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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND  
THE COUNCIL**

**on food intended for sportspeople**

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## on food intended for sportspeople

### 1. INTRODUCTION

This report is intended to meet the obligation set for the Commission by Article 13 of Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (hereinafter 'FSG Regulation')<sup>1</sup>. According to this Article, the Commission is required to present to the European Parliament and to the Council, after consulting the European Food Safety Authority (EFSA), a report on the necessity, if any, of provisions for food intended for sportspeople (hereinafter 'sports food').

The request for this report is linked to the repeal by the FSG Regulation of the framework on foodstuffs intended for particular nutritional uses<sup>2</sup>, as of 20 July 2016. This framework was established by a Council Directive<sup>3</sup> in 1989 and completed by the recast Directive 2009/39/EC.

Sports food can currently be classified either (1) as 'foodstuff intended for particular nutritional uses' under Directive 2009/39/EC or (2) as food for normal consumption governed by relevant horizontal rules of food law. The FSG Regulation does not include sports food within its scope, since it focuses on foods for certain vulnerable groups of consumers.

Thus, since a categorisation as foodstuff intended for particular nutritional uses will no longer be available to sports food, this type of food will be exclusively governed by horizontal rules of food law as from 20 July 2016.

This report reflects on potential consequences of the change of status for sports food.

It builds upon a market study carried out by the Food Chain Evaluation Consortium (FCEC Study)<sup>4</sup> between January 2015 and June 2015. This study includes more detailed information on the findings presented in this report. In the context of the preparation of this report, a consultation was carried out with national competent authorities and other interested parties.

The European Commission consulted the European Food Safety Authority (EFSA) which provided scientific and technical assistance regarding sports food<sup>5</sup>. EFSA compiled existing scientific advice in the area of nutrition and health claims and Dietary Reference Values for adults that are relevant to sportspeople and informed the Commission that its subsequent advice does not differ from the recommendations

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<sup>1</sup> OJ L 181, 29.6.2013, p. 35.

<sup>2</sup> OJ L 124, 20.5.2009, p. 21.

<sup>3</sup> Council Directive on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, OJ L 186, 30.6.1989, p.27.

<sup>4</sup> Study on food intended for Sportspeople – Final Report – Food Chain Evaluation Consortium (FCEC) - [http://ec.europa.eu/food/safety/labelling\\_nutrition/special\\_groups\\_food/sportspeople/index\\_en.htm](http://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/sportspeople/index_en.htm).

<sup>5</sup> EFSA, Technical report on Scientific and technical assistance on food intended for sportspeople, approved on 24.09.2015, <http://www.efsa.europa.eu/en/supporting/pub/871e>.

of the Report of the Scientific Committee on Food (SCF) adopted in 2001 on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen<sup>6</sup>.

## 2. MARKET OF SPORTS FOOD

Sports food is not defined in EU legislation. For the purpose of this report, taking also into account the analysis carried out in the context of the FCEC Study, the following definitions were used:

- **sports food:** all food products which target sportspeople, irrespective of the EU legislation under which they are placed on the market;
- **sportspeople:** people who practise sport once a week or more<sup>7</sup>;
- **lifestyle users:** people who practise sport less than once a week or not at all<sup>8</sup>.

### 2.1. Products present on the market, market size, value and prices

Different interested parties and scientific bodies have introduced throughout the years different categorisations of sports food for their purposes<sup>9</sup>. Taking these and the current market into account, the FCEC Study<sup>10, 11</sup> identified the following three categories of sports food: (1) sports drinks; (2) (protein-based) muscle strengthening, building and post exercise recovery products, and (3) energy and performance boosting products and products for on-going supplementation of sportspeople.

The EU wide market for sports nutrition and drinks was worth €3.07 billion (retail value) in 2014<sup>12, 13</sup>. The market for sports food at EU level has grown by 11.2% between 2009 and 2014, equivalent to a compound annual growth rate of 2.2%. This growth has mainly been driven by protein-based products, which grew by 68% over the period. Energy and performance boosting products grew by 54% while sports drinks shrank by 8%<sup>14</sup>.

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<sup>6</sup> The SCF Report concluded that the "*concept of a well-balanced diet is the basic nutritional requirement for athletes*". It further explained that "*taking the aspects of intense muscular exercise in consideration (...) individuals can benefit from particular foods and food ingredients beyond the recommended dietary guidelines for the general population*" and gave some advice on the nature and essential composition of sports food 28.02.2001 [http://ec.europa.eu/food/fs/sc/scf/out64\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out64_en.pdf).

<sup>7</sup> For the purpose of the consumer survey, the definition of sportspeople included the requirement to consume sports food at least once in the last year, FCEC Study, Section 3.3.1.

<sup>8</sup> FCEC Study, Section 3.3.1.

<sup>9</sup> FCEC Study, Section 3.1.1.1.

<sup>10</sup> FCEC Study, Section 3.1.1.2, Table 3.1.

<sup>11</sup> There are certain cases of borderline products which can be used by and might give the impression to be of interest for sportspeople. Still, because of their targeting of the general population, such borderline products were not considered as sports food when analysing the market in the context of the FCEC Study, FCEC Study, Section 3.1.1.3.

<sup>12</sup> FCEC Study on the basis of data from Euromonitor, Section 3.2.1.1.

<sup>13</sup> The largest Member State markets were: (1) UK (EUR 732m), (2) Spain (EUR 491m), (3) Germany (EUR 452m), (4) Italy (EUR 358m), (5) Sweden (EUR 185m), (6) Netherlands (EUR 153m) and (7) France (EUR 128m), FCEC Study on the basis of data from Euromonitor, Section 3.2.1.1.

<sup>14</sup> FCEC Study, Section 3.2.1.1.

The number of sports food products present in the market can be estimated, on the basis of the innovation rate at EU level<sup>15</sup>, to between approximately 20,000 and 30,000 with the highest number of products in the category of the protein-based sports food<sup>16</sup>.

In terms of market value in the EU, 61% of all sports food belongs to the category of sports drinks, 26% to protein based products and 13% to energy and performance boosting products<sup>17</sup>.

The consumer price of sports food is fairly equal across the different distribution channels. However, the wholesale price at which the manufacturer sells to different distribution channels may vary significantly. The most expensive category is clearly the (protein-based) muscle strengthening, building and post exercise recovery products, followed by performance boosting products, and products for on-going supplementation of sportspeople. The least expensive category of sports food is the category of sports drinks<sup>18</sup>.

## **2.2. Structure of the market, distribution channels**

Findings show that large multinational companies dominate the market of sports drinks, while SMEs<sup>19</sup> entirely or mainly focus on sports nutrition<sup>20</sup>.

61.2% of lifestyle users and 44.3% of sportspeople considered supermarkets/generalists shops as the most important distribution channel for sports food, followed by sports supermarkets. The importance of online channels and internet is still not significant when purchasing sports food but its use amongst lifestyle users is higher than amongst sportspeople<sup>21</sup>. Additional distribution channels for sports food include specialised shops, pharmacies and fitness centres<sup>22</sup>.

## **2.3. The marketing of sports food**

Information on the label was identified as one of the most significant marketing techniques for the sector<sup>23</sup>. Information on the label can relate to the (1) sale denomination: clear description of the function of the products (e.g. "energy bars"); (2) brand and packaging (e.g. the use of photos of sportspeople); (3) clear instructions for use (e.g. "during or after physical activity"); (4) composition and ingredients; (5) use of information such as "high energy", "source of glucose"; (6) use of information suggesting beneficial health effects for sportspeople with respect to the particular characteristics of the product.

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<sup>15</sup> "The most suitable method identified for estimating the number of FISP [food intended for sportspeople] products on the market is based on innovation. According to industry interviewees, innovation at EU level in terms of new products represents between 8% and 12% of the products on the market in a given year.", FCEC Study, Section 3.1.1.4.

<sup>16</sup> FCEC Study, Section 3.1.1.4.

<sup>17</sup> FCEC Study, Section 3.1.1.5, Table 3.4.

<sup>18</sup> FCEC Study, Section 3.1.3.

<sup>19</sup> Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, OJ L 124, 20.5.2003, p. 36.

<sup>20</sup> FCEC Study, Section 3.2.1.4, Table 3.13.

<sup>21</sup> FCEC Study, Section 3.3.2, Figure 3-7.

<sup>22</sup> FCEC Study, Section 3.3.2.

<sup>23</sup> Other marketing techniques used in relation to sports food are: sponsoring of sports events, endorsement by famous sportspeople, specialised press advertising, mainstream media, word-of-mouth advertising, web marketing and internet communication, FCEC Study, Section 3.3.3.

Sportspeople and lifestyle users identified the following elements of importance for the label: the list of ingredients, followed by the expected results/effects and consumption instructions, side effects, warnings on potential overdoses and use of natural ingredients/procedures in the preparation<sup>24</sup>. However, the two groups of consumers have slightly different interests when ranking the importance of the mentioned information. For example, receiving information on the expected results or effects of the product is more relevant for sportspeople, while lifestyle users are more interested in side effects or the use of natural ingredients<sup>25</sup>.

### 3. CONSUMER UNDERSTANDING AND CONSUMPTION HABITS

Sportspeople and lifestyle users have a very diverse degree of awareness of their nutritional needs in relation to sports activity and knowledge about products and their properties<sup>26</sup>. The more general the intended use of a sports food is, the more widespread is the use among different groups of consumers<sup>27</sup>.

Sportspeople consume more sports food in relation to sport than to other activities<sup>28</sup> and they are willing to spend more on such products than lifestyle users<sup>29</sup>. The trend is reversed for consumption not related to sport or physical activities<sup>30</sup>. Less sportspeople than lifestyle users consume sports food in relation to physical effort other than sport<sup>31</sup>. Energy increase and recovery are the main reasons declared by both groups of consumers for the consumption of sports food<sup>32</sup>.

Still, the reasons for consumption are not necessarily reflected in the intended use of the sports food which is particularly valid for lifestyle users<sup>33</sup>.

Information on the particular nutritional characteristics of sports food and its beneficial health effect for sportspeople can be provided either under Article 9 of Directive 2009/39/EC, as mandatory requirement, if sports food is classified as food intended for particular nutritional uses or as authorised claim under Regulation (EC) No 1924/2006<sup>34</sup>, if sports food is classified as food for normal consumption and

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<sup>24</sup> 28% list of ingredients, 19% expected results/effects, 18% consumption instructions, 14% side effects, 13% warnings on potential overdoses and 9% use of natural ingredients/procedures in the preparation, FCEC Study, Section 3.3.3, Figure 3-8.

<sup>25</sup> FCEC Study, Section 3.3.3, Figure 3-9.

<sup>26</sup> FCEC Study, Section 3.3.1.

<sup>27</sup> FCEC Study, Section 3.3.1.1.

<sup>28</sup> 68% of sportspeople consume sports food in relation to sport activities, compared to just 15.6% of lifestyle users, FCEC Study, Section 3.3.1.1, Figure 3-3.

<sup>29</sup> FCEC Study, Section 3.3.1.2.

<sup>30</sup> 57.7% of lifestyle users use sports food neither in the context of sport nor physical activity and this is only the case in 16.1% of sportspeople, FCEC Study, Section 3.3.1.1, Figure 3-3.

<sup>31</sup> 15.9% of sportspeople indicated that they consume sports food in relation to physical effort other than sport, compared to 26.7% of lifestyle users, FCEC Study, Section 3.3.1.1, Figure 3-3.

<sup>32</sup> FCEC Study Annexes, Consumer Survey, Section 6.5, Figure 6-9.

<sup>33</sup> 20% of performance boosting products and 14.6% of protein-based products are consumed by lifestyle users in relation to wellness and health. Taste preferences have been indicated as the most important reason behind consumption of sports drink products (24% of lifestyle users and 9.4% of sportspeople; percentages which confirm and justify the efforts operators make to mainly innovate in terms of taste and flavours). Taste preferences have been indicated by 11.5% of lifestyle users as the reason for consumption of sport energy bars, compared to 4.8% of sportspeople, who mainly consume these products in relation to energy increase (27%) and energy recovery (24%), FCEC Study Annexes, Consumer Survey, Section 6.5, Figure 6-9.

<sup>34</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404, 30.12.2006, p. 9.

governed by horizontal rules of food law. Hence, consumers usually have no means to identify under which legislation such information is provided and identify whether a claim has been authorised according to the procedure laid down in Regulation (EC) No 1924/2006 or not<sup>35</sup>. Findings of the consumer survey show that the trust of consumers in non-authorised claims is not lower than the trust in authorised claims<sup>36</sup>. Although information on the expected results or effects of sports food was identified as important for sportspeople<sup>37</sup> on the basis of the consumer survey, the influence of the presence of a claim when purchasing sports food can be questioned<sup>38</sup>.

#### **4. OVERVIEW OF THE APPLICABLE LAW FOR SPORTS FOOD UNTIL 20 JULY 2016**

Sports food has to comply with the provisions laid down in Regulation (EC) No 178/2002<sup>39</sup> (so called 'General Food Law'). However, as a result of the possibility to classify sports food either (1) as 'foodstuff intended for particular nutritional uses' under Directive 2009/39/EC until 20 July 2016, when this Directive will be repealed or (2) as food for normal consumption governed by relevant horizontal rules of food law, the treatment of sports food varies amongst Member States. Some Member States require notification of sports food classified as food intended for particular nutritional uses in accordance with Directive 2009/39/EC and have laid down other specific rules (e.g. definition, composition, labelling). For sports food not classified as food intended for particular nutritional uses and governed by horizontal rules, Member States might require notification at national level under the legislation for fortified foods and food supplements<sup>40</sup>.

##### **4.1. Sports food classified as 'food intended for particular nutritional uses'**

Sports food can be classified as 'foodstuff intended for particular nutritional uses' if it complies with the definition laid down in Directive 2009/39/EC. Such foodstuffs are defined as foods which (1) are the result of a special composition or manufacturing process, (2) are clearly distinguishable from foodstuffs for normal consumption, (3) are suitable for their claimed nutritional purpose, and (4) are marketed in such way that such suitability is indicated.

Article 3 of Directive 2009/39/EC lays down the general requirement that the nature and composition of the foods concerned shall be such that the product is appropriate for the intended particular nutritional use. Article 4 of Directive 2009/39/EC requires to adopt under its framework additional specific Directives for certain groups of foodstuffs for particular nutritional uses, amongst others for 'food intended to meet the expenditure of intense muscular effort, especially for sportsmen'. However, since 1989, when the concept of foodstuffs intended for particular nutritional uses was established, no such specific rules have been adopted for sports food. As a result, if classified as food intended for particular nutritional uses, such products have to comply solely with the more general rules of Directive 2009/39/EC.

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<sup>35</sup> FCEC Study, Section 3.3.3.

<sup>36</sup> FCEC Study, Section 3.3.3, FCEC Study, Annexes, Consumer Survey, Section 6.10, Table 6.3.

<sup>37</sup> FCEC Study, Section 3.3.3, Figure 3-9.

<sup>38</sup> FCEC Study, Annexes, Consumer Survey, Section 6.11, Table 6.4.

<sup>39</sup> 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, OJ L 31, 1.2.2002, p. 1.

<sup>40</sup> FCEC Study, Section 3.4.1.1.

Article 9 of Directive 2009/39/EC requires, as a general rule, that food intended for particular nutritional uses shall comply with the labelling requirements of Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs<sup>41</sup> (Directive 2000/13/EC has been replaced by Regulation (EU) No 1169/2011 on the provision of food information to consumers<sup>42</sup>). In addition, some specific labelling and compositional requirements were laid down in Directive 2009/39/EC for these products, which will be analysed in detail in Chapter 6 of this report. National competent authorities are responsible to check compliance of foods intended for particular nutritional uses with the provisions of Directive 2009/39/EC.

#### **4.2. Sports food classified as food for normal consumption and governed by relevant horizontal rules of food law**

If sports food is not classified as food intended for particular nutritional uses, it may have to comply with the relevant requirements of some of the following horizontal food law measures: (1) Regulation (EC) No 1924/2006 on nutrition and health claims made on foods; (2) Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods<sup>43</sup> (so called 'fortified food'); (3) Regulation (EU) No 1169/2011 on the provision of food information to consumers; (4) Directive 2002/46/EC on food supplements<sup>44</sup> and, (5) Regulation (EC) No 258/97 on novel foods and novel food ingredients<sup>45</sup> (the Regulation will be repealed, as of 1 January 2018, by Regulation (EU) 2015/2283 on novel food<sup>46</sup>). Compared to the legislative framework of Directive 2009/39/EC, there are differences regarding how and which information can be provided to the consumer and regarding the composition of the product concerned. These differences will be analysed in detail in Chapter 6 of this report.

### **5. CHANGES INTRODUCED BY THE FSG REGULATION**

In 2011, the Commission adopted a legislative proposal to simplify the legal framework applicable to foods intended for particular nutritional uses<sup>47</sup>. The proposal aimed at abolishing the concept of food intended for particular nutritional uses by repealing Directive 2009/39/EC, including the specific Directives adopted under this

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<sup>41</sup> Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, OJ L 109, 6.5.2000, p. 29.

<sup>42</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 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 (EC) No 608/2004, OJ L 304, 22.11.2011, p. 18.

<sup>43</sup> Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on addition of vitamins and minerals and of certain other substances to foods, OJ L 404, 30.12.2006, p. 26.

<sup>44</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, OJ L 183, 12.7.2002, p. 51.

<sup>45</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.1997, p. 1.

<sup>46</sup> Regulation (EU) No 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, OJ L 327, 11.12.2015, p. 1.

<sup>47</sup> European Commission, 2011, *Proposal for a Regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes*, COM (2011) 353.

framework, and replacing it with a new framework covering only foods for certain vulnerable groups of consumers, for which specific composition and information rules were justified. This change was particularly relevant for sports food since it was often very difficult to understand whether a specific food product had to be considered as a food intended for particular nutritional uses by sportsmen or a food for normal consumption fortified in certain nutrients with a health claim targeting sportspeople. This also led to the situation that so-called 'legislation shopping' was reported, where operators chose to comply, on the basis of their convenience, either with Directive 2009/39/EC or with other horizontal rules of food law, as described under Chapter 4, point 4.2.

On the basis of the impact assessment carried out by the Commission in preparation of the Commission's proposal, sports food was excluded from its scope<sup>48</sup>. Consequently, the proposal foresaw that sports food currently placed on the market under Directive 2009/39/EC should comply with other relevant horizontal rules of EU food law after 20 July 2016, when the FSG Regulation enters into application.

## **6. SUMMARY OF THE ISSUES RELATED TO SPORTS FOOD AFTER 20 JULY 2016**

This chapter provides detailed analysis on how sports food currently classified as food intended for particular nutritional uses would be affected under the horizontal rules of food law in the absence of specific legislation after 20 July 2016 (when Directive 2009/39/EC is repealed) and whether there is the need for specific legislation for the concerned products. No change would occur for sports food currently considered as food for normal consumption governed by relevant horizontal rules of food law.

### **6.1. Food safety aspects**

Article 14 of General Food Law requires that food shall not be placed on the market if it is unsafe and lays down the requirements on how to determine whether a food is unsafe. According to Article 17 of the General Food Law, it is the responsibility of the food business operators to ensure compliance with these provisions and Member States are responsible for the enforcement. Those provisions already apply today to sports food, as they apply to all other foods.

Taking this into account, there will be no changes for sports food currently classified as food intended for particular nutritional uses regarding general safety requirements when governed by horizontal rules of food law.

### **6.2. Consumer information aspects**

Currently, sports food classified as food intended for particular nutritional uses has to comply with additional and specific information requirements compared to sports food not classified as such. After 20 July 2016, the evolution for sports food may be described as follows.

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<sup>48</sup> Commission Staff Working Paper, Impact Assessment Accompanying the Document "Proposal for a Regulation of the European Parliament and of the Council on food intended for infants and young children and food intended for special medical purposes", [http://ec.europa.eu/food/safety/docs/labelling\\_nutrition-special\\_groups\\_food-impact\\_assessment\\_en.pdf](http://ec.europa.eu/food/safety/docs/labelling_nutrition-special_groups_food-impact_assessment_en.pdf).

### Information on the particular nutritional characteristics of sports food and suitability

According to Article 9 of Directive 2009/39/EC, it is mandatory to indicate the particular nutritional characteristics and compositional elements or special manufacturing process which give the products their particular nutritional characteristics. In addition, Directive 2009/39/EC requires that foods intended for particular nutritional uses are marketed in a way to indicate the suitability for their claimed nutritional purposes. Such indications under Directive 2009/39/EC may imply nutritional and health benefits, however no authorisation is required for them.

After 20 July 2016, consumer information on sports food will have to be provided in accordance with Regulation (EU) No 1169/2011. Furthermore, information falling under the definition of nutrition and health claims provided for such products on a voluntary basis will have to comply with Regulation (EC) No 1924/2006. Consequently, only nutrition and health claims authorised pursuant to that Regulation will be allowed for use on sports food.

Currently, there are already seven authorised health claims targeting sportspeople and some additional ones which may be relevant<sup>49, 50</sup>. Health claims targeting sportspeople should be backed by scientific evidence specific for this target group and not for the general population. There are substances for which claims were not authorised<sup>51</sup>, sometimes despite a favourable conclusion of EFSA<sup>52</sup> regarding the beneficial effect for sportspeople of the product concerned, because the claim was considered as non-beneficial for the general population from the health policy point of view (e.g. 'high in sodium').

### Information on the designation of sports food and their intended use

Directive 2009/39/EC requires, in addition to the indication of their particular nutritional characteristics, that foods covered by its scope are intended for particular nutritional uses and are clearly distinguishable from foodstuffs for normal consumption. On this basis, operators have been designating the products as "sports food" or "product suitable for sports activity" and providing instructions for use, specifying the appropriate use of the products (e.g. before, during, after exercise).

In accordance with Article 17 of Regulation (EU) No 1169/2011, the name of the food shall be provided on a mandatory basis, and it shall be its legal name, where defined at EU or national level, or in the absence of this, its customary name, or if such customary name is not used, a descriptive name. That provision would apply to the designation of "sports food". Regarding the instructions for use, Article 9(1)(j) of Regulation (EU) No 1169/2011 requires its mandatory indication where, in the absence of such information, it is difficult for the consumer to make appropriate use of the food. The instructions for use, as specified in Article 27(1) of Regulation (EU) No 1169/2011, shall be indicated in such a way as to enable appropriate use to be made of the food. In addition, voluntary food information can also be given to the consumers in line with Chapter V of Regulation (EU) No 1169/2011.

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<sup>49</sup> FCEC Study, Section 3.3.4.1.

<sup>50</sup> Claims relevant for sportspeople on caffeine are under discussion. EFSA Panel on Dietetic Products, Nutrition and Allergies, 2011, Scientific Opinion on a list of health claims pursuant to Article 13(1) (EC) No 1924/2006, EFSA Journal 2011;9(4):2054; EFSA Panel on Dietetic Products, Nutrition and Allergies, 2015, Scientific Opinion on the safety of caffeine, EFSA Journal 2015;13(5):4102

<sup>51</sup> FCEC Study, Section 3.3.4.1.

<sup>52</sup> EFSA Scientific and technical assistance on food intended for sportspeople, 29.09.2015, <http://www.efsa.europa.eu/en/supporting/pub/871e>.

### 6.3. Compositional aspects

As explained under Chapter 4, point 4.1 of this report, foods intended for particular nutritional uses currently need to comply with the general requirement that their composition shall be such, that the product is appropriate for its intended particular nutritional use. Under the framework of Directive 2009/39/EC, Regulation (EC) No 953/2009<sup>53</sup> lists in its Annex certain categories of substances which may be added for specific nutritional purposes in certain foods for particular nutritional uses, including sports food. However, no specific provisions are laid down with respect to the values of these substances, when added.

Taking into account that no specific composition requirements have been set for sports food classified as food intended for particular nutritional uses, only the above mentioned requirements apply in respect to their composition.

After 20 July 2016, a sports food classified as food intended for particular nutritional uses will be considered under horizontal rules of food law either as a food supplement, where it falls under the definition of Directive 2002/46/EC or, in accordance with Regulation (EC) No 1925/2006, as a fortified food.

In the case of fortified food, Article 6(6) of Regulation (EC) No 1925/2006 states that vitamins and minerals added to the food should be present at least in a 'significant amount' according to the definition laid down in Regulation (EU) No 1169/2011. In sports food, vitamins and minerals are sometimes added at lower level than that 'significant amount', to ensure that the composition of the product best addresses the requirements of the body when carrying out a particular sports activity. In that context, it should be taken into account that Regulation (EC) No 1925/2006 provides for the possibility of granting a derogation to the requirement of the 'significant amount' in justified cases for certain categories of food. Consequently, there is an appropriate basis in place under Regulation (EC) No 1925/2006 which would allow that sports food classified nowadays as food intended for particular nutritional uses could continue to contain less than the significant amount of vitamins and minerals after 20 July 2016.

With respect to the addition of substances other than vitamins and minerals, no harmonisation took place up to now for fortified foods under Regulation (EC) No 1925/2006 and for food supplements under Directive 2002/46/EC. Hence, Member States have the possibility to introduce national rules in this respect, in compliance with Articles 34 to 36 of the Treaty on the Functioning of the European Union<sup>54</sup>, as to any other food products today classified as food supplements or fortified foods. Where Member States intend to adopt such rules, Articles 11 and 12 of Regulation (EC) No 1925/2006 apply. The situation is similar regarding maximum level of vitamins and minerals where harmonisation has not taken place either. After 20 July 2016, when sports food classified previously as food intended for particular nutritional uses will be governed by horizontal rules, such national provisions will apply to sports food.

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<sup>53</sup> Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, OJ L 269, 14.10.2009, p. 9.

<sup>54</sup> OJ C 326, 26.10.2012, p. 47.

#### 6.4. Aspects related to the notification required by national competent authorities

Article 11(1) of Directive 2009/39/EC requires notification for foods intended for particular nutritional uses which do not belong to one of the groups listed in Annex I to the Directive. Annex I lists those specific groups of foodstuffs intended for particular nutritional uses for which it was required to lay down specific provisions. Although sports food is listed in this Annex, no specific rules have been adopted. For this reason, different approaches have been introduced by Member States regarding notification, some requiring this for sports food classified as food intended for particular nutritional uses and some not.

After 20 July 2016, sports food previously classified as food intended for particular nutritional uses will have to comply with horizontal rules on food supplements or fortified foods. For food supplements and fortified foods, Member States may require notification for monitoring purposes. Whether a possible re-notification requirement for sports food previously classified as food intended for particular nutritional uses will be requested will depend on the decision of the Member States. Differences in this respect might be expected; however it should be noted that, already in the context of Directive 2009/39/EC, notification is not considered as a significant administrative burden for operators<sup>55</sup>.

#### 6.5. Additional aspects

After 20 July 2016, all sports food will have the same legal status. This would foster competition between manufacturers and, at the same time, would positively influence the competitiveness of the sector concerned. This can positively affect the price of sports food. There might be however some negative implication on the competitiveness of the specific sector of sports food manufacturers currently operating under Directive 2009/39/EC that would lose its specific position.

Re-labelling and re-notification costs (if obligations for such notifications are introduced) will not be significant, but additional costs stemming from certain reformulation of sports food considered today as food intended for particular nutritional uses might appear in order to comply with the requirements of Regulation (EC) No 1925/2006<sup>56, 57, 58</sup>. Additional costs for sports food currently placed on the market under Directive 2009/39/EC can also be expected in the context of applications for authorisation of health claims. Changes in the enforcement practices of the competent authorities compared to the current situation are not expected<sup>59</sup>.

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<sup>55</sup> FCEC Study, Section 4.2.1.1.

<sup>56</sup> Operators reported one-off relabeling cost for sports food previously placed as dietetic food on the market. It was also reported that operators periodically re-label their products, FCEC Study, Section 4.2.1.1.

<sup>57</sup> The need to reformulate could also stem from some national provisions, e.g. maximum levels of vitamins and minerals in food supplements which will only affect sports food when Directive 2009/39/EC is repealed, FCEC Study, Section 4.2.1.1.

<sup>58</sup> Such costs might have a higher proportional impact on SMEs than on larger players, FCEC Study, Section 4.2.2.

<sup>59</sup> On the basis of the survey carried out amongst national competent authorities, 41% of them did not foresee any changes to enforcement practices under this option and 18% only minor changes. Eight competent authorities (36% of respondents) foresee moderate changes under this option and one of them major changes, FCEC Study, Section 4.4.2.1.

## 7. SUMMARY OF NATIONAL COMPETENT AUTHORITIES' AND INTERESTED PARTIES' POSITIONS

The majority of national competent authorities believe that the existing horizontal rules of food law are either quite suitable or very suitable for regulating sports food<sup>60</sup>. Six national competent authorities have recognised the need for specific rules for sports food<sup>61</sup>.

Operators are clearly divided on the question whether specific legislation is necessary for sports food or whether sports food should be governed by horizontal rules of food law<sup>62</sup>.

An industry group in favour of specific provisions would like to ensure, through the introduction of specific definition, composition and information requirements for sports food, that such food products are clearly distinguishable from normal food. According to this group, under the current horizontal rules of food law, the quality of the product, including its safety and suitability for the target group and the proper communication on sports food, cannot be guaranteed, in particular as far as Regulation (EC) No 1924/2006 on nutrition and health claims is concerned. The position expressed by this group states that this would discourage innovation since the authorisation of new health claims may be beyond the means of operators<sup>63</sup>.

On the contrary, another industry group considers that the applicable horizontal rules of food law are sufficient to govern the different aspects (e.g. food safety, composition, and information) related to sports food and that the absence of specific legislation prevents 'legislation shopping'. In their opinion, sports food is not addressed to particular groups of vulnerable people but is intended to the wide range of population carrying out sports activity for different purposes (e.g. athletes for professional purposes, lifestyle and recreational users for health and wellbeing purposes). This group of operators believes that the introduction of specific rules, including a definition for sports food, could lead to excessive provisions which would negatively impact innovation<sup>64</sup>. However, this group of operators considers that some specific aspects, in particular regarding nutrition and health claims, are not adequately addressed under the horizontal rules of food law.

It is a general concern of food business operators that legislation, either of horizontal or specific nature, should adequately allow the provision of relevant information for sports food with particular attention to the nutritional characteristics and the intended use. There is also agreement that certain measures introduced at national level, for example in relation to food supplements and fortified foods, can lead to barriers in the Internal Market and would negatively influence cross-border trade in the EU<sup>65</sup>.

Finally, it should be mentioned that food business operators have raised the issue of the use of doping substances. However, this is not relevant to the European food legislation and should be addressed on the basis of international and voluntary standards<sup>66</sup>.

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<sup>60</sup> FCEC Study, Section 4.4.1.1.

<sup>61</sup> FCEC Study, Section 4.1.2.1.

<sup>62</sup> These differences can be observed throughout the whole FCEC Study.

<sup>63</sup> FCEC Study, Section 4.2.3.

<sup>64</sup> FCEC Study, Section 4.2.3.

<sup>65</sup> FCEC Study, Section 4.1.2.2.

<sup>66</sup> Study on doping prevention, European Commission, 12. December 2014, <http://bookshop.europa.eu/en/study-on-doping-prevention-pbNC0514065/>

## **8. CONCLUSION**

There are clear indications that sport has become mainstream in the general population. Consequently, people carrying out sports activity can hardly be characterised as a specific vulnerable group of consumers but rather as a target group of the general population who is protected at an appropriate level by horizontal legislation.

In view of the growing completion of the horizontal rules of food law which took place in the last years, an appropriate legislative framework is in place to ensure that sports food classified nowadays as food intended for particular nutritional uses can remain on the market and can operate. The horizontal rules of food law provide the necessary safeguards for these products in terms of food safety, food composition, consumer information and legal certainty. As a result, not only all sports food products will be subject to the same legal requirements but they will have the same level of harmonisation as other foods falling under the horizontal rules of food law. It is expected that, through the simplification and clarification of the legal framework applicable for sports food, legal certainty will be enhanced and the current fragmentation based on the different legal frameworks reduced.

From this analysis, it can be concluded that there is no necessity for specific provisions for food intended for sportspeople. Nevertheless, sports food may include some element of specificity and the analysis in this report shows that this may have to be taken into account by the Commission in the application and implementation of the horizontal rules, so that such specificities can be adequately addressed. The Commission will ensure proper application of horizontal legislation and monitor the developments after 20 July 2016.