety, not their function. In its Judgment made in the Joined Cases C-154/04 and C-155/04, <sup>(iii)</sup> the Court explicated in precise terms that the criteria for regulating ingredients (*in casu* forms of vitamins and minerals not embodied in products) are safety and bioavailability, to the exclusion of criteria of function, such as nutritional or medicinal needs. <sup>(liii)</sup>

Apart from the fact that regulating ingredients on the basis of their nutritional (physiological) function is precluded by the Union’s legislation and the Court’s case law, an evaluation of an active ingredient’s therapeutic/pharmacological effect can only have legal and classificatory consequences when performed in the context of evaluating an industrially prepared/processed finished product that embodies it, when that product is on the market and when it is readily available to consumers.

The scope of the Medicines Directive is explicitly limited to finished products, defined in Article 2.1 as “products for human use intended to be placed on the market in Member States.” Although both definitions of medicinal product concern substances, the limited scope of the Directive excludes application of the Medicines Directive in the regulation of “substances” not yet incorporated in finished products. The Medicines Directive cannot cross the “product” borderline behind which we find (“botanical”) “substances.” Evidently the definitions of medicinal products do *not* define or determine the scope of the Directive.

This point is not addressed by the German and the “Belfrit” authorities. The application of the Pharmacological Proviso in Food Law as a restrictive and prohibitive criterion in positive and/or negative lists authorizing and/or prohibiting the use of “botanical” ingredients in or as foods is irreconcilable with Union law and ECJ case law. In its *Stoffliste*, the BVL consistently and interchangeably uses the terms “substance” and “product” as if they were synonymous. The purpose of this exercise is obvious. By implying that a “substance” is a “product” and that a “product” is a “substance,” the BVL disregards the fact that the field of application of the Medicinal Products Directive is delimited to medicinal products and that it does not apply to substances that fall under the definition of medicine by function. BVL also disregards ECJ’s clear and unequivocal instruction that classification of a medicine by function is only possible when one evaluates (case-by-case) individual finished products. In this way, the BVL also avoids the ECJ’s instruction to take account of all characteristics.

In the Decree of 24 June 2014, the French authorities also stay clear of applying the ECJ’s case law by determining that the use of preparations isolated from plant particles [“botanicals”] which exercise a pharmacological activity is prohibited on the basis of no more than that activity. Furthermore, the Decree provides that “the use of plant preparations for which a well established medicinal use has been identified by the European Medicines Agency’s committee responsible for medicines based on plants is prohibited in the manufacturing of food supplements under conditions similar to that use.” This complicates things even further, because “well established medicinal use” is not synonymous with “pharmacological effect.” The term “well established medicinal use” applies only in the case

of traditional medicines. Apparently, the French authorities are trying to extend the Pharmacological Proviso from the definition of medicine by function to ingredients embodied in traditional medicines.

In any case, the “by function” test may not and cannot be applied to “herbal substances,” i.e. to “botanicals” not yet embodied in a finished product. The precedence of the legal provisions governing medicinal products over the legal provisions governing foods, laid down in Article 2.2. of the Medicines Directive, does not apply in the case of substances not yet embodied in finished products. The precedence clause applies only in the case of products intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.

“In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a ‘medicinal product’ and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.” (emphases added)

The preceding paragraph of Article 2 provides:

“This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.”

In 2010, DG SANCO published its interpretation of the term “placing on the market.”<sup>(liv)</sup>

“(9) According to the legal definitions, a product must be “made available” (*mis à disposition, überlassen*) with a view to distribution or use whilst making available is to be understood as the supply of a product (*fourniture, Abgabe*). The interpretation of these terms indicates that the mere termination of the manufacture is not sufficient for a product to be placed on the market. In addition, it must have entered into the distribution chain.

(12) According to the “Blue Guide”, placing on the market is considered not to take place where a product, amongst others, is

- in the stocks of the manufacturer, or the authorised representative established in the Community, where the product is not yet made available, unless otherwise provided for in the applicable directives; or
- not (yet) granted release for free circulation by customs, or has been placed under another customs procedure (for example transit, warehousing or temporary importation), or is in a free zone.”

The European Medicines Directive, the full title of which is *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to **medicinal products** for human use*, applies to - industrially prepared - finished products, defined in Article 2.1 as “products for human use intended to be placed on the market in Member States.” (emphases added) That the Medicines Directive concerns finished products, and not “substances” or “ingredients,” may also be concluded from the fact that the

Directive provides extensive rules describing the conditions for the “placing on the market” of medicinal products. The primary condition is that medicinal products may not be placed on the market “unless a marketing authorisation has been issued,” either by the competent authorities of a Member State or by the European Medicines Agency.

“TITLE III

**PLACING ON THE MARKET**

*CHAPTER 1*

**Marketing authorization**

*Article 6*

1. No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 1394/2007.”

In order to obtain an authorization to place a medicinal product on the market, an application shall be made. Apart from proof of pharmacological activity, therapeutic indications, etc., the application shall also provide “a summary, [...], of the product characteristics, a mock-up of the outer packaging, containing the details provided for in Article 54 [which regulates what information shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging], and of the immediate packaging of the medicinal product, containing the details provided for in Article 55 [which regulates the information that shall appear on immediate packagings which take the form of blister packs and are placed in an outer packaging], together with a package leaflet in accordance with Article 59 [which regulates that the package leaflet shall be drawn up in accordance with the summary of the product characteristics].”

Evidently, the Medicines Directive does not regulate “substances” not yet incorporated in finished products. Substances cannot be placed on the market, because marketing authorizations concern only finished products. Even though substances may fall within the definition of medicinal product, it is impossible to apply for an authorization to place a substance on the market. Without an authorization to be placed on the market, a medicinal product does not exist and the Medicinal Products Directive does not apply.

Clearly, the BVL and the “Belfrit” approaches interfere with the use of “botanicals” before the actual manufacturing of a finished product has even begun and, as a consequence, well before that product has been placed on the market. However, prior to their use in the manufacturing of finished products, “botanical” ingredients cannot be classified. Their classification can only take place once they have been incorporated into a finished product and once that finished product has been placed on the market, i.e. when it has left the warehouse of the manufacturer.

These approaches deprive food business operators access to ECJ jurisprudence in case they wish to challenge or seek redress of a grievance concerning the classification of a food

supplement containing a “botanical” ingredient. The prohibition of the “botanical” ingredient’s use has effect before the food supplement’s manufacturing and, as a consequence, before its placing on the market. This precludes that a court, and even the authorities acting under the courts’ supervision, can classify a finished product, when a food business operator seeks redress of a grievance concerning a classification he disagrees with, simply because the authorities prevented the product from coming into existence by being manufactured and placed on the market.

### **The Dutch “melatonin” case – “all characteristics”**

In the beginning of 2015, the Dutch Health Care Inspectorate (“*Inspectie voor de Gezondheidszorg*” / IGZ) made an attempt to apply and install the *Pharmacological Proviso* by making a public announcement that it had reached a decision to classify, “across the board,” all products containing more than 0,3mg of melatonin as medicines by function, irrespective of the examination of all the other characteristics of each individual product (including its composition, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail). NPN challenged the Inspectorate’s approach by filing a summary judgment procedure (“*Kort Geding*”) before the competent jurisdiction, the Court of Arnhem, arguing in particular that the Inspectorate had not followed the ECJ’s *Hecht Pharma* decision. (Case C-140/07)

In an initial summary judgment, the lower Court determined that the Inspectorate had acted correctly and that it had sufficiently taken account of the ECJ’s “all characteristics” classification criteria, by cursorily glancing over the market of food supplements containing melatonin. NPN not only appealed the summary judgment, it also filed a request for Proceedings on the Merits of the Case (“*Bodemprocedure*”) at the Court of The Hague.

In a judgment issued on the 28<sup>th</sup> of August 2015, the Arnhem Court of Appeals agreed with NPN and overturned the lower Court’s summary judgment. <sup>(lv)</sup> With regard to the Inspectorate’s use of a public announcement of its “across the board” application of the *Pharmacological Proviso* *ex ante* any “all characteristics” evaluation of a specific individual product, the Court of Appeals stated that such an approach was not in accordance with the ECJ’s *Hecht Pharma* judgment and that the Inspectorate had to immediately stop this activity and refrain from such further action until a final decision has been made by the Court of The Hague in the Main Proceedings.

The Arnhem Court of Appeals’ decision of 28 August 2015 is highly relevant in the context of this Explanatory Note, since the Court explicitly forbade the use of *Stoffliste*- and “Belfrit”-type public announcements and lists that lack the force of law as a means of influencing market participants prior to the evaluation of individual products in accordance with the “all characteristics” approach laid down by the ECJ in *inter alia* the *Hecht Pharma* Judgment. The *Pharmacological Proviso* is not a legal instrument that, on its own, i.e. not in direct connection with a product’s other characteristics, has the force of law, especially not when it is applied to ingredients and not, on a case-by-case basis, to individual finished products.

In the Dutch “melatonin” case, the Health Care Inspectorate “disclaimed” its approach in terms quite similar to those used by the BVL on its “*Stoffliste*” webpage. Its public announcement, so it pleaded, was merely intended as guidance and assistance to help market

participants to avoid problems in the marketing of food supplements containing melatonin. More in particular, the Inspectorate's announcement served the purpose of suggesting that, during a specific derogation period, market participants would be left alone on condition that they filed a request for marketing authorization for products containing more than 0,3 mg melatonin. It was precisely this way of offering "assistance" and "orientation aid" prior to and instead of making a conclusive appraisal of individual finished products that the Arnheim Court of Appeals explicitly forbade in grounds 4.1 and 4.2 of its judgment:

"4.1 In this appeal, the interpretation of the judgment of 15 January 2009, C-140/07 (Hecht-Pharma ECLI:EU:C:2009:5) of the European Court of Justice (ECJ) is primarily central. In this judgment, the Court holds, while making reference to its earlier case law, that the national authorities, under the supervision of the courts, must determine on a case by case basis whether or not a product falls under the definition of medicine by function (as provided in article 1, point 2 under b of Directive 2001/83/EC; codified in Section 2 of the [Dutch] Medicines Act), thereby taking into consideration all characteristics of the product, in particular the composition, the pharmacological properties as can be established in the present state of science, the manners of use, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (legal ground 32). From this follows, according to the ECJ, that products containing a substance exerting a physiological effect, cannot be systematically classified as medicine by function, without the competent authority assessing, applying the required due diligence, each product separately on a case by case basis, thereby taking into consideration in particular the pharmacological, immunological or metabolic properties thereof, as these can be established in the present state of science (legal grounds 39 and 40).

4.2 According to the [Arnheim] court's preliminary judgment, this [the ECJ's] judgment does not offer any indication for the position defended by IGZ [Dutch Healthcare Inspectorate] on appeal, in the sense that the assessment referred to by the ECJ could/should only take place at the time when the competent authority - *in casu* IGZ - actually acts in an enforcing manner with regard to the regulations that apply to products which are regarded as medicines, such as the prohibition laid down in Section 40 of the [Dutch] Medicines Act to place on the market, have in stock, sell, supply, hand-deliver, import or bring in or outside the territory of The Netherlands in any other manner medicines, without having the required marketing authorization. Most likely, the obligation, as well as the ensuing possibilities of examination by the courts, apply just as well when - as is the case here - the competent authority announces that it will (or may) act in an enforcing manner against a specific group of products when, after a specified date, these are traded without a marketing authorization, as IGZ has done with regard to products that contain a dose of melatonin of more than 0.3 mg. Such an announcement, as NPN has explained in its arguments, which were insufficiently contested by IGZ, has a far-reaching effect on the market, in particular because the market participants will act anticipatorily and will, from fear of high financial penalties, no longer want to keep the mentioned melatonin products in the product range. Therefore, and also having regard to the intention of Directive 2001/83/EC, it is reasonable to conclude that IGZ must *a priori* investigate and, if requested, under supervision of the courts, motivate that it justifiably classifies as

medicines the products containing more than 0.3 mg melatonin now that its authority to take action depends on this classification.”

### **Decision of the Court of The Hague in the Main Proceedings**

On the first day of June 2016, the Court of the Hague published its decision in the Main Proceedings. The Court confirmed the decision made by the Arnheim Court of Appeals. It stipulated the following:

“4.3 [...] It is furthermore not disputed that the Dutch Healthcare Inspectorate [IGZ], prior to sending its letters dated 9 November 2011, 5 August 2013 and 22 January 2015, [announcing that all products providing a daily dosage of  $\geq 0,3$ mg melatonin would be categorically qualified as medicines by function] had not conducted individualised research with regard to each separate melatonin containing product that was present in the Dutch market and in the course of which all characteristics of the product were taken into consideration, in particular the composition, the pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail. <sup>(lvi)</sup>

4.4 The court establishes that the group of products that contain a quantity of melatonin of 0.3 mg or more are, in the letters from IGZ referred to in 4.3, without proviso, classified as a medicine. Such, while the individualised research referred to in 4.3 had not taken place and, as the State [representing the Inspectorate] confirmed at the hearing, that it can occur - albeit in theory as far as the State is concerned - that the examination of a separate product that contains 0.3 mg or more melatonin may lead to the conclusion that this product is not a medicine. Considering that the State has taken the standpoint that in the event that IGZ undertakes enforcement in a specific case, a separate product must be examined in accordance with the characteristics of the Hecht-Pharma ruling *and* that it cannot be excluded that this examination will have an outcome other than that the classification as a medicine, which IGZ has attributed to the group of products to which belongs the separate product, it [the State] has brought forward insufficient facts, which justify the conclusion that the separate products demonstrate such a similarity that they, with regard to the case-by-case test described in Hecht-Pharma, can be equated with each other. All this leads to no other conclusion than that the classification given without proviso of the group of melatonin containing products as a medicine is in conflict with Union law. The court refers to paragraphs 37, 39 and 40 [...] of the Hecht-Pharma Judgment. That IGZ, prior to the notification of its enforcement policy, has “taken account” of all relevant characteristics of melatonin products is therefore insufficient. <sup>(lvii)</sup>

4.5 The court, unlike the State, judges that from the circumstances that this [Hecht-Pharma] Judgment (as well as the relevant previous rulings of the European Court of Justice) was pronounced in a case in which the national authority, in contrast to the present case, had already actually proceeded with enforcement of the medicinal products law, it cannot (a contrario) be concluded that the individualised assessment can be dispensed with in the event of an unconditional classification in the context of formulating enforcement policy. Neither in the Hecht-Pharma ruling nor in the

(preambles to the) Directives 2001/83 and 2004/27 can support be found for the position of the State. Moreover, the fact that this position is not only based on a broad interpretation and application of the concept of medicine, but also on a broad application of the authority to classify as a medicine, makes that it is not in proportion to the prevailing objections based on Union law against such practice, explicated by AG Trstenjak in paragraph 68 of the Conclusion [delivered in the Hecht-Pharma case].<sup>(lviii)</sup>

4.6. Therefore, a generic, unconditional examination of similar melatonin products on the basis of the finding that at dose equal to or exceeding 0.3 mg melatonin there are physiological processes by means of a pharmacological effect, without having conducted research into the other individual characteristics of the products mentioned in the Hecht-Pharma Judgment therefore was (and is) not permitted. The enforcement policy of IGZ as announced in its letter dated 9 November 2011 is therefore unlawful due to conflict with European law.”<sup>(lix)</sup>

The Court of The Hague deemed it conceivable that, instead of making the contested announcements, IGZ would for example announce by way of a public statement that, based on such and such scientific evidence, it is of the opinion that at a given daily dosage a certain ingredient has been found to exert a pharmacological effect. However, in paragraph 4.11 of its Judgment, the Court emphasized that such an announcement must be “accompanied by the notification that therefore an important medicine criterion must be deemed to be fulfilled, but that it is not excluded that a (necessary) individual test in the context of enforcement in a specific case shows that a product with such a dosage must (nevertheless) not be regarded as a medicine.”<sup>(lx)</sup>

Clearly, the Court does not allow any announcement that are unaccompanied by the “Hecht-Pharma” proviso. In no uncertain terms, the Court unequivocally ordered IGZ:

“5.1 [...] to take into consideration, with each (policy announcement and – determination that entails an) unconditional classification as medicine by function melatonin containing products, on a case by case basis and per each individual product, all characteristics of the product, in particular the composition, the pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail, and to conduct this test in a controllable and transparent manner;

5.2 [...] to permit a melatonin containing product onto the market, to permit that it is kept in stock, is sold, delivered and handed over, is imported or otherwise brought within or outside Dutch territory, and to refrain from relevant enforcement actions on the basis of the Medicines Act until [IGZ] has conducted its individual assessment (in the manner described in 5.1) with regard to this product;”<sup>(lxi)</sup>

In light of these two judgments, the approach applied by the BVL in the “Substance List - Category Plants and Plants parts” would not survive an examination by a Dutch Court, in that “with each (policy announcement and –determination that entails an) unconditional

classification as medicine by function melatonin containing products,” the competent [national] authorities must take into consideration “on a case by case basis and per each individual product, all characteristics of the product, in particular the composition, the pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail, and to conduct this test in a controllable and transparent manner.”<sup>(lxii)</sup>

Quite definitely, the German “*Stoffliste*,” even though it is not legally binding and in spite of the disclaimer that the BVL placed on its explanatory web-page<sup>(lxiii)</sup>, the “*Liste*” qualifies as a policy announcement and -determination that entails an unconditional classification of products containing the listed substances as medicines. In the “*Stoffliste*”, the BVL makes no distinction between substances (“*Stoffe*”) and products and use the terms interchangeably. For example, in point 4 of the *Stoffliste*’s Decision Tree, the BVL states: “If no significant pharmacological effects are identified, the substance can be classified as food. When reaching the pharmacologically effective dose, it [the substance] is defined as a medicinal product by function.” In any case, per its wording the “*Stoffliste*” will cause market participants to act in anticipation of a legally binding action undertaken by the BVL and/or other competent German authorities.

Likewise, the Pharmacological Proviso that forms part of the “Belfrit” approach and, more in particular, Article 11(3) of the French “Decree of 24 June 2014 establishing a list of plants, other than mushrooms, authorized in food supplements and the conditions of their use,” stand in contrast with the above-mentioned examination by the Dutch Courts.

### **Analysis of the introductory sections of the FC Roadmap**

In light of the foregoing, NPN provides the following detailed analysis of the introductory sections of the FC Roadmap. The stated purpose of this FC was formulated as follows:

“Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (“the Regulation”) was adopted in 2006 to govern the use of these claims in the labelling, presentation and advertising of foods. It aimed in particular at enabling consumers to make healthier choices by protecting them from misleading information and ensuring a level playing field for food business operators within the internal market. Nutrition claims are statements like 'low fat', 'high fibre', while health claims make the link between a food constituent and health, like 'Vitamin D is needed for the normal growth and development of bone in children'.

The purpose of this evaluation is to assess whether two specific elements required for the implementation of the Regulation have proven to be “fit for purpose” and whether the Regulation, to date, with respect to these elements, has achieved, at minimum burden, its overall objectives on truthful information to consumers and the facilitation of the free movement of foods bearing claims.

The evaluation will examine whether nutrient profiles provided for in the Regulation, which have not yet been adopted, are warranted and adequate to ensure the objectives of the Regulation. These nutrient profiles are thresholds of nutrients such as fat, salt

and sugars above which nutrition and health claims are restricted, thus preventing a positive health message on food high in these nutrients.

This evaluation will also examine whether the current rules concerning health claims on plants and their preparations used in foods are adequate, and how the use of such claims interacts with the current applicable food regulatory framework on plants and their preparations.

*NPN Comment: “... current rules concerning health claims on plants and their preparations used in foods ...” do not exist. The suggestion that the “adequacy” of non-existing rules must be examined is vacuous, since such rules do not exist. Also, there is no “interaction” between the use of health claims on plants and their preparations used in foods and the current applicable food regulatory framework on plants and their preparations. More precisely, there is no legal interaction between the Regulations that concern health claims and the Regulations and Directives that regulate market entry/exit of plants and their preparations used in or as foods.*

The results of this evaluation will be used to decide on the next steps regarding this policy area.”

The justification of the FC was worded as follows:

“In its Better Regulation Communication of 19 May 2015, the Commission announced to carry out an evaluation of the Regulation. This evaluation will focus on nutrient profiles and health claims on plants and their preparations added to foods. It will also consider the more general regulatory framework for the use of such substances in foods since it is closely related to the use of health claims.

*NPN Comment: There is no “close relation” between what is termed as “the more general regulatory framework for the use of such substances in foods [“plants and their preparations added to foods”] and the use of health claims. The use of health claims, as regulated in the NHCR, takes place in commercial communication:*

*Article 1.2 provides: “This Regulation shall apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.”*

*Nothing in the NHCR suggests or implies the existence of a “close relation” between the use of health claims in commercial communication and the regulatory framework that applies to a specific category of foodstuffs presented in the conditions of use which accompany the health claims.*

Since its adoption in 2006, the implementation of the Regulation remains incomplete since nutrient profiles, that the Commission was requested to set by January 2009, have not been established and due to the fact that health claims on plants and their preparations used in foods are still unregulated. In addition, the situation with regard

to the unregulated health claims on plants and their preparations has led to a broader reflection regarding the use of plants and their preparations used in foods.”

*NPN Comment: Health claims on plants and their preparations used in foods are not “still unregulated.” Since the Commission suspended the NHCR’s prohibition of health claims by placing health claims made on “botanicals” on hold and by allowing their use in commercial communication, the use of such claims takes place under the supervision of the individual Member States. Each Member State is responsible for the application of the relevant European Regulations and Directives that concern the protection of consumers against misleading commercial information. In this regard, it is up to the user to demonstrate the non-misleadingness of a health claim when challenged by the authorities of the Member State where the claim is used.*

The FC’s Content and subject were formulated as follows:

“Subject area

Before the adoption of the Regulation, nutrition and health claims were not harmonised. Member States took different orientations, ranging from the ban of health claims to an absence of any legislation, leading to internal market fragmentation. The aim is that the setting of lists of authorised nutrition and health claims at EU level would ensure the free movement of foods within the internal market.

*NPN Comment: While it is true that before the adoption of the NHCR, nutrition and health claims used in commercial communication were not positively harmonized, they were negatively harmonized by way of various European Regulations and Directives aiming at the protection of consumers against misleading information.*

While certain food business operators invested in research and development to substantiate the nutrition and health claims they made on their foods, others used nutrition and health claims as a marketing tool without ensuring that their claims were scientifically justified. This situation led to unfair competition and jeopardized the trust that consumers could have in scientifically justified claims.

*NPN Comment: The unfair competition and jeopardized trust alluded to in this paragraph were the result of a lack of action on the part of the relevant authorities in the various Member States.*

The Regulation stipulates that nutrition and health claims made on food must be based on and substantiated by generally accepted scientific evidence and that health claims should only be authorised for use in the Union after a thorough scientific assessment by the European Food Safety Authority (EFSA). The Regulation also provides for a list of permitted nutrition claims and for an authorisation procedure to establish the list of permitted health claims.

In addition, the Regulation obliges the Commission to set nutrient profiles, after consulting EFSA, which consist in maximum levels in foods of nutrients such as sugars, salt and fat, above which nutrition claims would be limited and health claims prohibited.”

With regard to plants and their preparations used in foods, the Commission observed the following :

“In the context of the implementation of the Regulation, more than 500 claims on plants and their preparations received an unfavourable assessment from EFSA in the context of their scientific assessments, and this raised many concerns among Member States and many stakeholders regarding health claims made on plants and their preparations used in food. To date, the remaining over 1500 submissions concerning such health claims have not yet undergone the scientific evaluation by EFSA.

*NPN Comment: Of the 4725 health claims placed on the Commission’s Consolidated List, EFSA rejected 500 claims on “botanicals” and another 1500 claims on “botanicals” were placed on hold by the Commission. Of the other over-2000 health claims only 224 were not rejected by EFSA. More than 2000 claims made on “non-botanicals” were rejected.*

*The reason for the Member States’ and stakeholders’ concerns was not found in EFSA’s unfavorable assessment as such. If that would have been the case, the rejection of claims on “non-botanicals” would have caused equal concerns. The real reason was the fact that specifically in the field of “botanicals,” the discrepancy between the treatment of health claims based on traditional use in the NHCR and similar medicinal claims in Article 16 of the Medicines Directive led to the need for “reflection.” The discrepancy does not concern claims on botanicals, it concerns the different appreciation of traditional use.*

The Regulation provides that all health claims, including those on plants and their preparations used in food, should be assessed on the basis of scientific evidence at 'the highest possible standard'.

*NPN Comment: This is a somewhat ambiguous way of stating that Recital 23 of the NHCR provides that “Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard. The “highest possible” standard applies to the assessment, not to the scientific evidence. The NHCR provides that scientific evidence must be “generally accepted.” It was EFSA which determined the standard for the scientific evidence.*

In this context, EFSA considers human studies as essential for the substantiation of claims. Hence, EFSA considered that evidence collected on the basis of experience gained over time with the actual consumption of the plants and preparations ('traditional use') alone cannot be considered sufficient to allow for the scientific substantiation of a health claim made on foods. Under the legislation on medicinal

products for human use, herbal medicinal products may undergo a simplified registration procedure instead of an authorisation procedure on the basis of criteria specified in the legislation on medicinal products for human use such as evidence on medicinal use throughout a period of at least 30 years 'traditional use'.

According to the latter legislation, the long tradition of the medicinal product makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience. Pre-clinical tests are not considered necessary, where the medicinal product on the basis of the information on its traditional use proves not to be harmful under specified conditions of use. Nevertheless, these medicines remain subject to general provisions applying to all medicines such as pharmacovigilance, good manufacturing practices etc.

Under the current EU rules, it is possible for a Member State on a case-by-case basis to classify a product as food or as medicine depending on its presentation and claimed effect. Therefore it is possible that differences exist between Member States in the classification of products. In other words, as EU law stands, it is possible that the same product is classified as a foodstuff in one Member State and as a medicinal product in another.

*NPN Comment: In this Position Paper, NPN amply dealt with this issue. The statement is not factual and leaves key elements of European law and Case Law unconsidered.*

Pending further action to regulate health claims on plants and their preparations, health claims made on such substances and which were submitted in the context of the establishment of the list of permitted health claims, may still be used pursuant to the transitional periods foreseen in Article 28(5) of the Regulation which requires that health claims comply with the Regulation and with the existing national provisions applicable to them.

The Regulation provides for the substantiation of health claims made on plants and their preparations used in foods by demonstrating the causal link between consumption of such foods and the claimed beneficial effect.

*NPN Comment: See arguments made supra. The NHCR is not “botanical”-specific. In addition, the NHCR does not mention the requirement of a “causal link” between the food and health. In Article 2.1.5 of the NHCR, a health claim is defined as “any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.” (emphasis added) A “relationship doesn’t necessarily mean a “causal link.” In Articles 6. 1 and 13.1(i) of the NHCR provide that health claims shall be based on “generally accepted scientific evidence.” This does not necessarily mean or imply that the evidence must exclusively demonstrate a “causal link.”*

This precludes any safety considerations by EFSA on the use of the substance in foods when assessing the claim.

*NPN Comment: This is a misstatement. The Regulation does not “preclude any safety considerations by EFSA on the use of the substance in foods when assessing the claim.” The Regulation was designed to prohibit, evaluate and reject and/or authorize health claims for use in commercial communication. Under Article 5.3, the Regulation provides that “Nutrition and health claims shall refer to the food ready for consumption in accordance with the manufacturer's instructions.” This implies that claims refer to readily consumable foods and/or food-products.*

*Several European Regulations and Directives regulate the safety of foods/foodstuffs. The Union’s General Food Law (Regulation 178/2002/EC) provides under Article 14 that foods/foodstuffs shall not be placed on the market if they are unsafe. In a number of paragraphs, Article 14 explains and regulates what shall be understood as “unsafe.”*

*Article 14.3 regulates that “In determining whether any food is unsafe, regard shall be had:*

- (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and*
- (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.”*

*The NHCR’s Article 5.3 regulates that when EFSA assesses a health claim, its assessment always concerns a food/foodstuff that is ready for consumption in accordance with the manufacturer’s instructions. Such instructions (Intended Normal Use - INU - of the product) must comply with Articles 14.3(a) and (b). In light of this, the Regulation (NHCR) makes a safety assessment redundant and meaningless in the context of assessing a health claim, because the safety of the food/foodstuff was established ex ante the assessment of the accompanying claim.*

*In the European Union, all authorized health claims are accompanied by conditions of use which the food business operator of finished products must follow in the manufacturing of the final product for which he wants to make use of a health claim. Most conditions of use that accompany authorized health claims do not refer to finished food products, but to food-ingredients (essential nutrients and/or other physiologically active substances). While such food ingredients fall under the definition of “food/foodstuff” laid down in EU’s General Food Law (Regulation 178/2002), health claims “shall refer to the food ready for consumption in accordance with the manufacturer’s instructions.”*

*Therefore, it is the responsibility of the manufacturer who uses a health claim to integrate EFSA’s/EU’s ingredient-based conditions of use and the related health claim in a final - ready for consumption - product by seeing to it that:*

- “(b) the nutrient or other substance for which the claim is made:*

*(i) is contained in the final product in a significant quantity as defined in Community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;” (NHCR Article 5)*

*and that*

*“(d) the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;” (NHCR Article 5)*

*In this regard, it is up to the manufacturer to see to it that final (finished) products shall be safe when used according to the instructions concerning the products’ intended normal use. Quite clearly, when establishing and formulating the intended normal use for a final product, the manufacturer considers and establishes the product’s - absolute – safety. Arguably, use of a final product could become unsafe when the product is used “to excess,” i.e. in quantities that greatly exceed those laid down in the product’s intended normal use instructions. However, this does not make the product unsafe. It makes a product’s excess abuse unsafe.*

*In light of this, Article 10.2(d) of the NHCR is not to be interpreted as an obligation to perform a safety assessment of the relevant food/foodstuff in the context of the evaluation of a health claim. In paragraph 4 of the General scientific guidance for stakeholders on health claim applications, EFSA clearly states: “It should be noted that a safety assessment is not foreseen under the framework of Regulation (EC) No 1924/2006. However, where relevant, the NDA Panel may recommend restrictions of use based on safety considerations.”<sup>(lxiv)</sup> Such recommendations do not per se concern a nutrient’s or other substance’s safety. They concern the possibly adverse effects of the use of safe ingredients used in or as foods. Evidently, the manufacturer of a final product for which he wants to use a health claim shall incorporate such recommended restrictions of use into the product’s intended normal use statement.*

*These provisos aim at the prevention of unsafe and/or undesirable use, rather than the prevention of unsafe foods-foodstuffs. Apart from preventing a nutritional imbalance when the conditions of use propose the ingestion of substances in quantities that greatly exceed those that can be obtained in the context of the normal consumption of a varied and balanced diet, food-products bearing health claims might lead to “over-use” beyond the quantities/dosages stipulated in the product’s intended normal use instructions when consumers seek to obtain the health effects no matter what and at all cost.*

*Other than this, in EU Food Law, the assessment of safety and health effects are organized as separate fields of regulation.*

This has given rise to increased concerns amongst the Member States on the authorisation of health claims on certain substances when no regard is given to the safety aspects of their use in foods. These concerns emerged strongly during the consultation of the Member States on the options for the way forward for those health claims on plants and their preparations that are “on hold”.

*NPN Comment: These concerns are unwarranted, groundless, without justification and contrary to the way EU Food Law is organized. The fact that during the process of evaluation and authorization of health claims “no regard is given to the safety aspects of their use in foods” is a clear misstatement, based on the apperception and implied suggestion that 1) this process should include a safety assessment (quod non) and that 2) since this process does not concern a food/foodstuff’s safety aspects, consumers would run the risk of being exposed to unsafe foods. The suggestion implies that outside the context of the Regulation (NHCR), the safety of foods is unregulated. This suggestion is evidently incorrect.*

*The combination of the assessment of safety and the evaluation/authorization of a claim of benefit has its place in Medicinal Products Law. This combination is relevant only because the Union’s pharmaceutical legislation concerns a medicine’s risks and benefits. Making the “giving regard to the safety aspects of a food/foodstuff” part of the evaluation/authorization of a health claim would introduce the pharmaceutical regulatory model into the Union’s Food Law.*

*As stated by NPN in this and previous comments, the Union’s Food Law is predicated on the separation of regulating safety and regulating health benefits. This is because the Union’s food-safety regulations preclude the marketing of unsafe foods. This is why Food Law does not concern a risk-benefit assessment. The assessment of risk in the context of Food Law is absolute. No matter how great a food/foodstuff’s benefits may be, if that food is unsafe, it will not be placed on the market. Given the effect of the Precautionary Principle in the Union’s Food Law, the potential risk of unsafety is already enough to prohibit market entry of a food. This is clarified in the “Article 8” procedure.*

*When Member States voice concerns about the potential unsafety of “botanicals,” they might take a look at the Union’s regulations that provide ample legal and administrative instruments to protect consumers against unsafe foods/foodstuffs.*

*The suggestion that the pharmaceutical model is required to address the problem that the NHCR precludes the authorization of health claims based on traditional use is not only unjustified, but completely beside the point and irrelevant to the matter at hand.*

An Overview Report which was finalised in 2015 based on a series of fact finding missions carried out by the Food and Veterinary Office (FVO) in Member States in 2013 and 2014 in order to gather information regarding the controls on food supplements highlights the problems that Member States face due to differing national rules for the use of plants and their preparations in foods. The report also highlights

issues with enforcement of existing rules in view of the increase in internet sales of such products.

*NPN Comment: In a harmonized situation, so-called “differing national rules for the use of plants and their preparations in foods” can only arise when Member States disregard the applicable harmonized rules. In this Paper, NPN showed that the rules for plants and their preparations in foods has been fully harmonized.*

The Commission concluded in a report adopted in 2008 on the use of substances other than vitamins and minerals in food supplements that substances "other than vitamins and minerals" (i.e. plants and plant preparations) have a very varied consumption pattern and that harmonisation in this area was currently not desirable.

*NPN Comment: The category of substances "other than vitamins and minerals" is much broader than “plants and plant preparations.” According to Recital 6 of the Food Supplements Directive 2002/46, “other substances” comprise “a wide range of [...] other ingredients that might be present in food supplements including, but not limited to, [...], amino acids, essential fatty acids, fibre and various plants and herbal extracts.*

The report also stresses that the “Community legal instruments described in this report already constitute a sufficient legislative framework for regulating this area and does not consider it opportune to lay down specific rules for substances other than vitamins and minerals for use in foodstuffs”. However, in those conclusions, the Commission did not rule out the possibility, at a later stage, of carrying out a supplementary analysis in order to check whether they are still valid. Such supplementary analysis should examine the legislative framework applicable to the addition of substances other than vitamins and minerals as well as the evolution of the market of the products concerned.”

With regard to the objectives of “applicable rules covering plants and their preparations,” the Commission observes that these rules were designed:

“- [t]o ensure that consumers are correctly informed on nutritional/health value of plants and their preparations contained in food and to allow them to make an informed choice on a healthy diet;  
 - to ensure that foods containing plants and their preparations that are placed on the market are safe;  
 - to ensure the free movement of foods containing plants and their preparations within the internal market.”

*NPN Comment: There are no “applicable rules covering plants and their preparations” specifically designed to “ensure that consumers are correctly informed on nutritional/health value of plants and their preparations contained in food and to allow them to make an informed choice on a healthy diet.” The*

*NHCR is non-specific with regard to claims concerning the “nutritional/health value” used in food-related commercial communication.*

With regard to what the Commission describes as “[h]ealth claims on plants and their preparations,” the Commission formulates the objective of applicable rule as follows:

“The Regulation [1924/2006/EC] should ensure reliable information to consumers, when trying to make healthier choices, by providing scientific justification of nutrition and health claims. This is aimed to be achieved by establishing an authorisation procedure, which requires a scientific assessment of the “the highest possible standard”. As a result through creation of a level playing field it should lead to securing investment and promoting innovation.”

*NPN Comment. The Commission equates the scientific justification with the scientific assessment of the justification, as if the justification and the assessment would both have to comply with the “highest possible standard.” However, an assessment of the highest possible standard may very well concern a scientific justification that differs from this standard.*

With regard to the objectives of the legislative framework concerning “plants and their preparations used in foods,” the Commission holds:

“The legislative framework with regard to other substances, such as plants and their preparations, is such that there is no specific harmonised legislation at EU level.

Nevertheless, food products containing the substances in question are covered by various Union legislative texts of general application, such as Regulation (EC) No 178/2002 on the general principles of food law, and other legal acts applicable to certain categories of foods, such as Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. Regulation (EC) No 1925/2006 was adopted at the same time as Regulation (EC) No 1924/2006 in 2006, and was considered to be complementary to that Regulation. Article 8 of Regulation (EC) No 1925/2006 lays down a procedure whereby the use of other substances in foods may be prohibited, restricted or placed under Union scrutiny if a harmful effect on health has been identified. This provision allows the regulation at EU-level of substances already on the market and for which potential safety concerns have been raised. However, this provision only allows the banning and restriction of plants and plant preparations in food. It does not constitute a “positive list” of permitted plants and plant preparations in food. To date, this provision has been used for two plants and their preparations.

In the absence of applicable secondary EU law, the primary EU law on free movement of goods applies. This is governed by Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU).”

*NPN Comment: Indeed, even if applicable secondary EU law were absent, quod non, the Principle of Mutual Recognition should apply.*

The Commission then concludes the introductory sections of the FC by defining the scope of the evaluation as follows:

“This evaluation, covering the 28 EU Member States, aims at covering the following aspects of the Regulation: 1. Nutrient profiles and 2. Health claims on plants and their preparations. In this context, the evaluation will, where necessary, extend to other regulatory aspects, such as safety requirements for the use of plants and their preparations in food.

*NPN Comment: In this regard, see in this Position Paper the first paragraph (“Roadmap”).*

This evaluation excludes from its scope other aspects of the Regulation, besides the two mentioned above. The reason is that an evaluation of the Regulation in its entirety would be premature at this stage given that the list of authorised health claims only came into application in December 2012.

This evaluation aims at covering the situation on the EU market since the application of the Regulation in July 2007.”

## **Conclusion**

Having arrived at this point of the “Roadmap,” NPN emphasizes once again that the current state of European law and case law precludes the existence or development of heterogeneous national determinations that would obstruct the free movement of traditional health claims and/or traditional therapeutic claims and/or the individual products bearing such claims. This state of affairs firmly precludes the approximation of provisions laid down by law, regulation or administrative action in Member States, simply because all the relevant provisions are part of the *acquis communautaire*. In addition, European case law has reached a sufficiently high level of clarity, that, where the *acquis* would still lead to issues of interpretation or doubt, such issues can be readily resolved by applying European case law.

Of course, this state of affairs does not preclude the improvement of existing harmonised measures. The European legislature may - and should - improve fully approximated regulations on grounds of e.g. requirements of “clarity and rationality” in case of divergence between the harmonising regulations demanding amendments of existing texts, or the risk that rigorously applied regulation may lead to removal of existing products and/or health claims. When improving existing harmonised regulations, the Union legislature must pay respect most of all to the principle of legal certainty. <sup>(lxv)</sup>

In this regard, NPN would also like to point out that the Court, when it assessed the legality of grounds for harmonising measures aimed at removing obstacles to trade, held that, “the emergence of such obstacles must be likely and the measure in question must be designed to prevent them.” When, in an already fully harmonised situation, further development and improvement of the harmonised measures is required, the Court’s vision still applies, in the

sense that the measures aimed at improving an existing lacuna must be genuinely designed to remedy it.

Therefore, a problem that finds its origin in “the current different legal treatment of botanicals in foods and medicines legislation *with respect to health claims / therapeutic indications*,” cannot and should not be remedied by a measure that is designed to remove an obstacle in the trade of certain food-products containing “botanicals,” especially not when, *with respect to health claims / therapeutic indications*, the “legal treatment” of these claims and indications has been fully harmonised.

The Nutrition and Health Claims Regulation, which forms part of Food Law, clearly amended Article 2 of the Food Labelling Directive 2000/13/EC. What was not foreseen, however, was that the Regulation would produce a “different legal treatment of botanicals in foods and medicines legislation with respect to health claims / therapeutic indications.” With respect to the principle of legal certainty, the most transparent, readily understandable, clear and foreseeable solution to remedy said difference can be found in the amendment of the NHCR, to the effect that the amendment shall allow the use of traditional health claims in commercial communication that accompanies food products. In the ANNEX to this Paper, NPN takes the liberty of suggesting the wording for such a Simplified Procedure Organizing the Application, Evaluation and Authorization of Health Claims based on Traditional Use.

In light of the foregoing, NPN proposes that the Commission, when making considerations regarding “the current different legal treatment of botanicals in foods and medicines legislation *with respect to health claims / therapeutic indications*,” will refrain from solving this problem by somehow integrating it in regulatory measures concerning the market entry/exit of “botanicals.” The marketability of “botanicals” and other “other substances” is well regulated under Article 8 of Regulation 1925/2006/EC, which, in and of itself, forms a closed regulatory system that conclusively approximated the relevant national provisions.

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Bert Schwitters / 15 June 2016

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**ANNEX**  
**to NPN - Position Paper - 15 June 2016**  
**Solving the current different legal treatment of health claims and medical  
claims based on traditional use**

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**Suggested Simplified Procedure**  
**Organizing the Application, Evaluation and Authorization**  
**of**  
**Health Claims based on Traditional Use**

8 June 2016

In this *Simplified Procedure for Health Claims based on Traditional Use*, NPN elaborates its position that the least onerous and least restrictive legislative measure to resolve the problems arising from the “different treatment” of traditional health claims and traditional therapeutic/medicinal claims should be found in the creation of:

- *a separate Union Regulation that organizes the market entry of traditional health claims via a simplified procedure, in ways equivalent and similar to those which, in Article 16 of Directive 2001/83/EC, have regard specifically to information regarding traditional medicinal use, or*
- *an amendment of Regulation 1924/2006/EC that specifically addresses the market entry of traditional health claims via a simplified procedure, in ways equivalent and similar to those which, in Article 16 of Directive 2001/83/EC, have regard specifically to information regarding traditional medicinal use.*

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Simplified Procedure  
Organizing the Application, Evaluation and Authorization  
of  
Health Claims based on Traditional Use

**Considering that:**

- 1) Regarding the particular characteristics of traditional health claims, especially their established and long tradition, it is desirable to provide a special, simplified authorisation procedure for such health claims. However, this simplified procedure should be applied only where no authorisation can be obtained pursuant to the procedures laid down in Articles 15 - 19 of Regulation 1924/2006/EC, in particular because of a lack of sufficient scientific literature demonstrating the relationship between a nutrient or another physiologically active substance (“other substance”), a food category, a food or one of its constituents and the traditional beneficial effect on health.
- 2) The long tradition of the health claim makes it possible to eliminate the need for clinical trials, in so far as the efficacy of the nutrient or other substance, the food category, the food or one of its constituents is plausible on the basis of established and long-standing use and experience.
- 3) A traditional health claim could be defined as a claim that states, suggests or implies that a traditional relationship exists between the consumption of a nutrient or other substance, a food category, a food or one of its constituents and health.
- 4) A traditional reduction of disease risk claim could be defined as a traditional health claim that states, suggests or implies that a traditional relationship exists between the consumption of a nutrient or other substance, a food category, a food or one of its constituents and the significant reduction of a risk factor in the development of a human disease.
- 5) The simplified authorisation should be acceptable only where the traditional health claim may rely on an established and sufficiently long use in the European Union. Use outside the Community should be taken into account only if the traditional health claim has been used within the Community for a certain time. Where there is limited evidence of use within the Community, it is necessary to carefully assess the validity and relevance of use outside the Community.
- 6) The requirement to show established traditional use in the European Union throughout a sufficiently long period could be satisfied even where the marketing of the nutrient or other substance, the food category, the food or one of its constituents in respect of which the traditional health claim is to be made and/or the use of the traditional health claim have not been based on a specific registration or authorisation.
- 7) With the objective of further facilitating the authorisation of traditional health claims and of further enhancing harmonisation, the European Commission shall establish in the Union

Register of Health Claims a list of traditional health claims that fulfil certain criteria, such as having been in use for a sufficiently long time and plausibility of the effect on health, and hence are considered to be correct when used under the appropriate conditions of intended normal use.

**With regard to the particularities of traditional health claims, NPN respectfully suggests the following Procedure for the Authorisation of a Traditional Health Claim**

1. A food business operator intending to use a traditional health claim may apply for the inclusion of the claim in the relevant list in the Union Register of health claims.
2. The application for inclusion of the traditional health claim in the Register shall be submitted to the competent national authority of a Member State that shall acknowledge receipt of the application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application.
3. The application shall include the reasons for the request and the following data:
  - (a) name and address of the applicant;
  - (b) the name/description of the nutrient or other substance, the food category, the food or one of its constituents in respect of which the traditional health claim is to be made and its particular characteristics;
  - (c) bibliographical or expert evidence to the effect that the effect on health is plausible and that the traditional health claim and the nutrient or other substance, the food category or the food or one of its constituents, in respect of which the traditional health claim is to be made, have been in use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the European Union;
  - (d) copies of more recent scientific studies which are of importance with respect to the traditional health claim;
  - (e) a proposal for the wording of the traditional health claim for which authorisation is sought including, as the case may be, specific conditions for use;
  - (f) a summary of the application.
4. The application and any additional information supplied by the applicant shall be sent without delay by the competent authority of the Member State to the European Food Safety Authority for an appropriate assessment as well as to the Commission and the Member States for information.
5. The Authority shall publish the summary of the application within 1 month after the date of receipt of the application. The Authority shall issue an opinion within a time limit of 5 months from the date of receipt of the request. Such time limit may be extended by up to 1 month if the Authority considers it necessary to seek supplementary information from the applicant. In such a case the applicant shall submit the requested information within 15 days from the date of receipt of the Authority's request.
6. In order to prepare its opinion, the Authority shall:
  - (a) verify that the relevant nutrient or other substance, the food category, the food or one of its constituents has been sufficiently characterised;

- (b) verify that the proposed wording of the traditional health claim is supported by adequate bibliographical or expert evidence;
- (c) verify that the traditional health claim and the nutrient or other substance, the food category, the food or one of its constituents, in respect of which the traditional health claim is to be made, have been in use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the European Union;
- (d) examine whether it is necessary to accompany the traditional health claim by special conditions of use;
- (e) examine whether the wording of the traditional health claim complies with the relevant criteria of understandability laid down in Recital 16 of Regulation 1924/2006/EC.

7. In the event that the opinion of the Authority holds that an authorisation of the traditional health claim may be issued, the opinion shall include the following particulars:

- (a) name and address of the applicant;
- (b) the name/description and the particular characteristics of the nutrient or other substance, the food category, the food or one of its constituents, in respect of which the traditional health claim is to be made;
- (c) the considerations on the basis of which the Authority concludes that the bibliographical or expert evidence concerning the effect of the traditional use on health is sufficient and plausible on the basis of long-standing use and experience;
- (d) the considerations on the basis of which the Authority judges that it has been sufficiently demonstrated that the traditional health claim and the nutrient or other substance, the food category, the food or one of its constituents, in respect of which the traditional health claim is to be made, have been in use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the European Union;
- (e) a proposal for the wording of the traditional health claim, including, as the case may be, the specific conditions of use;
- (f) where applicable, restrictions of use of the food and/or an additional statement or warning that should accompany the traditional health claim on the label and in the advertising.

8. In the event that the opinion of the Authority holds that an authorisation of the traditional health claim may not be issued, the opinion shall include the following particulars:

- (a) the name and address of the applicant;
- (b) the considerations on the basis of which the Authority judges that the nutrient or other substance, the food category, the food or one of its constituents, in respect of which the traditional health claim is to be made is insufficiently or incorrectly characterized;
- (c) the considerations on the basis of which the Authority judges that the bibliographical or expert evidence concerning the effect of the traditional use on health is insufficient or implausible on the basis of long-standing use and experience;
- (d) the considerations on the basis of which the Authority judges that it has been insufficiently demonstrated that the traditional health claim and the nutrient or other substance, the food category, the food or one of its constituents, in respect of which the traditional health claim is to be made, have been in use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the European Union.
- e) the considerations on the basis of which the Authority judges that the proposed wording of the traditional health claim does not satisfy the criteria of understandability laid down in Recital 16 of Regulation 1924/2006/EC.

9. The Authority shall forward its opinion to the Commission, the Member States and the applicant, accompanied by a report describing its assessment of the health claim and stating the reasons for its opinion and the information on which its opinion is based.

10. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public. The applicant or members of the public may make comments to the Commission within 30 days from such publication.

11. Within two months after receiving the opinion of the Authority, the Commission shall submit to the Standing Committee on Plants, Animals, Food and Feed (Section General Food Law) instituted by Article 58(1) of Regulation (EC) No 178/2002 a draft decision on whether or not to include the applied for traditional health claim in the relevant list of the Union Register, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration.

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Bert Schwitters / 15 June 2016

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<sup>i</sup> Commission Press Release - Brussels, 27 September 2010. Food: Commission reviews the progressive adoption of the list of permitted health claims. IP/10/1176.

<sup>ii</sup> See e.g. the Opinion of Advocate General Geelhoed delivered on 4 July 2002 in Case C-221/00.

<sup>iii</sup> Judgment of the Court (Sixth Chamber) of 23 January 2003 in Case C-221/00.

<sup>iv</sup> Judgment of the Court of 12 July 2005 in Joined Cases C-154/04 and C-155/04. In paragraph 86 of this Judgment, the Court also held that these market entry criteria should “relate only to grounds of human-health protection, to the exclusion of considerations concerning nutritional needs.” (emphasis added)

<sup>v</sup> Commission Implementing Regulation 2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.

<sup>vi</sup> Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

<sup>vii</sup> With regard to “other substances” that are generally and rather broadly defined as “botanicals,” Directive 2002/46/EC and Regulation 1925/2006/EC define “other substances” as “a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, [...], amino acids, essential fatty acids, fibre and various plants and herbal extracts.” Since the Commission, in Recital 10 of Regulation 432/2012/EC, defined “plant or herbal substances” as “botanical substances,” “botanicals” are officially categorized as a category of “other substances.”

<sup>viii</sup> Recital 5 in Commission Regulation 536/2013 of 11 June 2013 amending Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children’s development and health.

<sup>ix</sup> E.g.: Cases C-376/98 and C-380/03 (*Tobacco Advertising*), and cases C-434/02 (*Anold André*) and C-201/03 (*Swedish Match*).

<sup>x</sup> In Case C-210/03 (*Swedish Match*), the ECJ judged:

“28. Article 95(1) EC [replaced by Article 114 TFEU] provides that the Council is to adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

29. In this respect, it should be recalled that, while a mere finding of disparities between national rules is not sufficient to justify having recourse to Article 95 EC (see, to that effect, Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8419, paragraph 84), it is otherwise where there are differences between the laws, regulations or administrative provisions of the Member States which are such as to obstruct the fundamental freedoms and thus have a direct effect on the functioning of the internal market (see, to that effect, *Germany v Parliament and Council*, paragraph 95, and Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraph 60).

30. It also follows from the Court’s case-law that, while recourse to Article 95 EC as a legal basis is possible if the aim is to prevent future obstacles to trade resulting from the heterogeneous development of national laws, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them (see, to that effect, Case C-350/92 *Spain v Council* [1995] ECR I-1985, paragraph 35, *Germany v Parliament and Council*, paragraph 86, Case C-377/98 *Netherlands v Parliament and Council* [2001] ECR I-7079, paragraph 15, and *British American Tobacco (Investments) and Imperial Tobacco*, paragraph 61).

31. The Court has also held that, where the conditions for recourse to Article 95 EC as a legal basis are fulfilled, the Community legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made (*British American Tobacco (Investments) and Imperial Tobacco*, paragraph 62).”

<sup>xi</sup> Although Directive 2004/24/EC of 31 March 2004 concerns “herbal medicinal products,” this Directive applies in the broader context of all traditional medicines. Recital 2 of Directive 2004/24/EC provides: “Where the applicant can demonstrate by detailed references to published scientific literature that the constituent or the constituents of the medicinal product has or have a well-established medicinal use with recognised efficacy and an acceptable level of safety within the meaning of Directive 2001/83/EC, he/she should not be required to provide the results of pre-clinical tests or the results of clinical trials.”

<sup>xii</sup> To be sure, NPN notes that national and EU regulations cannot develop “in parallel,” at least not in the sense that “in parallel” would mean overlapping. Once national measures are harmonised, they cease to exist as national measures, leaving the remainder of the national measures unharmonised.

<sup>xiii</sup> See: *The European regulation of food supplements and food fortification. Intended normal use – the ultimate tool in organising level playing markets and regulations, or how to break the fairy ring around ‘other substances’*. Environmental Law & Management; (2007) 19 ELM. Lawtext Publishing Ltd.

<sup>xiv</sup> Discussion Paper on “Botanicals and Botanical Preparations widely used as food supplements and related products: Coherent and Comprehensive Risk Assessment and Consumer Information Approaches.” (2004) European Food Safety Authority, Brussels.

<sup>xv</sup> Commission Implementing Regulation 2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.

<sup>xvi</sup> The “average” consumer was defined by the European Court of Justice as “reasonably well-informed and reasonably observant and circumspect.”

<sup>xvii</sup> “Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.” Article 1.2 of Directive 65/65/EC.

<sup>xviii</sup> See Article 4.8 of Directive 2002/46/EC (Food Supplements).

<sup>xix</sup> Paragraph 55 of the Judgment of the Court (First Chamber) of 15 November 2007 in Case C 319/05. (“Garlic”)

<sup>xx</sup> Point 31 in the *Hecht-Pharma* Judgment, Case C-140/07, 15 January 2009.

<sup>xxi</sup> Case C-221/00; Commission of the European Communities v Republic of Austria.

<sup>xxii</sup> “Schließlich ist zum Argument der Bundesregierung betreffend die Verbrauchervorstellungen in Österreich darauf hinzuweisen, daß nach dem Gerichtshof das Recht eines Mitgliedstaats nicht dazu dienen darf, die gegebenen Verbrauchsgewohnheiten zu zementieren, um einer mit deren Befriedigung befaßten inländischen Industrie einen erworbenen Vorteil zu bewahren, wenn andere Maßnahmen zum Schutz der Verbraucher gegen Irreführungen bestehen. Diese Feststellung des EuGH kann - entgegen der Auffassung der Bundesregierung in der Antwort auf die mit Gründen versehene Stellungnahme - auf den vorliegenden Fall übertragen werden. *Mit dieser Rechtsprechung wie auch in anderen Urteilen hat der Gerichtshof betont, daß es unzulässig ist, staatliche Regelungen betreffend den Schutz der Gesundheit oder der Verbraucher allein an den im betreffenden Mitgliedstaat vorherrschenden Gegebenheiten zu orientieren.*” (emphasis added)

<sup>xxiii</sup> Judgment of the Court of 12 July 2005 in Joined Cases C-154/04 and C-155/04.

<sup>xxiv</sup> In points 65, 85 and 86 of its Judgment made in the Joined Cases C-154/04 and C-155/04, the Court held:

“65. As is stated in the 4th recital in the preamble to Directive 2001/15, the selection of the substances identified in the annex [(forms of) vitamins and minerals] to the directive took into account criteria of safety and availability for use by humans, criteria referred to in the 11th recital to Directive 2002/46.

85. [...] As the claimants in Case C 154/04 have observed, although the proposal for the directive mentioned at paragraph 37 of this judgment provided for a second criterion, namely that the vitamins and minerals in question should be ‘considered essential nutrients’, as is shown by the 7th recital in the preamble to the proposal, that criterion is no longer included in the 9th recital to Directive 2002/46. As regards the list in Annex II to the directive, it is apparent from the 11th recital that the only relevant criteria are those relating to the safety and bioavailability of the chemical substance in question of member states.

86. Such statements show that the relevant criteria for the purposes of the positive lists [of (forms of) vitamins and minerals] and the application of the procedure for modification of those lists can, as conceived by the Community legislature, relate only to grounds of human-health protection, to the exclusion of considerations concerning nutritional needs.”

<sup>xxv</sup> Judgment of the Court (First Chamber) of 9 June 2005 in Joined Cases C-211/03, C-299/03 and C-316/03 to C 318/03, in the proceedings HLH Warenvertriebs GmbH (C-211/03), Orthica BV (C-299/03 and C-316/03 to C-318/03) v Bundesrepublik Deutschland.

<sup>xxvi</sup> See paragraph 18 in the Judgment made on 26 May 2009 by the German *Bundesverwaltungsgericht* in the *Hecht-Pharma* case; BVerwG 3 C 5.09; OVG 11 LC 180/05 - OVG Lüneburg - 23.03.2006 - AZ: OVG 11 LC 180/05; Niedersächsisches OVG - 23.03.2006 - AZ: OVG 11 LC 180/05.

<sup>xxvii</sup> Opinion of the Advocate-General Geelhoed delivered on 3 February 2005 in Case C-211/03; HLH Warenvertriebs GmbH v Federal Republic of Germany.

<sup>xxviii</sup> According to the papers in the case, the contested product contained between 0.95 and 1.05 per cent natural allicin.

<sup>xxix</sup> In paragraphs 60-64 of the Opinion delivered on 21 June 2007 in the “Garlic” case (C-319/05), Advocate General Trstenjak argued:

“60. At this point, I believe that it should be pointed out that the legal assessment to be conducted by the Court must not be restricted to the health-promoting effect which garlic has as a foodstuff in the present state of scientific knowledge. Many products which are clearly foodstuffs according to the established view may also objectively serve therapeutic purposes. On the basis of the restrictive interpretation of the definition of ‘medicinal product’ advocated here, the question must be asked whether the contested product in itself offers any additional benefit compared with garlic in its natural form.”

In this paragraph, the Advocate General refers to the following footnote:

“40 — See also Köhler, H., loc. cit. (footnote 27), p. 850, who classifies among foodstuffs which serve therapeutic purposes herbal teas and other medicinal herbs, including grated carrots to combat intestinal parasites or garlic to prevent arteriosclerosis. He believes that it is absurd to classify them as medicinal products because of their therapeutic function alone.”

The Advocate General then continues:

“61. On this question I tend to concur with the view taken by the Commission that the product in question in the present case is not a medicinal product. The literature on which the German Government relies in its defence explains the effect of the foodstuff garlic, which can be achieved through consumption of that foodstuff, but also by taking garlic preparations in the form of capsules, powders or solutions. On closer examination the contested preparation proves to be nothing more than a concentrate of the natural active substance allicin, whose physiological effects can simply be achieved by taking a larger amount of the foodstuff garlic.

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62. Whilst it is recognised that the use of garlic has a positive effect on the human body, its effect should not be regarded as any greater or different from that of other vegetable or animal products which are taken as part of the daily diet. As the Commission argues in its application, that effect can also be achieved by using other foodstuffs and by adopting a certain diet. For example, sea fish such as salmon, tuna, herring and sardines contain omega-3 fatty acids, which also reduce the risk of arteriosclerosis. In addition, vitamin C, vitamin E and the mineral selenium are important and can all be taken as part of normal foodstuffs, but also as food supplements.

63. I do not believe that the arguments put forward by [the] Federal Government are conclusive enough to take the view that the product should be classified as a medicinal product 'by function' since the effects of such a preparation are not such as to prevent the risk of arteriosclerosis entirely. As can be seen from the letter from the German Government of 14 March 2003, which is Annex 4 to the application, apart from the active substance allicin the contested preparation does not contain any substances that could be classified as vitamins, minerals or other substances with a nutritional or physiological effect.

64. In any case, any effect of a foodstuff in reducing risks or promoting health must not automatically lead to classification as a medicinal product, otherwise the Member States would be free to impede trade specifically in those valuable foodstuffs and thus withhold them from consumers. It is clear that such a consequence is directly contrary to the objectives of free movement of goods.”

<sup>xxx</sup> Request for a preliminary ruling from the Verwaltungsgericht Braunschweig (Germany) lodged on 11 June 2015 - Queisser Pharma GmbH & Co. KG v Federal Republic of Germany.

<sup>xxxi</sup> OJ 2002 L 31, p. 1.

<sup>xxxii</sup> OJ 2006 L 404, p. 26.

<sup>xxxiii</sup> 78. Zur Vorlagefrage 3:

79. In Betracht kommt, dass das Verfahren nach Art. 8 der VO (EG) Nr. 1925/2006 i.V.m. den Durchführungsbestimmungen der VO (EU) Nr. 307/2012 die Zulässigkeit eines Zusatzes von Aminosäuren zu Nahrungsergänzungsmitteln abschließend regelt, keinerlei Möglichkeit für eine abweichende nationale Regelungen belässt und die in Rede stehende nationale gesetzliche Regelungen nach dem LFGB deswegen unanwendbar ist (so Meyer in: Meyer/Strein, LFGB/BasisVO/HCVVO, 2. Aufl., § 2 LFGB Rn. 34).

80. Der europäische Gesetzgeber hat dort ein Verfahren bereitgestellt, das die Verwendung sonstiger Stoffe betrifft, die nicht Vitamine oder Mineralstoffe sind, und die eine ernährungsbezogene oder eine physiologische Wirkung haben und deren Verwendung in Lebensmitteln ein potenzielles Risiko für die Verbraucher bergen kann. Die Verwendung von Aminosäuren in Nahrungsergänzungsmitteln wie des L-Histidins im Erzeugnis der Klägerin dürfte in den Anwendungsbereich der Verordnung fallen, zumal Art. 1 Abs. 2 der VO (EG) 1925/2006 Nahrungsergänzungsmittel nur im Hinblick auf Vitamine und Mineralstoffe vom Anwendungsbereich ausschließt und Aminosäuren in Satz 1 des Erwägungsgrunds 1 ausdrücklich erwähnt werden.

81. Hiernach kann erst dann, wenn sich im konkreten Einzelfall aufgrund einer wissenschaftlichen Bewertung der Risiken für die Verbraucher erweist, dass die Verwendung der Aminosäure im Nahrungsergänzungsmittel gesundheitsschädlich ist, deren Verwendung mit der Aufnahme in Anhang III Teil A verboten oder mit der Aufnahme in Anhang III Teil B an Bedingungen geknüpft werden. Sofern auf der Grundlage der verfügbaren wissenschaftlichen Erkenntnisse im Einzelfall ein potenzielles Risiko für die Verbraucher nachgewiesen ist, kann der Stoff in Anhang III Teil C aufgenommen werden. Nach Art. 8 Abs. 5 VO (EG) 1925/2006 würde spätestens binnen vier Jahren nach Aufnahme eines Stoffes in den Anhang III Teil C darüber entschieden, ob dessen Verwendung allgemein erlaubt oder ob er in Anhang III Teil A oder B aufgenommen wird.

82. Dafür, dass dieses Verfahren die Zulässigkeit der Verwendung von Aminosäuren in Nahrungsergänzungsmitteln abschließend regelt, könnte sprechen, dass Gegenstand und Ziel der Verordnung nach deren Art. 1 Abs. 1 ist, die Rechts- und Verwaltungsvorschriften der Mitgliedsstaaten über den Zusatz u.a. solcher „anderer“ Stoffe zu Lebensmitteln anzugleichen, um das Funktionieren des Binnenmarkts und gleichzeitig ein hohes Verbraucherschutzniveau zu gewährleisten. Ebenso ist im Erwägungsgrund 1 der VO (EG) 1925/2006, in dem Aminosäuren ausdrücklich erwähnt werden, von der Notwendigkeit die Rede, Gemeinschaftsvorschriften zu erlassen, um nationale Bestimmungen über den Zusatz von u.a. „anderen“ Stoffen zu harmonisieren. Zwar sind bislang - soweit ersichtlich - keine Entscheidungen im Verfahren nach Art. 8 der VO (EG) 1925/2006 ergangen; andererseits steht das Verfahren den Mitgliedsstaaten offen.

83. Unabhängig hiervon kommt - als selbstständig tragende Begründung - in Betracht, dass der Europäische Gesetzgeber mit dem Verfahren nach Art. 8 VO (EG) Nr. 1925/2006 ein in sich geschlossenes System zum Umgang mit sonstigen Stoffe - u.a. Aminosäuren - normiert hat. Dies könnte zur Folge haben, dass sich Mitgliedsstaaten, selbst wenn bis auf Weiteres grundsätzlich Raum für nationale gesetzliche Regelungen bleibt, nicht in prinzipiellem Widerspruch hierzu setzen dürfen. Die in Rede stehende nationale gesetzliche Regelung könnte dem Regelungsprinzip des Verfahrens nach Art. 8 VO (EG) Nr. 1925/2006 diametral entgegenstehen, indem sie die Verwendung von Aminosäuren in Lebensmitteln pauschal – unabhängig davon, ob im Einzelfall ein begründeter Verdacht einer Gesundheitsgefährdung besteht - verbietet und die Möglichkeit, nach den nationalen Vorschriften eine Ausnahmegenehmigung zu erhalten, den beschriebenen Einschränkungen unterliegt (vgl. Möstl, *Rechtliche Anforderungen für den Einsatz funktioneller Inhaltsstoffe im Lebensmittelbereich*, *Zeitschrift für Lebensmittelrecht* 2013, 682 ff.; Meyer, a.a.O., § 2 LFGB Rn. 38.). Die nationale gesetzliche Regelung könnte deswegen unanwendbar sein.

<sup>xxxiv</sup> *Rechtliche Anforderungen für den Einsatz funktioneller Inhaltsstoffe im Lebensmittelbereich*; Professor Dr. Markus Möstl; *Zeitschrift für das gesamte Lebensmittelrecht*; 6/2013.

<sup>xxxv</sup> Page 689 in *Rechtliche Anforderungen für den Einsatz funktioneller Inhaltsstoffe im Lebensmittelbereich*; Professor Dr. Markus Möstl; *Zeitschrift für das gesamte Lebensmittelrecht*; 6/2013.

<sup>xxxvi</sup> Regulation (EU) No 609/2013 of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009

<sup>xxxvii</sup> Pages 689 and 692 in Möstl's *Rechtliche Anforderungen für den Einsatz funktioneller Inhaltsstoffe im Lebensmittelbereich*.

<sup>xxxviii</sup> Article 15(1) enumerates: (a) vitamins; (b) minerals; (c) amino acids; (d) carnitine and taurine; (e) nucleotides; (f) choline and inositol.

<sup>xxxix</sup> Page 689-690 in Möstl's *Rechtliche Anforderungen für den Einsatz funktioneller Inhaltsstoffe im Lebensmittelbereich*.

<sup>xl</sup> Page 690 in Möstl's *Rechtliche Anforderungen für den Einsatz funktioneller Inhaltsstoffe im Lebensmittelbereich*.

<sup>xli</sup> Pages 691 and 692 in Möstl's *Rechtliche Anforderungen für den Einsatz funktioneller Inhaltsstoffe im Lebensmittelbereich*.

<sup>xlii</sup> Page 692 in Möstl's *Rechtliche Anforderungen für den Einsatz funktioneller Inhaltsstoffe im Lebensmittelbereich*.

<sup>xliii</sup> Möstl refers *inter alia* to the Judgment made by the ECJ in Case C-446/08; 29 April 2010; *Solgar Vitamin's France*.

<sup>xliv</sup> Page 692 in Möstl's *Rechtliche Anforderungen für den Einsatz funktioneller Inhaltsstoffe im Lebensmittelbereich*.

<sup>xlv</sup> Stoffliste des Bundes und der Bundesländer - Kategorie "Pflanzen- und Pflanzenteile; Bundesamt für Verbraucherschutz und Lebensmittelsicherheit; 2014.

<sup>xlvi</sup> Page 2 of the *Stoffliste*.

<sup>xlvii</sup> Page 2 of the *Stoffliste*.

<sup>xlviii</sup> See [http://www.bvl.bund.de/DE/01\\_Lebensmittel/03\\_Verbraucher/08\\_Stoffliste/1m\\_stoffliste\\_node.html](http://www.bvl.bund.de/DE/01_Lebensmittel/03_Verbraucher/08_Stoffliste/1m_stoffliste_node.html) Download 1 October 2015.

"Die Stoffliste ist nicht rechtsverbindlich, erhebt keinen Anspruch auf Vollständigkeit und ist für eine Fortschreibung offen, um neuen wissenschaftlichen Erkenntnissen und der Entwicklung des Marktes Rechnung zu tragen.

Eine abschließende Beurteilung von Produkten, die Pflanzen und Pflanzenteile enthalten, muss stets einzelfallbezogen unter Berücksichtigung aller beurteilungsrelevanten Kriterien erfolgen. Hierzu zählen unter anderem die Zubereitung und Dosierung, in der der Stoff verwendet wird. So können beispielsweise Extrakte aufgrund der verwendeten Extraktionsmittel oder des Herstellungsverfahrens erhebliche Unterschiede in Bezug auf die Zusammensetzung oder die ernährungsphysiologischen, pharmakologischen und toxikologischen Eigenschaften aufweisen. Bei Prüfung des Einzelfalles sind darüber hinaus auch Aufmachung, Werbung, Kenntlichmachung und Auslobung einzelner Produkte zu berücksichtigen."

<sup>xlix</sup> EFFL 2|2012; Traditional Knowledge for the Assessment of Health Effects for Botanicals – A Framework for Data Collection. Robert Anton, Mauro Serafini and Luc Delmulle.

EFFL 3|2013 187. Project BELFRIT. Harmonizing the Use of Plants in Food Supplements in the European Union: Belgium, France and Italy – A first Step. Guillaume Cousyn, Stefania Dalfra, Bruno Scarpa, Joris Geelen, Robert Anton, Mauro Serafini and Luc Delmulle.

<sup>1</sup> EFFL 3|2013 187. Project BELFRIT. Harmonizing the Use of Plants in Food Supplements in the European

Union: Belgium, France and Italy – A first Step. *Guillaume Cousyn, Stefania Dalfra, Bruno Scarpa, Joris Geelen, Robert Anton, Mauro Serafini and Luc Delmulle.*

<sup>li</sup> Point 31 in the *Hecht-Pharma* Judgment, Case C-140/07, 15 January 2009.

<sup>lii</sup> Judgment of the Court of 12 July 2005 in Joined Cases C-154/04 and C-155/04.

<sup>liii</sup> In points 65, 85 and 86 of its Judgment made in the Joined Cases C-154/04 and C-155/04, the Court held:

“65. As is stated in the 4th recital in the preamble to Directive 2001/15, the selection of the substances identified in the annex [(forms of) vitamins and minerals] to the directive took into account criteria of safety and availability for use by humans, criteria referred to in the 11th recital to Directive 2002/46.

85. [...] As the claimants in Case C 154/04 have observed, although the proposal for the directive mentioned at paragraph 37 of this judgment provided for a second criterion, namely that the vitamins and minerals in question should be ‘considered essential nutrients’, as is shown by the 7th recital in the preamble to the proposal, that criterion is no longer included in the 9th recital to Directive 2002/46. As regards the list in Annex II to the directive, it is apparent from the 11th recital that the only relevant criteria are those relating to the safety and bioavailability of the chemical substance in question of member states.

86. Such statements show that the relevant criteria for the purposes of the positive lists [of (forms of) vitamins and minerals] and the application of the procedure for modification of those lists can, as conceived by the Community legislature, relate only to grounds of human-health protection, to the exclusion of considerations concerning nutritional needs.”

<sup>liv</sup> Interpretative Document of the Commission’s Services / Placing on the market of medical devices: Brussels, 16 November 2010; SANCO/B/2/PBE/pdw Ares(2010) 332016.

<sup>lv</sup> Arrest. 28 Augustus 2015. Gerechtshof Arnhem-Leeuwarden. Zaaknummer Gerechtshof 200.167.066. (Zaaknummer rechtbank Gelderland C-05/278332); NPN v Ministry of Public Health, Well-being and Sports.

<sup>lvi</sup> 4.3 [...] Voorts is niet in geschil dat IGZ, voorafgaand aan de verzending van haar brieven van 9 november 2011 (2.2), 5 augustus 2013 (2.3) en 22 januari 2015 (2.5), geen geïndividualiseerd onderzoek had verricht ten aanzien van elk afzonderlijk melatonine-houdend product dat in Nederland op de markt was en waarbij waren betrokken alle kenmerken van het product, in het bijzonder de samenstelling, de farmacologische eigenschappen zoals deze bij de huidige stand van de wetenschap kunnen worden vastgesteld, de gebruikswijzen, de omvang van de verspreiding ervan, de bekendheid van de consument ermee en de risico’s die het gebruik ervan kan meebrengen.

<sup>lvii</sup> 4.4 De rechtbank stelt vast dat de groep producten die een hoeveelheid melatonine van 0,3 mg of meer bevatten in de in 4.3 genoemde brieven van IGZ zonder voorbehoud tvorden gekwalificeerd als geneesmiddel. Dit terwijl het in 4.3 bedoelde geïndividualiseerde onderzoek niet had plaatsgevonden en het, zoals de Staat ter zitting heeft bevestigd, wel kan voorkomen - zij het wat hem betreft in theorie - dat de toetsing van een afzonderlijk product dat 0,3 mg of meer melatonine bevat tot uitkomst heeft dat dat product geen geneesmiddel is. De Staat heeft, in aanmerking genomen zijn standpunt dat in het geval IGZ in een concreet geval overgaat tot handhaving een afzonderlijk product getoetst moet worden aan de kenmerken van het Hecht-Pharma-arrest én dat niet kan worden uitgesloten dat deze toets anders uitpakt dan de kwalificatie als geneesmiddel die IGZ aan de groep producten heeft gegeven waartoe het afzonderlijk product behoort, onvoldoende feiten naar voren gebracht die de conclusie rechtvaardigen dat de afzonderlijke producten een zodanige gelijkenis vertonen dat zij wat betreft de toets van “geval tot geval” zoals bedoeld in Hecht-Pharma aan elkaar gelijk kunnen worden gesteld. Een en ander laat geen ander oordeel toe dan dat de zonder voorbehoud gegeven kwalificatie van de groep melatonine-houdende producten als geneesmiddel in strijd is met het Unierecht. De rechtbank verwijst naar de onder 4.2.4 weergegeven paragrafen 37, 39 en 40 van het Hecht-Pharma-arrest. Dat IGZ zich voorafgaand aan de aankondiging van haar handhavingsbeleid “rekenschap” heeft gegeven van alle relevante kenmerken van melatonine-producten is dan ook niet afdoende.

<sup>lviii</sup> 4.5 De rechtbank is, anders dan de Staat, van oordeel dat uit de omstandigheid dat dit arrest (evenals de relevante daaraan voorafgegane arresten van het Europese Hof van Justitie) is gewezen in een zaak waarin de nationale autoriteit, in tegenstelling tot in de onderhavige zaak, reeds daadwerkelijk tot handhaving van de geneesmiddelenwetgeving was overgegaan, niet (a contrario) kan worden afgeleid dat de geïndividualiseerde beoordeling achterwege kan blijven bij onvoorwaardelijke kwalificatie in het kader van het formuleren van handhavingsbeleid. Noch in het Hecht-Pharma-arrest noch in de (considerans bij de) richtlijnen 200 1/83 en 2004/27 valt steun te vinden voor het standpunt van de Staat. Daarbij komt dat aan dit standpunt niet alleen een ruime uitlegging en toepassing van het begrip geneesmiddel, maar ook een ruime toepassing van de bevoegdheid tot het kwalificeren als geneesmiddel ten grondslag ligt, hetgeen zich niet verhoudt tot de in nummer 68 van de conclusie van AG Trstenjak geëxpliciteerde, overwegende Unierechtelijke bezwaren daartegen.

<sup>lix</sup> 4.6 Een generieke, onvoorwaardelijke beoordeling van getijksortige melatonine producten op grond van het oordeel dat bij een dosering vanaf 0,3 mg melatonine sprake is van fysiologische processen door middel van een farmacologisch effect, zonder onderzoek te hebben gedaan naar de overige individuele karakteristieken

van de producten benoemd in het Hecht-Pharma-arrest was (en is) dan ook niet toegestaan. Het handhavingsbeleid van IGZ zoals aangekondigd in haar brief van 9 november 2011 is dan ook onrechtmatig vanwege strijd met Europees recht.

<sup>lx</sup> 4.11 [...] vergezeld van de mededeling dat dus aan een belangrijk geneesmiddelen criterium geacht moet worden te zijn voldaan, maar dat niet uitgestoten is dat een (noodzakelijke) individuele toets in het kader van handhaving in een concreet geval uitwijst dat een product met een dergelijke dosering (toch) niet als geneesmiddel dient te worden beschouwd.

<sup>lxi</sup> 5.1. gebiedt de Staat (IGZ) om bij elke (beleidsaankondiging en -vaststelling die gepaard gaat met een) onvoorwaardelijke kwalificatie van melatonine-houdende producten als geneesmiddel naar werking, van geval tot geval en per individueel product, rekening te houden met alle kenmerken van het product, in het bijzonder de samenstelling, de farmacologische, immunologische en metabolische eigenschappen zoals deze bij de huidige stand van de wetenschap kunnen worden vastgesteld, de gebruikswijzen, de omvang van de verspreiding ervan, de bekendheid van de consument ermee en de risico's die het gebruik ervan kan meebrengen, en deze toets uit te voeren op controleerbare en transparante wijze;

5.2. gebiedt de Staat (IGZ) om een melatonine-houdend product toe te laten in het handelsverkeer, toe te laten dat het in voorraad wordt gehouden, wordt verkocht, wordt afgeleverd en ter hand gesteld, wordt ingevoerd of anderszins binnen of buiten het Nederlandse grondgebied wordt gebracht en zich te onthouden van het ter zake handhavend optreden op grond van de Geneesmiddelenwet totdat hij zijn individuele beoordeling (op de in 5.1 beschreven wijze) ten aanzien van dit product heeft uitgevoerd;

<sup>lxii</sup> Neither would the BVL's "Stoffliste" survive examination by a British Court. See the "glucosamin" Judgement made in the Court of Appeal (Civil Division) on Appeal of the High Court of Justice Queen's Bench Division Administrative Court in Case No: C1.2014/2019.

<sup>lxiii</sup> See Note lvi *supra*.

<sup>lxiv</sup> General scientific guidance for stakeholders on health claim applications; 18 January 2016; doi:10.2903/j.efsa.2016.4367; www.efsa.europa.eu/efsajournal EFSA Journal 2016;14(1):4367

<sup>lxv</sup> In his Opinion delivered on 29 April 2004 in Case C-161/04, Advocate General Geelhoed remarked that the principle of legal certainty underlies the approximation of laws in accordance with Article 95 EC, now Article 114 TFEU:

"79. The Bestimmtheitsgrundsatz or principle of precision which is invoked by the Republic of Austria is one expression of the principle of legal certainty. Article 6(1) EU, which declares that the European Union is founded on, *inter alia*, the rule of law, may indeed be considered as the formal Treaty basis of this principle. As the Court has ruled on various occasions the principle of legal certainty is a fundamental principle of Community law which requires that rules should be clear and precise, so that individuals may be able to ascertain unequivocally what their rights and obligations are and may take steps accordingly. [...] This principle is also specifically laid down in the Interinstitutional Agreement between the European Parliament, the Council and the Commission of 22 December 1998 on common guidelines for the quality of drafting of Community legislation. According to the first paragraph of these legally non binding guidelines Community legislative acts shall be drafted clearly, simply and precisely."

In its preamble, the Interinstitutional Agreement states:

"(1) clear, simple and precise drafting of Community legislative acts is essential if they are to be transparent and readily understandable by the public and economic operators. It is also a prerequisite for the proper implementation and uniform application of Community legislation in the Member States.

(2) according to the case-law of the Court of Justice, the principle of legal certainty, which is part of the Community legal order, requires that Community legislation must be clear and precise and its application foreseeable by individuals. That requirement must be observed all the more strictly in the case of an act liable to have financial consequences and imposing obligations on individuals in order that those concerned may know precisely the extent of the obligations which it imposes on them."



samen in  
gezondheidsproducten