

## Developments

### **A Review of EU Regulation of Sports Nutrition: Same Game, Different Rules**

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#### **Abstract**

Today's athletes, both professionals and amateurs, use a wide range of different nutritional substances to increase training performance, improve the recovery process, burn fat, gain muscle mass, etc. Although such substances are not always thoroughly researched for their potential effect on humans, they are popular and easy to obtain. Therefore, an adequate regulatory system is needed to ensure the protection of consumers. Currently, however, there are no specific provisions with regard to sports nutrition in EU law; thus, such products are usually marketed as food supplements, fortified foods, dietetic foods, and/or foods with nutrition or health claims. This article reviews the relevant legislation with a particular emphasis on policy developments regarding sports nutrition.

## A. Introduction

It is difficult to imagine today's professional sports without special sports nutrition.<sup>1</sup> Yet, there are also a considerable and highly latent number of amateur athletes—for example, gym users—as well as non-athletes who use sports nutrition products on a regular or occasional basis. According to market research prepared by the European Commission (Commission),<sup>2</sup> the majority of sports food consumers are “recreational users,”<sup>3</sup> whose market share is growing faster than that of bodybuilders and professional athletes, while the EU market itself is estimated to be worth billions of euro and rapidly growing.<sup>4</sup>

Sports nutrition includes a wide range of products—for example: weight gain powders, creatine, protein, essential amino acids, branched-chain amino acids (BCAA), glutamine, essential fatty acids, different testosterone boosters for muscle building, ephedra, caffeine, green tea extract, and L-carnitine for weight loss, as well as sports drinks for training performance enhancement—without mentioning common substances such as vitamins and minerals.<sup>5</sup> Not all of these substances may be safe for human health. Certain popular substances, such as ephedra, were identified as unsafe and therefore banned by some national authorities and sports associations.<sup>6</sup> Even common substances such as vitamins and minerals carry their own potential risks.<sup>7</sup> In fact, concern over the adverse health

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<sup>1</sup> Generally, the term “sports nutrition” in this article covers nutritional substances used by athletes to gain some additional benefit from training.

<sup>2</sup> *Proposal for a Regulation on Food Intended for Infants and Young Children and on Food for Special Medical Purposes*, at 17, SEC (2011) 762 final, Impact Assessment (June 20, 2011) [hereinafter Impact Assessment].

<sup>3</sup> *Id.* The presented groups of consumers are defined as follows: “Bodybuilders” are people who are engaged in the sport of bodybuilding, which entails building up muscle through a combination of weight training and increased caloric intake. “Athletes” include all professional sportspeople, excluding bodybuilders. “Recreational users” are people who do sports on the weekends and fitness enthusiasts. “Lifestyle users” include people who use sports nutrition products for purposes other than sports or exercise.

<sup>4</sup> *Id.* at 62.

<sup>5</sup> Richard B. Kreider et al., *ISSN Exercise & Sport Nutrition Review: Research & Recommendations*, 7 J. INT'L SOC'Y SPORTS NUTRITION 1 (2010); Ron J. Maughan et al., *The Use of Dietary Supplements by Athletes*, 25 J. SPORTS SCI. 103 (2007).

<sup>6</sup> Kreider et al., *supra* note 5.

<sup>7</sup> Ron J. Maughan et al., *Dietary Supplements*, 22 J. SPORTS SCI. 96 (2004); Melvin H. Williams, *Dietary Supplements and Sports Performance: Introduction and Vitamins*, 1 J. INT'L SOC'Y SPORTS NUTRITION 1 (2004); Melvin H. Williams, *Dietary Supplements and Sports Performance: Minerals*, 2 J. INT'L SOC'Y SPORTS NUTRITION 43 (2005).

effects of these substances has been reflected in EU legislation<sup>8</sup> and case-law of the European Court of Justice (ECJ).<sup>9</sup> Substances usually referred to as safe if taken by healthy individuals and in proper dosage—for example, creatine—may also pose a risk,<sup>10</sup> while others—for example, protein—still lack the appropriate scientific evidence.<sup>11</sup> However, these and other nutritional substances may be easily obtained by anyone in gyms, sports inventory stores, dietary supplements stores, drugstores, supermarkets, and of course online, either directly from manufacturers or from online retailers.<sup>12</sup>

### B. General Legal Concerns

When regulating nutritional substances, two fundamental issues include safety and efficacy of a specific substance.<sup>13</sup> With regard to safety, the assessment and regulation of the safety levels of substances *per se* and their intake regime—for example, setting the proper dosage—are of utmost importance.<sup>14</sup> If a substance is proven to be safe, another question is how to ensure its efficacy—to find out whether a certain product meets the needs of the consumer, and whether the claims of the manufacturer are justified.<sup>15</sup> Naturally, both issues should be regarded from the purely scientific point of view of the effect of one or more substances on the human organism.<sup>16</sup> Therefore, both safety and

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<sup>8</sup> See Directive 2002/46 of the European Parliament and of the Council of 10 June 2002, 2002 O.J. (L 183) 51, recital 13 (EC) [hereinafter Food Supplements Directive] (discussing the approximation of the laws of the Member States relating to food supplements).

<sup>9</sup> See Case 174/82, *Officier van Justitie v. Sandoz*, 1983 E.C.R. 2445, para. 11; Case C-192/01, *Comm'n v. Denmark*, 2003 E.C.R. I-9693, para. 43; Case C-24/00, *Comm'n v. France*, 2004 E.C.R. I-1277, para. 50; Case C-446/08, *Solgar Vitamin's France v. Ministre de l'Économie, des Finances et de l'Emploi*, 2010 E.C.R. I-3973, para. 36.

<sup>10</sup> Basturk Taner et al., *The Effects of the Recommended Dose of Creatine Monohydrate on Kidney Function*, 4 NEPHROLOGY DIALYSIS TRANSPLANTATION PLUS 23 (2011).

<sup>11</sup> Lonnie M. Lowery & Lorena Devia, *Dietary Protein Safety and Resistance Exercise: What Do We Really Know?*, 6 J. INT'L SOC'Y SPORTS NUTRITION 1 (2009).

<sup>12</sup> Maughan et al., *supra* note 5, at 104. Notably, the authors refer to online sales as by far the most problematic when it comes to consumers' protection because "internet selling has effectively removed most of the national controls that might protect the consumer." *Id.* at 110. It is worth mentioning that the question of sales by mail order has indeed been approached specifically by the ECJ in Case C-497/03, *Comm'n v. Austria* (Oct. 28, 2004). The case originated from the prohibition on the sale of food supplements by mail order, laid down in Austrian national law. The ECJ stated that such measure had equivalent effect to a quantitative restriction on imports, while the aim of protecting consumers against health risks and misrepresentation, which was put forward in order to justify such a prohibition, could have been achieved by more lenient means.

<sup>13</sup> Regulation 1924/2006 of the European Parliament and of the Council of 20 December 2006 on Nutrition and Health Claims Made on Foods, 2006 O.J. (L 404) 9, recitals 1 and 14 [hereinafter Health Claims Regulation].

<sup>14</sup> Food Supplements Directive, *supra* note 8, at recitals 11 and 13.

<sup>15</sup> Health Claims Regulation, *supra* note 13, at recital 15.

<sup>16</sup> *Id.* at recital 17.

efficacy should always be substantiated by strong scientific research.<sup>17</sup> Yet, scientific research about sports nutritional substances is not always persuasive<sup>18</sup> or impartial,<sup>19</sup> and unlike some medicinal products, a physician's prescription is not required to obtain such products. Accordingly, information about them often comes from sport instructors and coaches, advertisements, internet forums, and personal experience.<sup>20</sup> Keeping in mind how easy it is to obtain these products, this situation is worrying and demands for a more adequate policy.

### C. General Legislation on Food

With regard to sports nutrition, relevant legislation is divided into two categories: general legislation on foods and specific legislation on certain nutritional substances.

In terms of general legislation, sports nutrition must comply with general food law requirements set by the Food Law Regulation,<sup>21</sup> which pursue a "high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade."<sup>22</sup> These general requirements include risk analysis,<sup>23</sup> precautionary principle,<sup>24</sup> protection of consumers' interests,<sup>25</sup> transparency,<sup>26</sup> and traceability and identification.<sup>27</sup> The principal requirement of food safety stipulates that unsafe food should not be placed on the market.<sup>28</sup> Food safety requires appropriate labeling that must not be

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<sup>17</sup> *Id.*; see also Kreider et al., *supra* note 5, at 4–7.

<sup>18</sup> Health Claims Regulation, *supra* note 13.

<sup>19</sup> Kreider et al., *supra* note 5, at 5–6; Maughan et al., *supra* note 5, at 104.

<sup>20</sup> Kathryn Froiland et al., *Nutritional Supplement Use Among College Athletes and Their Sources of Information*, 14 INT'L J. SPORT NUTRITION & EXERCISE METABOLISM 104 (2004).

<sup>21</sup> See Regulation 178/2002 of the European Parliament and of the Council of 28 January 2002, 2002 O.J. (L 31) 1 (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>22</sup> *Id.* at art. 5(1).

<sup>23</sup> *Id.* at art. 6.

<sup>24</sup> *Id.* at art. 7.

<sup>25</sup> *Id.* at art. 8.

<sup>26</sup> *Id.* at arts. 9–10.

<sup>27</sup> *Id.* at art. 18.

<sup>28</sup> *Id.* at art. 14(1). See Bernd van der Meulen, *The Core of Food Law*, 3 EUR. FOOD & FEED L. REV. 117 (2012). In Case C-636/11, *Karl Berger v. Freistaat Bayern*, Apr. 11, 2013, para. 35, the ECJ stated that if a foodstuff does not fulfill the food safety requirements under article 14(5), it prejudices the interests of consumers, the protection of whom, as stated in article 5, is one of the objectives of food law.

misleading or attributing therapeutic effect, must contain compulsory ingredient list information, including indication of allergens, condition of use, and the expiration date.<sup>29</sup>

In the absence of specific EU safety rules, food is deemed safe when it conforms to the specific provisions of national food law of the Member State where the food is marketed, if such provisions are drawn up and applied without prejudice to the Treaty on the Functioning of the European Union (TFEU), in particular Articles 34 and 36.<sup>30,31</sup>

Concerning nutrition and health claims, it should be noted that the provisions of the relevant act (Health Claims Regulation), often tend to conflict with provisions of specific legislation; thus, it is wiser to discuss it in the context of specific legal acts, namely the Food Supplements Directive, Fortified Foods Regulation,<sup>32</sup> and the Dietetic Foods Framework Directive.<sup>33</sup>

#### D. Specific Legislation on Nutritional Substances

##### I. Food Supplements Directive

The scope of this Directive might be described in short through its recitals 4 and 5—the category of food supplements<sup>34</sup> is necessary because some consumers, due to their

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<sup>29</sup> See Regulation 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, amending Regulations 1924/2006 and 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC, and Commission Regulation 608/2004, 2011 O.J. (L 304) 18.

<sup>30</sup> Regulation 178/2002, *supra* note 21, at art. 14(9).

<sup>31</sup> Consolidated Version of the Treaty on the Functioning of the European Union, Oct. 26, 2012, 2012 O.J. (C 326) 47 [hereinafter TFEU]. This rule, often referred to as the “principle of mutual recognition,” is traced back to the renowned Case 120/78, *Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)*, 1979 E.C.R. 649, available at <http://curia.europa.eu/>. According to the ECJ, this principle can be defined as follows: There is no valid reason why products should not be introduced into one of the Member States provided that they have been lawfully produced and marketed in any other Member State; the sale of such products may not be subject to legal prohibition on the marketing set by the national rules. *Id.* at para. 14. Therefore, such products can be sold in other Member States with no additional restrictions, omitting those justified under the above-mentioned article 36 of the TFEU, which shall be discussed further.

<sup>32</sup> Regulation 1925/2006 of the European Parliament and of the Council, Dec. 20, 2006, 2006 O.J. (L 404) 26, On the Addition of Vitamins and Minerals and of Certain Other Substances to Foods (EC) [hereinafter Fortified Foods Regulation].

<sup>33</sup> Directive 2009/39 of the European Parliament and of the Council, May 6, 2009, 2009 O.J. (L 124) 21, On Foodstuffs Intended for Particular Nutritional Uses (EC) [hereinafter Dietetic Foods Framework Directive].

<sup>34</sup> Food supplements under article 2(a) are defined as:

foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with

particular lifestyles or for other reasons, may choose to supplement their intake of some nutrients through food supplements. Yet, a high level of protection for consumers must be ensured, thus such products should be safe and appropriately labeled.

The Directive establishes a positive list of vitamins and minerals in Annex I—for example, vitamin B2, vitamin C, and magnesium—in the forms presented in Annex II—for example, riboflavin, L-ascorbic acid, and magnesium chloride respectively—that may be used for the manufacture of food supplements.<sup>35</sup> Normally, substances listed in Annex II must meet the purity criteria, either adopted by the Commission<sup>36</sup> or specified by EU legislation for the manufacture of other foodstuffs,<sup>37</sup> but if the latter is not specified “generally acceptable purity criteria recommended by international bodies shall be applicable and national rules setting stricter purity criteria may be maintained.”<sup>38</sup> Currently, however, there is no specific EU legislation on this matter exclusively; instead, there is a relevant act concerning the purity criteria on food additives, other than colors and sweeteners,<sup>39</sup> which includes some of the substances listed in Annex II of the Food Supplements Directive.

Notably, Annex I and Annex II do not include substances other than vitamins and minerals, although the definition of food supplements covers a much broader and non-exhaustive list of substances, many of which are, or potentially could be, used in manufacture of sports nutrition.<sup>40</sup> Moreover, unspecified substances often form a significant part of the food supplements’ market. For example, in 2005, their share of the market was

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a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

Food Supplements Directive, *supra* note 8, at art. 2(a). “Nutrients” are defined as vitamins and minerals. *Id.* at art. 2(b).

<sup>35</sup> *Id.* at art. 4(1).

<sup>36</sup> *Id.* at art. 4(2).

<sup>37</sup> *Id.* at art. 4(3).

<sup>38</sup> *Id.* at art. 4(4).

<sup>39</sup> See Commission Directive 2008/84, Aug. 27, 2008, 2008 O.J. (L 253) 1 (EC) (laying down specific purity criteria on food additives other than colors and sweeteners).

<sup>40</sup> Study undertaken for D.G. Sanco, European Commission. European Advisory Servs., *The Use of Substances with Nutritional or Physiological Effect Other than Vitamins and Minerals in Food Supplements*, at 9–10 (2007), [http://ec.europa.eu/food/safety/docs/labelling\\_nutrition-supplements-2007\\_a540169\\_study\\_other\\_substances\\_en.pdf](http://ec.europa.eu/food/safety/docs/labelling_nutrition-supplements-2007_a540169_study_other_substances_en.pdf).

approximately fifty percent, including tonics (seven percent) and other substances (forty-three percent), with the market itself estimated around € 5 billion.<sup>41</sup>

The Commission studied the situation<sup>42</sup> and prepared a report in 2008.<sup>43</sup> Taking into account varied consumption habits, scientific and methodological difficulties, as well as current legal instruments, the Commission concluded that “laying down specific rules applicable to substances other than vitamins and minerals for use in food supplements is not justified,” doubting “the feasibility of such a measure, which, in any case, is not necessary in the short term” because “the Community legal instruments . . . already constitute a sufficient legislative framework for regulating this area.”<sup>44</sup> This signifies that the adoption of specific rules concerning such nutrients is postponed to a later date once adequate and appropriate scientific data about them become available.<sup>45</sup> In the absence of specific rules, national rules may apply pursuant to Article 14(9) of the Food Law Regulation, invoking the mechanism of mutual recognition between Member States under Article 34 of the TFEU.<sup>46</sup>

A similar situation occurred with the setting of maximum amounts of vitamins and minerals in food supplements. The Food Supplements Directive obliges the Commission to adopt “maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer” taking into account: (1) upper safe levels of these substances established by scientific risk assessment based on generally accepted scientific data—having in mind the varying degrees of sensitivity of different consumer groups—; and (2) intake of vitamins and minerals from other dietary sources.<sup>47</sup> When such maximum levels are set, reference intakes of vitamins and minerals for the population should be taken into account as well.<sup>48</sup> Moreover, to ensure that significant amounts of these substances are present in food supplements, minimum

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<sup>41</sup> *Characteristics and Perspectives of the Market for Food Supplements Containing Substances Other Than Vitamins and Minerals*, COM (2008) 824 final (Dec. 5, 2008), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2976:FIN:EN:PDF> [hereinafter *Characteristics and Perspectives*].

<sup>42</sup> European Advisory Servs., *supra* note 40.

<sup>43</sup> *Characteristics and Perspectives*, *supra* note 41.

<sup>44</sup> *Id.* at 11–12.

<sup>45</sup> Case C-88/07, *Comm’n v. Spain*, 2009 E.C.R. I-1353, para. 28; Food Supplements Directive, *supra* note 8, at recital 8.

<sup>46</sup> *Id.*; see also European Advisory Servs., *supra* note 40, at 58.

<sup>47</sup> Food Supplements Directive, *supra* note 8, arts. 5(1) & (4).

<sup>48</sup> *Id.* art. 5(2).

amounts per daily portion of consumption as recommended by the manufacturer should be appropriately set.<sup>49</sup>

It must be emphasized, though, that as long as the Commission does not adopt the maximum amounts, national legal provisions of the Member States apply, pursuant to Article 11(2) of the Directive.<sup>50</sup> On one hand, while free at the moment to adopt the maximum amounts themselves, Member States are still bound by the requirements set in Articles 5(1) and (2) “while waiting for the Commission to lay down those amounts pursuant to Article 5(4).”<sup>51</sup> On the other hand, in the absence of harmonization and while uncertainties continue to exist in the current state of scientific research, it is for the Member States to decide their intended level of protection of human health and life and whether to require prior authorization for the marketing of foodstuffs, taking into account the requirements of the free movement of goods within the EU.<sup>52</sup> Such discretion is particularly wide as long as

it is shown that there is still uncertainty in the current state of scientific research as to certain substances, such as vitamins, which are not as a general rule harmful in themselves but may have special harmful effects solely if taken to excess as part of the general diet, the composition of which cannot be foreseen or monitored.<sup>53</sup>

The ECJ has stated on multiple occasions<sup>54</sup> that this discretion flows from Article 36 of the TFEU, which establishes that the general prohibition of quantitative restrictions and

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<sup>49</sup> *Id.* art. 5(3). These, however, have not yet been laid down. See Case C-137/13, *Herbaria Kräuterparadies GmbH v. Freistaat Bayern*, Op. of AG Sharpston, May 8, 2014, para. 46.

<sup>50</sup> Case C-446/08, *Solgar Vitamin's France v. Ministre de l'Économie, des Finances et de l'Emploi*, 2010 E.C.R. I-3973, paras. 21–24. Earlier, the Court expressed that article 11(2) of the Food Supplements Directive operates in a similar way to the above-mentioned article 14(9) of the Food Law Regulation and permits national rules to apply in the absence of specific EU rules. See Case C-319/05, *Comm'n v. Germany*, 2007 E.C.R. I-9811, para. 84.

<sup>51</sup> *Solgar Vitamin's France*, Case C-446/08 at para. 32.

<sup>52</sup> *Id.* at para. 35; see also Case 104/75, *Criminal Proceedings Against Adriaan de Peijper*, 1976 E.C.R. I-613, 635; Case 272/80, *Criminal Proceedings Against Frans-Nederlandse Maatschappij voor Biologische Producten BV*, 1981 E.C.R. I-3277, para. 12; Case 174/82, *Officier van Justitie v. Sandoz*, 1983 E.C.R. 2445, paras. 16–17; Case C-192/01, *Comm'n v. Denmark*, 2003 E.C.R. I-9693, para. 42; Case C-24/00, *Comm'n v. France*, 2004 E.C.R. I-1277, para. 49.

<sup>53</sup> *Solgar Vitamin's France*, Case C-446/08 at para. 36; see also *Denmark*, Case C-192/01 at para. 43; *France*, Case C-24/00 at para. 50.

<sup>54</sup> *Sandoz*, Case 174/82 at paras. 16–17; Case C-42/90, *Criminal proceedings against Jean-Claude Bellon*, 1990 E.C.R. I-4863, paras. 10–11; Case C-400/96, *Criminal Proceedings Against Jean Harpegnies*, 1998 E.C.R. I-5121,



measures having equivalent effect on the free movement of goods<sup>55</sup> shall not preclude prohibitions or restrictions on imports, exports, or goods in transit justified on the grounds of protection of human health.

The above-mentioned case of *Solgar Vitamin's France and Others* provides an example of such discretion. As stated by the Court, the principle of protection of human health stipulates that in the absence of specific amounts laid down by the Commission, if it is impossible for the national authorities to calculate precisely the intake of vitamins and minerals from other dietary sources pursuant to Article 5(1)(b), a Member State may, where genuine risks are known to exist, set the maximum levels of such vitamins or minerals used in supplements to zero.<sup>56</sup>

Nevertheless, the discretion of the Member States with regard to protection of human health under Article 36 of the TFEU is not absolute. The ECJ expressed on many occasions that in exercising such discretion, the Member States must comply with the principle of proportionality. Therefore, the means chosen must be confined to what is actually necessary to ensure the safeguarding of public health or to satisfy overriding requirements regarding, for example, consumer protection. This means the pursued objective could not be attained by less restrictive measures.<sup>57</sup> For example, in *Solgar Vitamin's France and Others* the national court asked the ECJ whether it is possible for a Member State setting maximum amounts to take into account not only the varying degrees of sensitivity of different consumer groups<sup>58</sup> but also "the fact that a measure addressed solely to a group of consumers who are particularly exposed to risk . . . might dissuade that group from using a nutrient that would be beneficial to it in small amounts."<sup>59</sup> Consequently, "whether taking into account that difference in sensitivity might result in the application to the entire population of the maximum level appropriate for sensitive sections of the population, in particular children."<sup>60</sup> The ECJ replied that such considerations were not

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para. 29; *Denmark*, Case C-192/01 at para. 42; *France*, Case C-24/00 at paras. 49–50; *Solgar Vitamin's France*, Case C-446/08 at para. 48.

<sup>55</sup> TFEU arts. 34–35.

<sup>56</sup> *Solgar Vitamin's France*, Case C-446/08 at para. 48.

<sup>57</sup> *Sandoz*, Case 174/82 at para. 18; Case C-247/84, *Criminal Proceedings Against Léon Motte*, 1985 E.C.R. I-3887, para. 23; Case C-304/84, *Criminal Proceedings Against Claude Muller*, 1986 E.C.R. I-1511, para. 23; Case C-178/84, *Comm'n v. Germany*, 1987 E.C.R. I-1227, para. 28; *Bellon*, Case C-42/90 at para. 14; *Harpegnies*, Case C-400/96 at para. 34; *Denmark*, Case C-192/01 at para. 45; *France*, Case C-24/00 at para. 52; *Solgar Vitamin's France*, Case C-446/08 at para. 54.

<sup>58</sup> *Food Supplements Directive*, *supra* note 8, at art. 5(1)(a).

<sup>59</sup> *Solgar Vitamin's France*, Case C-446/08 at para. 49.

<sup>60</sup> *Id.*

relevant and the application of the measures in question is contingent on the principle of proportionality.<sup>61</sup>

Similarly, national authorities are limited when it comes to establishing maximum amounts of substances, which, due to the absence of known health risks, have no safe upper limits. The ECJ stressed that, when setting of these amounts, States must rely on “a scientific assessment of the risks to human health based on the relevant scientific data and not on purely hypothetical considerations.”<sup>62</sup> Such a scientific risk assessment could reveal the persistence of scientific uncertainty with regard to the existence or extent of real risks to human health.<sup>63</sup> As the Court stated in *National Farmers’ Union and Others* and later reiterated in *Commission v. Denmark*, *Commission v. France*, and *Solgar Vitamin’s France and Others*, on such occasions, the Member States may apply the precautionary principle and “take protective measures without having to wait until the reality and seriousness of those risks are fully demonstrated.”<sup>64</sup> In any case, the ECJ practice explicitly provides that the risk assessment itself cannot be based on purely hypothetical considerations.<sup>65</sup> An academic consideration alone will not suffice either, as stated by the Court of Justice of the European Free Trade Association States (EFTA Court) in *EFTA Surveillance Authority v. Norway*.<sup>66</sup>

Overall, the courts addressed justification of the precautionary principle quite thoroughly in the above-mentioned cases. For example, they questioned the appropriateness of risk assessment considering the existence of a possible cumulative effect of the presence on the market of several sources—whether natural or artificial—of a particular nutrient in light of scientific and practical uncertainty.<sup>67</sup> Both the EFTA Court and the ECJ agreed that a proper application of the precautionary principle would, firstly, require the identification of the potentially negative health consequences, and, secondly, require a comprehensive

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<sup>61</sup> *Id.* at para. 61.

<sup>62</sup> *Id.* at para. 65.

<sup>63</sup> *Denmark*, Case C-192/01 para. 49; *France*, Case C-24/00 at para. 56; *Solgar Vitamin’s France*, Case C-446/08 at para. 67.

<sup>64</sup> Case C-157/96, *Queen v. Ministry of Agric., Fisheries & Food*, 1998 E.C.R. I-2211, para. 63; *Denmark*, Case C-192/01 at para. 49; *France*, Case C-24/00 at para. 56; *Solgar Vitamin’s France*, Case C-446/08 at para. 67.

<sup>65</sup> Case C-236/01, *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri*, 2003 E.C.R. I-8105, para. 106; *Denmark*, Case C-192/01 at para. 49; *France*, Case C-24/00 at para. 56; *Solgar Vitamin’s France*, Case C-446/08 at para. 67.

<sup>66</sup> Case E-3/00, *EFTA Surveillance Auth. v. Norway*, 2001 EFTA Ct. Rep. 73, para. 29.

<sup>67</sup> *Id.*; *Denmark*, Case C-192/01 at para. 50; *Solgar Vitamin’s France*, Case 446/08 at para. 68.

assessment of the health risk(s) based on the most reliable and most recent scientific data and international research available.<sup>68</sup> Consequently, it was decided that

[w]here it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialize, the precautionary principle justifies the adoption of restrictive measures, provided that they are non-discriminatory and objective.<sup>69</sup>

Therefore, with respect to setting the maximum amounts of vitamins and minerals in food supplements, the ECJ concluded in *Solgar Vitamin's France and Others* that the Food Supplements Directive precludes such settings where, in the absence of a genuine risk to human health, upper safe limits have not been established, unless such a measure is justified in accordance with the precautionary principle and an assessment reveals that scientific uncertainty persists regarding the existence or extent of real risks to human health.<sup>70</sup>

Other important requirements of the Food Supplements Directive include a prohibition on attributing or referring to therapeutic effect in food supplement labeling, presentation, and advertising,<sup>71</sup> specific information on the labeling—for example, details on nutrients and warnings not to exceed the recommended intake,<sup>72</sup> and the presentation form of such information—in numerical form, percentage, and graphical form.<sup>73</sup> The presented information on the amount of substances must be based on the analysis conducted by the

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<sup>68</sup> *EFTA Surveillance Auth.*, Case E-3/00 at para. 30; *Monsanto Agricoltura Italia*, Case C-236/01 at para. 113; *Denmark*, Case C-192/01 at para. 51; *Solgar Vitamin's France*, Case C-446/08 at para. 69.

<sup>69</sup> *EFTA Surveillance Auth.*, Case E-3/00 at paras. 31–32; *Denmark*, Case 192/01 at paras. 52–53; *Solgar Vitamin's France*, Case C-446/08 at para. 70.

<sup>70</sup> *Solgar Vitamin's France*, Case C-446/08 at para. 73. The Court, however, acknowledged that after the upper safe limits have been established, the possibility of setting such maximum amounts at a level significantly lower than those limits cannot be excluded if the setting of those amounts can be justified by the criteria set in articles 5(1) and (2) and that it complies with the principle of proportionality. Such assessments should be carried out by the national courts on a case-by-case basis.

<sup>71</sup> Food Supplements Directive, *supra* note 8, at art. 6(2).

<sup>72</sup> *Id.* at art. 6(3).

<sup>73</sup> *Id.* at arts. 8–9.

manufacturer.<sup>74</sup> Stating or implying that “a balanced and varied diet cannot provide appropriate quantities of nutrients in general” is also prohibited, pursuant to Article 7.

## *II. Fortified Foods Regulation*

Much like the Food Supplements Directive, the Fortified Foods Regulation deals with foods<sup>75</sup> that could be of benefit to either the whole population or some subgroups, due to different nutritional requirements and changing dietary habits.<sup>76</sup> Examples of such foods include: cereals fortified with vitamin D, energy bars fortified with folic acid,<sup>77</sup> cornflakes fortified with thiamine, riboflavin, niacin, and iron,<sup>78</sup> and different vitamin-enriched drinks and confectionary.<sup>79</sup> The majority of the provisions reflect safety as the highest priority; both Annexes I and II establish positive lists of substances which may be added to foods,<sup>80</sup> and Annex III establishes a negative list that identifies the harmful effect of certain substances and ingredients.<sup>81</sup> So far, the European Food Safety Authority (Authority) has considered two substances for inclusion in Annex III—yohimbe and species of ephedra.<sup>82</sup> The latter, due to the risk it poses, was specifically classified in list A as a “prohibited substance”, while the former was put under Community scrutiny.<sup>83</sup>

A key difference between the Fortified Foods Regulation and the Food Supplements Directive is the fact that the Fortified Foods Regulation covers the addition of vitamins and

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<sup>74</sup> *Id.* at art. 9(1).

<sup>75</sup> Article 1(1) refers to fortified foods as an “addition of vitamins and minerals and of certain other substances to foods,” with “other substance” meaning “substance other than a vitamin or a mineral that has a nutritional or physiological effect.” Fortified Foods Regulation, *supra* note 32, at arts. 1(1) & 2(2).

<sup>76</sup> *Id.* at recital 8.

<sup>77</sup> Case C-41/02, *Comm’n v. Netherlands*, 2004 E.C.R. I-11375, para. 15.

<sup>78</sup> Case E-3/00, *EFTA Surveillance Auth. v. Norway*, 2001 EFTA Ct. Rep. 73, para. 1.

<sup>79</sup> Case C-24/00, *Comm’n v. France*, 2004 E.C.R. I-1277, para. 58.

<sup>80</sup> Fortified Foods Regulation, *supra* note 32, at art. 3(1). Notably, both Annexes cover essentially the same substances as the Annexes of the Food Supplements Directive, namely vitamins, minerals, and their compositions, thus leaving out all other substances.

<sup>81</sup> *Id.* at art. 8(2).

<sup>82</sup> *Addition of Vitamins and Minerals*, EUR. COMM’N (Jan. 7, 2015), [http://ec.europa.eu/food/safety/labelling\\_nutrition/vitamins\\_minerals/index\\_en.htm](http://ec.europa.eu/food/safety/labelling_nutrition/vitamins_minerals/index_en.htm).

<sup>83</sup> Commission Regulation 2015/403 of Mar. 11, 2015, Amending Annex III to Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as Regards *Ephedra* Species and Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille), 2015 O.J. (L 67) 4.

minerals to foods whether to restore the initial nutritional balance in the foods<sup>84</sup> or to help resolve a deficiency in the whole or specific population.<sup>85</sup> There must be an evident need present in order to comply with the requirements of the Regulation. This necessity is reflected in Article 3(2) and includes, *inter alia*, a possibility to demonstrate the deficiency of relevant substances by clinical or sub-clinical evidence. The ECJ, however, stated that the absence of a nutritional need within the population of a Member State, although relevant to the assessment of public health risks, cannot, by itself, justify a total prohibition—on the basis of Article 36 of the TFEU—of the marketing of such products lawfully manufactured and/or marketed in other Member States.<sup>86</sup> The Court stressed that such concern over consumers' health may be achieved by more lenient means. For example, the "appropriate labeling, informing consumers about the nature, the ingredients and the characteristics of fortified foodstuffs, can enable consumers who are at risk from excessive consumption of a nutrient added to those products to decide for themselves whether to use them,"<sup>87</sup> and moreover, such solution "is consonant with the protection of public health without imposing serious restrictions on the free movement of goods."<sup>88</sup>

At the same time, with regard to the establishment of purity criteria for vitamin formulations and mineral substances,<sup>89</sup> the provisions of the Regulation are essentially similar to those of the Food Supplements Directive. For example, the maximum amounts of vitamins and minerals added to foods must be based on generally acceptable scientific data and intake from other dietary sources,<sup>90</sup> taking into account the contribution of individual products to the overall diet of the population in general or of subgroups in cases

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<sup>84</sup> Fortified Foods Regulation, *supra* note 32, at recital 6.

<sup>85</sup> *Id.* at recital 7.

<sup>86</sup> Case C-95/01, Criminal Proceedings Against John Greenham & Léonard Abel, 2004 E.C.R. I-1333, para. 46; Case C-41/02, Comm'n v. Netherlands, 2004 E.C.R. I-11375, para. 61; Case C-192/01, Comm'n v. Denmark, 2003 E.C.R. I-9693, para. 54; Case C-24/00, Comm'n v. France, 2004 E.C.R. I-1277, para. 60; Case C-446/08, Solgar Vitamin's France v. Ministre de l'Économie, des Finances et de l'Emploi, 2010 E.C.R. I-3973, para. 60; Joined Cases C-211/03, C-299/03, and C-316/03 to C-318/03, HLH Warenvertriebs & Orthica, 2005 E.C.R. I-5141, para. 69. It must be observed that the EFTA Court adopted an analogical position in *EFTA Surveillance Auth. v. Norway*, Case E-3/00, EFTA Surveillance Auth. v. Norway, 2001 EFTA Ct. Rep. 73, para. 28. Furthermore, as might be perceived in both EFTA and ECJ cases, this position applies not only in respect to fortified foods, but to food supplements as well.

<sup>87</sup> Case 216/84, Comm'n v. France, 1988 E.C.R. I-793, para. 16; Case C-17/93, Criminal Proceedings Against J.J.J. Van der Veldt, 1994 E.C.R. I-3537, para. 19; *France*, 2004 E.C.R. para. 75; *Solgar Vitamin's France*, 2010 E.C.R. para. 51.

<sup>88</sup> *Van der Veldt*, Case C-17/93 at para. 19; Case C-319/05, Comm'n v. Germany, 2007 E.C.R. I-9811, para. 95; *Solgar Vitamin's France*, Case C-446/08 at para. 51.

<sup>89</sup> Fortified Foods Regulation, *supra* note 32, at art. 5.

<sup>90</sup> *Id.* at art. 6.

of proximity of intakes of certain substances to the upper safe levels.<sup>91</sup> Hence, the transitional measures allow the Member States to apply existing national provisions on maximum, as well as minimum, amounts of the vitamins and minerals listed in Annex I in the absence of the specific EU provisions.<sup>92</sup> However, Member States must still uphold the free movement of goods—for example, the principle of proportionality as in the case of food supplements—as cited in the case-law above.

### *III. Health Claims Regulation*

Although claims on particular characteristics of foods have existed in the EU for some time,<sup>93</sup> the Health Claims Regulation was the first act to harmonize rules for such claims at the EU level.<sup>94</sup> The Regulation applies to both nutrition claims and health claims<sup>95</sup> made in commercial communications, whether in the labeling, presentation, or advertising of foods to be delivered to the final consumer.<sup>96</sup> The regulation acts as umbrella legislation, covering all products with such claims,<sup>97</sup> without prejudice to some specific provisions set, for example, in cases of dietetic foods and food supplements.<sup>98</sup>

The Regulation's promotion of scientific substantiation for the use of nutrition and health claims<sup>99</sup> is the cornerstone of the whole act,<sup>100</sup> stipulating that such claims must be justified, i.e. based on and substantiated by generally accepted scientific evidence, which should be made fully available to the competent authorities of the Member States.<sup>101</sup>

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<sup>91</sup> *Id.* at art. 6(5)(a).

<sup>92</sup> *Id.* at art. 17(3).

<sup>93</sup> See Fiona Lalor & Patrick G. Wall, *Health Claims Regulations: Comparison Between USA, Japan and European Union*, 113 BRIT. FOOD J. 298 (2011).

<sup>94</sup> Health Claims Regulation, *supra* note 13, at recital 10.

<sup>95</sup> See *id.* at arts. 2(2)(4) & (5) (supplying definitions of nutrition and health claims).

<sup>96</sup> *Id.* at art. 1(2)(d).

<sup>97</sup> An example of nutrition and health claims on a sports nutrition product, a BCAA complex: "BCAA complex is a source of Vitamin B6, which contributes to: the regulation of hormonal activity; normal energy-yielding metabolism; the reduction of tiredness and fatigue; normal functioning of the immune system and nervous systems; normal protein and glycogen metabolism; normal red blood cell formation." *BCAA Complex*, SCITECH NUTRITION, [http://www.sciteconline.com/language/en/products/scitec\\_nutrition/bcaas/bcaa\\_complex](http://www.sciteconline.com/language/en/products/scitec_nutrition/bcaas/bcaa_complex) (last visited Aug. 13, 2015).

<sup>98</sup> Health Claims Regulation, *supra* note 13, at art. 1(5).

<sup>99</sup> *Id.* at recital 17.

<sup>100</sup> Lalor & Wall, *supra* note 93, at 307.

<sup>101</sup> Health Claims Regulation, *supra* note 13, at art. 6.

These authorities then communicate this data to the Authority, which carries out the scientific assessment as part of the authorization procedure, established by Articles 15–17.

All claims must meet two-level requirements: general and specific. General requirements include general principles<sup>102</sup> and conditions<sup>103</sup> for all permitted claims. Furthermore, Article 5(2) of the Regulation permits the use of claims only if an average consumer<sup>104</sup> can be expected to understand the claimed beneficial effects.

Specific requirements are set differently for nutrition and health claims. The main requirement for nutrition claims presumes that only claims listed in the Annex<sup>105</sup> and that conform with provisions of the Regulation are permitted.<sup>106</sup> For health claims, Article 10(2) provides a range of mandatory conditions which should be met in the labeling, or in case of absence of the labeling, in the presentation and advertising.<sup>107</sup>

Notably, all health claims should not only comply with general and specific requirements of the Regulation, but also be authorized and included in the lists of authorized claims provided in Articles 13–14.<sup>108,109</sup> Otherwise, such claims are prohibited pursuant to Article 10(1).<sup>110</sup>

<sup>102</sup> *Id.* at art. 3. For example, that the use of nutrition and health claims shall not be false or misleading, give rise to doubt about the safety of other foods, etc.

<sup>103</sup> *Id.* at art. 5. For example, that the nutrient or other substance, present in food, has been scientifically shown to have a beneficial nutritional or physiological effect, is contained in due quantity, etc.

<sup>104</sup> According to recital 16, the Regulation takes as a benchmark an average consumer, who is reasonably well-informed, reasonably observant, and circumspect, taking into account social, cultural, and linguistic factors, as interpreted by the Court of Justice. *Id.* at recital 16.

<sup>105</sup> For example, “high protein,” “source of vitamins/minerals,” “source of omega-3 fatty acids,” etc.

<sup>106</sup> *Id.* at art. 8(1).

<sup>107</sup> These include: a statement indicating the importance of a varied and balanced diet, the pattern of consumption required to obtain the claimed beneficial effect, a statement addressed to persons who should avoid using the food, and an appropriate warning for products that are likely to present a health risk if consumed to excess.

<sup>108</sup> According to the latter, health claims are classified into three types: “function” health claims (related to growth, development, and functions of the body, psychological and behavioral functions, and slimming or weight-control) under art. 13(1), risk of disease reduction claims, and children development and health claims under arts. 14(1)(a) and (b), respectively. *Health Claims*, EUR. COMM’N, [http://ec.europa.eu/food/food/labellingnutrition/claims/health\\_claims\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/claims/health_claims_en.htm) (last visited Aug. 13, 2015).

<sup>109</sup> Case C-609/12, *Ehrmann AG v. Zentrale zur Bekämpfung unlauteren Wettbewerbs eV*, paras. 25–30 (Apr. 10, 2014), <http://curia.europa.eu/>.

<sup>110</sup> Generally, in case of non-compliance, the products in question may not be marketed after 31 July 2009. Health Claims Regulation, *supra* note 13, at art. 28(1). However, derogations are possible in cases of certain trademarks, brand names, or fancy names that may be construed as nutrition or health claims according to article 1(3). *Id.* at

So far, the existing case-law demonstrates that the main problem with the assessment of the two-level requirements by national courts relates primarily to the understanding of the concept of the health claim. For example, in *Deutsches Weintor*, the ECJ was asked whether the words “easily digestible” in a description of a certain wine constituted a health claim.<sup>111</sup> The question was all the more relevant considering that Article 4(3) of the Regulation proscribes, without exception, all health claims relating to the category of beverages containing more than one-point-two percent by volume of alcohol, which includes wine. The Court replied that the starting point for defining a health claim is the relationship that must exist between a food, or one of its constituents, and health. Because the definition provides no information as to whether that relationship must be direct or indirect, or as to its intensity or duration, the term “relationship” must be understood in a broad sense.<sup>112</sup> Similarly, in *Swan Pharmaceuticals*, the ECJ provided an interpretation for yet another issue: The definition of the second type of health claim, namely the reduction of disease risk claim under Article 2(2)(6).<sup>113</sup>

With respect to some uncertainty about the concept of a health claim, it must also be mentioned that the Health Claims Regulation foresees a possibility that general health-related benefits of a certain product are referred to in a health claim.<sup>114</sup> These would only be allowed if accompanied by a specific health claim included in one of the mentioned lists of authorized claims. However, a specific health claim must have some relevance to the

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art. 1(3). Products bearing such marks or names may continue to be marketed until 19 January 2022 pursuant to article 28(2). *Id.* at art. 28(2). The ECJ stated, though, that this provision applies only to food, bearing a mark/name, which must be considered a nutrition or health claim within the meaning of the Regulation and which, in that form, existed before 1 January 2005. Case C-299/12, *Green - Swan Pharmaceuticals CR, a.s. v. Státní zemědělská a potravinářská inspekce, ústřední inspektorát*, para. 37 (July 18, 2013), <http://curia.europa.eu/>. At the same time, with regard to trademarks and brand names and their relationship to common commercial communications under article 1(2) of the Health Claims Regulation, the Court held that such communication may constitute a trade mark or brand name, provided that it is protected by the applicable legislation, which is for the national court to ascertain. Health Claims Regulation, *supra* note 13, at art. 1(2) para. 32.

<sup>111</sup> Case C-544/10, *Deutsches WeintoreG v. Land Rheinland-Pfalz*, 2012 E.C.R. I-526, para. 26.

<sup>112</sup> *Id.* at para. 34. Therefore, a health claim may cover a description such as “easily digestible,” accompanied by a reference to the reduced content of substances frequently perceived by consumers as being harmful. *Id.* at para. 41.

<sup>113</sup> The product in question contained a following statement on its packaging: “The preparation also contains calcium and vitamin D3, which help to reduce a risk factor in the development of osteoporosis and fractures.” *Id.* at para. 11. The national court asked whether a reduction of disease risk claim must necessarily expressly state that the consumption of a category of food, a food or one of its constituents significantly reduces a risk factor in the development of a human disease. *Id.* at para. 21. The ECJ gave a negative answer and stated that it is sufficient that that claim may simply give the average consumer the impression that the reduction of a risk factor is significant. *Id.* at para. 24.

<sup>114</sup> Health Claims Regulation, *supra* note 13, at art. 10(3).



general reference, and if the latter is very broad—for example, “for good health”—several specific health claims should preferably accompany it.<sup>115</sup> The Commission pointed out that some claims submitted for authorization during their scientific assessment proved too general or unspecific for evaluation; hence, authorization was not granted to such claims.<sup>116</sup> Meanwhile, certain health claims are prohibited *per se*.<sup>117</sup>

To summarize, it must be acknowledged that although the provisions of this Regulation provide all essential elements for managing health and nutrition claims, there are still some problems. For example, the establishment of specific nutrient profiles by the Commission—that should have occurred by 19 January 2009<sup>118</sup>—turned out to be a difficult task to perform. Although the Commission conducted extensive consultations on this matter,<sup>119</sup> it adopted no final decision. Despite that, the impact of this act on the regulation of sports nutrition must be viewed as positive due to scientific certainty and consumer protection priorities. Hence, due to the lack of scientific substantiation, many health claims on different sports nutrition products have not received authorization.<sup>120</sup>

#### *IV. Dietetic Foods Framework Directive*

This Directive is quite different from previous acts because it covers foods for particular nutritional uses (dietetic foods)<sup>121</sup>—i.e. nutritional substances which are used to fulfill the particular requirements of certain distinctive and recognizable categories of people (subgroups), listed in Article 1(3). Athletes are categorized as persons in a particular

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<sup>115</sup> Commission Implementing Decision of Jan. 24, 2013, Adopting Guidelines for the Implementation of Specific Conditions for Health Claims Laid Down in Article 10 of Regulation 1924/2006 of the European Parliament and of the Council, 2013 O.J. (L 22) 25, annex.

<sup>116</sup> *Id.*

<sup>117</sup> For example, claims suggesting that health could be affected by not consuming the food or making reference to the rate or amount of weight loss, etc. Health Claims Regulation, *supra* note 13, at art. 12.

<sup>118</sup> *Id.* at art. 4.

<sup>119</sup> Opinion on the setting of nutrient profiles for foods bearing nutrition and health claims pursuant to Article 4 of the Regulation (EC) No 1924/2006. European Food Safety Authority, final (Feb. 25, 2008), [http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/nda\\_op\\_ej644\\_nutrient%20profiles\\_en%2C3.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/nda_op_ej644_nutrient%20profiles_en%2C3.pdf)

<sup>120</sup> See, e.g., relevant health claims on glutamine, carnitine, whey protein, BCAA, creatine, etc. For detailed information see *EU Register on Nutrition and Health Claims*, EUR. COMM’N, <http://ec.europa.eu/nuhclaims/?event=search> (last visited Aug. 13, 2015).

<sup>121</sup> Art. 1(2) defines dietetic foods as “[f]oodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.” Dietetic Foods Framework Directive, *supra* note 33, at art. 1(2).

physiological condition, rendering them eligible to obtain special benefit from consumption of certain dietetic foods.<sup>122</sup>

Notably, a product must meet all three conditions to be considered a dietetic food.<sup>123</sup> Accordingly, only products complying with the requirement of particular use for certain subgroups may be characterized as “dietetic” or “dietary”.<sup>124</sup> Otherwise, establishment of such characteristics is prohibited.<sup>125</sup> Therefore, the main requirement for dietetic foods is their appropriateness for the particular nutritional use as intended by the manufacturer.<sup>126</sup> As the ECJ stated in *Rombi and Arkopharma*, this should always be ascertained by national authorities.<sup>127</sup> Thus, if a certain product which contains L-carnitine promoting weight loss is intended by the manufacturer to be a product for slimming, disregarding the exact circle of consumers that may benefit from it, it would most likely be treated as a food supplement,<sup>128</sup> a fortified food,<sup>129</sup> or a food with health or nutrition claim.<sup>130</sup> Meanwhile, the same product intended as a fat burner—or performance enhancer for athletes, as it was in the *Rombi and Arkopharma* case—would be considered a dietetic food because it would meet all three conditions laid down in Article 1(2) of the Dietetic Foods Framework Directive.<sup>131</sup> This option is especially relevant because athletes are identified as a subgroup by the Dietetic Foods Framework Directive due to the introduction and inclusion of a

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<sup>122</sup> *Id.* at art. 1(3)(b).

<sup>123</sup> Case C-107/97, *Criminal Proceedings Against Max Rombi and Arkopharma SA*, 2000 E.C.R. I-3367, paras. 37–39.

<sup>124</sup> Dietetic Foods Framework Directive, *supra* note 33, at art. 2(1).

<sup>125</sup> *Id.* at art. 2(2).

<sup>126</sup> *Id.* at art. 3(1).

<sup>127</sup> See *Max Rombi*, Case C-107/97 at para. 42 (“It is for the national court alone to ascertain whether the products at issue . . . are actually suitable for the nutritional purposes that Arkopharma claims they are, that is, whether they do facilitate weight loss or are, in the case of sportsmen, performance-enhancing.”). Consequently, the only way for national authorities to treat such products as normal foods is to establish that they are not suitable for the nutritional purposes claimed by the manufacturer or that they do not fulfill the particular nutritional requirements of one of the categories of persons referred to in article 1(3). Dietetic Foods Framework Directive, *supra* note 33, at art. 1(3) para. 43.

<sup>128</sup> As a substance with nutritional/physiological effect. See European Advisory Servs., *supra* note 40.

<sup>129</sup> *Id.*

<sup>130</sup> Currently, L-carnitine is not granted an authorization for health claims related to weight-reduction. The main reason for this is the lack of scientific substantiation on such claimed effect of this product. *Supra* note 120. Still, such health claims may potentially become possible in case of proper scientific substantiation in the future.

<sup>131</sup> Case C-107/97, *Criminal Proceedings Against Max Rombi and Arkopharma SA*, 2000 E.C.R. I-3367, paras. 37–39.

category of “foods intended to meet the expenditure of intense muscular effort, especially for sportsmen” in Annex I.<sup>132</sup>

Regulation (EC) No. 953/2009 supplements the Dietetic Foods Framework Directive. It categorizes nutritional substances in its Annex, including some substances—other than vitamins and minerals—which are highly popular among athletes, such as amino acids and the above-mentioned L-carnitine. According to Article 2(1) of this Regulation, while no restrictions are imposed on substances included in this Annex, as long as they fall within the listed categories of substances, all unmentioned substances that qualify under the listed categories are prohibited. Meanwhile, substances not belonging to the mentioned categories may still be used.<sup>133</sup> Hence, the creation of new categories can render some substances—belonging to them but not defined in the Annex—as illegal, as may have occurred with creatine, which ultimately was not categorized.<sup>134</sup>

The labeling on dietetic foods must indicate particular nutritional characteristics<sup>135</sup> and, in the absence of specific provisions, include particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product such characteristics, together with the available energy value, carbohydrate, protein, and fat content.<sup>136</sup>

Finally, with regard to mutual recognition among Member States, the same principles in the case of other foods are applied to dietetic foods.<sup>137</sup>

Overall, the dietetic foods’ legal regime may seem the most appropriate for sports nutrition regulation, especially because it has initially targeted the adoption of specific legislation for such products. Unfortunately, the regime was seriously compromised by certain factors. For example, because the purpose of dietetic food for a certain subgroup is objectively provable, while a population-undefined category, such as, for example, food supplements, is only required to meet the “claimed nutritional purposes,”<sup>138</sup> bypassing of

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<sup>132</sup> This category first appeared in Directive 89/398/EEC and reappeared later in Directive 2009/39/EC as a category, for which specific provisions, laid down by a specific directive, should have been developed over the years.

<sup>133</sup> Dietetic Foods Framework Directive, *supra* note 33, at art. 2(2).

<sup>134</sup> European Advisory Servs., *supra* note 40, at 71.

<sup>135</sup> Dietetic Foods Framework Directive, *supra* note 33, at art. 9(2).

<sup>136</sup> *Id.* at art. 9(3).

<sup>137</sup> Case C-270/02, *Comm’n v. Italy*, 2004 E.C.R. I-1559, para. 26; Case C-24/00, *Comm’n v. France*, 2004 E.C.R. I-1277, para. 76.

<sup>138</sup> See Andreas Meisterernst, *Foods for Particular Nutritional Uses—Death Sentence Passed for Sound Reasons?*, 6 EUR. FOOD & FEED L. REV. 315 (2011).

one rule in favor of another could easily occur.<sup>139</sup> The ambiguity of sports nutrition regulation under this Directive is also reflected in the anticipated adoption of the specific Directive, which—while never adopted—included a relevant report prepared by the Scientific Committee on Food in the early 2000s intended to be used as a scientific base for the future legislation.<sup>140</sup> Moreover, over the years, the whole regime has been subjected to critique not only by the EU legislators, but by the industry, as well identified as being burdensome and causing internal market distortions.<sup>141</sup>

### **E. The Reform of the Dietetic Food Sector and Regulation (EU) No. 609/2013**

The pertaining ambiguous situation with current classification and nutritional substance regulation in the EU and Member States forced the Commission to initiate a substantial reform of the sector, meant to clarify the position of different categories of dietetic foods and their relation to other foods. As early as 2009, the Commission issued a working paper aimed at the potential options for revising the Dietetic Foods Framework Directive, addressing such problematic aspects as difficulties with defining dietetic foods, administrative burdens, and lastly, the situation with highlighted categories, for which no specific legislation has been developed.<sup>142</sup> Regarding the development of a specific Directive for sports foods, the Commission acknowledged that such an option would be difficult to implement due to the wide variety and heterogeneity of products on the market.<sup>143</sup>

In 2011, after further consultations with stakeholders and Member States, the Commission prepared a proposal for a new Regulation,<sup>144</sup> accompanied by an impact assessment.<sup>145</sup> The proposal, like the working paper, limited itself by saying that no consensus could be reached with regard to the development of specific provisions due to widely diverging

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<sup>139</sup> Impact Assessment, *supra* note 2, at 13.

<sup>140</sup> *Report of the Scientific Committee on Food on Composition and Specification of Food Intended to Meet the Expenditure of Intense Muscular Effort, Especially for Sportsmen* (Feb. 28, 2001), [http://ec.europa.eu/food/fs/sc/scf/out64\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out64_en.pdf). The report covered a wide range of sports nutrition, mentioned in the introductory part of this article.

<sup>141</sup> Meisterernst, *supra* note 138, at 319.

<sup>142</sup> *Id.* at 317–18.

<sup>143</sup> *Id.* at 315.

<sup>144</sup> *Proposal for a Regulation on Food Intended for Infants and Young Children and on Food for Special Medical Purposes*, COM (2011) 353 final (Jan. 28, 2012).

<sup>145</sup> Impact Assessment, *supra* note 2.

views on the nature of such legislation<sup>146</sup> and further proposed to abolish the sports foods category because it was not “essential for certain well-established groups of consumers with specific nutritional needs.”<sup>147</sup> The concept of dietetic foods was also subject to an abolishment.

Meanwhile, the impact assessment, as a detailed presentation of work carried out by the Commission, provided deeper insight into the problem by analyzing information obtained from the external study and focused consultations with the Member States and industry representatives.<sup>148</sup> It provided a brief overview of different regulatory rules on sports foods at the Member States’ level—rules that lead to market distortions. Given the size of the sports nutrition market in the EU, such distortions are most unwanted. Moreover, the impact assessment highlighted another long-standing problem: The existence of the sports foods category in the Dietetic Foods Framework Directive “results in Member States having to consider sports foods *per se* as dietetic foods intended for a particular group of the population.”<sup>149</sup> Because the Commission found out that the majority of sports food consumers are recreational users—amateur athletes—such people should not be considered a particular group, as their distinction from the general population seems poorly asserted. However, Member States approach this problem in disparate ways, contributing to the mentioned market distortions.<sup>150</sup>

Another market distortion is the conflict between provisions of the Dietetic Foods Framework Directive with other legislation, especially the Health Claims Regulation. The 2009 working paper presented situations of uncertainty between health claims and suitability for subgroups,<sup>151</sup> whereas the impact assessment stressed that, according to Member States’ reports, such uncertainty “is being used by some operators to circumvent the rules of subsequent legislation”; i.e. notifying normal foods as dietetic in order to avoid the requirements of the Health Claims Regulation, particularly in the case of “potential dietetic foods for which no specific rules have been laid down and where the classification as dietetic foods, food supplements or fortified foods is not always obvious.”<sup>152</sup>

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<sup>146</sup> *Proposal for a Regulation on Food Intended for Infants and Young Children and on Food for Special Medical Purposes*, *supra* note 144, at 14.

<sup>147</sup> *Id.* at 8.

<sup>148</sup> Impact Assessment, *supra* note 2, at 4.

<sup>149</sup> *Id.* at 17.

<sup>150</sup> *Id.*

<sup>151</sup> “‘Food suitable for people with digestion disorders’ (indication of suitability) and ‘food that facilitates digestion’ (health claim).” Meisterernst, *supra* note 138.

<sup>152</sup> Impact Assessment, *supra* note 2, at 13.

For example, the impact assessment asked whether “branched chain amino acid products in a food supplement form” are dietetic foods or food supplements and concluded that “depending on the answer, differing rules may be applied by Member States distorting the market further.”<sup>153</sup>

In June 2013, the European Parliament voted in favor of the proposal, abolishing the concept of dietetic foods and, consequently, sports foods—a step warmly welcomed by the industry.<sup>154</sup> The adopted Regulation (EU) No. 609/2013<sup>155</sup> emphasized that the category of sports foods was abolished due to “widely diverging views among the Member States and stakeholders concerning the scope of specific legislation, the number of subcategories of food to be included, the criteria for establishing compositional requirements and the potential impact on innovation in product development”<sup>156</sup> and concluded that “specific provisions should not be developed at this stage.”<sup>157</sup> Furthermore, the EU legislators agreed that different views exist as to whether additional rules are needed to ensure adequate protection of sports nutrition consumers, emphasizing that the Commission should be invited, after consulting the Authority, to submit to the European Parliament and the Council a report on the possible necessity of further provisions concerning such food based on the earlier assessment work.<sup>158</sup> Such a report should be submitted by 20 July 2015 and it may, if necessary, be accompanied by an appropriate legislative proposal.<sup>159</sup>

Hence, the new Regulation, unlike the Dietetic Foods Framework Directive, only foresees a possibility of developing specific legislation sometime in the future. In other words, the Regulation deems such a possibility as clearly contingent. However, considering the twenty-year history of sports foods category, it seems quite improbable that such provisions would be developed in the near future because the studies conducted by the

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<sup>153</sup> *Id.*, at 14.

<sup>154</sup> Gary Roethenbaugh, *ESSNA Welcomes “Dramatic Changes” in EU law Covering Sports Nutrition*, (June 14, 2013), <http://www.triathlonbusiness.com/2013/industry-news/essna-welcomes-dramatic-changes-in-eu-law-covering-sports-nutrition/>.

<sup>155</sup> Regulation 609/2013 of the European Parliament and of the Council of June 12, 2013, On food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control, Repealing Council Directive 92/52, Commission Directives 96/8, 1999/21, 2006/125, and 2006/141, Directive 2009/39 of the European Parliament and of the Council and Commission Regulations 41/2009 and 953/2009, 2013 O.J. (L 181) 35.

<sup>156</sup> *Id.* at recital 32.

<sup>157</sup> *Id.*

<sup>158</sup> *Id.* at recital 33.

<sup>159</sup> *Id.* at art. 13. As of late August 2015, however, the report has not yet been submitted.

Commission revealed no pressing need for that. Moreover, it is questionable whether it would even be feasible to adopt a specific legislation due to the range of factors which led to the abolishment of the sports foods' category.

Overall, the new Regulation acknowledged that the Dietetic Foods Framework Directive turned out to be less "adapted to an evolving and innovative food market" than the Food Supplements Directive, Fortified Foods Regulation, and Health Claims Regulation; therefore, the provisions of those acts would adequately regulate a number of the categories of food covered by it with less administrative burden and more clarity.<sup>160</sup> A similar situation is expected with regard to consumer protection.<sup>161</sup>

It is still too early to predict whether the provisions of the new Regulation will substantially improve the general policy.<sup>162</sup> However, it is clear enough that it leaves out some of the existing problems—for example, the absence of a whole range of substances, other than vitamins and minerals, in the Annexes of the Food Supplements Directive and the Fortified Foods Regulation.

#### F. Conclusion

Although the existing policy constitutes a comprehensive approach for regulating nutritional substances, including sports nutrition, it still has a long way to go in terms of fully implementing relevant legal provisions. The persisting uncertainty with regard to substances other than vitamins and minerals, the absence of specific rules regarding maximum amounts of vitamins and minerals present in nutritional substances, the failure to establish nutrient profiles at the EU level, and other issues present challenges for the future. At the moment, these problems result in an increase in the role of the mutual recognition principle. However, the diverging views among Member States tend to create potentially unwanted market distortions, as seen in the example of the dietetic foods sector. And although the recent reform of the latter may eventually bring more clarity, it refers to a limited circle of foods and cannot resolve all problems.

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<sup>160</sup> *Id.* at recital 11.

<sup>161</sup> Impact Assessment, *supra* note 2, at 36–39.

<sup>162</sup> The Regulation, with some exceptions, will apply from July 20, 2016. Regulation 609/2013, *supra* note 155, art. 22.

