



European Commission  
Directorate General for Health and Food Safety

Study on food intended for  
Sportspeople

**Final Report**

Framework Contract for evaluation  
and evaluation related services - Lot 3: Food Chain

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## **S1. Executive summary**

### **S1.1. Terms of reference and scope**

The Commission shall submit a report to the European Parliament and to the Council (after having consulted the European Food Safety Authority) on the necessity, if any, of provisions for food intended for sportspeople. This report is required 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 ("the FSG Regulation"). The Food Chain Evaluation Consortium was therefore appointed by DG SANTE to carry out a study to provide the evidence base for this report. Agra CEAS Consulting was the project leader for this study and was supported by Areté and Euromonitor<sup>1</sup>.

The study covered two main tasks:

- (a) A description of the current market of foods intended for sportspeople.
- (b) An assessment of the evolution of the market of foods intended for sportspeople after 2016 if no specific measures were to be proposed by the Commission.

In absence of official definitions, and for the purpose of the study, the following key definitions were used:

**Food intended for sportspeople (FISP):** all food products which target sportspeople, irrespective under which European legislation they are placed on the market. **Sportsdrinks** includes FISP in drink form, while **sports nutrition** covers FISP products in food rather than drink form.

**FISP / products placed on the market as sportsfood according to Directive 2009/39/EC:** any food product which target sportspeople and which is placed on the market as dietetic food in line with Directive 2009/39/EC.

**Foods not intended for sportspeople / foods other than FISP:** products which are not intended for sportspeople. These may also be consumed by sportspeople in relation to sporting activity.

**SME:** a small or medium enterprise, as defined by Recommendation 2003/361/EC, i.e.: *an enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.*

**Other horizontal rules of food law:** horizontal rules of food law excluding specific provisions for foods for particular nutritional uses) laid out in Directive 2009/39/EC. One example is Directive 2002/46/EC on food supplements.

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<sup>1</sup> Euromonitor is a market intelligence firm which produces market reports for a wide range of consumer industries, including sportsdrinks and sports nutrition

**Sportspeople:** People which do practice sport once a week or more.

## **S1.2. Methodology**

Information was gathered for this study via several complementary data collection tools: a literature review (including an analysis of Euromonitor data on the market); exploratory and semi-structured personal interviews with stakeholders; a survey of EU-28 Competent Authorities<sup>2</sup>; a consumer survey<sup>3</sup>; and five Member State case studies (France, Germany, Italy, Spain and UK).

Fieldwork for this study took place between February and May 2015. Survey results and case study findings were provided as independent annexes. Evidence and findings from the various data collection tools were systematically checked and cross-checked in order to create the final analysis.

## **S1.3. Findings theme 1: the current market for FISP**

### **S1.3.1. FISP on the market**

No single, universally accepted categorisation of FISP exists. Various categorisations of FISP were identified during the course of the study. Arguably the most widely accepted of these is that developed by the Scientific Committee on Food (SCF) in 2001<sup>4</sup>. There are several other notable categorisations from the industry (both producers and retailers) itself. In developing a categorisation for the purpose of this study, it was necessary to ensure that the resulting classification:

- was close enough to existing classifications to be understood and for data existing data to be mapped;
- was understandable for consumers, and;
- enabled discrete classification.

The final categorisation adopted for the study, along with the main types of product (sub-categories), importance of each category / product type, the main formats and ingredients, is presented in Table 1. In developing this categorisation, it was necessary to deal with certain so-called “borderline” products; that is to say products for which there are doubts as to whether or not they are FISP. Notable examples, along with the decision taken regarding their inclusion or exclusion are:

- ***Vitamin, mineral and joint supplements.*** These were excluded from the definition of FISP primarily on the basis that evidence suggested such supplements do not tend to target only sportspeople.
- ***Energy drinks.*** These were excluded from the definition of FISP on the basis that stakeholders unanimously agreed they are not FISP products.

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<sup>2</sup> 24 of 28 Member States partially or fully completed this survey.

<sup>3</sup> 1221 replies were received (242-247 per MS) from the five case study Member States

<sup>4</sup> The 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. (SCF/CS/NUT/SPORT/5 Final (corrected), 28 February 2001).

- **Weight loss products.** Light version of FISP, and weight loss products with another clear sports function covered by the adopted categorisation (such as muscle mass gain) were included in the corresponding category. Other weight loss products were excluded from the definition of FISP.
- **General foods.** General foods using words such as *sport* and *exercise* were omitted from the categorisation of FISP. It should be noted that only a few specific cases of such foods were identified during the study.
- **Ready meals and meal substitutes.** Sample ready meal / meal substitute products examined either fell under the category of protein (protein bars), or were excluded from the classification as they crossed over into the areas of weight loss or generic foods.

**Table 1: Categorisation for the study**

Study categorisation	Key functions	Major categories (types of product)	Complexity and main ingredients	Main formats	Estimated importance all FISP (% EU value)
<b>Sportsdrinks</b>	Hydration; generally used during/after exercise	Carbohydrate-electrolyte drinks (CE)	Complex; carbohydrate, electrolyte (sodium, potassium etc.)	RTD	49%+
		Carbohydrate drinks	Single+; carbohydrates	RTD	>=6%
		Low energy CE drinks	Complex; carbohydrate, electrolyte (sodium, potassium etc.)	RTD	>=6%
<b>(Protein-based) muscle strengthening, building and post exercise recovery products</b>	Build/rebuild muscles, gain weight, recovery. Generally to be taken after exercise.	Protein only (strength / muscle build)	Single+; protein	Powder	13-21%
		Protein + carbohydrates recovery products	Complex; protein, carbohydrates	Powder	1-3%
		Protein + carbohydrates mass gainers	Complex; protein, carbohydrates	Powder	1-5%
		All in one muscle builders	Complex; protein, carbohydrates, creatine, BCAA, amino acids, etc.	Powder	3%
<b>Energy and performance boosting products, and products for on-going</b>	Improve performance; generally to be taken either (1) pre-exercise (2) during exercise	Energy bars and cakes	Single+; Carbohydrates	Food	4-8% combined
		Energy gels	Single+; Carbohydrates; sometimes with caffeine	Food	

<b>supplementat ion of sportspeople</b>	or (3) as an ongoing supplement. A minority of products may be taken after exercise.	Pre-work out all-in-one	Complex; combinations based on caffeine and creatine bases.	Powder / RTD	$\geq 4\%$
		Single ingredient supplements	Single; BCAA or single amino acids or caffeine.	Capsule / powder	$\geq 3\%$

In terms of the number of FISP products on the market, no single source of data was identified during the study, and several challenges were identified in arriving at an estimation, *inter alia*: different methods of counting products (e.g. the inclusion or exclusion of different flavours / pack sizes of the same product); the dynamic nature of the market; and the impact of grey market products on any estimate. Based on new product launch data and an annual innovation rate of 8-12%, it is estimated that there are 20 000 – 30 000 FISP products on the EU market. Over half of these are protein products. A little under 40% of products are energy / performance boosting, and about 10% are sportsdrinks. However, in terms of importance by value, sportsdrinks is the most important product category; it represents 61% of the EU FISP market by value. Protein products are second most important category with 26%.

The main ingredients by category were identified in Table 1. The most significant combination of ingredients with synergistic effects identified during the study were carbohydrate and electrolyte. Carbohydrate and protein were identified as an ingredient combination which may have synergistic effects in terms of mass gain and recovery. The addition of vitamins to carbohydrate based products may have synergistic effects in terms of substance processing; in this context it should be noted that there are authorised health claims relating the impact of vitamin B6 on the synthesis of protein and glycogen. Other emerging combinations of ingredients were identified by interviewees.

### **S1.3.2. Operators and markets**

The EU market for FISP was worth 3.07bn EUR in 2014 according to Euromonitor data. The most important Member States, in order, were: UK, Spain, Germany, Italy and Sweden. The market had grown at a compound annual growth rate of 2.2% between 2009 and 2014, though it should be noted that the market for sports nutrition grew substantially over the period while that of sportsdrinks shrank.

In terms of structure of the chain, there are substantial differences between the sportsdrinks chain and the sports nutrition chain.

The **sportsdrinks** sector tends to be dominated by large multinationals, and there is a high level of operator concentration; evidence suggests the top 3 or 4 operators tend to account for 80% of the value of the market in an individual Member State. The level of integration of these operators tends to be high up to the point of distribution.

The **sports nutrition** sector, on the other hand, has a significantly lower degree of concentration and is significantly varied. Due to this high degree of variation, a classification with five categories of sports nutrition operator was developed for the study:

1. ***Ingredient manufacturers***: for some companies in this category, sports nutrition may be a key focus; for others it may be one of various primary food processing operations. Most companies are large but there are some SMEs.
2. ***Independent subsidiaries of multinationals***: these companies specialise in sports nutrition but are owned by a large multinational. These companies tend to be large.
3. ***Specialised nutrition companies with integrated sports nutrition operations***. These companies manufacture specialised nutrition products including sports nutrition products. Most are larger companies but there are also some SMEs.
4. ***Branded focused subsidiaries of larger companies***. The parent company is a larger company active in the broader retail area, though the subsidiary may be an SME.

5. **Focused mainly/exclusively on sports nutrition.** Sports nutrition is the key focus of these companies. Many are SMEs, though there are also some larger companies.

The level of integration varies between sports nutrition companies. Ingredient production and FISP manufacture may be integrated, as may FISP manufacture and branding. It was noted that the use of contract manufacture is fairly common in the sports nutrition sector.

An abridged version of the strengths, weaknesses, opportunities and threats of the FISP sector identified during the course of the study are presented below.

<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>• Expertise of operators and evidence provided by them on product effectiveness</li> <li>• Innovation of sector</li> <li>• High (and increasing) consumer demand</li> </ul>	<p><b>Weaknesses</b></p> <ul style="list-style-type: none"> <li>• Increasing competition requiring continuous investments to protect market shares</li> <li>• High production costs</li> <li>• Challenges in exporting both intra and extra-EU due to different national regulations and requirements</li> </ul>
<p><b>Opportunities</b></p> <ul style="list-style-type: none"> <li>• Increasing number of people involved in semi-competitive sport activity</li> <li>• Increased general consumer interest in healthy lifestyles and physical activity</li> <li>• Increasing personalization /tailoring to meet specific nutritional needs of different sports</li> </ul>	<p><b>Threats</b></p> <ul style="list-style-type: none"> <li>• Uncertainty surrounding the post-2016 legal framework</li> <li>• Reputation of the market due to non-compliant products</li> </ul>

As implied above, innovation is a key driver of competitiveness, but there are substantial related costs. Over the period 2012-14, there was an average of approximately 2,360 new FISP products per year. Evidence suggests that the protein category accounted for the majority of these new launches. The nature of innovation varies between the more mature sportsdrinks segment, where the focus is on new flavours, formats and packaging; and the sports nutrition segment, where there is more innovation in terms of new ingredients or combinations of ingredient, and new formats.

In terms of third country trade, there is no significant trade in sportsdrinks due to the bulky nature of the products. For sports nutrition, the US is the main exporter of FISP to the EU. This trade is driven by a higher perceived quality of US products, and more innovative ingredients and composition. That said, some of the products which are imported from the US may not be compliant with EU regulation, but their method of import (e.g. direct sales via internet) make it particularly difficult for competent authorities to take action against such products. The flipside of the drivers for import from the US make it more difficult for EU based operators to export to the US. However, EU based operators may export to neighbouring EFTA countries, the middle East, Australia, Russia and South Africa.

### **S1.3.3. Consumers, distribution and marketing**

Two main groups of consumers of FISP were identified during the course of the study:

- **Sportspeople**, defined as people which do practice sport and have consumed FISP at least once in the last year. This category comprised the three sub-groups of: body builders and mass intense sportspeople; athletes (professional and semi- professional); and amateur users.
- **Lifestyle users**, defined as people who do not practice sport at all or practice sport less than once a week. This category comprised the two sub-groups of: lifestyle users; and recreational users.

A small part of FISP consumers may not be sportspeople nor lifestyle users but rather people involved in extreme physical activities other than sport, for example the military, emergency services or manual labour.

The nature and habits of these two main groups; sportspeople and lifestyle users; varied in the following ways:

- Type of product consumed.
- Basis of consumption, i.e. whether or not consumption is related to sport.
- Expenditure.
- Awareness of nutrition needs.

The main distribution channels of FISP identified were, in order of overall importance:

- Supermarkets / general retailers.
- Sports Supermarkets (e.g. Decathlon).
- Specialized shops.
- Pharmacies and parapharmacies.
- Fitness centres and clubs.
- Online channel / internet.

However, the importance of different channels depended on different factors, most notably:

- **Type of user:** supermarkets were more important for lifestyle users than for sportspeople.
- **Type of product:** While supermarkets dominate distribution of sportsdrinks and play an important role for energy bars, their importance diminishes substantially for protein based products and performance boosting products. At the same time, pharmacies, specialised shops and the online channel have a higher relative importance for protein based products and performance boosting products.

Marketing techniques can vary significantly in the FISP industry in relation both to the size of the operator and to its focus on a particular product category. In all cases, information on labels (images, statements and instructions) are used, though interviewees placed a limited importance on the use of approved health claims. In general terms, the marketing techniques used for sportsdrinks and sports nutrition products differed due to the different size of operators / volume of the market, and consequently the ability to afford certain methods of marketing. *Sportsdrinks* operators may use adverts in the general media; endorsements by famous sportspeople. *Sports nutrition* operators tend to organise and sponsor events, place adverts in specialised magazines and use web marketing and communication.



Foods other than FISP but which can be associated to sport activity have been identified in the course of the study and can be grouped in two main sub-categories:

- **Normal foods** (milk, fruits and vegetables, etc.) which are generally consumed by sportspeople because of their composition and their suitability in relation to sport activity;
- **Borderline products** whose composition does not define them as FISP in the context of this study but which are sometimes associated – both by consumers and by operators – as of interest by sportspeople. These products are often marketed with more or less explicit references to sport activity.

### **Health claims**

Regulation (EC) No 1924/2006 lays down harmonised rules for the use of nutrition claims, and includes a process for authorising health claims relating to foods or specific substances. There are seven authorised health claims of clear, direct relevance to sports activity, and it was confirmed during the study that these claims are used to some extent on FISP. Furthermore, some claims of indirect relevance to sport (such as reduction of fatigue, normal energy yielding metabolism and normal muscle function in relation to certain vitamins and minerals) are used on FISP. The use of unauthorised claims on FISP was identified by Competent Authorities in some cases; most notably for branch chain amino acids, glutamine and beta-alanine. However, there is a certain degree of difficulty (and subjectivity) in distinguishing between unauthorised health claims, and mandatory indications required by Directive 2009/39/EC; consequently there is a clear overlap in terms of the message communicated to the consumer under health claims legislation and through mandatory indications required by Directive 2009/39/EC.

The extent to which reformulation or fortification of FISP took place after 2012 in order to use certain authorised health claims varied, with decisions made on an operator by operator basis. No evidence was uncovered to suggest that this practice was widespread. . In this context, it should also be noted that the high rate of innovation of the sector should be taken into account, so while existing FISP products may not have been reformulated to a great extent, new products introduced after 2012 may have been formulated in order to use certain health claims. No evidence was uncovered to suggest that foods not intended for sportspeople were reformulated in order to use claims of direct relevance to sports activity, though this does not preclude the possibility that this may occur in the future.

#### **S1.3.4. Legislation**

National rules on sportsfood were identified in nine Member States<sup>5</sup>. While the areas covered by these rules varied between Member States, the most common areas covered were:

- Labelling (6 Member States)
- Notification (5 Member States)
- Composition (3 Member States)

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<sup>5</sup> BG, DK, EE, FR, HU, IT, PL, PT and RO.

On balance, national rules were perceived by stakeholders to have negative impacts on operators through impacts on the internal market, competitiveness, SMEs and third country trade; but positive impacts on consumers through consumer protection, and CAs through enforcement practices.

With regards to legislation in third countries, there is no specific legislation on FISP in the US. However, there is specific legislation in Australia which covers definition, categorisation, composition and labelling. Switzerland has national legislation which implicitly includes sportsfood. Stakeholders reported that some third countries require certificates of compliance with EU legislation for EU based operators who which to export to these countries; however it is not clear if these certificates of compliance are contingent on the existence of specific legislation for FISP in the EU.

#### **S1.4. Findings theme 2: evolution of the market after 2016 if no measures are taken at EU level**

##### **S1.4.1. General evolution and internal market**

The main drivers of the market for FISP are closely connected to the opportunities and threats explained under S.1.3.2. The three main drivers identified during the study were: innovation; increased levels of participation in sport; and, the movement to mainstream consumption of FISP. It should be noted that there was conflicting evidence on the validity and importance of the last two drivers.

Data from Euromonitor predicts that the FISP market will continue to grow over the period 2014-19, albeit at a lower annual rate of 0.8% (vs 2.2% for the period 2009-14).

Regulation (EU) 609/2013 will repeal Directive 2009/39/EC and the specific Directives adopted under its framework. Following the repeal of Directive 2009/39/EC, Member States with specific national legislation for sportsfood will be able to maintain these provisions provided that they remain compatible with EU law. It is the responsibility of national competent authorities to ensure that this is the case. Member States will also be able to adopt new national legislation provided that it is in line with EU law. New national provisions will have to be notified to the European Commission, which shall evaluate the compatibility of any national provisions with EU law.

In the absence of specific national legislation for sportsfood, products will have to comply only with the horizontal rules of food law after 20 July 2016. Operators indicated that following the repeal of Directive 2009/39/EC, FISP which were previously placed on the market as sportsfood in accordance with the Directive will have to either be placed on the market as food supplements in accordance with Directive 2002/46/EC, or as fortified foods in accordance with Regulation (EC) No 1925/2006.

Based on information collected from the Competent Authority (CA) survey and case studies, six Member States are expected to have national legislation on sportsfood after 2016. These six Member States represent 24% of the EU FISP market by value. The areas which are most likely to be covered by national legislation are composition (4 Member States / 23% of the EU market), definition and labelling (both 3 Member States / 20% of the EU market).

Considerable concerns were expressed about the potential impact of national rules on sportsfood on the internal market. Concerns were also expressed about certain cross-cutting

provisions for all food products in certain Member States (e.g. restrictions on the use of caffeine); however, it is important to note that the FISP will face the same level of harmonisation as other food products falling under other horizontal rules of food law, and consequently the free circulation of FISP placed on the market under other horizontal rules of food law will not be more disadvantaged than that of other foods.

#### **S1.4.2. Operators and market impacts**

In terms of changes in cost stemming from the repeal of Directive 2009/39/EC, three potential sources were identified:

- **Relabelling** – a one-off extra cost of around 150 EUR per label. The extent to which relabeling is necessary will depend on whether adjustments have already been made and also on the relabeling cycle of products.
- **Notification** – there may be savings in Member states where there is a notification fee. However, these may be offset or exceeded by any cost stemming from notification for FISP placed on the market as food supplements or fortified foods.
- **Reformulation** – the extent to which reformulation is necessary, and consequently the cost of any reformulation would depend on a variety of factors.

In terms of impacts on competitiveness, there are arguments for negative impacts and for no or positive impacts. It seems likely that the competitiveness of individual operators will be impacted differently depending on their situation; certain operators may benefit from the “mainstreaming” of FISP, while other operators may feel that mainstreaming leads to unfair competition.

As previously noted, innovation was considered as an important economic driver of the FISP sector. Stakeholders were divided on the impact of innovation post 2016. On one side, certain operators feared that innovation would be negatively impacted in the absence of specific vertical legislation for FISP due to the following reasons:

- Reduced ability to communicate on products and hence innovation (stemming from the disappearance of the mandatory statement requirement for products placed on the market as sportsfood in accordance with Directive 2009/39/EC).
- Uncertainty related to obtaining the authorisation of new health claims.
- Uncertainty stemming from the possible introduction of national rules.

On the other side, certain other operators considered the introduction of vertical legislation on FISP as a potential threat given that such legislation could lead to categorisations which limit the ability to launch certain new products. Consequently, the absence of specific legislation for sportsfood was preferred by these operators. This group of operators also believed it may be possible for new health claim dossiers to be submitted through industry collaboration.

Impacts on SMEs were judged to be similar to those on operators as a whole, though it was noted that any reformulation costs and impacts stemming from changes to innovation may have higher proportional impacts on SMEs. Similarly, the impact on third country operators will be in line with that on operators on a whole. No substantial impacts on third country trade were identified.

### **S1.4.3. Consumer impacts**

Uncertainty surrounding the legal framework for FISP and its interpretation at national level after 2016 makes predictions on changes in consumer choice and behaviour after the repeal of PARNUTs difficult. Possible impacts on consumer choice identified were:

- Reformulation due to composition criteria in certain Member States, or restrictions stemming from other horizontal rules of EU or national food law.
- Changes to the range of products available stemming from the possible emergence of products using different ingredients in lower quantities, or from reduced availability of certain niche products.

In terms of consumer behaviour, instructions for use were considered important by consumers. As is touched on in the next section, the nature of instructions which can be provided may be impacted by the interpretation of national CAs of certain provisions of other horizontal rules of food law.

Stakeholder views on consumer protection were divided; some believed that other horizontal rules of food law were sufficient to ensure consumer protection, while others expressed concerns as to how information on the product label will be impacted, and how any impact may affect consumer protection. There were diverging views as to whether sportspeople can be considered a vulnerable group of consumers. Furthermore, stakeholders were also divided on the group of consumers which should be the focus of consumer protection in the context of FISP; i.e. whether consumers of FISP, or the general public should be the focus.

In terms of price, given that legislation is not a key driver of price (cost and market factors are), no significant impacts on price were generally foreseen. That said, any national legislation with compositional requirements, or any change to the nature of products on the market could impact the price of FISP.

### **S1.4.4. Regulatory environment and competent authorities**

Stakeholders and CAs were divided on the suitability of other horizontal rules of food law for the regulation of FISP, with various arguments provided for and against their suitability. Among CAs, a higher percentage of CAs believed other horizontal rules to be suitable than that which believed them to be unsuitable.

Three groups of potential problems with other horizontal rules for the regulation of FISP were identified. These were:

- **Potential issues with other horizontal rules of EU food law.** These are potential issues which have been linked to EU law and for which there are potential impacts regardless of national interpretation. Issues included: the inability of some sportsdrinks to reach the minimum levels of fortification required by Regulation (EC) No 1925/2006; possible issues with the indication of sodium on sportsdrinks; questions over the suitability of certain authorised health claims; and the potential for issues in the case that nutrient profiles foreseen in Regulation (EC) No 1924/2006 are adopted.
- **Potential issues stemming from national interpretation of other horizontal rules of EU food law.** These are potential issues which have been linked to EU law, but for which there is a degree of subjectivity depending on interpretation of the EU level law. Consequently there may either be no issue, minor issues or more significant issues depending on the

interpretation of Member State CAs. Possible issues identified included: the provision of instructions for use which contain certain sport or exercise related words; and the possibility for certain FISP products to be placed on the market as food supplements.

- **Potential issues stemming from other rules of national food law.** These are issues which have been identified which are caused by the existence of certain provisions at national level. These national provisions may be linked to certain pieces of EU legislation. Possible issues included: the ability to use certain substances for fortification; and national provisions on the maximum levels of vitamins and minerals which may be used in food supplements.

The majority of CAs replying to the survey foresaw no or only minor changes to enforcement practices after 2016. Controls are often performed as part of wider controls on food products. However, in some Member States, the authority which is responsible for controls may change as FISP cease to fall inside the category of PARNUTS. While there are conflicting opinions on the degree of legal clarity which will be provided after 2016, any improvement in legal clarity will also facilitate CA enforcement.

### List of Acronyms

AESGP	Association of the European Self-Medication Industry
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (France)
BCAA	Branch chain amino acid
BEUC	European Consumers' Association
CA	Competent Authority
CAGR	Compound Annual Growth Rate
CE	Carbohydrate-electrolyte
CN	Common nomenclature (tariff code nomenclature)
CR	Concentration ratio
DG	Directorate General
DGCCRF	Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (French CA)
EAC	DG Education and Culture of the European Commission
EFSA	European Food Safety Authority
EHFA	European Health and Fitness Association

EHPM	European Health Product Manufacturers
ESSNA	European Specialist Sports Nutrition Alliance
EU	European Union
EUR	Euro (currency)
EDI	Swiss Federal Internal Market department
FCEC	Food Chain Evaluation Consortium
FCE-SID	US Food Canning Establishment and Process Filings requirements
FDA	US Food and Drug Administration
FISP	Food intended for sportspeople (see definitions)
FSSF	Formulated supplementary sports foods (Australia and New Zealand)
GBP	British pound (currency)
GFL	General Food Law
HMB	B-hydroxy b-methylbutyrate monohydrate (ingredient)
HS	Harmonised System (tariff code nomenclature)
MS	Member State
PARNUTS	Particular nutritional uses
PARNUTS-IME	Foodstuffs intended for particular nutritional uses intended to meet the expenditure of intense muscular effort and especially for sportsmen (category identified in Directive 2009/39/EC)
RTD	Ready to drink
SANTE	DG Health and Food Safety of the European Commission
SCF	Scientific Committee on Food
SFNS	Syndicat Français de la Nutrition Spécialisée
SME	Small or medium enterprise
SNE	Specialised Nutrition Europe

SWOT	Strengths, weaknesses, opportunities and threat (analysis)
UK	United Kingdom
UN	United Nations
UNESDA	Union of European Soft Drinks Associations
US(A)	United States of America





## 1 INTRODUCTION

### 1.1 Context

The Commission shall submit a report to the European Parliament and to the Council (after having consulted the European Food Safety Authority) on the necessity, if any, of provisions for food intended for sportspeople. This report is required 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 ("the FSG Regulation"). The Food Chain Evaluation Consortium was therefore appointed by DG SANTE to carry out a study to provide the evidence base for this report. Agra CEAS Consulting was the project leader for this study and was supported by Areté and Euromonitor.

Our study covered two main tasks:

- (c) A description of the current market of foods intended for sportspeople
- (d) An assessment of the evolution of the market of foods intended for sportspeople after 2016 if no specific measures were to be proposed by the Commission.

These two main tasks were further broken down into 25 study questions.

This Final Report details the methodology followed for the fieldwork and analysis and presents findings.

### 1.2 Methodology

The study followed four main stages, namely:

- Structuring
- Observing (data gathering)
- Analysis
- Judgement

There was close collaboration with Commission services throughout the study in order to ensure satisfactory progress at each stage.

#### 1.2.1 Structuring

The **structuring** phase comprised an initial kick-off meeting with Commission Services, which was followed by a series of *exploratory interviews* by the contractor with selected key stakeholders in order to refine their understanding of the issues around the study questions. The stakeholders interviewed during this phase are listed below:

- SNE
- ESSNA
- DG SANTE
- DGCCRF (French CA)
- Europe Active

The exploratory interview programme was accompanied by an *initial literature review*, an *initial review of Euromonitor data* and the *development of the study tools*; namely the surveys, the main phase interview guide and case studies.

The design of survey questionnaires benefitted from a series of discussions between the survey team and the Steering Group, both of which provide useful insights and suggestions.

The final selection of case studies was agreed based on the initial selection contained in our proposal and following further discussions with Commission services. The selected case studies; the four main case study Member States of France, Germany, Italy and UK plus a limited case study in Spain; were chosen based on the following main factors:

- Presence/absence of a national specific legislative framework for sportsfood
- Importance of the national market of foods intended for sportspeople (FISP)
- Penetration rate (share of consumers purchasing FISP)
- Other relevant issues such as claim issues, consumption habits, product launches etc.

The structuring phase ended with the submission of an Inception Report.

### 1.2.2 Observing

The observing phase of the study consisted of data collection through the various tools designed during the structuring phase.

Following agreement, the two *survey questionnaires* were launched. Details of the surveys, the dates they were completed, the methods of dissemination and replies received are set out in Table 1.1.

**Table 1.1: Overview of survey implementation**

Survey	Implementation period	Methodological notes	Replies
Competent authority	9 March – 16 April 2015*	Dissemination to national CAs Several follow up reminders by contractor and promotion by DG SANTE.	24 of 28 MS**
Consumer survey	23 March – 8 April 2015	Covered consumers aged 14-65 across the five case study Member States	1,221 completed replies (242-247 per MS)

\* Extensions were subsequently granted on a case-by-case basis, with the final replies received by early May 2015.

\*\* This number includes BG which supplied a limited written contribution not covering all issues.

The full survey results are presented in separate annexes.

A number of EU level stakeholders were contacted for *interview*. Table 1.2 contains a breakdown of the stakeholders who ultimately agreed to be interviewed. Interviews were completed in accordance with a structured interview topic guide.

**Table 1.2: Experts and stakeholders interviewed in the context of the study**

Industry	Consumer / user	Regulatory (EU and national level)
AESGP EHPM ESSNA Food supplements Europe SNE UNESDA	BEUC EHFA EU Athletes' Association	EAC EFSA SANTE

Note: while other stakeholders were contacted (notably DG GROW and UEAPME), interviews were declined due to a lack of relevant knowledge.

*Case studies* were carried out to a guidance document which contained background to the study, a topic guide with an elaboration of the issues to be investigated and a guide to writing up. Fieldwork for the case studies, which comprised interviews with Competent Authorities, industry (SNE and / or ESSNA representatives plus individual operators, depending on their availability) and (where relevant and possible) end users (BEUC or EHFA members), plus the identification and review of relevant literature, was carried out during April 2015.

The *literature review* and the *review of Euromonitor data* which started during the inception phase, continued during the observation phase. A complete list of relevant literature can be found in section 5.

Finally, data were *checked and validated*. Interview notes were sent to the interviewees for validation. Relevant documents identified during the literature review were cross-checked.

### 1.2.3 Analysis

During the analysis phase, evidence from the data collection tools (survey results, interviews and case studies) were combined with findings from the literature review and analysis of Euromonitor data in order to address the issues under the two study themes. For each issue, evidence and findings were systematically checked and cross-checked in order to create the final analysis.

### 1.2.4 Reporting

Reporting was carried out in accordance with a structure agreed with the steering group following the interim note. Reporting was completed during May and June 2015.

The report is structured as follows:

- Section 2 contains key definitions for the study.
- Section 3 contains the findings for the first task (FISP on the market at present).
- Section 4 contains the findings for the second task (Evolution of the market for FISP after 2016).

## 2 KEY DEFINITIONS FOR THIS STUDY

### 2.1 Definition of sportsfood

There is no universally accepted definition of what constitutes “sportsfood”. Directive 2009/39/EC includes a group of foodstuffs titled “foods intended to meet the expenditure of intense muscular effort, especially for sportsmen”, but does not provide a definition. In reality, products which target sportspeople are not limited to being placed on the market under the group of foodstuffs defined in Directive 2009/39/EC; they may also be placed on the market under other legislation. Consequently, the scope of the study is not limited only to foods placed on the market under Directive 2009/39/EC, but considers all products specifically targeting sportspeople regardless of their method of placing on the market. The term *food intended for sportspeople (FISP)* is used to refer to this broader group of products. The categories of products which comprise FISP are defined under study question A1 (section 3.1.1.1). Borderline cases, and products which are excluded from the group of FISP are explored in 3.1.1.3.

### 2.2 Formal definitions for this study

For the purpose of this study, the following formal definitions will be used:

**Food intended for sportspeople (FISP):** all food products which target sportspeople, irrespective under which European legislation they are placed on the market. It includes both sportsdrinks and sports nutrition (see below for definitions).

**Sportsdrinks:** products falling into the category of the same name as defined in section 3.1.1.2.

**Sports nutrition:** FISP products in food rather than drink form, i.e. the two categories of FISP products other than sportsdrinks defined in section 3.1.1.2.

**FISP / products placed on the market as sportsfood according to Directive 2009/39/EC:** any food product which target sportspeople and which is placed on the market as dietetic food in line with Directive 2009/39/EC.

**FISP placed on the market under other horizontal rules of food law:** food products which target sportspeople and are placed on the market under legal measures other than Directive 2009/39/EC.

**Foods not intended for sportspeople / foods other than FISP:** products which are not intended for sportspeople. These may also be consumed by sportspeople in relation to sporting activity.

**SME:** a small or medium enterprise, as defined by Recommendation 2003/361/EC, i.e.: *an enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.*

**Other horizontal rules of food law:** horizontal rules of food law excluding specific provisions for foods for particular nutritional uses) laid out in Directive 2009/39/EC. One example is Directive 2002/46/EC on food supplements.

**Sportspeople:** People which do practice sport once a week or more.

*A definition of the different types of consumers is provided in section 3.3.1.*

### **3 THEME 1: THE CURRENT MARKET FOR FISP**

#### **3.1 FISP on the market**

##### *3.1.1 AI Products on the market*

###### 3.1.1.1 Existing categorisation of products on the market

No single, universally accepted categorisation of FISP exists. Various categorisations of FISP were identified during the course of the study; the main categorisations identified are summarised below.

#### **SCF (2001)**

The Scientific Committee on Food (SCF) developed a categorisation of foodstuffs intended for particular nutritional uses (PARNUTS) intended to meet the expenditure of intense muscular effort, especially for sportsmen (PARNUTS-IME). This categorisation, which was based on a review of scientific literature in the sports nutrition area and consensus reports from sports organisations, was completed in the preparation for a specific directive on PARNUTS-IME foodstuffs. The SCF identified the following categories:

1. Carbohydrate-rich energy foods
2. Carbohydrate electrolyte-solutions
3. Protein and protein components
4. Supplements
  - a. Essential nutrients
  - b. Other food components

While not all stakeholders interviewed during the course of the study considered the SCF categorisation to be a full reflection of the current market for FISP, it was arguably the most widely accepted of the existing categorisations. Certain interviewees noted that some Member State Competent Authorities informally adhere to the SCF classification for products placed on the market as sportsfood in accordance with Directive 2009/39/EC.

#### **Publicly available categorisations by EU industry representatives**

EU industry representatives SNE and ESSNA have adopted their own classifications which are used in public communication. These are as follow:

##### ***SNE***<sup>6</sup>:

1. Carbohydrate electrolyte-solutions
2. High protein products
3. Carbohydrate-rich energy foods
4. Supplements
5. Carbohydrate-protein products

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<sup>6</sup> <http://www.specialisednutritioneurope.eu/foods-intended-for-sports-people> accessed 26/5/15 and supplemented by SNE (2014).

**ESSNA<sup>7</sup>:**

1. Powdered foods, bars and drinks
2. Carbohydrate drinks
3. Protein powders
4. Amino acids
5. Creatine
6. Micronutrients
  - a. Vitamins and minerals / electrolytes
  - b. Weight / fat loss support
  - c. Hormone products

SNE's classification is similar to that of the SCF (2001), with the addition of the carbohydrate-protein category. ESSNA's classification, while similar to a degree, varies more substantially overall with the inclusion of some entirely new independent categories such as amino acids and creatine.

**Euromonitor<sup>8</sup>'s market-based classification**

Data on FISP are collected and classified for Euromonitor on the basis of the classification below. This classification is considered by Euromonitor to be a true reflection of the major categories of FISP on the market.

- Protein
  - Bars
  - Powder
  - Ready to drink (RTD)
  - Other
- Non-protein sports nutrition
- Sportsdrinks.

**Retailer classification**

No single universal retailer classification of FISP exists; each uses its own depending on various factors, *inter alia* the range of products stocked and the target market. Interviewees commented that, from an end-user perspective, the classification by product *function* may be easier to understand than classification by *ingredient*. A filtered sample categorisation from a major online retailer is provided below. This categorisation can be considered broadly representative of categorisations used by retailers.

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<sup>7</sup> <http://www.essna.com/wp-content/uploads/2014/07/ESSNA-Sports-Nutrition-Booklet-DESIGNED-FINAL.pdf> accessed 26/5/15

<sup>8</sup> Euromonitor is a market intelligence firm which produces market reports for a wide range of consumer industries, including sportsdrinks and sports nutrition. The classifications used by Euromonitor for market intelligence are intended to reflect the nature of products on the market.

- Protein
- Bars
- Drinks/Hydration
- Pre-Workout
- During Workout
- Post-Workout
- Mass Gainers
- Nitric Oxide
- Creatine
- Recovery
- Amino Acids
- Energy & Endurance

It should be noted that some products may fall into more than one of the categories identified above (e.g. protein and post-work out).

### 3.1.1.2 Categorisation of products on the market for the purpose of the study; most significant sub-categories and their key characteristics (function and format)

In developing a categorisation for the study, the following factors had to be considered:

- **Proximity to existing categorisations:** any new categorisation had to be sufficiently similar to existing categorisations for stakeholders to understand it and relate it to the categorisations they use, and for existing data to be meaningfully fitted to the new categorisation.
- **Consumer understanding:** the categorisation had to be sufficiently simple in order that it could be easily understood by consumers, particularly in the context of the consumer survey performed for the study.
- **Discreteness of classification:** there are some challenges in clearly separating some products according to certain criteria. For example, products may not always be easily classifiable by function. Many amino acids, while widely considered performance enhancing, may be taken both before and after exercise. Creatine, which was recognised by SCF and subsequently by EFSA<sup>9</sup> as increasing physical performance during short-term, high intensity exercise, may be taken more as a supplement than a pre-exercise performance booster. In terms of the compositional complexity of products, there is not always a clear connection between the format of a FISP and its compositional complexity.
- **“Borderline” products:** there are certain products for which there are doubts as to whether they can be considered FISP. These so-called borderline cases are examined in more detail in section 3.1.1.3.

The final categorisation of products adopted for the study, together with the most significant sub-categories (types of product in each overarching category) and the key characteristics of each sub-category are presented in Table 3.1. This categorisation was developed in collaboration with stakeholders.

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<sup>9</sup> EFSA Journal 2011;9(7):2303; the panel on dietetic food products, nutrition and allergies concluded that creatine increases in physical performance during short-term, high intensity, repeated exercise bouts if over 3g is consumed daily. However, no cause and effect relationship was established between creatine and an increase in endurance capacity or performance.





**Table 3.1: Categorisation of FISP products for this study**

Study categorisation	Key functions	Major categories (types of product)	Ingredients			Main formats			
			Complexity	Main ingredients	Capsule	Food	Powder	RTD	
<b>Sportsdrinks</b>	Hydration; generally used during/after exercise	Carbohydrate-electrolyte drinks (CE)	Complex	Carbohydrate, sodium, potassium etc			b	A	
		Carbohydrate drinks	Single+	Carbohydrates			b	A	
		Low energy CE drinks	Complex	Carbohydrate, sodium, potassium etc			b	A	
<b>(Protein-based) muscle strengthening, building and post exercise recovery products</b>	Build/rebuild muscles, gain weight, recovery. Generally to be taken after exercise.	Protein only (strength / muscle build)	Single+	Single ingredient; protein		c	A	b	
		Protein + carbohydrates recovery products	Complex	Protein, carbohydrates		b	A		
		Protein + carbohydrates mass gainers	Complex	Protein, carbohydrates			A		
		All in one muscle builders	Complex	Complex; protein, carbohydrates, creatine, BCAA, amino acids, etc.		b	A		
<b>Energy and performance boosting</b>	Improve performance; generally to	Energy bars and cakes	Single+	Carbohydrates, possibly other ingredients including protein and vitamins.		A			

<b>products, and products for on-going supplementation<sup>10</sup> of sportspeople</b>	be taken either (1) pre-exercise (2) during exercise or (3) as an ongoing supplement. A minority of products may be taken after exercise.	Energy gels	Single+	Carbohydrates; sometimes with caffeine		A		
		Pre-work out all-in-one	Complex	Complex; combinations based on caffeine and creatine bases.	c		A	A
		Single ingredient supplements	Single	Single ingredient; BCAA, single amino acids, caffeine.	A		A	c

Source: FCEC based on interviewees and desk research.

**Key:**

**Complexity:** single = single ingredient; single+ = while based on a single ingredient, micronutrients may commonly be added in small quantities; complex = 2+ major ingredients.

**Formats:** A = large part or majority of such products; b = small part or minority of such products; c = very small part of such products.

RTD = ready to drink.

<sup>10</sup> It is recommended that certain products e.g. non-essential amino acids such as l-arginine are consumed on a daily basis. Recommended consumption is therefore not directly linked to the period of exercise (i.e. before, during or after), but rather is ongoing.

### 3.1.1.3 Products on the borderline

Certain cases of borderline products, i.e. those where it is unclear whether they are targeted specifically at sportspeople, were identified through interviews, desk research and case studies during the course of the study. These are examined below, along with the final judgement relating to their inclusion or exclusion from the definition of FISP for the study.

#### **Vitamin, mineral and joint supplements**

- SCF's classification included such supplements under category of "Supplement – essential nutrient". However, their 2001 report also concluded that there is scientific consensus that with adequate dietary intake, there is no further need for additional supplementation of vitamins, essential micronutrients and trace elements. A report from French specialist nutrition organisation SFNS (2012) also concluded that, with the exception of vitamins B and C, athletes have similar vitamin and mineral needs to that of the general population.
- According to industry interviewees, producers of vitamin, mineral and joint supplements will generally target the widest market possible in order to maximize profits. Consequently it is very rare that operators in the area of vitamin, mineral and joint supplements specifically target sportspeople. Just a handful of smaller operators may choose to partly market their products to target this niche. Evidence from the UK case study corroborated the finding that operators in the area of supplements who target sportspeople will consider sportspeople just one of multiple target groups for such products.
- From field examinations of certain dedicated sports nutrition distribution outlets (in the context of case studies), it was possible to find vitamin, mineral and joint supplements for sale through such dedicated sports nutrition distribution channels. However, the range of such products was generally small, and in many cases the product for sale did not bear any indication of the product's specific relevance for sportspeople (i.e. the product is often a generic dietary supplement being sold through a dedicated sports nutrition channel).

**Judgement:** vitamin, mineral and joint supplements have been excluded from the definition of FISP for this study.

#### **Energy drinks**

- Interviewees noted that energy drinks may be marketed in a way to target sportspeople. There has been activity in the area of health claims for the two main ingredients of taurine and caffeine. However, applications for sport related health claims for taurine have been negatively assessed by EFSA and rejected by the Commission (see section 3.3.4.1). Following the recent safety assessment of EFSA, the health claims for caffeine are currently under consideration at the time of writing.
- According to data from Euromonitor, the EU market for energy drinks is several times larger than the rest of the sports nutrition and sportsdrinks market combined.
- There was unanimous agreement from interviewees that energy drinks are not FISP products; this has been affirmed by scientific studies in certain Member States (e.g. France - ANSES (2012)).

**Judgement:** energy drinks have been excluded from the definition of FISP for this study.

### **Weight loss products**

- Operators active in the FISP area are, in several cases, also active in the area of weight loss (see also section 3.2.1.4). That said, interviewees reported that operators active in the two areas tend to keep the two sets of products entirely separate.
- Directive 96/8/EC sets out provisions on certain foods intended for use in energy-restricted diets for weight reduction, including provisions on composition, hence clearly delimiting the PARNUTS category of foods intended for weight reduction<sup>11</sup>.
- A degree of crossover between the areas of protein based products and weight loss products was noted by some interviewees, though at present this category was considered to be fairly small. Areas of crossover included:
  - “Shaping” products (primarily marketed to women exercising to lose weight and tone certain body parts).
  - Combinations of protein and weight loss products which target muscle mass gain for certain sportspeople, or products combining protein with l-carnitine for muscle gain and weight reduction.
  - Light versions of certain products (e.g. whey protein).
- Evidence from case studies suggested that the connection between “fat burning” products and sport may be made in some cases.
- From a field examination of certain dedicated sports nutrition distribution outlets (in the context of case studies), various different products for weight management could be found for sale through such dedicated sports nutrition outlets. The method of placing on the market of these products is not clear. Given the presentation of certain products as meal replacement, it is likely that at least some of these products are placed on the market under Directive 96/8/EC.
- Interviewees had differing views on the extent to which some weight loss products can be considered FISP.

**Judgement:** “light” versions of products with a sports related function, and products which combine a clear sports related function (e.g. muscle mass gain) with weight loss are included in the corresponding FISP categorisation. All other products for weight loss are excluded from the scope of FISP for the purpose of this study.

### **General food products which can be marketed to sportspeople**

- Some examples of general food products which are not normally targeting sportspeople but can be marketed to them, generally on the basis of authorized health claims in turn facilitating the use of certain words such as “sport” or “exercise” (through the connection permitted in

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<sup>11</sup> Nonetheless, Article 13 (1) (c) in conjunction with Article 13 (3) of Regulation (EC) No 1924/2006 provides for a list of certain authorised claims which may be used in reference to slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

article 10 (3) of Regulation (EC) No 1924/2006), were identified during the course of the study through interviews, desk research and case studies.

- Examples include: certain soft drinks (including energy drinks), pasta, tea, alcohol-free beer, muesli and nuts. Sample labels are provided in the separate photo annex.
- Only a handful of such products were identified. Interviewees considered such products not to be FISP as their composition is not considered to be suitable for sportspeople.

**Judgement:** there is no coherent category of these products. Only a handful of individual cases with varying characteristics have been identified. Consequently, these products have not been included in the categorisation for this study outlined in Table 3.1. Instead, they are examined on a case-by-case basis where relevant.

### **Ready meals / meal substitutes**

- One interviewee commented that a fairly new area is that of ready meals for sportspeople. These may either be consumed for healthy lifestyle reasons or due to sportspeople travelling in foreign countries.
- Evidence from a field examination of certain dedicated sports nutrition distribution outlets suggested that there are only a few ready meals which appear to be targeting sportspeople. The majority of ready meal or meal replacement products sold through such outlets are either: (1) protein bar based products with other ingredients which are considered part of the protein category; (2) meals for weight loss<sup>12</sup>; or (3) generic foods with no specific indication of their relevance for sport (e.g. almonds, sunflower seeds, dried fruits).

**Judgement:** ready meal and meal substitutes are excluded from the definition of FISP for the purpose of this study.

#### 3.1.1.4 Number of FISP products on the market

### **Methodological challenges**

Estimating the number of FISP products on the market poses a certain number of challenges. More specifically:

- There are different definitions of the number of products. Products with the same composition may be sold in different pack sizes leading to multiple versions of compositionally identical products. Some products with the same basic composition may be available in multiple different flavours.
- Sub-contracted manufacturers are widely used for the manufacture of sports nutrition products (see section 3.2.1). Evidence from case studies suggests that some of these manufacturers may produce compositionally identical products for different brands, consequently increasing the number of products on the market despite their identical composition.
- Some products may be available for sale in multiple Member States, meaning that the sum of national level estimates is greater than the actual number of products on the EU market.

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<sup>12</sup> There is an overlap with the borderline issue of weight loss products; please see the section above for more information.

- The market for FISP products is very dynamic, with products constantly appearing and disappearing from the marketplace. Operators themselves tend to have a broad range of products and sell individual products in low volumes. While large operators may be tracked by market data, there is also a large number of small operators (see section 3.2.1.4) which are not tracked.
- Interviewees noted that there is a large grey market of products which, while available to EU consumers, may not fully conform to EU legislation and which cause enforcement difficulties for national Competent Authorities (CAs). A significant example is that of products sold directly to EU consumers from third country based operator which do not comply with EU labelling requirements. The inclusion or exclusion of these products could affect the number of products on the market.

### Data available on the number of products

At national level, only a handful of CAs replying to the national CA survey (8 from 24) were able to provide data on the number of FISP product on their national market. This data is presented in Table 3.2. There are more than a thousand products on the market in the majority of Member States for which data was provided.

**Table 3.2: number of FISP products on the market and their evolution since 2011**

MS	Total	Sportsdrinks	Muscle strengthening	Performance boosting	Other	Evolution since 2011
BG	>1 015	No data	725	290		
CY	~2 550	~50	1 500	1 000		large decrease
EL	~1 000					
FR	1 000					slight increase
HR	>350	>50	>150	>150	No data	slight increase
IE	>1 050	>80	>750	>170	>50	slight increase
MT	695	25	300	170	200	about the same
NL	1 050	130	500	250	170	

Source: CA survey.

Notes: MS did not specify whether numbers provided included different flavours and formats. Greyed cells indicate cells for which Member States did not provide any data.

No single EU-level data source was identified. The most suitable method identified for estimating the number of FISP 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. Using these figures in conjunction with data from Innova<sup>13</sup> on new FISP products for the period 2012-14, it is possible to estimate the total number of products on the market. These estimates are provided in Table 3.3; they indicate a total of between 20,000 and 30,000 FISP products on the EU market, with protein being the category with the most products. Further information on the importance of the different categories is provided on the basis of market value data in section 3.1.1.6.

**Table 3.3: estimated number of FISP products on the EU market calculated on the basis of the innovation rate**

	Sportsdrinks	Protein based	Energy / performance	Total
<b>Average annual new products 2012-14</b>	179	1 294	889	2 362
<b>Estimated number of products at 12% innovation</b>	<b>1 492</b>	<b>10 783</b>	<b>7 408</b>	<b>19 683</b>
<b>Estimated number of products at 8% innovation</b>	<b>2 237</b>	<b>16 175</b>	<b>11 113</b>	<b>29 525</b>

Source: FCEC based on data from Innova and interviewee estimations.

Notes: Innova categories transposed as follows: Sportsdrinks = drinks RTD Protein based = powders, protein based RTD. Energy / performance / supplementation = bars, supplements, others (e.g. gels).

Innovative products counted in terms of new products/formulations/formats but not different pack sizes.

### 3.1.1.5 Differences between Member States in the importance of categories

Data from Euromonitor showed that the most important category of product at the EU level, in terms of value, is sportsdrinks (Table 3.4). However, the importance of categories varies between Member States, as is shown in the second line of the table. That said, sportsdrinks is the most important category in the majority of Member States.

**Table 3.4: Importance of categories at EU level in terms of value (2014); and importance of products for Member EU 28 Member States**

	Sportsdrinks	Protein based products	Energy and performance boosting products	Total
<b>Member States for which category is most</b>	BE, BG,CY, DE, DK, EE, EL, ES, HR, IE, IT, LU, LV, MT, NL, PL,	AT, FI, FR, HU, PT, RO, SE, UK (8)	CZ, LT (2)	

<sup>13</sup> The Food and Beverage database of Innova Marketing Insight is an online database which tracks the new food and drinks launches in the world.



<b>important</b>	SI, SK (18)			
<b>EU-28 value EUR million</b>	1 858.3	801.7	406.6	3 066.6
<b>% all FISP at EU-28 level</b>	61%	26%	13%	

### 3.1.1.6 Importance of product types by category

Data on the importance of the sub-categories of product (product types) measured in terms of market value importance are presented in Table 3.5.

**Table 3.5: Importance of product types by category at EU level (measure: proportion of market value)**

Study categorisation	Sub-categories (types of product)	Importance of category (%)	Estimated % importance all FISP
<b>Sportsdrinks</b>	Carbohydrate-electrolyte (CE) drinks	80%+	49%+
	Carbohydrate drinks	>=10%	>=6%
	Low energy CE drinks	>=10%	>=6%
<b>(Protein-based) muscle strengthening, building and post exercise recovery products</b>	Protein only (strength / muscle build)	50-80%	13-21%
	Protein + carbohydrates recovery products	5-10%	1-3%
	Protein + carbohydrates mass gainers	5-20%	1-5%
	All in one muscle builders	~10%	3%
<b>Energy and performance boosting products, and products for on-going supplementation of sportspeople</b>	Energy bars	30-60%	4-8%
	Energy gels		
	Pre-work out all-in-one	>=30%	>=4%
	Single ingredient supplements	>=20%	>=3%

Source: FCEC based on interviewee estimations (final column based on estimations applied to Euromonitor data at EU level).

### 3.1.2 A2 Ingredients

#### 3.1.2.1 Sportsdrinks – key ingredients

The most common ingredients of products in this category are:

- Carbohydrates
- Electrolytes; sodium, potassium, magnesium and calcium
- Water

Light versions of sportsdrinks will contain lower carbohydrates, while carbohydrate only drinks will not contain electrolytes. In some Member States (e.g. France) vitamins are requested by national legislation on a mandatory basis.

Interviewees reported a trend in recent years towards the use of a combination of different minerals, sodium, potassium, magnesium and calcium, in order to reflect the composition of sweat. In some cases, the industry has independently moved towards this mix of minerals due to the perceived benefits; in certain Member States the mix may be recommended or mandated. Interviewees reported the use of combinations of different sources of carbohydrates such as glucose and fructose in certain cases due to the benefits they can provide in releasing energy at different times. Table 3.6 summaries the main ingredients of sportsdrinks by type of product.

**Table 3.6: Main ingredients and sample composition of sportsdrinks by type of product (sub-category)**

Sub-categories (types of product)	Main ingredients	Sample composition (per 100ml)
Carbohydrate-electrolyte (CE) drinks	<ul style="list-style-type: none"> <li>• Carbohydrate</li> <li>• Electrolyte</li> </ul>	<p><b><i>Gatorade tropical burst</i></b></p> <p>Carbohydrate 6g</p> <p>Mineral content: sodium chloride 76mg; sodium citrate 76mg; monopotassium phosphate 40mg; magnesium oxide 9mg.</p> <p>(Protein and fat 0g)</p>
Carbohydrate drinks	<ul style="list-style-type: none"> <li>• Carbohydrate</li> </ul>	<p><b><i>Atlantic multipower energy charge</i></b></p> <p>Carbohydrates 14g</p> <p>Sodium &lt;0.03g</p> <p>(protein, fibre and fat &lt;0.1g)</p>
Low energy CE drinks	<ul style="list-style-type: none"> <li>• Carbohydrate</li> <li>• Electrolyte</li> </ul>	<p><b><i>Lucozade sport lite</i></b></p> <p>Carbohydrate 2g</p> <p>Salt 0.09g</p>

		Niacin 0.54mg Vitamin B6 0.05mg Vitamin B12 0.09 µg Pantothenic acid 0.2mg Calcium 37mg (Protein and fat 0g)
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Source: FCEC based on interviewees and desk research.

### 3.1.2.2 Protein based products – key ingredients

Protein is the key ingredient which underpins the category. Interviewees reported that the range of proteins used in recent years has expanded, and this was corroborated by case study findings. While whey protein has historically been the main type of protein used, alternative sources such as casein, soya, pea and other vegetable protein may now be found in some products. It is also possible to find the aforementioned different types of protein used in combinations in some products. Interviewees reported that this different range of proteins has emerged for cost and price reasons. On the cost side, it allows manufacturers to reduce production price while on the price side, it provides consumers with different pricing points. Nonetheless, one interviewee noted that some forms of protein are considered of a low quality which is not suitable for sports nutrition.

Several products in this category may also contain other ingredients, the most common of which is carbohydrate.

Table 3.7 summarises the main ingredients of protein based products by product type, and provides the sample composition of one product for each category. It is important to note that, as reported by one interviewee, with increasing customisation of products to specific sports or end users (an identified source of innovation – see section 3.2.3), composition of products in a sub-category may vary significantly.

**Table 3.7: Main ingredients and sample composition of protein-based products by type of product (sub-category)**

Sub-categories (types of product)	Main ingredients	Sample composition (per 100g)
Protein only (strength / muscle build)	<ul style="list-style-type: none"> <li>Protein (types indicated above)</li> <li>Vitamins and minerals (sometimes)</li> </ul>	<p><b><i>Isostar High protein 90</i></b></p> <p>Protein 82g</p> <p>Carbohydrates 7.7g</p> <p>(fat 1.7g, fibre 0g)</p> <p>Minerals: Sodium 0.1g, calcium</p>

		1000mg, magnesium 250mg Vitamins: E 14mg, C 72mg, B1 0.87mg, B2 1.9mg, B6 1.9mg
Protein + carbohydrates recovery products	<ul style="list-style-type: none"> <li>• Protein (types indicated above)</li> <li>• Carbohydrate</li> <li>• BCCAs (sometimes)</li> </ul>	<b><i>Overstim.s recovery</i></b> Protein 26.7g Carbohydrates 61.6g (Fat 0.6g, fibre 0.5g) Sodium 0.76g, calcium 692mg, potassium 642mg, magnesium 203mg Vitamin B1 0.78mg
Protein + carbohydrates mass gainers	<ul style="list-style-type: none"> <li>• Protein (types indicated above)</li> <li>• Carbohydrate</li> <li>• Vitamins and minerals (sometimes)</li> </ul>	<b><i>Myprotein gainer</i></b> Protein 34g Carbohydrates 46g (fat 9.8g, dietary fibre 3.3g)
All in one muscle builders	<ul style="list-style-type: none"> <li>• Protein (types indicated above)</li> <li>• Carbohydrate</li> <li>• BCCAs</li> <li>• Creatine</li> <li>• HMB</li> <li>• Betaine</li> </ul>	<b><i>Maximuscle Cyclone</i></b> Protein 42.9g Carbohydrate 18.9g (Fat 8.9g, fibre 2g) Creatine 6.3g (creatine monohydrate 7.2g) Glutamine 16.1g Calcium HMB 2.1g Salt 1g Zinc 4.1mg

Source: FCEC based on interviewees and desk research.

All products in powder form.

Main ingredients are the functional ingredients identified in literature by interviewees. Products may contain additional ingredients for reasons of taste, texture, etc.

### 3.1.2.3 Energy, performance and supplement products – key ingredients

A wide range of ingredients is used in this category, with considerable differences between product types. Energy bars and gels are based on carbohydrates; most commonly a combination of fructose and glucose, and may also contain additional vitamins, amino acids,

protein or caffeine. As is the case for sportsdrinks, in some Member States (e.g. France) vitamins are mandated by national legislation.

Interviewees reported that caffeine and creatine are important ingredients for non-carbohydrate based products in this category, and Beta-Alanine is increasing in importance. Other ingredients include various forms of amino acids. While substances have traditionally been sold alone, interviewees reported that ingredients are increasingly combined in order to create all in one, pre-exercise products. This is reflected by the previously identified sub-category of “pre-work out all in one” which is estimated to account for up to 4% of the overall EU FISP market (Table 3.5).

Table 3.8 summarises the main ingredients of energy, performance and supplement products by product type. As for protein based products, increasing customisation of products to specific sports or end users can lead to significant differences in the composition of products in a sub-category. It should also be noted that the single ingredient supplement product grouping comprises products based on a large number of different single ingredients. The ingredients identified by interviewees as the most important are identified in the table. As noted in Table 3.5, these types of product form a small part (less than 3%) of the overall EU market.

**Table 3.8: Main ingredients and sample composition of energy, performance and supplement products by type of product (sub-category)**

Sub-categories (types of product)	Main ingredients	Sample composition (per 100ml)
Energy bars	<ul style="list-style-type: none"> <li>• Carbohydrates</li> <li>• Vitamins (sometimes)</li> <li>• Caffeine (sometimes)</li> </ul>	<p><b>Powerbar energize</b></p> <p>Carbohydrates 70.9g</p> <p>Protein 10.5g</p> <p>(Fat 3.6g, fibre 1.45g)</p> <p>Sodium 345mg</p> <p>Magnesium 137mg</p>
Energy gels		<p><b>Powerbar powergel (r) original</b></p> <p>Carbohydrates 65g</p> <p>(Fat 0g, protein &lt;1g)</p> <p>Sodium 205mg</p>

Sub-categories (types of product)	Main ingredients	Sample composition (per 100ml)
Pre-work out all-in-one	Combinations of: <ul style="list-style-type: none"> <li>• BCCA</li> <li>• Caffeine</li> <li>• Creatine</li> <li>• Beta-alanine</li> <li>• Citrulline</li> <li>• Arginine</li> <li>• Betaine</li> <li>• B-vitamins</li> </ul>	<b><i>N.O. Explode pre workout (shortened ingredient list)</i></b>  Amino Acids 55g (in order of presence: L-Arginine, L-Lysine, Glycine, N-Acetyl L-Tyrosine , Taurine, L-Phenylalanine)  Creatine 15g  Beta Alanine 13g  Inositol 9.5g  Choline 2g  Betaine 7.5 g  Caffeine 1.5g  Various vitamins and minerals
Single ingredient supplements	One of: <ul style="list-style-type: none"> <li>• Creatine</li> <li>• HMB</li> <li>• Caffeine</li> <li>• Beta-alanine</li> <li>• Citrulline</li> <li>• Arginine</li> <li>• Glutamine</li> </ul>	<b><i>Enervit creatine sport (powder*)</i></b>  Creatine: 88g  Fat, carbohydrates, protein 0g

Source: FCEC based on interviewees and desk research.

\* Tablet form also available; detail nutritional composition not identified but tablets described as pure creatine.

Main ingredients are the functional ingredients identified in literature by interviewees. Products may contain additional ingredients for reasons of taste, texture, etc.

### 3.1.2.4 Combinations of ingredients with synergistic effects in FISP

The most common combination of ingredients with a synergistic effect is the carbohydrate-electrolyte-water combination found in sportsdrinks (see section 3.1.2.1.). According to SCF (2001), this combination of ingredients addresses the two main factors which contribute to fatigue during exercise: the depletion of the body's carbohydrate reserve; and the onset of dehydration resulting from the loss of water and electrolytes in sweat. The EFSA panel on Dietetic Products, Nutrition and

Allergies identified a cause and effect relationship between carbohydrate-electrolyte solutions and: (a) the enhancement of water during exercise; (b) the maintenance of endurance performance<sup>14</sup>.

<sup>14</sup> EFSA Journal 2011;9(6):2211

Certain other combinations of ingredients with synergistic effects were identified, namely:

- **Carbohydrate-protein.** This was reported by interviewees to have a significant effect in terms of mass gain and recovery; considerable consumer-orientated literature on this effect can also be found on the internet. Research on this effect appears to return conflicting results. For example, while Williams, et al. (2003) found that these ingredients in combination were more effective for recovery than carbohydrates alone, Betts, et al. (2005) and Green, et al. (2008) did not identify such additional benefits.
- **Creatine and carbohydrate.** This combination was reported by one interviewee to have an insulin effect. No relevant research on this effect was identified during the course of the study.
- **Protein or carbohydrate with certain vitamins.** Interviewees reported that the addition of vitamins to protein and/or carbohydrate based products can have a synergistic effect in terms of substance processing. For example, B vitamins assist the body with carbohydrate and protein metabolism. It should be noted that there is an authorised health claim linking vitamin B6 to normal protein and glycogen metabolism.

Looking forward, interviewees noted that there are emerging combinations of ingredients with synergistic effects (for example omega 3 can enhance protein synthesis) which are not yet widely used in FISP.

### *3.1.3 A3 Price*

Table 3.9 presents data on the price of FISP by product type, based on a random sample of between five and ten products for each product type.

**Table 3.9: Price of FISP by product types (August 2014)**

Study categorisation	Sub-categories (types of product)	Average price EUR	Average size	Price per unit EUR
<b>Sportsdrinks</b>	Carbohydrate-electrolyte drinks (CE)	1.27	500 ml	0.25 / 100 ml
	Carbohydrate drinks	1.36	466 ml	0.29 / 100 ml
	Low energy CE drinks	1.71	1,500 ml	0.11 / 100ml
<b>(Protein-based) muscle strengthening, building and post exercise recovery products</b>	Protein only (strength / muscle build)	32.64	793g	4.11 / 100g
	Protein + carbohydrates recovery products	17.43	626g	2.79 / 100g
	Protein + carbohydrates mass gainers	42.37	2,089g	2.03 / 100g
	All in one muscle builders	52.66	1,193g	4.41 / 100g
<b>Energy and performance boosting products, and products for on-going supplementation of sportspeople</b>	Energy bars	3.75	76g	4.94 / 100g
	Energy gels	1.80	31g	1.44 / 100 ml
	Pre-work out all-in-one	40.36	780g	5.18 / 100g
	Single ingredient supplements ( <i>creatine capsules</i> )	27.43	136 units	20.24 / 100 capsules

Source: FCEC based on Euromonitor and supplemented by desk research; based on a minimum sample of five products of each type spanning different Member States.

Currency exchange rates from 14/8/2014 used for non EUR currencies.

Interviewees considered consumer price to be fairly equal across different channels; this is broadly coherent with the economic law of one price concept<sup>15</sup>. However, the wholesale price at which the manufacturer sells to different distribution channels may vary significantly. It

<sup>15</sup> The law of one price stipulates that a good must sell for the same price in all locations.



was noted that multiple retailers hold considerable pricing power and hence will place downward pressure on the prices at which they purchase products.

## **3.2 Operators and market**

### *3.2.1 A6 Market structure*

#### 3.2.1.1 Quantification of the market

According to data from Euromonitor, the EU wide market for sports nutrition and drinks was worth 3.07 bn EUR (retail value) in 2014. The largest Member State markets, in order, were:

- UK (EUR 732m)
- Spain (EUR 491m)
- Germany (EUR 452m)
- Italy (EUR 358m)
- Sweden (EUR 185m)
- Netherlands (EUR 153m)
- France (EUR 128m)

The market for FISP at EU level has grown by 11.2% between 2009 and 2014, equivalent to a compound annual growth rate (CAGR) 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 sportsdrinks shrank by 8% (Table 3.10).

**Table 3.10: Value of the EU market for FISP, 2009-14; growth rates and importance of categories**

Year	2009		2014		5 year CAGR
	Value EUR m	% all FISP*	Value EUR m	% all FISP*	
Sportsdrinks	2016.1	66%	1858.3	61%	-1.6%
Protein based products	476.2	16%	801.7	26%	11%
Energy and performance boosting	264.8	9%	406.6	61%	9%
<b>All FISP</b>	<b>2757.1</b>		<b>3066.6</b>		<b>2.2%</b>

Source: FCEC based on Euromonitor

Euromonitor values used: Sports nutrition: retail value. Sportsdrinks: total value (off trade and on trade)

\* Figures may add up to more than 100 due to rounding

As indicated in Table 3.4 of section 3.1.1.5 (and repeated above in Table 3.10), the most important sector at EU level is that of sportsdrinks. This is also the case for the majority of Member States, though the protein segment is the most important in a number of Member States including, most significantly, the UK and Sweden.

A full breakdown of the EU market for FISP broken down by Member State and product category is provided in the unpublishable annex.

### 3.2.1.2 Overall market structure of FISP

An overview of the chain for FISP is shown below.

**Figure 3-1: overview of the chain for FISP**



Source: FCEC based on interviewees and desk research

Information from Euromonitor data and case studies, and corroborated by interviewees indicates that there are significant differences between the nature of actors in the sportsdrinks sector and those in the sports nutrition sector. These two sectors will therefore be examined separately.

### 3.2.1.3 Sportsdrinks sector

Evidence from case studies indicates that the sector tends to be dominated by large multinationals (generally soft drink manufacturers, but also a few larger sports nutrition manufacturers); and there is generally a high level of concentration (in excess of 75%) among the largest three or four operators (Table 3.11).

**Table 3.11: Concentration ratios (CR) of sportsdrink operators in case study Member States**

MS	CR-3 ratio	CR-4 ratio
DE		42.2%*
ES	90.8%	92%
FR	88%	
IT		77.9%
UK	88%	

Source: case studies

\* Private label products play an important role in Germany; the CR-4 + other private label ratio is 63.2%

2013 or 2014 data depending on Member State

Availability of data on CR ratios based on availability identified during case studies. Data for CR-8 ratios is not available due to the high level of concentration of the sector.

Interviewees reported that, due to the domination of the sector by large multinationals, the presence of SMEs was somewhat constrained. Nonetheless it was noted that some SMEs are present, but that they tend to specialise in small market niches such as powder formats or very local markets rather than the large RTD market. The reason given for this is that the distribution of powdered products or products for local markets is easier to manage; it is possible for operators to sell powders direct to consumers online; and there is no (or less) direct competition with the large multinationals. No estimates of the number of SMEs present in the area were identified; however given the extent to which multinationals dominate the market it can be concluded that SMEs are significantly less important than in the sports nutrition sector. This is also corroborated by the comparatively low number of sportsdrinks products on the market; while sportsdrinks is the largest category of FISP by value, it also accounts for the lowest number of products (section 3.1.1).

According to interviewees, the level of integration of the large operators which dominate the sector tends to be high up to the point of distribution. As RTD products are bulky in nature, production tends to take place close to end markets; meaning that multinational producers tend to have multiple EU production sites.

### 3.2.1.4 Sports nutrition sector

Evidence from case studies indicates that, while the level of concentration in the sports nutrition sector is quite high, it is significantly lower than that of the sportsdrinks sector (Table 3.12).

**Table 3.12: Concentration ratios (CR) of sports nutrition operators in case study Member States in 2014**

MS	CR-4 ratio	CR-8 ratio
DE	57.9%	78.1%
ES	52.8%	62.1%
FR*	66.2%	84.6%
IT	68.8%	84.6%
UK	55.2%	70.2%

Source: case studies

\* 2013 data

Consequently, the nature of operators in the sports nutrition sector is also considerably more varied than in the sportsdrinks sector; not only does the size of operators vary, but also their ownership structure, degree of focus on sports nutrition, geographical scope and areas of operation within the sports nutrition chain. As a result, it is very difficult to generalise about the nature of sports nutrition operators. A classification of the major types of operators has been developed in order to assist with the identification of operators. This, classification, which is based on a combination of interviewees, case study findings and desk research, is presented in Table 3.13.

In terms of geographical coverage, information from interviewees and case studies suggests a more geographically fragmented picture for sports nutrition than for sportsdrinks; though there is some variation by operator category. This is at least partly likely to be due to the more portable nature of the products vis-a-vis sportsdrinks. Category 2 and 3 companies tend to actively sell products on several EU markets; though key operations may be restricted to just one or two Member States (by way of example, one company interviewed during the course of the study which fell into one of these categories reported that, while products are sold EU wide, manufacturing is restricted to just two sites). Category 5 companies may sell throughout the EU, or may be more national in their focus.

On balance, the majority of operators by number are likely to fall into category 5 (which is coherent with the presence of SMEs in this category; SMEs are not generally found among the other categories of operator). However, the importance of categories in terms of market share varies between Member States. Evidence from case study Member States suggests that in some cases (e.g. France), independent companies focused entirely or mainly on sports nutrition (i.e. category 5) are responsible for at least 60% of sales by value. In other Member States (e.g. the UK), the market is dominated by category 2 and category 4 companies; and independent, sports nutrition focused companies are responsible for under 40% of sales by value.

As noted in the table, some operators are involved in multiple stage of the chain. According to interviewees, operations which are fairly commonly integrated within one operator are:

- Ingredient production and branded manufacture / sub-contracted manufacture.
- Branded manufacture and retail.

Finally, the use of sub-contracted manufacture was considered by interviewees to be fairly common. Subcontracted manufacturers will produce products to customer specification, and their customers will then perform branding (and possibly retail operations). Subcontractors tend to specialise in certain types of products, e.g. energy bars or protein powders. Evidence from interviewees suggests that the majority of sub-contracted manufacture is performed by companies falling in category 1 (ingredient manufacturers) or category 3 (specialised nutrition companies).

**Table 3.13: Classification of the main groups of sports nutrition operator**

Classification	Overview	Size	Operations	Examples
1: ingredient focused companies	Companies focused on the production of ingredients, including for sports nutrition products. The degree of focus varies significantly between companies; in some cases, sports nutrition may be a key focus (1.a), while in others it may be just part of much larger primary food processing operations (1.b).	Generally larger than SME. 1.a companies are significantly smaller than cat 1.b companies, however. There are a few SMEs among 1.a companies.	Ingredient production  Contract manufacture	1.a: Glanbia, Volac, Aminolabs  1.b: Friesland Campina, Fonterra, Kerry Dairies
2: Independent, dedicated subsidiaries of larger food / health product multinationals	Operators which are fully dedicated to the area of sports nutrition. They are owned by larger food / health product multinationals, but they operate independently / the name of the parent company is not used for branding. Two sub categories can be identified:  2.a: the parent company is active in the wider area of food or consumer health  2.b: the parent company focuses on the area of particular nutritional uses (similar to category 3 companies).	Larger than SME	Manufacture  Branding  Retail (some)	2.a: Maxinutrition (a subsidiary of Glaxosmithkline PLC), Powerbar (a subsidiary of Post Holdings)  2.b: Isostar (a subsidiary of Nutrition et Sante), Holland and Barrett (a subsidiary of NBTY; but crossover with category 4)
3: specialised nutrition companies with	The company is active in the wider area of specialised nutrition and health (generally dietetic foods) and has leveraged its expertise and reputation from neighbouring areas (e.g. weight	Generally larger than SMEs, though there are a few SMEs active in the area	Manufacture  Branding  Contract	Atlantic Multipower (Atlantic Grupa)  Herbalife

Classification	Overview	Size	Operations	Examples
integrated sports nutrition operations	management, vitamin and mineral supplements) in order to manufacture sports nutrition products under the same brand. Sports nutrition, while significant, may not be the most important area of the company.	(primarily as contract manufacturers)	manufacture (some)  Retail (some)	
4: branding (and retail) focused subsidiaries of larger retail companies.	The company is a subsidiary of a larger retail focused company. The company focuses on the branding and retail of products and generally uses sub-contracted manufacturers for production of products.	Parent company larger than SME. Subsidiary may be SME size.	Branding  Retail  Manufacture (some)	Myprotein (The Hut group)  PHD nutrition (Walgreens via Boots UK)  Aptonia (Decathlon)
5: companies focused entirely or mainly on sports nutrition	The independent company* is focused either entirely or primarily on sports nutrition. In some cases the company may have operations in neighbouring areas, but sports nutrition remains the key focus.	Significant presence of SMEs; though some larger companies also present.	Manufacture  Branding  Some operators: contract manufacture  Some	Enervit  Dietesport  EA Pharma

Classification	Overview	Size	Operations	Examples
			operators: retail	

Source: FCEC based on interviewees, case studies and desk research

\* While the company itself may be independent rather than a subsidiary of a larger company, desk research suggests that in some cases the company may be held by private equity.



### 3.2.2 A9 Economic opportunities

A number of elements related to the potential evolution of the market and the main general trends recognized by players have emerged from interviews. The following SWOT<sup>16</sup> analysis summarizes the most relevant aspects identified for the industry.

**Table 3.14: SWOT analysis**

<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>• Sector with historically high margins, although they have been reducing in recent years</li> <li>• Expertise of operators and evidence provided by them on product effectiveness</li> <li>• Innovation of sector</li> <li>• High (and increasing) consumer demand</li> <li>• Wide and segmented product range, including tailoring of products</li> <li>• Product availability, also thanks to different distribution channels</li> <li>• Taste, user friendliness and consumer satisfaction</li> </ul>	<p><b>Weaknesses</b></p> <ul style="list-style-type: none"> <li>• Increasing competition requiring continuous investments to protect market shares</li> <li>• Current claim regulations often not ensuring returns comparable with the costs associated to the approval procedure</li> <li>• High production costs</li> <li>• Increased regulatory risk when multilingual packages are made (non-homogenous interpretation at Member State level, numerous packs reprints, etc.)</li> <li>• Some negative perceptions due to the historical image of the industry (usage by bodybuilders, certain products with questionable claims and connection with doping); though this is dissipating.</li> </ul>
<p><b>Opportunities</b></p> <ul style="list-style-type: none"> <li>• Increasing number of people involved in semi-competitive sport activity, especially endurance sports in which nutrition is all-important (marathons, triathlons, running, cycling, etc.)</li> <li>• Increased general consumer interest in healthy lifestyles and physical activity</li> <li>• Market growth boosted by increasing interest of people for</li> </ul>	<p><b>Threats</b></p> <ul style="list-style-type: none"> <li>• Uncertainty surrounding the post-2016 legal framework</li> <li>• Some sportspeople still insufficiently educated on nutrition</li> <li>• Potential slowdown of innovation due to uncertain regulatory environment</li> <li>• Reputation of the market related to doping scandals: presence on the market of non-compliant imported products could lead to a negative</li> </ul>

<sup>16</sup> The SWOT (Strengths, Weakness, Opportunities, Threats) analysis permits to identify the strong and weak aspects (strengths / weaknesses) which define a certain study object. The identification of strengths and weaknesses allows for the subsequent identification of opportunities (probable and favourable events) and of threats (probable and adverse events) which the study object might have to face, in light of its strengths and weaknesses. The identification of strengths, weaknesses, opportunities and threats is extremely useful to define the room for improvement in specific aspects of the study object, including the effectiveness in pursuing defined objectives and in achieving certain results.

<p>nutrition and health</p> <ul style="list-style-type: none"> <li>• Sportspeople’s education on nutrition is improving (thanks to journals, websites, health professionals, etc.)</li> <li>• FISP potentially contributing to general public health and promotion of physical activity and fight against obesity</li> <li>• Increasing personalization and tailoring to meet increasingly specific nutritional needs of different sports</li> </ul>	<p>image of the sector</p> <ul style="list-style-type: none"> <li>• Confusion between nutritional needs for a balanced diet and needs during exercise Presence on the EU market – mainly via internet sales – of an increasing number of products coming from third countries which are not compliant with EU and national legislation</li> </ul>
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Source: Interviewees

Notes: Most of interviewees with producers and retailers have been performed in the context of national case study reports; for this reason, only aspects reported by interviewees in more than one country or those reported at EU level are included in the above table

The most significant economic opportunities highlighted during interviews are represented by general trends in consumer lifestyles. First of all, the number of sportspeople participating in semi-demanding physical events is constantly increasing (this is particularly evident with reference to runners and cyclers); secondly, it is more and more evident to operators in the industry the increasing attention paid - not only by sportspeople - to healthy lifestyle and nutrition.

If the first aspect will probably contribute in enlarging the potential market for FISP strictly intended, the second trend is already manifesting its effects in the growing number of healthy products with more or less direct references to sport activity (e.g. “raw products” with ingredients barely processed).

On the other side, current challenges identified for the industry which could become in the near future actual threats are represented by the presence of non-compliant products on the market (these products are manufactured for their near-totality in third countries and are purchased via internet), potentially leading to a bad image of the “FISP” sector in general.

As for the legal framework after the end of PARNUTs, a great uncertainty is widely recognized across all categories of operators: the most direct effect of this could be a slowdown of the pace of innovation until a clearer regulatory framework will be defined.

### 3.2.3 A10 Innovation

Operators consider innovation as one of the driving forces of the economic performance and of the competitiveness of the sector. According to certain interviewees, the most innovative companies gain a strong competitive advantage which can lead to an increased market share. For this reason, the sector is considered to be innovative, and the rate of innovation is increasing in the sector. According to data from Innova database, 3,684 new FISP were launched in Europe in 2014. In 2013, there were 2,459 new products; in 2012, 943<sup>17</sup> (see also Table 3.3).

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<sup>17</sup> This includes products imported into the EU for the first time.

According to interviewees, operators' willingness to launch new products which appeal to consumers stems from the following drivers:

- ***New consumer target groups***: consumers of FISP are increasing beyond the traditional target group, and companies are competing to attract them. New target groups which drive the innovation originate from the interest of:
  - People who do not practice sports and who consume FISP for wellbeing and health reasons;
  - People interested in certain sports or in doing certain types of activities traditionally not related with the consumption of FISP (e.g. people involved in certain extreme sports or in emergency services, or members of the Army).
- ***Core target group of consumers***: people who already consume FISP express more specific and defined needs, in terms of ingredients and formats. This target group of consumers is dynamic and inclined to explore new products (e.g. RTDs are gaining popularity because they are easy to use and because they meet the demand of certain consumers).
- ***Research and development of new ingredients and new combinations of ingredients***;
- ***Progress of nutrition science*** (which is a fairly recent science) can modify the previous knowledge on the suitability of certain ingredients, allowing better tailored doses.
- ***New technologies***, which in some cases can facilitate the use of new formats or result in better taste characteristics. Consumers have different preferences on the way they obtain nutrients but technical barriers can prevent the use of certain formats for some nutrients. New technologies can contribute to overcome such technical barriers (e.g. suspension of certain proteins in liquid).
- ***Cost of production***: the introduction of ingredients which can substitute the most expensive ingredients is emerging in the marketplace. E.g. alternative proteins from eggs or meat are increasingly popular because of the rising cost of milk whey proteins.

To keep alive the interest of the core group of consumers, and to attract new groups of consumers, interviewees reported that companies can introduce different typologies of innovation:

- ***New or improved flavours***: this type of innovation is very common. Sportsdrinks and products targeting the more general public are frequently the object of this type of innovation.
- ***New ingredients***: innovation of specialized products relies upon the use of new ingredients and/or of new combinations of ingredients. This type of innovation includes new versions or chemical forms of ingredients already used (e.g. new types of protein), new formulas that can increase the intake of certain nutrient, ingredients already used in supplements or in other products but not previously used for FISP (e.g. botanicals) and, less frequently, the introduction of new substances.
- ***New formats***: the launch of new formats has the main aim of attracting consumers who look for products with increased ease of use. For this reason, many companies have launched their products in gel or in RTD formats.
- ***New packaging***: new attracting packaging and special edition packaging are both an innovation and a marketing technique for mass products like sportsdrinks.

The category of products where innovation is more frequent is powders<sup>18</sup>, which accounted for almost 2/3 of the new products launched in 2014 according to data from Innova. Supplements, with 612 new products launched in 2014, are the second FISP category in terms of innovation. Sportsdrinks are a less innovative segment, with 233 new product launches in 2014. However, 127 new sportsdrinks were launched in 2013, i.e. the number of new sportsdrinks launches on the European market increased by 83% from 2013 to 2014. According to interviewees, innovation in sportsdrinks is mainly in terms of flavours, format and packaging. In terms of composition, sportsdrinks can be considered a mature product which is rarely the object of an extensive innovation of formulas.

Being a very innovative sector, research and development activities was reported by interviewees to often constitute a substantial cost item for FISP producers. Highly related with innovation is also the cost of new ingredients and of ingredients with higher purity. These ingredients are generally produced by few specialized companies, often based in Asia according to interviewees, which have the contractual power to ask for a high price. Nevertheless, innovative producers are usually rewarded from the market, and investment in innovation ensures a high return. Several mechanisms for this were identified by interviewees. Consumers can perceive innovation and recognize that new products or products which contain highly pure ingredients are worth a premium price. Innovation has also been reported as a way to strengthen commercial relations with distribution channels. Retailers are keen to introduce new products that attract clients in their stores. Innovative companies can benefit of stronger contractual conditions compared to less innovative companies.

Innovation costs also include the costs to be compliant with rules both at EU and Member State level. In certain Member States (e.g. Italy) operators reported that national rules that regulate the research laboratories are similar to the rules that regulate the pharmaceutical sector, with higher costs for the FISP sector compared with other food sectors. A reported example of the high incidence of innovation costs in relation to the compliance with EU legislation is the procedure foreseen by Regulation (EC) No 258/97 on novel foods.

Innovation costs are generally associated with the time span needed for an idea to become a product placed on the market. Short-term innovations, i.e. minor innovations in the pack size and/or innovation of flavours, are less expensive than long-term innovations, i.e. innovation focusing on formulas and ingredients. On average, the period from the start of the innovation process to the launch of a new product on the market lasts 1-2 years according to interviewees. However, regulatory constraints and the introduction of more extensive innovation with the associated technical challenges can contribute to extend this period (e.g. in case of introduction of new ingredients which require an authorization under the novel foods regulation, or under other specific pieces of legislation, this period can last five or more years).

The necessity of being innovative in order to be competitive is a sector entrance barrier for new companies, and may limit certain opportunities for SMEs, which are often unable to bear these additional costs.

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<sup>18</sup> Powder products mainly comprise protein products.

### 3.2.4 A8 Trade

Interviews performed with experts and operators across different countries revealed some general trends regarding import and export of FISPs in the EU.

More specifically, any interviewee able to provide qualitative information on trade indicated the US as the main exporter of such products to the EU, mainly thanks to the high reputation of US products among European consumers in terms of quality and functionality. Additional reasons behind the preference for US products have been identified in the more innovative ingredients and compositions: it is worth noting that some of these products, thanks to less restrictive laws in force in the US, might be non-compliant with EU regulations, and therefore cannot theoretically be sold in Europe; despite this, it is generally accepted among operators that, mainly because of the increasing importance of internet sales, these products are requested by consumers and are increasingly available on the market, in spite of them being non-compliant with the regulation in force in the EU.

Table 3.15 below summarizes the main trade flows inside and outside EU, according to elements collected during interviews.

**Table 3.15: Most recurrent exporters and importers according to interviewees**

Interview	Main exporters to EU	Main importers from EU	Main EU importers	Main EU exporters
#1	US, although limited by doping and ingredient issues	Australia, South Africa	-	-
#2	US	Russia	Poland	-
#3	US	South America, Morocco, United Arab Emirates	Portugal, UK, France, Italy, Netherlands, Belgium, Germany, Czech Republic, Poland, Malta	Spain, France, Italy, Belgium, Germany, Netherlands, UK
#4	<p><b>Finished products:</b></p> <p>US, Russia, China, Switzerland, Turkey, Iceland</p> <p><b>Ingredients:</b></p> <p>US, South Africa, Brazil</p>	<p><b>Finished products:</b></p> <p>China, Turkey, Pakistan, US, Canada</p>	-	-
#5	-	Russia, South Africa,	-	-

Interview	Main exporters to EU	Main importers from EU	Main EU importers	Main EU exporters
		Turkey		
#6	US	-	-	-

Source: Interviews

As previously stated, the US market is both the most important worldwide and the most relevant in terms of exports to the EU; on the other hand, according to interviewees EU products often do not meet the expectation of US consumers in terms of ingredients and of their concentration. An operator reported that the high costs of innovation and the substantial investments needed are seen as an obstacle for the construction of dedicated product lines for export markets with a less restrictive regulatory framework. Nonetheless, some interviewees also highlighted how it is often easier for a European producer (at least theoretically), to market its products in the US rather than within the EU: this is basically due to the lack of harmonization on certain matters (e.g. the maximum allowed levels of substances) across Member States.

Additional information has been provided with reference to ingredients producers, which appear to be mainly based in east Asia (especially in China), and which supply both EU and US producers.

As for quantitative trade data, it has not been possible to directly estimate the volume of intra and extra European trade; the difficulties encountered are mainly linked with the absence of a classification of FISP in the international trade statistics databases (Eurostat COMEXT, UN Comtrade). Furthermore, no interviewee has been able to indicate amounts of import/exports or to indicate any source of such information.

In order to provide some general quantitative indications, an analysis on Eurostat has been performed, selecting on the basis of HS6 and CN8 classification, certain substances most frequently contained in FISP. This analysis cannot be considered exhaustive, and has a number of serious limitations:

- Absence of any clear relation between these substances and their specific utilization in FISP production;
- HS6 and CN8 are classifications based on the product's intrinsic features and on market sector; as no reference to FISP or other similar categories is made in CN8 classification in the Eurostat COMEXT database, the following substances could be traded in a much wider context than the one relevant for the present study.

In order to manage the above limitations as much as possible, a number of choices had to be made in the approach to the analysis:

- Exclusion from the analysis of too generic categories (sportsdrinks would fall under HS6 220290 – other non-alcoholic beverages and sport supplements would fall under

HS6 210690 - other food preparations not elsewhere classified), since the weight of relevant products is likely to be extremely low on the total trade volumes<sup>19</sup>;

- Inclusion in the analysis of the sole categories of ingredients which appear to be detailed and defined narrowly enough to ensure a clear (albeit not certainly exclusive) relation with FISP.

The analysed product categories are reported in Table 3.16 below.

**Table 3.16: HS6 product categories analysed as proxy of FISP trade**

FISP category / ingredient category	Classification	Code	Complete description
Proteins	HS6	210610	Protein Concentrates And Textured Protein Substances
Whey and whey derivatives	HS6	040410	Whey And Modified Whey, Whether Or Not Concentrated Or Containing Added Sugar Or Other Sweetening Matter
Casein	CN8	35011090	Casein for the manufacture of foodstuffs and fodder and other types of casein (excl. the manufacture of artificial textile fibres and other industrial uses)
Albumin	CN8	35022091	Milk albumin "lactalbumin", incl. concentrates of two or more whey proteins, containing by weight > 80% whey proteins, calculated on the dry matter, fit for human consumption, dried "e.g. in sheets, scales, flakes, powder"
Albumin	CN8	35022099	Milk albumin "lactalbumin", incl. concentrates of two or more whey proteins, containing by weight > 80% whey proteins, calculated on the dry matter, fit for human consumption (excl. dried [e.g. in sheets, flakes, crystals, powder])
Albumin	CN8	35029070	Albumins, fit for human consumption (excl. egg albumin and milk albumin [incl. concentrates of two or more whey proteins containing by weight > 80% whey proteins, calculated on the dry matter])

<sup>19</sup> It is also important to note that, according to different interviewees, the trade volumes for sportsdrinks should be extremely limited due to their bulky nature which does not favour international trade.

Source: Eurostat COMEXT database

In the following tables, EU imports and exports in value of the above products for the year 2014 are reported; a threshold at ten Euro million has been considered for individual import and export flows<sup>20</sup>.

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<sup>20</sup> Countries whose imports from and exports to the EU28 market were under ten Euro million were excluded from the analysis.



**Table 3.17: Proteins (HS6 210610) – 2014 EU imports and exports in EUR 000s**

<b>Imports</b>						
	<u>Reporter</u>					
	<b>Germany</b>	<b>Spain</b>	<b>France</b>	<b>UK</b>	<b>Italy</b>	<b>EU28</b>
<u>Partner</u>						
<b>Eu28_Intra</b>	<b>21,894</b>	<b>46,306</b>	<b>26,636</b>	<b>78,375</b>	<b>35,254</b>	<b>427,736</b>
Netherlands	12,122	6,526	6,313	22,700	5,301	83,010
UK	398	3,484	1,927	0	7,188	75,729
Belgium & Lux	1,069	1,967	9,766	16,807	13,004	54,506
France	1,665	14,786	0	17,366	1,774	53,613
Germany	0	3,194	3,216	5,488	1,568	41,267
Ireland	6	5,765	1,525	5,442	0	20,503
Denmark	1,196	1,248	417	86	1,197	14,419
Italy	923	1,315	1,582	1,861	0	13,680
Czech Republic	911	4,607	98	599	32	11,350
Poland	590	357	125	4,382	620	10,470
<b>Eu28_Extra</b>	<b>6,218</b>	<b>9,458</b>	<b>7,717</b>	<b>29,089</b>	<b>2,238</b>	<b>133,612</b>
United States	1,483	5,031	941	21,385	302	75,972
Serbia	302	2,041	4,948	2,178	488	26,053
China	3,379	1,091	785	1,761	95	12,936
<b>Exports</b>						
	<u>Reporter</u>					
	<b>Germany</b>	<b>Spain</b>	<b>France</b>	<b>UK</b>	<b>Italy</b>	<b>EU28</b>
<u>Partner</u>						
<b>Eu28_Intra</b>	<b>19,765</b>	<b>14,099</b>	<b>32,478</b>	<b>171,187</b>	<b>11,930</b>	<b>421,358</b>

France	757	2,851	0	39,349	1,879	60,925
UK	1,611	277	1,613	0	2,570	55,440
Netherlands	1,364	101	11,270	26,308	147	54,240
Germany	0	943	4,737	23,699	1,261	41,326
Italy	377	2,825	4,715	12,226	0	27,885
Spain	450	0	5,784	7,202	1,394	27,518
Ireland	67	301	665	19,302	50	21,542
Sweden	244	59	693	13,101	25	19,298
Poland	2,514	1,225	81	3,315	434	16,785
Austria	9,350	131	284	3,592	653	15,166
Portugal	136	3,618	333	3,768	57	10,732
Belgium & Lux	849	426	1,776	1,859	536	10,043
<b>Eu28_Extra</b>	<b>12,710</b>	<b>12,249</b>	<b>6,799</b>	<b>23,807</b>	<b>11,108</b>	<b>116,413</b>
United States	4,217	239	1,033	941	4,504	14,582
Switzerland	3,343	239	233	6,921	792	13,082
Russia	283	353	0	229	1,451	10,013

Source: Eurostat COMEXT

**Table 3.18: Whey and whey derivatives (HS6 040410) – 2014 EU imports and exports in EUR 000s**

<b>Imports</b>						
	<u>Reporter</u>					
	<b>Germany</b>	<b>Spain</b>	<b>France</b>	<b>UK</b>	<b>Italy</b>	<b>EU28</b>
<u>Partner</u>						
<b>Eu28_Intra</b>	<b>225,502</b>	<b>44,287</b>	<b>205,033</b>	<b>60,876</b>	<b>80,707</b>	<b>1,444,695</b>
Germany	0	4,801	54,754	17,453	33,208	429,324
France	23,879	13,137	0	5,905	20,457	197,113
Netherlands	39,324	6,263	19,977	14,389	4,462	182,390
Italy	41,527	92	69,155	2	0	149,997
Poland	26,050	1,357	2,024	658	5,990	78,544
Ireland	6,215	2,942	9,302	15,304	1,508	66,463
UK	5,434	647	2,916	0	716	65,025
Austria	44,287	77	2,760	2	4,682	64,716
Denmark	10,334	6,370	8,140	927	1,229	49,888
Belgium & Lux	6,992	1,232	10,095	5,694	201	39,309
Spain	161	0	23,115	301	940	32,143
Lithuania	2,564	49	2,013	0	1,411	16,281
Czech Republic	10,096	0	135	27	4	14,474
Portugal	0	6,697	199	214	611	12,309
<b>Eu28_Extra</b>	<b>5,001</b>	<b>3</b>	<b>14,303</b>	<b>231</b>	<b>978</b>	<b>32,357</b>
Switzerland	1,941	3	13,831	128	0	20,373
<b>Exports</b>						
	<u>Reporter</u>					

	Germany	Spain	France	UK	Italy	EU28
<u>Partner</u>						
<b>Eu28_Intra</b>	<b>426,496</b>	<b>29,810</b>	<b>194,303</b>	<b>81,567</b>	<b>164,008</b>	<b>1,405,369</b>
Netherlands	239,292	5,347	78,465	44,462	41,119	492,507
Germany	0	152	26,560	5,763	47,559	215,860
France	49,894	20,242	0	4,780	66,057	182,329
Italy	35,313	1,153	17,872	272	0	75,026
Belgium & Lux	11,403	93	29,821	1,416	0	73,319
Ireland	13,513	0	7,458	14,803	0	59,045
UK	15,090	990	3,538	0	2,888	46,331
Spain	5,570	0	14,211	1,503	551	43,562
Poland	13,426	0	2,318	618	2,190	38,167
Denmark	12,681	0	2,534	7,073	126	37,171
Austria	12,440	0	479	0	2,631	20,381
Czech Republic	1,819	0	1,953	308	228	14,218
Bulgaria	852	0	2,196	0	199	10,750
<b>Eu28_Extra</b>	<b>96,506</b>	<b>13,552</b>	<b>258,403</b>	<b>16,989</b>	<b>3,223</b>	<b>803,163</b>
China	36,518	2,525	87,100	6,453	0	266,213
Indonesia	14,630	10	34,303	0	0	93,414
Malaysia	6,610	1,206	14,606	638	0	59,429
Thailand	3,118	3,830	11,580	2,984	48	44,003
Japan	6,543	254	4,352	1,235	0	29,458
South Korea	3,320	793	3,659	0	0	22,794
Philippines	585	13	7,199	537	0	22,208
Russia	577	0	6,164	145	418	19,504
Switzerland	622	0	8,084	0	0	17,931
Pakistan	0	0	13,902	0	0	17,742
Singapore	6,372	0	2,607	210	0	15,763

Vietnam	940	2,675	880	0	0	13,941
South Africa	1,945	0	9,156	4	218	12,938
Australia	7	0	1,329	861	0	11,864
New Zealand	0	0	4,733	0	0	11,256

Source: Eurostat COMEXT

**Table 3.19: Albumin (CN8 35022091/35022099/35029070) – 2014 EU imports and exports in EUR 000s**

Imports						
	Reporter					
	Germany	Spain	France	UK	Italy	EU28
Partner						
<b>Eu28_Intra</b>	<b>46,370</b>	<b>12,554</b>	<b>21,540</b>	<b>55,946</b>	<b>7,427</b>	<b>264,370</b>
Netherlands	13,703	1,412	5,179	27,663	1,711	79,680
Germany	0	3,684	2,444	15,769	1,265	64,932
Denmark	5,803	3,785	8,647	1,571	1,068	28,647
UK	6,010	814	2,840	0	573	26,233
Ireland	3,047	997	1,111	2,564	2,139	18,356
France	1,888	1,582	0	4,710	592	16,144
<b>Eu28_Extra</b>	<b>13,970</b>	<b>10,523</b>	<b>2,010</b>	<b>447</b>	<b>289</b>	<b>55,157</b>
United States	9,242	10,523	1,703	447	289	44,356
Exports						
	Reporter					
	Germany	Spain	France	UK	Italy	EU28
Partner						
<b>Eu28_Intra</b>	<b>94,411</b>	<b>136</b>	<b>14,905</b>	<b>33,599</b>	<b>1,449</b>	<b>281,752</b>

UK	26,081	0	3,720	0	3	69,510
Netherlands	17,900	0	2,311	7,478	0	34,853
Germany	0	111	1,468	7,283	22	27,431
Hungary	7,754	0	6	3,902	0	23,992
Denmark	12,838	0	11	457	0	17,603
Belgium & Lux	2,157	0	827	3,677	2	16,712
France	3,134	0	0	2,097	0	14,085
Poland	3,544	0	2,451	1,185	321	12,962
Spain	3,506	0	1,567	1,174	26	11,478
Ireland	2,157	0	1,256	900	0	11,148
<b>Eu28_Extra</b>	<b>81,516</b>	<b>6</b>	<b>6,174</b>	<b>10,740</b>	<b>7</b>	<b>129,395</b>
China	54,098	0	981	0	0	55,079
United States	8,237	0	264	8,892	0	22,609

Source: Eurostat COMEXT

**Table 3.20: Casein (CN8 35011090) – 2014 EU imports and exports in EUR 000s**

<b>Imports</b>						
	<u>Reporter</u>					
	<b>Germany</b>	<b>Spain</b>	<b>France</b>	<b>UK</b>	<b>Italy</b>	<b>EU28</b>
<u>Partner</u>						
<b>Eu28_Intra</b>	<b>43,868</b>	<b>43,880</b>	<b>12,619</b>	<b>27,084</b>	<b>63,290</b>	<b>272,161</b>
Ireland	12,979	15,985	8,352	19,538	27,783	104,940
France	14,570	21,454	0	4,311	23,790	93,138
Netherlands	5,357	3,731	638	1,136	4,495	23,250
Germany	0	610	3,009	69	2,556	21,165
Austria	10,314	0	61	0	50	10,508
<b>Eu28_Extra</b>	<b>58,853</b>	<b>173</b>	<b>519</b>	<b>44</b>	<b>1,469</b>	<b>103,545</b>
New Zealand	40,722	0	511	0	1,298	47,934
Ukraine	3,872	31	0	0	0	20,178
India	6,351	0	0	0	171	18,786
Belorussia	7,773	0	0	0	0	13,129
<b>Exports</b>						
	<u>Reporter</u>					
	<b>Germany</b>	<b>Spain</b>	<b>France</b>	<b>UK</b>	<b>Italy</b>	<b>EU28</b>
<u>Partner</u>						
<b>Eu28_Intra</b>	<b>35,295</b>	<b>2,014</b>	<b>101,971</b>	<b>54</b>	<b>3,602</b>	<b>292,148</b>
Italy	2,537	2,003	29,015	1	0	70,081
Spain	633	0	21,613	1	1,311	49,200
Germany	0	0	15,546	5	5	40,438
Netherlands	10,621	0	15,142	1	1	38,349

UK	248	0	3,569	0	71	24,602
Poland	8,292	0	2,164	0	10	15,399
France	6,219	11	0	22	31	15,018
Belgium & Lux	1,012	0	5,294	4	0	14,634
<b>Eu28_Extra</b>	<b>28,730</b>	<b>217</b>	<b>88,182</b>	<b>135</b>	<b>389</b>	<b>283,166</b>
United States	2,208	0	15,685	35	0	71,369
Mexico	4,491	0	9,302	0	0	44,962
Russia	24	0	4,806	0	76	21,822
Egypt	364	0	11,405	0	0	18,860
Canada	12,002	0	1,176	0	0	15,323
Tunisia	385	0	10,352	0	0	13,214
Morocco	128	80	6,883	0	0	11,457

Source: Eurostat COMEXT

### 3.3 Consumers, distribution and marketing

#### 3.3.1 A12 Identification of consumers

Traditionally, consumers of FISP are mainly professional and semi-professional sportspeople. In particular, bodybuilders have mostly been associated to the use of certain types of products, e.g. muscle mass builders. According to evidence from interviewees, case studies and the consumer survey, this situation seems now to be changing: new user groups are emerging and the market share they represent is rapidly increasing. In the light of such evolution, the main groups of FISP consumers have been identified in Table 3.21 below.



**Table 3.21: Main group of consumers**

<b>Sportspeople</b>	
<i>People which do practice sport and have consumed FISP at least once in the last year.</i>	
Sportspeople are an heterogeneous group, which comprises the following sub-categories:	
<b>Body builders and mass intense sportspeople</b>	This group looks for proteins and supplements aiming at gaining muscle mass, for aesthetic reasons or to be more competitive in sports where muscle mass is an advantage.
<b>Athletes (professional and semi- professional)</b>	<p>Consumers belonging to this group look for products aiming at improving their performance and endurance.</p> <p>While their nutritional needs are outside the normal, the high level athletes form a very small part of the general population. Bodybuilders and professional and semi-professional athletes are usually well informed and look only for highly specialized products. The main sources of information about products that address their special needs are personal trainers and sport nutrition experts. In fact, high level athletes are likely to have their own dedicated nutritionists who control their dietary intake. The average expenditure on FISP is often higher than the one of the other groups<sup>21</sup>.</p>
<b>Amateur users</b>	This group consists of consumers who practice sports for health and fitness reasons, but with a medium-high level of frequency and intensity (e.g. people training for a marathon). A growing number of people are joining this group and operators are particularly interested in attracting them. These users are, in general, less informed about FISP with respect to professional ones and are interested in improving also their physical condition and appearance.
<b>Lifestyle users</b>	
<i>People who do not practice sport at all or practice sport less than once a week.</i>	
This group is mainly composed by people who give a particular attention to health and wellbeing. Their consumption of FISP is more related to health nutrition than to the attempt of improving or recovering from a sport performance. Lifestyle users can	

<sup>21</sup> Nonetheless it should be noted that certain interviewees commented that top level sportspeople may receive FISP products for free due to sponsorship or endorsement arrangements.

be categorized in two sub-categories which have similar consumption patterns.

<b>Lifestyle users</b>	Lifestyle users are consumers who do not consume FISP in relation to sport activities. Certain operators consider the lifestyle group far from their target, while others have launched separated product lines to address their needs. On the other side, other operators (e.g. some producers of sportsdrinks) may specifically address this target group.
<b>Recreational users</b>	Recreational users are consumers involved in the sport activity mainly during the week end and in general a few days per month, namely they do not have a structured routine of intense sport or exercise. Their consumption habits in relation to FISP are often similar to those of lifestyle users.

**People involved in extreme physical activities other than sport**

A small part of FISP consumers may not be sportspeople nor lifestyle users but rather people involved in extreme physical activities other than sport, for example the military, emergency services or manual labour.

Source: FCEC based on interviewees, consumer survey and literature review

Two main consumer groups have been identified for the purpose of the study; sportspeople and lifestyle users. A description of a third group of consumers (People involved in extreme physical activities other than sport) emerged from the interviews with operators and consumer associations. Consumers which are part of this group represent only a small part of FISP consumers but they do not consume FISP neither for health and wellbeing nor in relation to sport activities.

Sportspeople and lifestyle users, the two main groups of consumers are characterized by a very diversified degree of awareness of their nutrition needs in relation to sports activity and of knowledge about products and their properties. For this reason operators launch on the market different products for each group and may also use different distribution channels and marketing techniques. In section 3.3.1.1, 3.3.1.2 and 3.3.1.3 a description of the consumer habits, including preferences on retail channels, of average annual expenditure and of the reasons behind the consumption for each group is provided. In section 3.3.3 a similar analysis for each group is provided in relation to the importance of the information on the labels of FISP. Unless indicated otherwise, evidence in this section is take from the consumer survey. For a full description of the results emerging from the consumer survey see the annex (separate annexe document).

**3.3.1.1 Consumption habit**

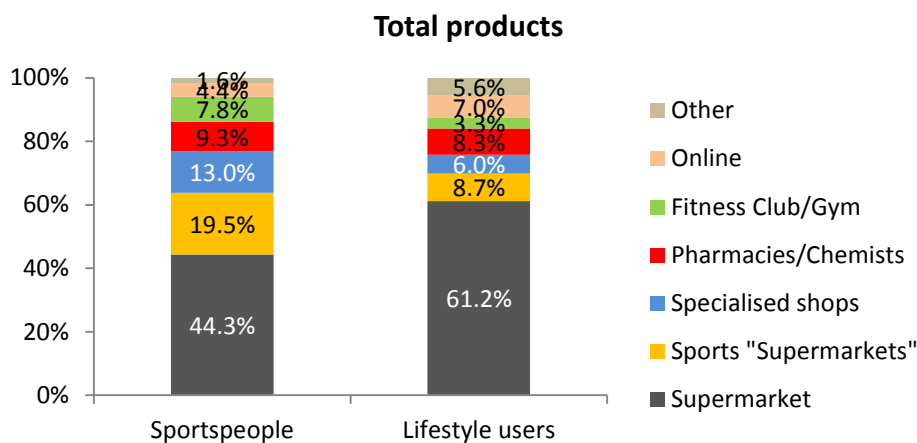
36.3% of all respondents to the consumer survey reported the use of some kind of FISP. In relation to the typologies of FISP consumed by the two groups of consumers, the use of certain products is higher among sportspeople than lifestyle users. More specifically, protein-based products and performance boosting products are respectively consumed by the 71% and by the 63.4% of sportspeople consumers compared to 46.3% and the 36.3% of lifestyle users. The proportion of consumers using sport energy bars is less divergent among lifestyle users (60.6%) and sportspeople (84.9%). Finally, in relation to sportsdrinks, the proportion of

consumers using these FISP is similar across the two consumer profiles; 79% among lifestyle users and 84.8% among sportspeople.

As a general rule, the more a product is “generic” (i.e. do not target specific sports) the more widespread its use among different profiles of consumers. On the other hand, products which target specific group of consumers are less widespread among non-target groups.

From the analysis of distribution channels by consumer group, a similar conclusion can be drawn. Sportspeople are more inclined in purchasing FISP in specific distribution channels, while more than half of lifestyle users purchase FISP in general food retailers, as shown in Figure 3-2.

**Figure 3-2: Retail channels by user group**

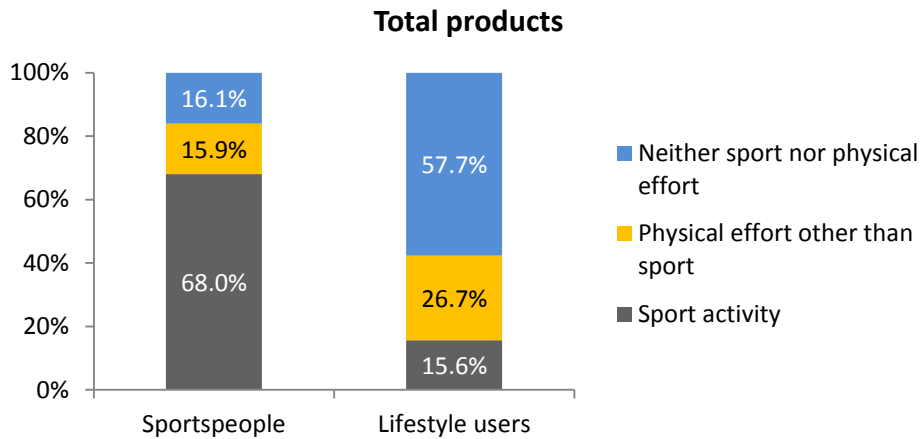


Source: consumer survey

Both groups of consumers normally purchase more specialist products in specialist retailers and less specialist products in general food retailers. More concretely, 80.8% of lifestyle users and the 56.9% of sportspeople purchase sportsdrinks in supermarkets while, only 31.3% for sportspeople and to 27.5% lifestyle users purchase performance boosting products through this channel. For an additional analysis of distribution channels please refer to the next section, 3.3.2.

Figure 3-3 shows the main reason for FISP consumption, differentiated by consumer group – sportspeople and lifestyle users. Within the group of sportspeople, consumption is more related with sport activities than to other factors; 68% of sportspeople consumes FISP in relation to sport activities, compared to just 15.6% of lifestyle users. The ratio is reversed for consumption not related with sport or physical activities; 57.7% of lifestyle users compared to 16.1% of sportspeople. Finally, among sportspeople, 15.9% of respondents indicated that they consume FISP in relation to physical effort other than sport, compared to 26.7% of lifestyle users.

**Figure 3-3: Distribution of respondents on the basis of consumption habits**

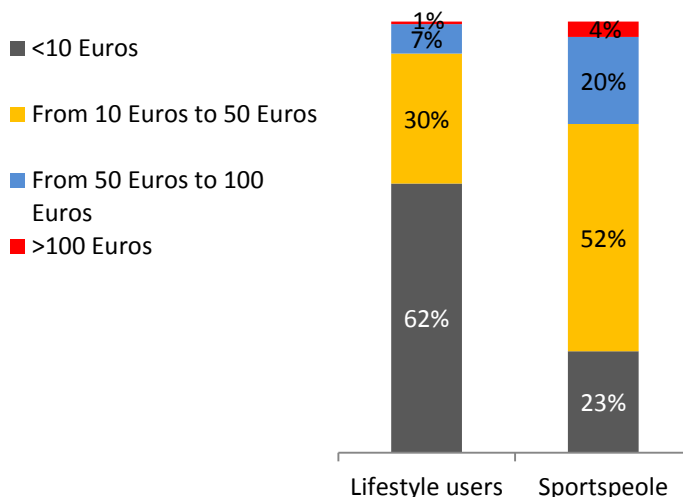


Source: Consumer survey

### 3.3.1.2 Annual expenditure

The annual expenditure of consumers differs on the basis of the group of consumers. Figure 3-4 below shows the annual expenditure on FISP by lifestyle users and sportspeople.

**Figure 3-4: Annual expenditure for FISP by user group**

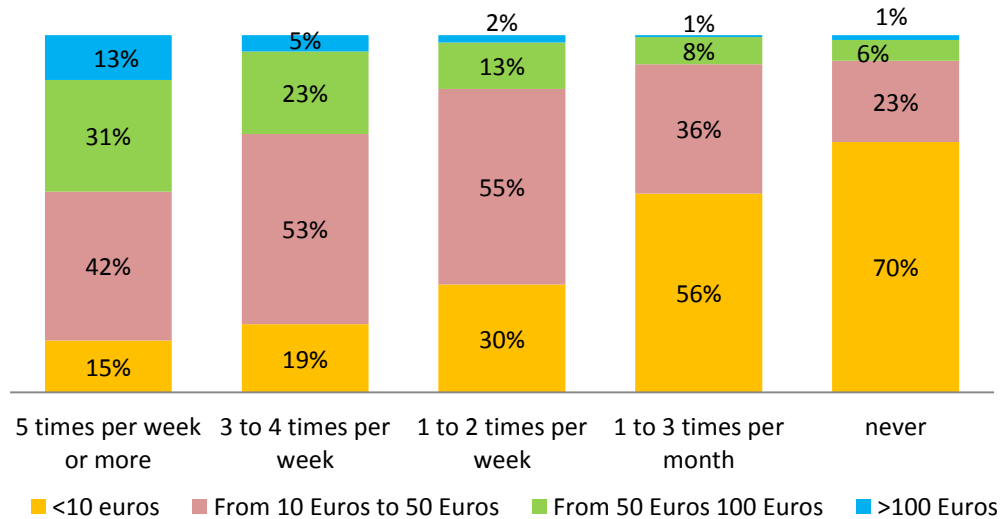


Source: Consumer Survey

More than the half of lifestyle users spend less than 10 Euros annually and only a minor percentage of this group spend more than 50 Euros. The most significant expenditure category for sportspeople is higher: 52% of the respondents of sportspeople spend from 10 to 50 Euros and almost a quarter spend more than 50 Euros. 4% of sportspeople spend more than 100 Euros, while only 1% of lifestyle users reach this top category of annual expenditure.

Figure 3-5 presents more data on the correlation between the frequency of sport activities and annual expenditure on FISP.

**Figure 3-5: Annual expenditure by frequency of sport activity**



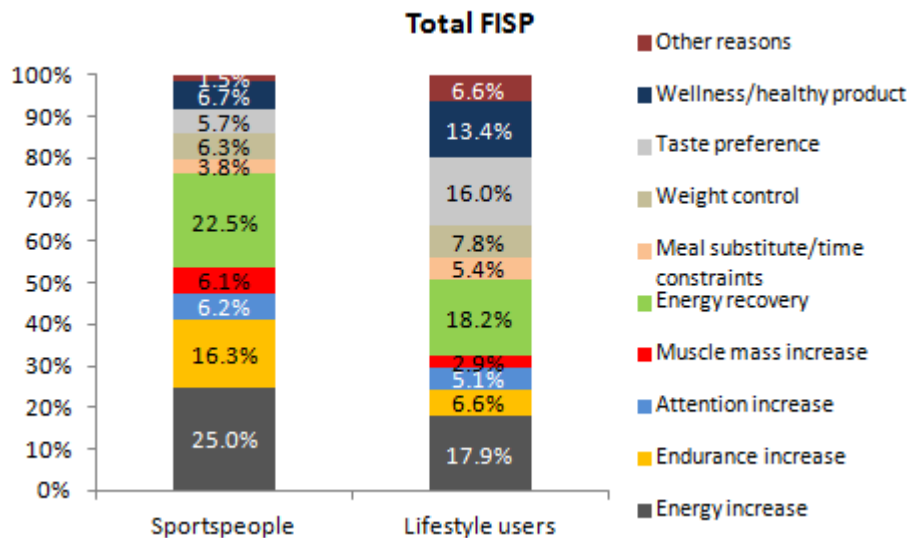
Source: consumer survey

Annual expenditure grows in parallel with frequency of sport activity. 13% of sportspeople who practice sport almost daily spend more than 100 Euros per year. This percentage decreases in the group of respondents who practice sport from three to four times per week (5%). On the other hand, lifestyle users, namely respondents who do never practice sport or who practice sport from one to three times per month, mainly belong to the group which spends less than 10 Euros per year (respectively 56% and 70%), and only a very small percentage spend more than 100 Euros (1% and 1%).

### 3.3.1.3 Reasons behind consumption

Consumer survey results allow a comparison of the motivations behind the consumption of FISP by sportspeople and lifestyle users. Figure 3-6 shows the main reasons for consumption of the two groups.

**Figure 3-6: Reasons behind consumption**



Source: consumer survey

Endurance, energy increase and energy recovery are the main reasons behind the consumption of FISP for sportspeople. Lifestyle users are mostly driven by the search for energy recovery or energy increase, taste preferences, and health and wellbeing.

According to the consumer survey results, motivations behind the consumption of FISP do not necessarily reflect the original “objectives” for which these products were intended. This is particularly true for lifestyle users. For instance, 20% of performance boosting products and 14.6% of protein-based products are consumed by lifestyle users in relation to wellness and health. Taste preference have been indicated as the most important reason behind consumption of sportsdrink 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 main reason of 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%).

The results of the consumer survey analysed in this paragraph confirm the information collected from other sources, most notably interviews and case studies. Operators launch new products differentiated on the basis of the consumer group they want to attract. In fact these groups differ by preferred retail channels, motivations behind consumption, relative consumption of different categories of products and level of annual expenditure. Amateur users can be considered in this sense a borderline category; interviewees revealed that certain patterns of consumption of this category can be similar to those of lifestyle users. In view of replacing the traditional categories of FISP consumers (namely bodybuilders and professional athletes) by the emerging categories of lifestyle users and amateur users, operators may modify their commercial strategy in order to extend the range of their customers in order to include these new emerging categories. At the same time, the majority of operators do not want to withdraw from the market of more specialised products, which not only attract consumers with higher annual expenditure but also contributes to building the image of the brand. Some firms decided to focus only on certain segments of the market while others, mainly producers of sportsdrinks, may enter the market with the main aim of attracting non

specialised target groups of consumers. However, differentiation in terms of marketing techniques and innovation strategies reflect this trend.

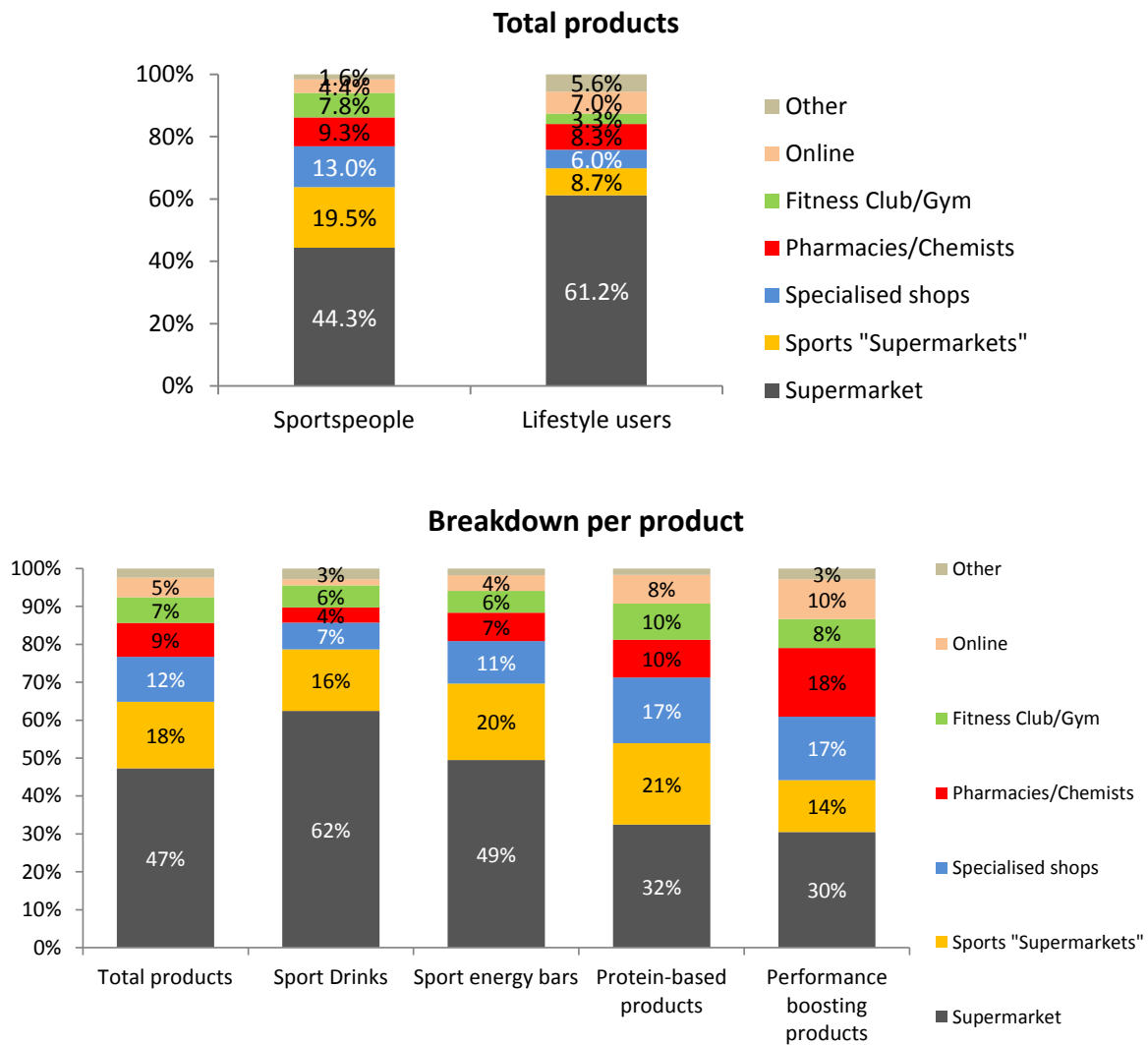
### *3.3.2 A7 Distribution channels*

According to elements emerging from interviews and case studies, and the results of the consumer survey, the main distribution channels for FISP in the EU are:

- Specialized shops.
- Sports Supermarkets (e.g. Decathlon).
- Supermarkets / general retailers.
- Pharmacies and parapharmacies.
- Fitness centres and clubs.
- Online channel / internet.

Although the importance of different distribution channels can vary significantly in each Member State (see case studies), Figure 3-7 below summarizes the relative weight of the above channels for sportspeople and lifestyle users according to the consumer survey.

**Figure 3-7: Main distribution channels at EU level**



Source: consumer survey

According to results of the consumer survey, both sportspeople and lifestyle users purchase most FISP in non-specialised large retail outlets (e.g. supermarkets). These are followed, in terms of importance, by sport supermarkets (e.g. Decathlon, Sports Direct, etc.). Despite this, supermarkets appear to be much more important for lifestyle users than for sportspeople. In general terms, sportspeople purchase around 56% of total products through more specialized channels (i.e. not supermarkets), while for lifestyle users this percentage falls to 39%. The internet is the only other channel where lifestyle users purchase in a higher percentage than sportspeople (7% and 4.4%, respectively).

Most industry interviewees agreed that the aforementioned channels cover almost the entire market for FISP. Despite this, there was difficulty in measuring effectively the relative importance of each channel, resulting in very different ranking according to the different respondents; for example, some interviewees identified sports supermarkets as the largest channel, and others the internet. For this reason, in the consumer survey annexe (separate annexe document) contains a more complete breakdown of the distribution channels in



relation both to the Member States and to the nature of consumers (sportspeople and lifestyle users) and has been used as the basis of information on distribution channels.

#### 3.3.2.1 Specialized shops

Specialized shops can be generally considered the “entry” distribution channel, especially for Member States where the market has developed only recently. According to the consumer survey, specialized shops are more important in Germany and Italy (14% and 13% on total purchases, respectively); the products most frequently bought in such retail outlets are protein-based and performance boosting products (17% of the total purchases for both product categories).

According to interviewees, in some Member States (e.g. Germany), these shops are often located next to gyms, thus creating a sort of “spontaneous” consumer journey; in other cases, like in Italy, some vertical integration between producers and specialized retailers<sup>22</sup> does exist, with examples of consolidation trends within the sector. One interviewee referred to the potential risk related to lack of the required expertise by the personnel in these shops, although this seems in contrast with the general perception of high specialization and the role of expert played by this channel.

#### 3.3.2.2 *Sports supermarkets*

Sports supermarkets play an important role in the FISP distribution, accounting for 19.5 % of total purchases for sportspeople and 8.7% for lifestyle users. According to the consumer survey, France is by far the Member State where this channel is more important (26% on total purchases with respect to an average of 18% across the five case study countries), while the most relevant product categories in it are protein-based products and sport energy bars (21% and 20% of the total purchases for the product category, respectively).

A general trend boosting the importance of this channel is the increasing presence in the EU market of private labels: some evidence in this respect emerged from interviews as well as from desk research, demonstrating how players like Decathlon and Sports Direct are increasingly developing their own products leveraging on their developed distribution network (see also section 3.2.1.4).

#### 3.3.2.3 *Supermarkets / generalists*

It is generally recognized by operators that supermarkets play a central role with reference to sportsdrinks sales; this is consistent with the general indication that the more “specialist” a product is, the less likely it is offered by generalized channels (namely supermarkets and online generalist retailers like Amazon and Argos).

Supermarkets represent by far the most important retail channel across the five analysed Member States: according to the consumer survey, the highest relative weights are found in

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<sup>22</sup> In September 2012 Enervit S.p.A., leading player on the Italian market, completed the acquisition of the retail channel Vitamin Store, which owns 70 stores (of which 64 in franchising) across Italy.

Spain and Italy (54% and 51%, respectively). On average, the channel covers around 62% of total sportsdrinks and 49% of sport energy bars distribution.

#### 3.3.2.4 Pharmacies and parapharmacies

According to the consumer survey, the importance of pharmacies is higher in UK and Italy (11% of total sales) than in Spain, France and Germany; as already reported for specialized shops and sports supermarkets, the product categories mainly sold through this channel are the more technical ones: performance boosting products (18% of their total sales), and protein-based products (10%).

Some concerns surround the pharmacies channel in the context of the envisaged changes in regulation after 2016: some of the interviewees highlighted the risk that with the repeal of PARNUTs, the sale of some FISP through pharmacies could be prohibited in certain Member States as it is not permitted to sell food products which are placed on the market under other horizontal rules of food law; only food product covered by very specific legislation (i.e. Directive 2009/39/EC in the case of FISP).

#### 3.3.2.5 Fitness centres and clubs

The role of fitness centres in FISP distribution seems limited in absolute value, although different operators reported how the sale of these products represents a relevant part of gyms revenues. According to the consumer survey, Germany is the Member State where this channel is more developed (13% of total FISP sales, versus an average of 7% across the five case study countries), and the most common products sold here are protein-based products (10% of total product category's sales). These last figures appear consistent with what emerged during interviews, where operators put in relation the gym channel mainly with muscle mass products.

The importance of fitness centres also stems from their role for the transmission of information about products among consumers; on the other hand, some interviewees also put in evidence an issue of insufficient expertise and competence of the personnel, which can become relevant with respect to anti-doping and health-related concerns. An interesting case of vending machines in fitness centres was identified in Germany (see case study annexe).

#### 3.3.2.6 Online channel / internet

Most operators reported that internet is a fast-growing channel; even though they were not able to estimate the growth rate. There are mainly three types of internet web-sites dedicated to the sales of FISP products:

- specialized web-sites of third party distributors;
- producers' on-line shops;
- mass marketing web platforms (e.g. Amazon).

The consumer survey results show that Germany and UK are the Member States with the highest relative weight of internet purchases (9% and 7%, respectively). With respect to the breakdown among categories, performance boosting and protein-based products are the most represented products in the channel (10% and 8% of the total purchases for the product category, respectively).

According to interviewees, sportsdrinks do not lend themselves to distance selling due to the bulky nature of the product and its low value. On the contrary, certain products such as protein powders are considered of particular interest for this channel due to their format and their relative high price, which could lead to significant absolute (rather than relative) savings for consumers from shopping around.

Interviews with consumer associations, CAs and operators indicated the internet channel as the primary source for consumers of illegal and/or counterfeit products (including products which are in compliance with local third country requirements but that are not in compliance with EU legislation); with respect to this problem, two main concerns emerged during interviews:

- **Health protection and anti-doping concerns:** internet is the main channel through which products manufactured in third countries – which may contain dangerous ingredients and/or doping substances – enter the EU;
- **Fair competition issues:** EU producers of FISP must comply with an extensive regulatory framework covering ingredients, labelling, use of claims, etc. while producers from third countries are generally subject to a much less demanding regulatory framework in those countries.

### 3.3.3 All Marketing techniques

Marketing techniques can vary significantly in the FISP industry in relation both to the size of the operator and to its focus on a particular product category. Operators aim to provide the most relevant information for each group of consumers and their needs, and consequentially at using the most appropriate marketing technique.

According to information collected from interviewees in collaboration with the results of the consumer study, the following marketing techniques are the most significant for the sector:

- **Information on the labels:**
  - Sale denomination: a clear description of the function of the products (e.g. energy bars).
  - Brand and packaging (e.g. the use of photos of sportspeople).
  - Clear instructions of use (e.g. during or after physical activity).
  - Composition and ingredients.
  - Use of information such as “high energy”, “source of glucose”, which would be considered as nutrition claims - although not authorized - according Regulation (EC) No 1924/2006; but which can currently be used due to the mandatory indication provisions of Directive 2009/39/EC.
  - Use of health claims approved under Regulation (EC) No 1924/2006.

With reference to labelling, FISP operators reported as central elements of the communication to consumers the use of images related to sport (e.g. runners or cyclers for endurance products), the use of statements such as “energetic” and “for sport”, as well as instructions for use (pre-during-post exercise); especially for products not related to the muscle segment (where consumers are instead already very informed on dosage and timing for use).

- **Sponsoring of sport events:** sponsoring of sport events is widespread at national and local levels. It allows operators to approach specific segments of consumers and to tailor product advertising on the basis of the type of sporting event, of its participants and of its attendance.
- **Endorsement by famous sportspeople:** product endorsement by sport champions is a widely used marketing technique to present new products to the market. Engaging top professional athletes as testimonials for products – in the attempt to create an association between the performance of the athlete and the consumption of the product - is a marketing technique which actually targets amateur sportspeople and the general public rather than other professional athletes. Sponsorship of athletes or of teams is comparable to this marketing technique. A famous example of this technique is the sponsorship of the FC Barcelona football team by the U.S. brand Herbalife. It was noted by some interviewees that, among other benefits, famous sportspeople who endorse FISP may receive products for free in return.
- **Specialist press advertising:** this technique includes traditional advertising on magazines but also reviews from the editors, which are considered as a much more powerful marketing tool. Producers may offer new products to the editors, and specifically request for a test and a review of these products.
- **Mainstream media:** this comprises advertising on radio and on television, more often on sport channels. There is not an extensive use of advertising on mainstream media, because of the very high costs of this technique.
- **Word-of-mouth advertising:** this technique can be either planned and guided by the companies, or can originate independently in sport environments like gyms.
- **Web marketing and internet communication:** this channel includes the use of keyword advertising, which allows direct advertising to specific targeted groups, and the use of internet forums, a technique similar to the word-of-mouth advertising.

Event sponsorship and specialised press were considered as the most important channels for advertising by interviewees: they allow to approach specific segments of the target population and to establish a personal and trusted relationship with customers. The use of mainstream media, like radio and TV, has costs that cannot be afforded by most FISP operators. In general terms, the more specific a product is, the less it is promoted through mass media.

Following on from the above, interviewees noted that marketing techniques differ significantly between the sportsdrinks and the sports nutrition segment. In the sportsdrinks arena, where the majority of the market is under the control of global corporations (e.g. PepsiCo, Coca-Cola, etc.), major players largely use mainstream media as television, endorsement by famous sportspeople and appealing packaging: these techniques imply large investments which can be afforded only by the leading global players. Leading brands especially were reported to use endorsement or sponsoring. This seems consistent both with the investment needed for this channels and with the target population of the products, which is not particularly specific (especially if compared with many specific sport nutrition products). Sportsdrink brands compete to attract general consumers and have, as significant competitors, producers of soft drinks and energy drinks. For this reason, they invest more in

advertising on mainstream media and use strategies similar to the ones used by the general drink producing companies (e.g. sportsdrink producers can also use dedicated branded fridges in grocery and other stores to advertise their products). These strategies are reflected in the share of the distribution channels: sportsdrinks are mainly purchased through non-specialist retailers, like big stores and sport supermarkets.

As for sports nutrition, on one hand the average size of the leading players is slightly lower (see section 3.2.1.4), on the other hand, the objective to approach specific segments of consumers implies the use of more specific (and less expensive) channels. The most important and common technique reported by interviewees is represented by organization and sponsorship of events, which allows companies to be in contact with specific categories of sportspeople with their own specific needs/products (e.g. runners, bodybuilders, etc.).

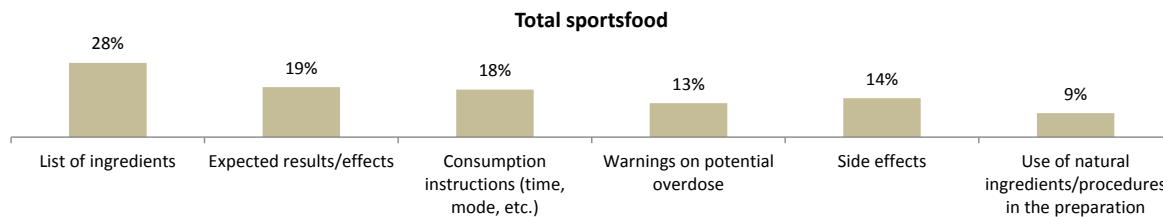
According to interviewees and as corroborated by desk research, producers use stands within the “main” sport events not only to promote products, but also to receive direct feedback from consumers and to strengthen their relationship with “opinion leaders” in the field. Communication on FISP products goes also through informal channels, like internet forums and word of mouth. Those methods are complicated to control for the competent authorities and by operators themselves, and are generally not recorded. Interviewees reported that controlling the information exchanged on internet forums is challenging because either it may not originate from the operator or it may not be traceable. However, operators consider monitoring the reaction to the launch of new products and feedback on offered services crucial, therefore even if they cannot control through marketing techniques this channel, they usually engage in web monitoring.

Other relevant communication channels identified by interviewees for FISP are specialized magazines – although their importance has been decreasing in recent years – and web marketing / key word advertising. With regards to the latter, the impressive growth of online purchases led also companies to paying attention to creating appealing, user-friendly and well organized websites, also taking into account the different product targets.

The use of claims and the extent of their diffusion is analysed in section 3.3.4. However, the results of the consumer survey (separate annexe document) provide an overview of the importance of the presence of certain information on the label of FISP, which can be considered as an important strategy to attract customers and a part of the marketing techniques.

Consumers consider the list of ingredients as the most important item reported on the label (30% of preferences), followed by expected results/effect (19%) and consumption instructions (18%). These preferences are shown in Figure 3-8.

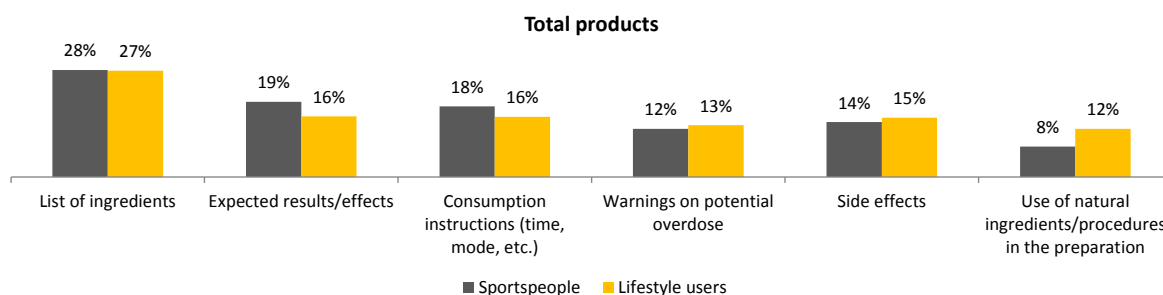
**Figure 3-8: Most important information on the label**



Source: Consumer survey

Consumers do not change their preferences on the basis of the type of products; there are only slight differences reported. However, minor differences have been detected on the basis of the group of consumers. The importance of the information about expected results/effects is higher for surveyed sportspeople, while lifestyle users are more interested in warning on potential overdose, side effects and on indication of the use of natural ingredients and of the procedures used in the preparation (Figure 3-9).

**Figure 3-9: Most important information on labels for sportspeople and lifestyle users**

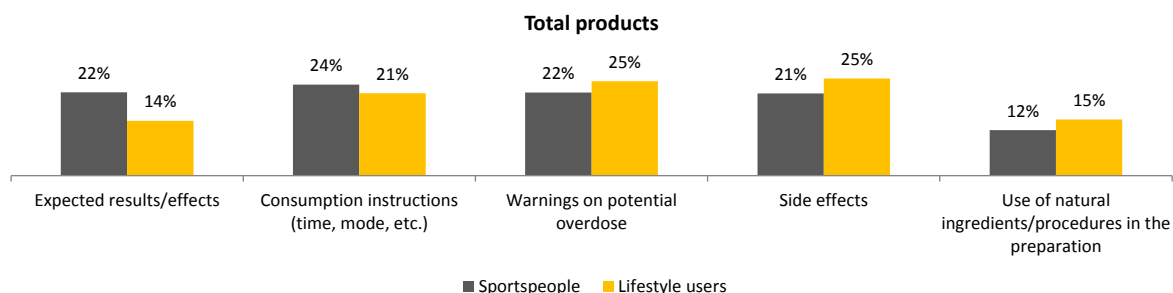


Source: consumer survey

Interviewees noted that, in general, marketing for elite athletes often relies on the advice from trainers and nutritionists. In this sense, the label is considered an important source of technical information, such as ingredients and composition. The influence of the other information on consumption of the specific substances by professional athletes is likely to be limited, mainly because professional athletes have access to specialist consultancy to meet their nutrition needs.

22% of sportspeople respondents in the survey considered that information on the expected results/effects and on consumption instructions should never be missing on the label of the products, while lifestyle users consider important the presence of indications on potential overdose and on side effects (Figure 3-10).

**Figure 3-10: Information on labels that should not be missing**



Source: consumer survey

The importance of claims in purchasing decisions of consumers can be partly analysed in light of these survey results. Indication of expected results and on the effects of a product are considered very important by most of respondents. Health claims, where authorised, can be related to this type of information; however the indications required under article 9 of Directive 2009/39/EC can also provide this information.

The presence of claims on the label of FISP is considered very important by 42.9% of the survey respondents, while only 14.8% considered claims not at all important in their purchasing decisions.

However, it should be noted that consumers usually have no means to identify authorized health claims and non-authorized health claims. The analysis on the level of trust in claims does not show a higher level of trust in authorized claims. 45.9% of respondents trust very much health claims which have been approved, against 45.1% for non-authorized claims. This may raise some concerns on the influence on purchasing habits of claims which have not been approved, and which may provide false or anyway misleading information.

### 3.3.4 A5 Claims

#### 3.3.4.1 Background to claims in the context of FISP

Regulation (EC) No 1924/2006 lays down harmonised rules for the use of nutrition claims, and includes a process for authorising health claims relating to foods or specific substances. Permitted nutrition claims are of interest to the general population and with some exceptions (e.g. high protein), are not specifically relevant for sportspeople. Nutrition claims that could be of interest for sportspeople are currently not allowed (e.g. high energy). According to article 10 (3) of the regulation, “*Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14*”; therefore allowing for the possibility to indicate general, non-specific benefits of food if an authorised health claims is used.

With respect to health claims, after the consolidation of Member State lists, around 4600 health claims were submitted to EFSA. In 2012, Regulation (EC) No 432/2012 established a list of 222 permitted health claims on the basis of favourable assessments from EFSA. Following the establishment of this list, non authorised claims could not be used any more (with the exception of pending claims). Further health claims have subsequently been authorised and rejected following assessments by EFSA.

Among the claims which have been authorised or rejected since the establishment of a list of permitted health claims in 2012, it is possible to find a number of claims with a strong relevance for FISP. More specifically:

## Authorised claims

- There are seven authorised health claims of clear, direct relevance to sports activity. Three further claims relating to caffeine are currently under consideration at the time of writing following the recent safety assessment of EFSA. The authorised claims are presented in Table 3.22.
- In addition to the seven claims of direct relevance for sports, there are several authorised claims of a more indirect relevance to sports activity. These are presented in Table 3.23.

## Rejected claims

- In the region of 100 claim dossiers connected to sport activity were rejected. A list of the main substances together with the number of rejected claims is presented in Table 3.24.

**Table 3.22: Authorised claims targeting sportspeople**

Substance	Claim	Conditions / restrictions on use
Carbohydrates	Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive and/or long lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.	The claim may be used only for foods intended for adults who have performed highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.
Carbohydrate-electrolyte solutions	Carbohydrate-electrolyte solutions contribute to the maintenance of endurance performance during prolonged endurance exercise.	None.
Carbohydrate-electrolyte solutions	Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise.	None.
Creatine	Creatine increases physical performance in successive bursts of short-term, high intensity exercise.	The claim may be used only for foods targeting adults performing high intensity exercise .
Protein	Protein contributes to a growth in muscle mass.	None.
Protein	Protein contributes to the maintenance of muscle mass.	None.
Vitamin C	Vitamin C contributes to maintain the normal function of the immune system during and after intense physical exercise.	None.

Source: FCEC based on EU register of health claims

**Table 3.23: Authorised claims which may be considered relevant for sportspeople**



Claim	Substance
Contributes to normal energy-yielding metabolism	Biotin, Calcium, Copper, Iodine, Iron, Magnesium, Manganese, Niacin, Pantothenic acid, Phosphorus, Riboflavin (B2), Thiamine, Vitamin B12, Vitamin B6, Vitamin C
Contributes to normal muscle function	Calcium, Magnesium, Potassium
Contributes to the maintenance of normal muscle function	Vitamin D
Contributes to normal neurotransmission	Calcium,
Contributes to maintenance of normal connective tissues	Copper
Contributes to the normal formation of connective tissue	Manganese
Contributes to normal functioning of the nervous system	Biotin, Copper, Iodine, Magnesium, Niacin, Potassium, Riboflavin (B2), Thiamine, Vitamin B12, Vitamin B6, Vitamin C
Contributes to normal amino acid synthesis	Folate
Contributes to normal oxygen transport in the body	Iron
Contributes to electrolyte balance	Magnesium
Contributes to normal protein synthesis	Magnesium, Zinc
Contributes to normal collagen formation for the normal function of cartilage	Vitamin C
Contributes to the maintenance of normal regulation of the body's temperature	Water
Contributes to the reduction of tiredness and fatigue	Folate, Iron, Magnesium, Niacin, Pantothenic Acid, Vitamin B2, Vitamin B12, Vitamin B6, Vitamin C,

Source: FCEC based on EU register of health claims accessed 15/2/15

**Table 3.24: Substances for which more than one claim targeting sportspeople have been rejected**

Substance	Number of rejected claims
Carnitine	8
Whey Protein	8
Carbohydrate foods and beverages	6
Branched-chain amino acids	5
Casein protein hydrolysate	5
Glutamine	5
Bovine colostrum	4
Sodium phosphate	4
Beta-alanine	3
Carbohydrate electrolyte drinks	3
Astaxanthin from <i>Haematococcus pluvialis</i>	2
Carbohydrates	2
Coenzyme Q10;(Ubiquinone)	2
Corn protein hydrolysate titrated at 29 % glutamine	2
Creatine	2
EAS Phosphagen Elite	2
HMB (B-hydroxy B-methylbutyrate monohydrate)	2
L-carnosine	2
Taurine	2
Whey Protein	2

Source: FCEC based on EU register of health claims accessed 15/2/15

**Methodological notes:**

The database of health claims was searched for non-authorised claims which specifically targeted sportspeople. More specifically:

- The following keywords searched for: Endurance, exercise, physical, muscle mass, sport, athlete
- Results which clearly did not target sportspeople were removed. This primarily led to the removal of certain entries intended for physical maintenance in old age, and certain entries relating to the maintenance of muscle mass and loss of fat during weight reduction.
- It should be noted that a couple of claims straddled the areas of exercise / muscle mass and weight management. References to these claims were included in the results. Similarly, some claims straddled the areas of joint health and exercise; these were also retained.

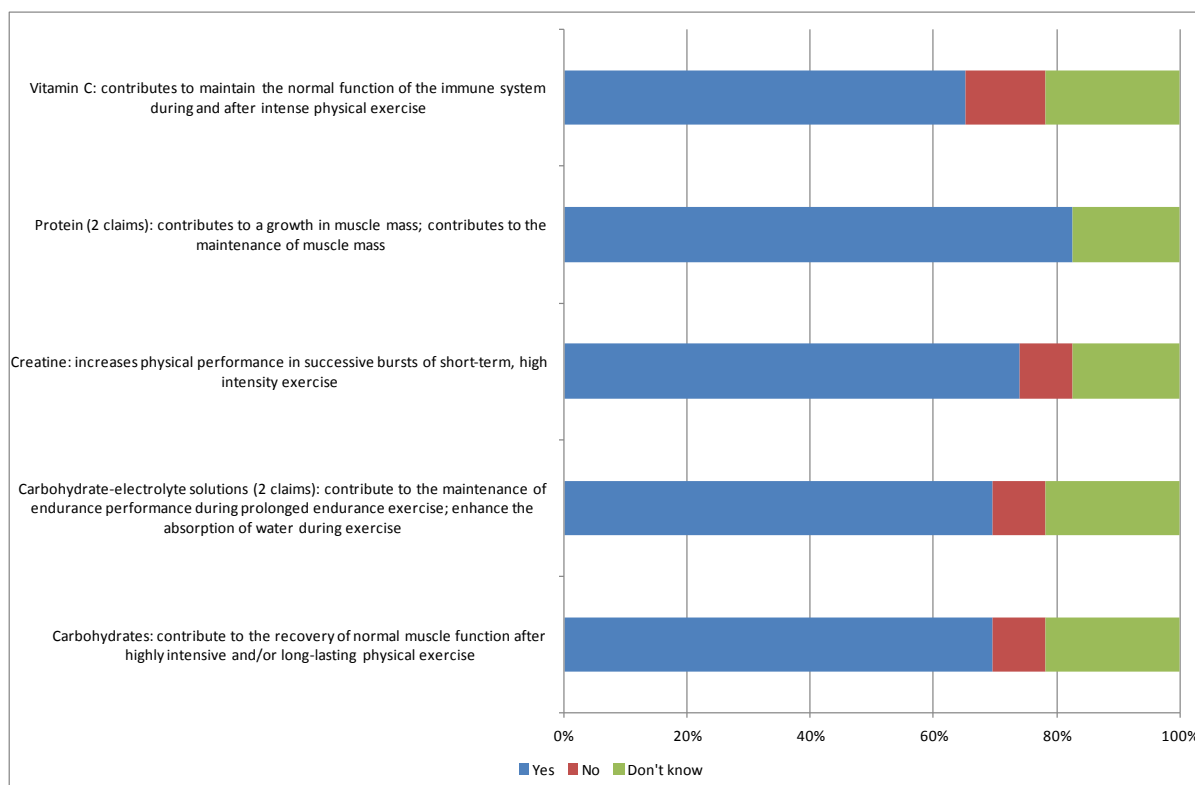
Articles 9 (2) and (3) of Directive 2009/39/EC requires the indication on the label of the particular nutritional characteristics and elements of the composition providing these characteristics for products placed on the market as sportsfood in accordance with Directive 2009/39/EC. National transposition of the Directive in some cases may provide further labelling possibilities for sportsfood products placed on the market as PARNUTS. According to article 2 (1) of Regulation (EC) No 1924/2006, a 'claim' means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics. While indications under Directive 2009/39/EC may imply nutritional or health benefits, they cannot be considered claims as defined by Regulation (EC) No 1924/2006 at present as they are mandatory. Regulation (EC) No 1924/2006 also applies without prejudice to community provisions for PARNUTs (Article 1 (5)).

### 3.3.4.2 Use of authorised claims on FISP

Evidence on the use of authorised claims on FISP was collected through a combination of the CA survey, interviews and case studies (including market observation).

Figure 3-11 displays information from CAs on the use of the seven authorised claims previously identified in Table 3.22. For all claims, a majority of CAs had identified the use of the claim in relation to FISP. That said, there were some differences in the number of CAs which had identified the use of claims for certain substances. The claims that were identified as being used in relation to FISP by the highest number of CAs was those for protein (over 80% of CAs). The claim for vitamin C was identified as being the least widely used (just over 60% of CAs identified its use in relation to FISP).

**Figure 3-11: Use of authorised health claims on FISP according to Competent Authorities**



Source: CA survey. N=23

Question: Have you identified the use of the following claims on FISP?

Evidence from interviewees and case studies corroborated the findings of the CA survey in relation to the claims for protein, creatine and carbohydrate-electrolyte drinks. Interviewees were in unanimous agreement that the relevant authorised claims for all three substances are used by FISP fulfilling the criteria, and market observation in the context of case studies suggested these claims are widely used on these products. However, there was considerably less evidence to suggest that the claims for carbohydrates and vitamin c are used in relation with FISP. While some interviewees believed that there were FISP products using these claims, others had not thus far identified the use of the claim in relation to FISP. On balance,

the use of these two claims on FISP appears to be lower. In the case of the claim for carbohydrates, one reason identified for this by interviewees was the recent authorisation of the claim (January 2015) in relation to the research period for the study (February – April 2015). Interviewees also noted that use of the on-hold caffeine claims was low due to uncertainty about their eventual authorisation.

The use, to some degree, of certain other claims relating to minerals and vitamins from Table 3.23 on FISP were identified by interviewees and through field observation during the course of case studies. More concretely, the claims which were identified as used on FISP, along with the substances to which they were connected, are:

- Contributes to the reduction of fatigue (niacin, vitamins B2, B6, C).
- Contributes to normal energy yielding metabolism (niacin, vitamins B1, B2, B6).
- Contributes to normal muscle function (magnesium).
- Contributes to the protection of cell constituents from oxidative damages (vitamin B2).

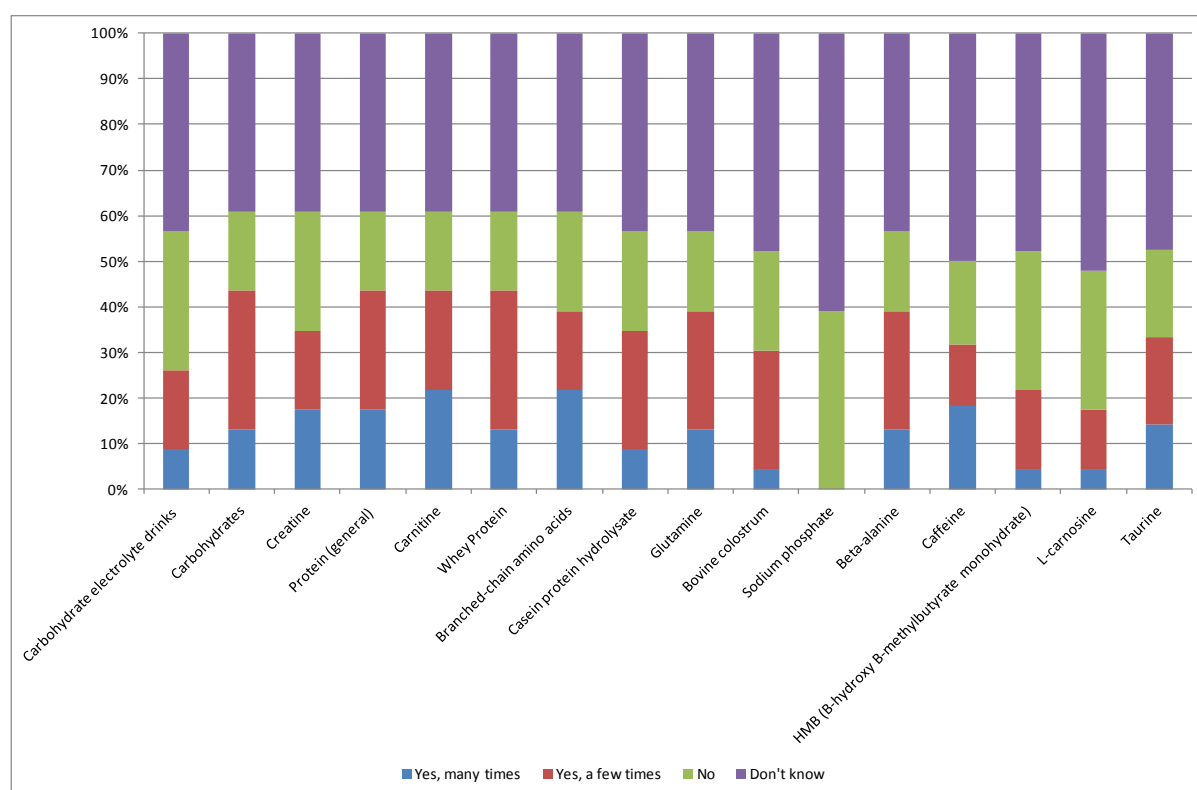
#### 3.3.4.3 Communication in relation to substances without relevant authorised health claims, and the use of unauthorised claims

As noted in section 3.3.4.1, articles 9 (2) and (3) of Directive 2009/39/EC require the indication on the label of the particular nutritional characteristics and elements of the composition providing these characteristics for products placed on the market as sportsfood in accordance with Directive 2009/39/EC. Consequently, there is the possibility (obligation) for some communication in relation to certain substances without relevant authorised health claims for products placed on the market as sportsfood in accordance with Directive 2009/39/EC. However, as noted by interviewees (including case study interviewees), the borderline between what constitutes a mandatory indication under Directive 2009/39/EC, and what may be perceived to be a health claim is somewhat blurred, and decisions in this regard are the responsibility of national CAs. It is important to note in this context that the definition of a claim according to Article 1 (2) of Regulation (EC) No 1924/2006 excludes messages and representations that are obligatory under EU or Member State legislation; and that Regulation (EC) No 1924/2006 applies without prejudice to community provisions for PARNUTs (Article 1 (5) of Regulation (EC) No 1924/2006).

In view of the above, there is a certain degree of difficulty (and subjectivity) in distinguishing between unauthorised claims, and indications required by Directive 2009/39/EC. There is a clear overlap in terms of the message communicated to the consumer under health claims legislation and under the mandatory indications required by Directive 2009/39/EC. In addition, there is in clarity as to whether certain statements should legally be considered a mandatory statement required by Directive 2009/39/EC or a health claim in accordance with Regulation (EC) No 1924/2006. The mandatory indication requirements of Directive 2009/39/EC may be used to make statements which are not permitted under health claims legislation, and the distinction as to which legislation a statement falls under is only legal. Furthermore, the obligation to communicate in relation to certain substances only exists for products placed on the market as sportsfood in accordance with Directive 2009/39/EC. However, as observed during case studies, in the absence of notification procedures for such products in certain Member States, there may be some in clarity with regards to the method of placing on the market of FISP.

In the context of the survey, Member States Competent Authorities were asked whether they had identified the use of any unauthorised claims in relation to certain major substances with rejected health claim dossiers which were identified in Table 3.24, plus the five substances with authorised health claims identified in Table 3.22. The results of the CA survey are presented in Figure 3-12.

**Figure 3-12: Identification of the use of unauthorised claims in order to target sportspeople**



Source: CA survey. N=23; except caffeine (N=22) and taurine (N=21)

The use of unauthorised claims identified by CAs varied significantly between substances. Unauthorised claims used in relation to BCAA, carnitine and beta-alanine were identified by most CAs (roughly 40% of CAs reported the use of unauthorised claims for these substances to some degree). At the other extreme, the use of unauthorised claims in relation to sodium phosphate, HMB and l-carnosine was particularly low. CAs were asked to provide further information on the unauthorised claims they had identified. Many (but not all) of unauthorised claims appear to relate to information on the internet or product promotional material rather than on the product label. A full list of these unauthorised claim statements identified by CAs is provided in the survey annexe (separate annexe document).

In summary, evidence suggests that there is presently communication in relation to substances without relevant authorised health claims. However, the extent to which this is due to the use of indications required by Directive 2009/39/EC, and the extent to which it is due to the use of unauthorised claims is unclear.

## Generic indications under articles 9 (2) and (3) of Directive 2009/39/EC

Some examples of generic indications currently used on FISP in accordance with article 9 (2) and (3) of Directive 2009/39/EC (or national legislation) were provided. These included:

- (Product) for sportspeople.
- For use before / during / after exercise / physical activity.
- Sports nutrition product rich in <ingredient>.
- High <ingredient> / source of <ingredient> (e.g. carbohydrates).
- Function: rebuild strength / aid recovery / etc.
- High energy (e.g. carbohydrate products)
- Contains sodium (e.g. sportsdrinks).

### 3.3.4.4 Fortification of FISP in order to use authorised health claims

Evidence from various sources including interviews, case studies and the CA survey indicated that, following the entry into force of the list of authorised health claims in 2012, some FISP were fortified or reformulated in order to use authorised health claims. However, the extent to which this occurred varied between operators. More specifically:

- The majority of CAs (81%; n=22) reported that there was no change in the fortification of FISP following the entry into force of health claims legislation. The remainder (19%) indicated that there had been a slight increase in fortification practices.
- Operators (including contract manufacturers) and stakeholders interviewed in the context of case studies reported that the decision as to whether to fortify or reformulate FISP following the entry into force of health claims legislation varied between individual operators. While some operators chose to fortify or reformulate products (including in order to support non-specific claims through article 10 (3) of Regulation (EC) No 1924/2006), other operators did not make any changes to their products.

In conclusion, while fortification and reformulation of FISP was identified following the entry into force of the list of authorised health claims, no evidence was uncovered to suggest that it was widespread. In this context, it should also be noted that the high rate of innovation of the sector should be taken into account (see section 3.2.3); while existing FISP products may not have been reformulated to a great extent, given the perceived widespread use of authorised health claims, new products introduced after 2012 would appear to have been formulated in order to use certain health claims. Interviewees noted that, even if fortification and reformulation was not widespread, relabeling was.

### 3.3.4.5 Reformulation of foods not intended for sportspeople to use authorised health claims relevant for sportspeople

Among the seven claims identified as directly relevant for sportspeople, the conditions of use of the claims on carbohydrates and creatine limit their use to foods targeting adults performing high intensity exercise. The claims on CE solutions, protein and vitamin C are not restricted to this target group (see Table 3.22).

CAs were asked to what extent foods not intended for sportspeople were reformulated after the entry into force of health claims legislation in order to make claims relevant for sportspeople<sup>23</sup>. The majority of CAs (62%; n=21) had not identified reformulation in order to use claims. Of the remainder, 24% had identified limited reformulation and 14% moderate reformulation.

### 3.3.5 *A4 Foods not intended for sportspeople*

With regards to foods other than FISP but which can be associated to sport activity, two main sub-categories came up in the course of interviews:

1. **Normal foods** (milk, fruits and vegetables, etc.) which are generally consumed by sportspeople because of their composition and their suitability in relation to sport activity;
2. **Borderline products** whose composition does not define them as FISP but which are sometimes associated – both by consumer and by operators – as of interest by sportspeople and as potential competitors of FISP. These products are often marketed with more or less explicit references to sport activity (e.g. images of sports in the packaging, claims related to endurance/workout, etc.).

It is worth noting that some products might belong to both of these sub-categories, on the basis of how they are marketed<sup>24</sup> (see also section 3.1.1.3 for certain already identified examples)

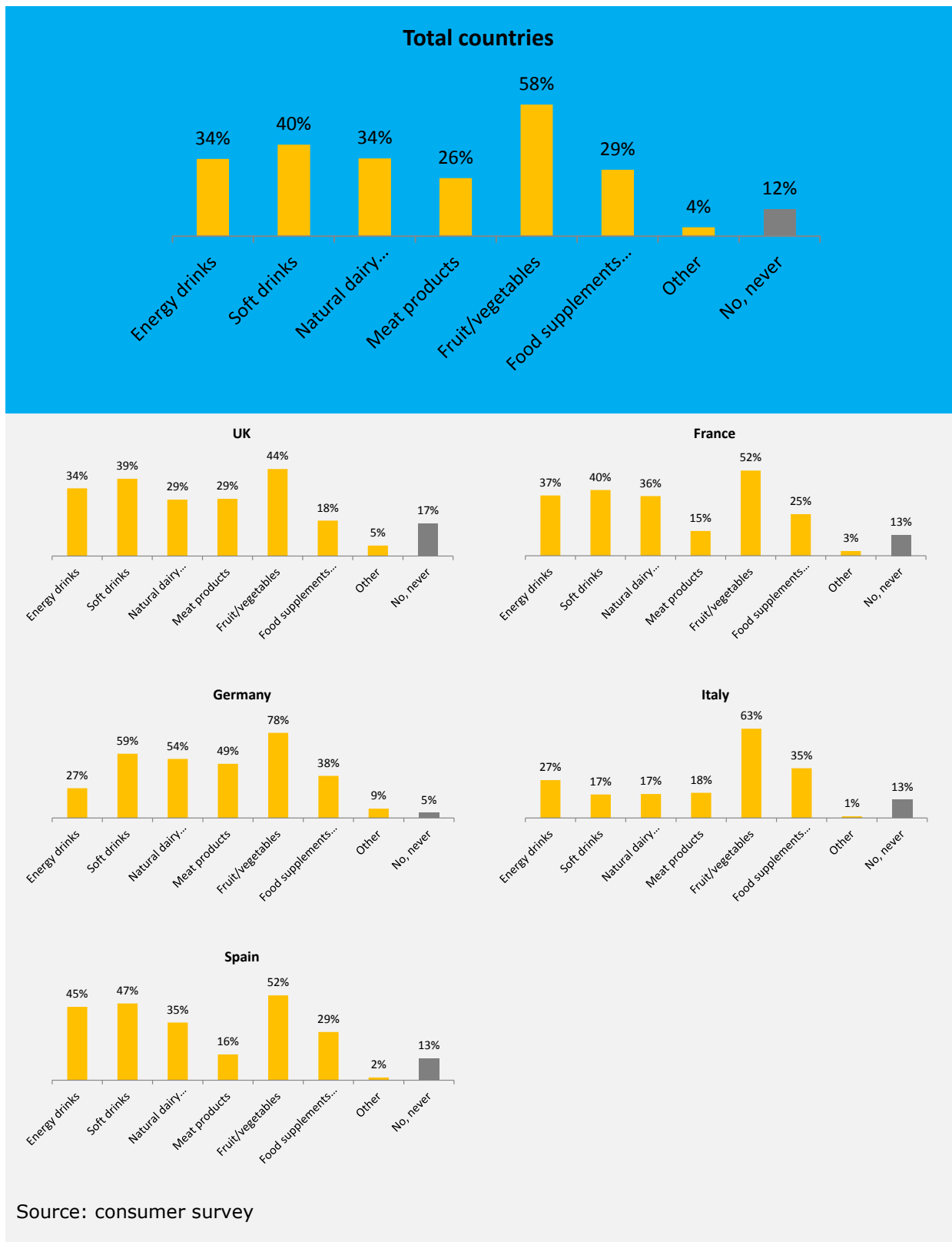
The consumer survey provided some information in this context: Figure 3-13 below summarizes the preferences for different groups of products in relation to sport activity in the five countries under analysis.

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<sup>23</sup> Claims relevant for sportspeople were defined as the seven claims identified in Table 3.22.

<sup>24</sup> By a way of example, dry fruits might belong to the first category but in case they are marketed as suitable for sport activity they will also fall into the borderline products group.

**Figure 3-13: Foods other than FISP used in relation with sports activity**

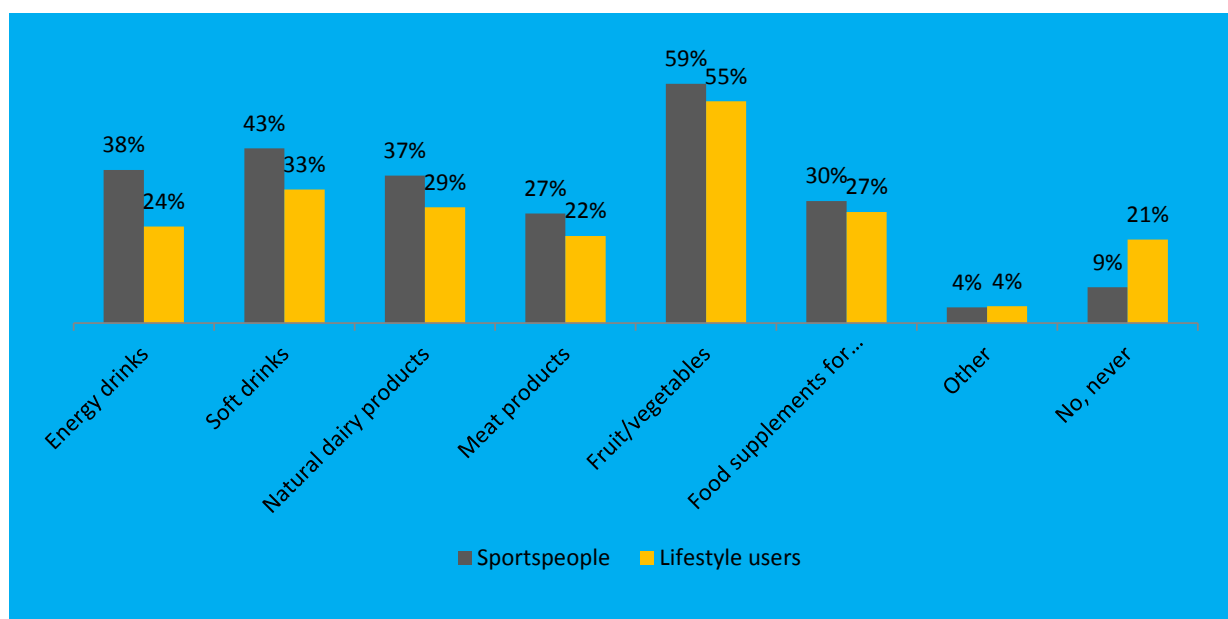


Nearly 60% of the surveyed subjects consume fruits and vegetables in relation to sport activity. On the opposite side, only 12% of respondents do never consume any products other than food specifically intended for sportspeople in relation to sport activities.



Some differences are also in the consumption habits of these products among sportspeople and lifestyle users as evident in Figure 3-14 below.

**Figure 3-14: Foods other than FISP among sportspeople and lifestyle users**



Source: consumer survey

The product category where there is the most significant difference between sportspeople and lifestyle users are the energy drinks, consumed by 38% of sportspeople and by 24% of lifestyle users. Energy drinks are also very commonly consumed in relation with sports activity in Spain (45% of preferences) and in France (37%).

The association between consumption of energy drinks and sport has also been reported during several interviews with operators and consumer/athletes associations, in spite of scientific evidence in some Member States indicating that such drinks are not suitable for sports activity (see also 3.1.1.3). Energy drink marketing techniques often make use of the images of sports. Certain energy drink brands are sponsors of sport events and/or teams, often related to motor racing and “extreme” kinds of sports (e.g. skydiving). The increase in the consumption of energy drinks, which contain caffeine, was reported by interviewees as a probable reason for the request of a reconsideration of the health claims on caffeine: in the recent 2015 EFSA opinion on the safety of caffeine it is reported that single doses of caffeine up to 200 mg do not give rise to safety concerns when consumed < 2 hours prior to intense physical exercise under normal environmental conditions. On the other hand, some FISP producers pointed out how energy drinks are not suitable for sports since they are hypertonic and not effective in maintaining or restoring hydration status; their packaging often reporting images of sport it is widely recognized by operators as unfair competition to FISP. The industry itself highlighted the difference between energy drinks and sportsdrinks<sup>25</sup>.

<sup>25</sup> According to one EU level industry interviewee: “Energy drinks are functional beverages with a stimulating effect and unique combinations of characterizing ingredients including caffeine, taurine, vitamins and other substances with a nutritional or physiological effect. Taurine, for example, is not usually contained in sportsdrinks and evidence suggests that it is not specifically beneficial for sporting activity. Sportsdrinks, unlike energy drinks, are usually designed to be isotonic or hypotonic in order that they hydrate effectively. Energy drinks will generally contain a higher concentration of sugars than sportsdrinks (and are

Certain food supplements are attractive for sportspeople even if they do not target specifically such group, for example the ones containing substances as spirulina and eleutheroccus are considered of particular interest for sportspeople, as well as those containing glucosamine, chondroitin, omega 3, vitamins and minerals. Among respondents in the survey, about 30% declared to consume food supplements for overall good health in relation to sport activities with the highest consumptions in Germany and Italy (38% and 35%, respectively).

Evidence collected through interviews provided additional examples of other food products associated with sport activities are:

- Honey;
- Dried fruits;
- Cereal bars and trek bars;
- Dairy products<sup>26</sup>.

Common knowledge and producer marketing techniques are the main reasons behind the consumption of such products in relation to sport activity. Lifestyle users are considered more sensitive to the marketing techniques which associate foods not targeting sportspeople to wellness and fitness.

Additional elements were provided in some interviews with reference to what are the key differences between these products and FISP in terms of composition and ingredients (please see also section 3.1.2 for a complete overview on ingredients). On one hand some interviewees noted that sportspeople basically need the same foods that the rest of population needs but in higher quantities, due to their more intense physical effort; on the other side producers stressed substantial differences and advantages which can be summarized as follows:

- **Convenience and packaging:** examining, by way of example, protein-based products and milk, to obtain 20g of protein would require 2/3 of a litre of milk. However, the same contribution can be achieved with one scoop of whey protein. As well as being convenient sources in terms of concentration, FISP can also be packaged in ways which are easier to consume.
- **Tailoring of nutrients:** using the same example of milk, in the case milk is consumed it is consumed with all other nutrients present and consumers may or may not want these nutrients. The other nutrients present can be controlled in FISP products; unwanted nutrients can be removed and other desirable nutrients may be added. Furthermore, there is no “one size fits all” solution for FISP consumers, the mixes of nutrients may therefore differ between FISP products. On this latter point, the industry works more and more with athletes to

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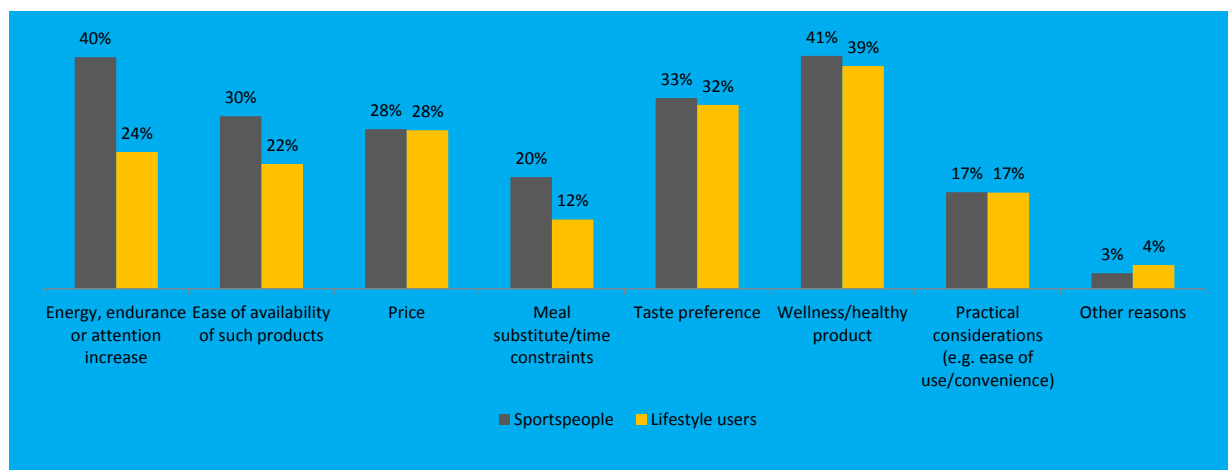
hypertonic). Ingredients, such as caffeine, may also be that are typically found in energy drinks but which may be contained in sportsdrinks will generally be contained in sportsdrinks at much lower levels.”

<sup>26</sup> Interviewees indicated that there has been a specific campaign in the UK to promote consumption of milk and dairy products in relation to sports activity.

develop different, tailored solutions which results in increasing categories of products specific for different sports.

The consumer survey also investigated which were the main reasons behind consumption of foods other than FISP in relation to sport activity (Figure 3-15).

**Figure 3-15: Reasons behind consumption of foods other than FISP**



Source: consumer survey

### 3.4 Legislation

#### 3.4.1 A13 National rules

##### 3.4.1.1 National rules in place

#### National legislation

Nine of the 24 Member State CAs which replied to the CA survey identified the existence of national legislation covering the placing on the market of FISP. Member States which have been identified to have national legislation are presented in Table 3.25.

**Table 3.25: National legislation covering the placing on the market of FISP in the EU-28**

MS with national legislation	MS without national legislation	MS for which national legislation has not been identified**
BG	AT	CZ
DK	BE	FI
EE	CY	SK
FR	DE	
HU	EL	
IT	ES*	
PL	HR	
PT	IE	
RO	LT	
	LU	
	LV	
	MT	
	NL	
	SE	
	SI	
	UK	
<b>9 Total</b>	<b>16 Total</b>	<b>3 Total</b>

Source: CA survey supplemented by case studies and desk research

\* During the course of the Spanish case study, it was confirmed that Royal Decree 1809/1991 is the reference national regulation for transposition of Directive 2009/39/EC; and that this decree does not contain any specific provisions for food intended to meet expenditure of intense muscular effort.

\*\* CAs from these Member States did not reply to the survey. Desk research was performed in order to check for the existence of national legislation. No national legislation covering the placing on the market of FISP was found during the desk research<sup>27</sup>.

<sup>27</sup> For FI and SK, information on national legislation for PARNUTs was identified. FI: <http://www.mmm.fi/fi/index/etusivu/elintarvikkeet/ravitsemus/erityisruokavaliolismisteet.html> accessed 1/6/15

SK : [http://www.uvzsr.sk/docs/info/hv/predaj\\_potraviny\\_v\\_kompetencii\\_org\\_ver\\_zdrav\\_za\\_UVZSR.pdf](http://www.uvzsr.sk/docs/info/hv/predaj_potraviny_v_kompetencii_org_ver_zdrav_za_UVZSR.pdf) accessed 1/6/15

The areas covered by national legislation (where it exists) are set out in Table 3.26. The most commonly covered areas are notification and labelling. It should be noted that no information on the areas covered by national legislation was identified for Bulgaria.

**Table 3.26: Areas covered by national legislation**

MS	Notification	Authorisation	Definition	Composition	Labelling	Marketing	Outlets	Other
DK				x				
EE	x							
FR			x	x	x			
HU			x		x			
IT	x				x			
PL	x				x			
PT	x				x			
RO	x	x		x	x	x		
<b>Tot</b>	<b>5</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>6</b>	<b>1</b>		

Source: CA survey

Note: information on areas covered was not provided by BG reply to the CA

### Soft rules

Certain non-legislatively binding national soft rules with relevance for FISP were identified in some Member States. Where present, these soft rules are presented in Table 3.27. In addition to the soft rules outlined in the table, it was noted by one interviewee that there are restrictions or soft rules relating to the use of caffeine in all foods in several Member States, *inter alia* Czech Republic, Finland and Estonia.

**Table 3.27: National level soft rules relevant for FISP**

MS	Notification	Definition	Composition	Labelling	Other
CY	x				
DE		x	x		
EE	x				
IT		x	x	x	
PL					x
RO	x				
SE					x

SI		x	x		
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Source: CA survey; cross checked with case studies and interviews

### 3.4.1.2 Impact of the national rules in place

Perception about the impact of national legislation varied to a degree between stakeholder and the areas covered by the national legislation. A summary of the impacts of national rules by area of impact (internal market, competitiveness, etc.) is presented in Table 3.28. On balance, national rules were perceived by stakeholders to have negative impacts on operators through impacts on the internal market, competitiveness, SMEs and TC trade; but positive impacts on consumers through consumer protection, and CAs through enforcement practices.

**Table 3.28: Summary of the impacts identified by stakeholders of national legislation relating to the placing on the market of FISPs (by area of impact)**

Area of impact	Negative impacts	Neutral impacts	Positive impacts
<b>Internal market</b>	Different national rules can lead to a fragmentation of the internal market. Products may require different labelling or composition in different Member States, or be placed on the market under different legislation.	In the absence of compositional rules or definitions, impacts of national rules may be minimal.	
<b>Third country (TC) market access</b>	TC operators may not be aware of national rules (notification cited as an example).	In the absence of compositional rules or a notification obligation, impacts of national rules may be minimal.	National rules may provide clarity to TC operators importing to the MS.
<b>Competitiveness</b>	<p>In some MS, there are fees for notification (e.g. PT) or for the evaluation of certain ingredients (e.g. DK).</p> <p>For operators selling products in multiple MS, there may be costs stemming from the negative impacts described under “internal market”.</p>	Labelling costs may not be significant and are similar to those for other food industry segments.	National rules (particularly in relation to composition) can provide a certain guarantee of product quality which can benefit the image of the industry.
<b>Innovation</b>	Compositional requirements and safety evaluations for new ingredients may restrict innovation.	In the absence of composition rules, there is little impact on innovation.	



Area of impact	Negative impacts	Neutral impacts	Positive impacts
<b>SMEs</b>	Impacts on SMEs were considered to be the same as those on competitiveness with the extra provision that the bureaucratic burden caused by any national legislation may be proportionally higher for SMEs.		
<b>Price</b>	Fees for notification or evaluation of certain ingredients may have slight impacts on prices.	For MS in which there is no notification charge, there is no notable impact on price.	
<b>Consumer choice and protection</b>		Limited impact without compositional criteria.	Notification allows the detection of unsafe products or unauthorised substances; and checks for misleading labelling.  Notification can facilitate market monitoring, consequently with positive impacts on consumer protection.
<b>Legal clarity</b>	In the absence of a definition at national level, legal clarity is limited.  Outdated legislation in some MS negatively impacts legal clarity.		National definitions (where present), labelling provisions and notification requirements can provide legal clarity.
<b>CA enforcement</b>	Notification may result in a slightly higher workload for some MS CAs.		Notification procedure or ingredient evaluation provides an additional check.  Notification can facilitate market monitoring / help ensure there is a clear market

Area of impact	Negative impacts	Neutral impacts	Positive impacts
			monitoring procedure.

Source: FCEC based on CA survey, interviewees and case studies.

### 3.4.2 A14 Third country rules

#### 3.4.2.1 USA

As concluded in section 3.2.4, the most important trading partner for the EU in the area of FISP is the USA. There is no specific federal legislation for FISP in the USA. FISP products are generally sold as supplements; as such are regulated under the 1994 Dietary Supplement Health and Education act, and are also subject to supplement Good Manufacturing Practices requirements and other relevant regulations. However, FISP can also be sold as foods<sup>28</sup>.

Dietary supplements covered the 1994 act do not need approval from the U.S. Food and Drug Administration (FDA) prior to being marketed, except in the case that a new dietary ingredient is used in the product. In this latter case, a pre-market review for safety data and other information is required.

Establishments bottling / packaging sportsdrinks are required to register and file scheduled processes under the US Food Canning Establishment and Process Filings requirements (FCE-SID). The FCE-SID is not specific to sportsdrinks; it applies to all low-acid canned (including bottled or jarred) or acidified foods<sup>29</sup>.

#### 3.4.2.2 Legislation in other significant third country trading partners

Legislation on FISP was identified in three significant trading partner third countries

##### **Switzerland**

The *Speziallebensmittel Verordnung des EDI* (Special food regulation of the Swiss Federal Internal Market department) contains provisions on foods for people with higher energy or nutrient requirements. This recognises four categories of product:

1. Products for the provision of energy.
2. Products with a defined vitamin and mineral content, or with other substances relevant for people with higher nutrient needs.
3. Protein and amino acid preparations.
4. Combinations of the first three categories.

The regulation contains certain compositional and labelling requirements for these products.

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<sup>28</sup> <http://www.nutraingredients-usa.com/Markets/Science-certifications-drive-export-potential-of-US-made-sports-nutrition-products-experts-say>; <http://www.nsf.org/consumer-resources/health-and-safety-tips/dietary-sports-supplements-tips/understanding-regulations/>; <http://www.crnusa.org/CRNRegQandA.html> accessed 2/6/15

<sup>29</sup> <http://www.registrarcorp.com/fda-food/fce-sid/>; <http://www.usada.org/energy-drinks-vs-sports-drinks/> accessed 2/6/15

It is important to note that the regulation does not refer directly to sportspeople or sport; the relation to sportspeople of the group of foods for people with higher energy or nutrient requirements is implied rather than explicit. According to EDI (2015), there are ongoing changes to Swiss food law; these may, in time, result in different legislation for FISP.

### **Australia and New Zealand**

In Australia and New Zealand, *Standard 2.9.4 of the Australia New Zealand Food Standards Code* regulates FISP (which are called “Formulated supplementary sports foods (FSSFs)” by the standard). The standard covers the following area:

- A general definition of FSSFs.
- A categorisation of particular FSSFs and their compositional requirements.
- Compositional requirements in the form of maximum one-day amounts for various nutrients including vitamins, minerals and amino acids; and restrictions on the amino acids which can be used.
- Labelling requirements; both general labelling requirements, and certain ingredient specific claims.

In New Zealand, sports-related products may also be manufactured under the New Zealand Food (Supplemented Food) Standard 2010. Products which comply with the New Zealand Regulations can be imported into Australia under the Trans-Tasman Mutual Recognition Arrangement.

### **Norway**

Norway effectively transposed the EU Directive 89/398/EEC<sup>30</sup> on foodstuffs for particular nutritional uses into national legislation through national regulation no. 1382 of 21 December 1993 (last modified in 2012<sup>31</sup>). National regulation 196 of 1993 on drinks for use in demanding physical exertion previously regulated sportsdrinks, but this regulation was repealed in 2013 (the allowable amount of magnesium under regulation 196 of 1993 was lower than what is considered significant amount by national nutrition labelling regulations).

According to Schjoll et al. (2009), the composition of FISP placed on the market under this national regulation must be suitable for target user, and must be clearly distinguished from products for consumption by the general population. The Norwegian Food Safety Authority uses the 2001 SCF report as a guide for determining the suitability of a product for sportspeople.

### **Other TC trading partners**

According to interviewees, some third countries (e.g. Russia, South Africa and Turkey) require certification of compliance with EU legislation for products before they can be imported. However, the certification that is accepted depends on the categorisation of food products as adopted by the third country itself (e.g. whether FISP are considered to be food

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<sup>30</sup> Directive 2009/39/EC recast Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses.

<sup>31</sup> <https://lovdata.no/dokument/SF/forskrift/1993-12-21-1382> accessed 3/6/15

supplements, PARNUTs, products, etc. by the third country's legislation). Interviewees were unable to elaborate on this point or to identify specific examples of where certification is contingent on compliance with specific legislation for FISP. It is therefore possible, though not confirmed, that some third countries may have certification requirements for EU exports pertaining specifically to FISP.

## 4 THEME 2: EVOLUTION OF THE MARKET AFTER 2016

### 4.1 General evolution and internal market

#### 4.1.1 *B1 General evolution*

##### 4.1.1.1 Drivers of the market for FISP

In general terms, the drivers of the market for FISP are closely connected to the opportunities and threats identified during the SWOT analysis in section 3.2.2.

Various interviewees identified **innovation** (in its various forms) as a key driver of the market for FISP (see section 3.2.3). In this context, it was noted by some interviewees that consumers of FISP have certain expectations for innovation which may, in turn, propel operators to release either new products or new versions of products. A particular aspect of innovation which was identified by certain interviewees as an important driver in recent years was the tailoring of products to certain types of athlete or certain sports. Innovation was expected to remain a driver of the market for the foreseeable future. Some interviewees noted that the US market tends to be ahead of the rest of the world by several years in the area of FISP (both in terms of products on the market and general market development); and in view of this, the US market may act as a good barometer of how the EU market may evolve.

According to evidence from case studies, **increased levels of participation** in sport have been a significant driver of the FISP market in some Member States in recent years (e.g. France, Germany, UK). However, evidence from Eurobarometer (2013) does not corroborate this trend at EU level; according to EU level figures, the proportion of EU citizens which plays sport once a week or more did not change between 2009 and 2013 (41%). On the other hand, the proportion that never exercises or does sport increased over the same period from 39% to 42%. However, overall it is fair to conclude that, in Member States that have undergone increases in participation levels in sport in recent years, this trend may continue and consequently may remain an important driver for the FISP market.

Certain interviewees believed that a significant driver of the market was its movement to **mainstream consumption**, with products not being consumed exclusively by sportspeople but by the general public, including consumers with interests in health and well-being (see also section 3.3.1). Consequently, new categories of product may be emerging (e.g. weight-loss / sports nutrition crossover products; see section 3.1.1.3), and FISPs are increasingly convenience-orientated (i.e. in RTD or bar form rather than powder or capsule). There is conflicting evidence as to the extent to which this “mainstreaming” can be considered a significant driver; and it should be noted that not all interviewees shared the view that the market was moving to mainstream consumption. Evidence for and against the validity of this driver are presented in Table 4.1 below. In summary, while there is evidence to suggest that the mainstream consumption of FISP is a driver, the importance of “mainstreaming” as a driver and the suitability of certain FISP for mainstream consumption is unclear.

**Table 4.1: Arguments for and against the move to mainstream consumption as a driver of the FISP market.**

In favour	Against
<ul style="list-style-type: none"> <li>• Distribution channels are predominantly mainstream (supermarkets, internet, large sports good shops), with specialist channels (gyms and dedicated outlets) account for a minority of distribution (see section 3.3.2).</li> <li>• A significant proportion of consumers consume FISP neither in relation to sport nor physical activity (see section 3.3.1).</li> <li>• New products ranges of FISP are emerging to support everyday health and wellbeing.</li> </ul>	<ul style="list-style-type: none"> <li>• FISPs generally contain certain nutrients in levels which are not needed by non sportspeople, and which may be incompatible with the concept of well-being or a healthy lifestyle (see section 3.1.2).</li> <li>• The sportsdrinks segment; the biggest at EU level, and arguably the most mainstream, is currently contracting. This is at least partly driven by certain health-driven concerns (e.g. high sugar consumption).</li> <li>• It is unclear to what extent new product ranges focused on health and wellbeing can be considered FISP (see section 3.1.1.3).</li> </ul>

Source: FCEC based on interviewees and previous study questions

#### 4.1.1.2 General outlook for the FISP market.

Data from Euromonitor, which forecasts future market value at national level based a combination of behavioural equations, data intensive time series techniques based on recent and present figures, and industry opinion<sup>32</sup>, predicts that the market for FISP in the EU will increase from around 3bn in 2014 to just under 3.2bn EUR in 2019. This represents a CAGR of 0.8%; down from 2.2% for the period 2009-14. This growth is predicted to be driven by sports nutrition products; protein based products are forecast to increase at 6.2% p.a., and energy and performance products by 4.7%. Sportsdrinks on the other hand are forecast to contract by 3% p.a (Table 4.2).

**Table 4.2: Market forecast of the value of FISP in the EU to 2019**

Category	2014 value EUR m	2019 value EUR m	CAGR 2014-19	CAGR 2009-14
Sportsdrinks	1 858.3	1 599.3	-3.0%	-1.6%
Protein based	801.7	1 080.6	6.2%	11%
Energy and performance	406.6	511.6	4.7%	9%

<sup>32</sup> Legislative outlook is taken into account through industry opinion. However, in view of the uncertainty surrounding FISP, the figures provided do not make a specific provision for the change of legal position of these products.

Total	3 066.6	3 191.4	0.8%	2.2%
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Source: FCEC based on Euromonitor

#### 4.1.1.3 Legal position of FISP after 2016

Regulation (EU) 609/2013 will repeal Directive 2009/39/EC and the specific Directives adopted under its framework. Regulation (EU) No 609/2013 includes only a limited category of specific foods in its scope. While Directive 2009/39/EC recognised ‘food intended to meet the expenditure of intense muscular effort, especially for sportsmen’ as a PARNUTs category, Regulation (EU) 609/2013 does not.

Following the repeal of Directive 2009/39/EC, Member States with specific national legislation for sportsfood will be able to maintain these provisions provided that they remain compatible with EU law. It is the responsibility of national competent authorities to ensure that this is the case. Member States will also be able to adopt new national legislation provided that it is in line with EU law. New national provisions will have to be notified to the European Commission, which shall evaluate the compatibility of any national provisions with EU law.

In the absence of specific national legislation for sportsfood, products will have to comply only with the horizontal rules of food law after 20 July 2016. EU legislation of key importance will include:

- 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.
- 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.
- Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.
- 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.
- 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.
- Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

Table 4.3 lays out the main changes (at an EU level) for products currently placed on the market as sportsfood in accordance with Directive 2009/39/EC following the repeal of the Directive in July 2016. It should be noted that the information set out in the table relates to EU level changes only, and that changes are likely to vary between Member States based on, most notably, any present or future national legislation on sportsfood.

**Table 4.3: Changes in regulation of FISP at EU level with the repeal of PARNUTS**

Area	Current provisions under Directive 2009/39/EC	under (and	Regulation post 2016
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	related legislation)	
Labelling	Label must contain an indication of the product's particular nutritional characteristics and information on the qualitative and quantitative composition or manufacturing process providing these ( <i>article 9</i> ).	No specific provisions beyond the general provisions laid out in Regulations (EU) No 1169/2011 and (EC) No 1924/2006 and Directive 2002/46/EC or Regulation (EC) No 1925/2006 <sup>33</sup> .
Addition of substances	List of substances which can be added is laid out in Regulation (EC) 953/2009.	Addition of vitamins and minerals, and other substances regulated by Regulation (EC) No 1925/2006.
Composition / suitability*	Products should be suitable for the intended nutritional use / the nature or composition of the products referred shall be such that the products are appropriate for the particular nutritional use intended (( <i>articles 1 and 3</i> )).	No specific provisions on suitability foreseen; claims authorised under Regulation (EC) No 1924/2006 may play a role.

Source: FCEC based on legislation

\* While SCF has laid out categories of FISP, it is important to note that these are not legislatively binding.

According to interviewees, following the repeal of Directive 2009/39/EC, FISP which were previously placed on the market as sportsfood in accordance with the directive will have to either be placed on the market as food supplements in accordance with Directive 2002/46/EC, or as fortified foods in accordance with Regulation (EC) No 1925/2006. Certain potential issues regarding the possibility to use these instruments for placing on the market of FISP were raised by stakeholders. It should be noted that several of these issues pertain to interpretations of the EU level legislation, or the existence of certain national level provisions from which products placed on the market as sportsfood under Directive 2009/39/EC are currently exempt. These issues are examined in more detail in section 4.4.1.2.

While the legal position of all FISP will change in all Member States with the repeal of Directive 2009/39/EC, evidence from the CA survey suggests that two member states; Bulgaria and Denmark; intend to keep their national legislation after 2016. Full details on the expected national legislation are provided in section 4.1.2.

<sup>33</sup> Directive 2002/46/EC for products placed on the market as food supplements; Regulation (EC) No 1925/2006 for products placed on the market as fortified foods.

#### 4.1.2 B2 National legislation and internal market

##### 4.1.2.1 Specific national legislation on FISP after 2016

Table 4.4 presents the likely legal position of FISP after July 2016 on a Member State by Member State basis. The table is based primarily on answers to the CA survey, but is supplemented also by case studies and interviews. Certain important caveats should be noted:

- Three CAs replying to the survey; Germany, Italy and Lithuania; indicated that the future legal position of FISP is unclear as a political decision would be required. Evidence from the German case study suggested that, in the absence of EU level legislation, national legislation is, on balance, likely in Germany given widespread stakeholder agreement on the issue. Evidence from the Italian case study suggests existing legislation will probably be repealed and new national legislation is unlikely in Italy; though this is based on the expectation that most FISP in Italy will be notified as food supplements after July 2016. Given there is currently no national legislation in Lithuania, it is assumed that this will not change.
- Conflicting indications were provided in the survey reply by Belgium, Estonia, Ireland and Romania (see CA survey annex, separate annexe document). Balancing these indications, it has been assumed that there will be no specific legislation in these three Member States and FISP will be covered by other horizontal rules of food law.
- No reply to the survey was provided by Czech Republic, Finland, Slovakia or Spain. For the first three Member States, no existing national legislation has been identified, and so it is assumed that FISP will be covered by other horizontal rules of food law going forwards. In the case of Spain, according to case study findings there have been some discussions with regards to the introduction of specific national legislation for FISP. However, on balance, evidence suggests that the introduction of specific national legislation is unlikely; therefore it is assumed that FISP will be covered by other horizontal rules of food law after July 2016.

**Table 4.4: Likely legal position of FISP after 20 July 2016 by Member State**

National legislation			No specific national rules for sportsfood; FISP to be covered by other horizontal rules of food law
<i>Existing national legislation kept</i>	<i>Existing national legislation amended or replaced</i>	<i>New national legislation introduced</i>	
BG	FR	DE	AT
DK	HU		BE
	EE*		CY
			CZ
			EL
			ES
			FI
			HR
			IE
			IT
			LT
			LU
			LV
			MT
			NL
			PL
			PT
			RO
			SE
			SI
			SK
			UK

**Total: 6****Total: 22**

Source: FCEC based on CA survey and supplemented by case studies and findings of section 3.4.1.

In summary, it is considered likely that there will be national provisions in six Member States; Bulgaria, Denmark, Estonia, France, Germany and Hungary. However, it is important to note that this is by no means certain. As already mentioned, it was indicated that a political decision is required in Germany, so despite the converging opinion of German stakeholders, it is possible that no national legislation would finally be introduced. On the other hand, the possibility that certain Member States introduce national at a later date cannot be excluded. For example, the discussions in Spain suggest that there is a certain level of interest in national legislation. While Italy does not foresee national legislation, there is the assumption that FISP products will be notified as food supplements, and if this eventually does not occur, a change in position may be a possibility.

Table 4.5 sets out areas which are likely to be covered by national legislation in the 6 Member States where national legislation is considered probable. Once again, certain important caveats should be noted:

- Provisions for Estonia, France and Hungary are based on indications of probability provided in the survey (it is assumed that legislation will be introduced for all areas which were marked “fairly likely” or “very likely” in the survey reply). Areas which were indicated “neither likely nor unlikely” or which were indicated as unlikely to a degree have been excluded.
- Provisions for Denmark are based on existing provisions identified in the CA survey.
- Provisions for Germany are based on case study findings.
- No information was provided by the Bulgarian CA with regards to provisions which exist at present, and therefore it is not possible to indicate which provisions are likely to remain going forwards.

**Table 4.5: Likely areas covered by national legislation after 2016**

M S	Notification	Authorisation	Definition	Composition	Labelling	Marketing	Outlets
DE			X	X	X		
DK				X			
EE	X						
FR			X	X	X	X	
HU	X		X	X	X		

Source: FCEC based on CA survey and supplemented by case studies  
No information available for BG.

In summary, composition is the area which is likely to be covered by national legislation in most Member States (4), followed by labelling and definition (3) and notification (2). No Member States foresee an authorisation process or measures covering distribution outlets

Without knowledge of the precise national provisions which will exist post 2016 (which will only become apparent *ex-post*), it is not possible to provide more precise comments on the

extent to which national legislation of different Member States will be similar in the future. The only concrete indication is from Denmark; according to the CA survey, existing national legislation is not believed to be similar to that of any other EU Member State.

#### 4.1.2.2 Impact on internal market

The six Member States which are likely to have national regulation in place for FISP after 2016 represented 24 % of the EU market in value terms in 2014. A breakdown of the proportion of the market impacted by area of rules is provided in Table 4.6.

**Table 4.6: % of total EU market in 2014 value terms predicted to be impacted by national rules after July 2016 (and impacted at present – last column).**

Area of rules	% total EU market (value terms) to be impacted by rules after July 2016	% total EU market (value terms) be impacted by rules at present
Composition*	23%	8%
Definition*	20%	5%
Labelling*	20%	20%
Notification*	1%	16%
Marketing*	>1%	1%
<b>All national rules</b>	<b>24%</b>	<b>24%</b>

Source: FCEC based on CA survey, case studies and Euromonitor data

\* As no information on future provisions in Bulgaria is available, Bulgaria has been excluded from these calculations. For reference, Bulgaria represented under 1% of the EU market value in 2014 according to Euromonitor.

In the absence of details on the national rules which will be in force after 2016, it is not possible to firmly assess the nature of impacts on the internal market. However, based on impacts of existing national legislation (section 3.4.1.2), changes to the legal position of sportsfood (section 4.1.1.3) and interviewee comments, the following impacts seem likely:

- **Composition:** specific formulations may be necessary for certain Member States in some cases. It is very likely that certain FISP which are available on the market of Member States without specific legislation will not be accepted as FISP in some Member States with national rules due to non-compliance with national composition criteria. This latter point may also be relevant for Member States with **definition** criteria.
- **Labelling:** given indications of purpose required under Article 9 of Directive 2009/39/EC will no longer exist after 2016, it seems relatively likely that any national provisions will result in labelling in the Member State concerned that is substantially different from that permitted in Member States which regulated FISP under other horizontal rules of food law<sup>34</sup>.

<sup>34</sup> It is assumed that any mandatory national provisions on the labelling of FISP will, due to article 2 (1) of Regulation (EC) No 1924/2006, fall outside the definition of a health claim in the Member State concerned.

Consequently, different labelling is likely to be required for the same product in different Member States. On balance, it seems likely that the impact is likely to be slightly greater than that of the present scenario. At present, while in some Member States (e.g. Italy) labelling provisions were perceived to form internal market barriers, in others (e.g. France) it was felt that there is no significant barrier as national labelling provisions are sufficiently close to those foreseen in Directive 2009/39/EC (see case study annex).

- **Notification:** notification is predicted to impact just 1% of the EU market; and findings in section 3.4.1.2 suggested that notification is not generally a significant burden at present.

Interviewees for their part generally expressed significant concerns about the potential impact of national rules on the internal market and the free movement of goods throughout the EU. Various interviewees noted that the impact on the internal market will not just stem from specific national provisions for FISP after 2016, but also from more cross-cutting national provisions which can affect FISP. In some cases, these are rules which already impact FISP placed on the market as sportsfood in accordance with Directive 2009/39/EC; for example national limits on the maximum levels of caffeine (see also section 3.4.1). In other cases, these are national rules which did not affect products placed on the market in accordance with Directive 2009/39/EC, but may in future affect FISP as these are placed on the market as food supplements or fortified foods. This can include, for example, national maximum levels for the addition of vitamins and minerals to food supplements which have been adopted in some, but not all Member States; or the national authorisation of certain substances for fortification of food (see also section 4.4.1). However, it is important to note that the FISP will face the same level of harmonisation as other food products falling under other horizontal rules of food law. This point, while not identified by interviewees, is important given that FISP will have the same advantages and disadvantages in terms of harmonisation as other food, and consequently the free circulation of FISP will not be more disadvantaged than that of other foods.

## **4.2 Operators and market impacts**

### *4.2.1 B4 Impacts on competitiveness and operator costs*

#### **4.2.1.1 Current costs stemming from obligations, and changes to them after 2016**

No significant specific costs for operators stemming directly from Directive 2009/39/EC were identified by interviewees. In Member States where there is a notification obligation for sportsfood placed on the market in accordance with Directive 2009/39/EC, there is a small administrative burden for companies; but evidence from case studies and the CA survey suggests that this is not significant. Certain Member States may impose a fee for notification (EL, IT, PT, PL in certain cases – see survey annex, separate annexe document) in which case there can be an additional cost for operators stemming from this; however this cost would not appear to be significant (e.g. 160.20 EUR per product in IT). Evidence from the CA survey suggests that, at present, there is no other additional cost for operators stemming from national legislation. While mandatory labelling indications under EU or national legislation could be considered a potential source of extra cost, it was only considered relevant by certain stakeholders in the case that the label has to be explicitly changed; otherwise it was noted that labelling is a cost that operators have to bear in any case, and that its cost for FISP is unlikely to differ from that for other food sectors. Industry interviewees

noted that differing national legislation across the EU at present may result in operators bearing some extra costs for specific formulations or labelling in certain Member States (see also section 4.1.2).

Based on the changes to the legal position at EU level identified in sections 4.1.1 and 4.1.2, and comments provided by interviewees, changes in operator costs stemming directly from a change in obligations in 2016 can be classified into three areas:

- **Relabeling; *extra cost***; operators will have to perform a one-off relabeling of all products which were previously placed on the market as sportsfood in accordance with Directive 2009/39/EC. There would probably be additional relabeling for FISP in Member States in which labelling provisions are introduced after July 2016 (currently predicted to be three Member States). One interviewee estimated that operators would have to bear one off costs of EUR 150 per product label impacted. Evidence from case studies and interviewees suggests that some operators may have already started placing products on the market under other legislation and relabeling them accordingly. It was also reported that operators periodically relabel FISP of their own accord (about every three years).
- **Notification; *possible saving***; operator may save the notification fee in Member States where there is a notification obligation (and fee for this) for products placed on the market as sportsfood in accordance with Directive 2009/39/EC. However, if products are subsequently notified as food supplements or fortified foods and there is also a fee for this, then there may be no (or even a negative) saving.
- **Reformulation; *possible extra cost***; the extent to which reformulation is necessary depends on a variety of factors (which are outline in section 4.3.1.1). In some cases the need to reformulate would stem from EU level legislation if suitable changes were not made to certain horizontal rules (e.g. the inability of some carbohydrate-electrolyte drinks to attain the minimum levels of fortification for certain mineral nutrients as required by Regulation (EC) No 1925/2006). However, it should be noted that in many cases the need to reformulate would stem from certain national provisions which will only affect FISP once Directive 2009/39/EC is repealed (e.g. maximum levels of vitamins and minerals in food supplements). National level provisions on composition for FISP, where introduced, could also cause the need for reformulation.

In summary, changes in operator costs from relabeling and notification are not likely to be significant; and as implied above, the extent to which individual operators need to relabel will depend on various factors, therefore operators will not be uniformly affected equally by relabeling costs. However, the situation with regards to reformulation is less clear. Depending on any adjustments to EU and national legislation, reformulation could be either minor or widespread; and operator costs impacted accordingly.

#### 4.2.1.2 Impacts on competitiveness and other impacts on operators

Industry interviewees were divided with regards to the possible impacts on competitiveness, and other impacts on operators after 2016. Certain interviewees also felt that the impacts on competitiveness and operators would depend on changes to certain other horizontal rules, and the approach to enforcement taken by Member State CAs. Arguments provided by stakeholders are summarised in Table 4.7.

**Table 4.7: Summary of impacts on competitiveness and other impacts on operators**

Negative impacts	No impact or positive impacts
<ul style="list-style-type: none"> <li>• Directive 2009/39/EC (most notably the labelling provisions under article 9) can be considered a licence to operate for producers of FISP, and with the repeal of the directive, this licence will be revoked.</li> <li>• While Directive 2009/39/EC mandates communication on important ingredients for which there may not authorised health claims (and hence facilitates a certain level of innovation), the repeal of the directive will remove this possibility. Authorisation of a new health claim may be beyond the means of operators; they will therefore struggle to include innovative ingredients in FISP (see also section 4.2.3).</li> <li>• FISP currently on the market will enter into competition with other products which may have compositions which are less suitable for sportspeople (e.g. products with 12% protein which use the authorised health claim; protein only strength and muscle building FISP currently on the market may contain 80-90% protein). This may in turn lead to an overall reduction in the quality of FISP.</li> <li>• Any change in the nutritional balance of FISP stemming from the above point may also impact the perception of EU products in third countries (and consequently impact operators which export).</li> </ul>	<ul style="list-style-type: none"> <li>• The regulation of FISP by other horizontal rules of food law should create clarity for operators at an EU level.</li> <li>• Assuming that the repeal of Directive 2009/39/EC leads to a more harmonized internal market, operators will have more cross border opportunities inside the EU.</li> <li>• Compositional requirements, where they exist, at present, can both impact innovation and cause a burden to operators. In the absence of compositional requirements operators can be more innovative and introduce new products.</li> <li>• Authorised health claims provide the opportunity to communicate on several key ingredients. The industry can collaborate in order to submit collective generic claims for other important substances.</li> <li>• Regulation under other horizontal rules of food law is coherent with the evolution of the market towards mainstream (rather than niche) consumption, and may provide operators with corresponding opportunities.</li> </ul>

Source: FCEC based on interviewees



The validity of both sets of arguments depends on a variety of factors. For example, certain arguments indicating that there will be positive impacts on operators and competitiveness are contingent on the assumption that the EU market for FISP will become more harmonised after 2016 if regulated by other horizontal laws of food law. Section 4.1.2.2 however indicated that in certain areas such as composition, the level of harmonisation may become lower due to the introduction of specific national provisions for composition in some Member States. Similarly, certain arguments indicating that the removal of a licence to operate given the inability to communicate on some important ingredients is not entirely coherent with findings relating to composition (section 3.1.2) and claims (section 3.3.4) given that there are authorised claims for several major ingredients.

Summarising the impacts on competitiveness, it seems likely that individual operators will be impacted differently depending on their situation. It is likely that certain operators may benefit from certain opportunities opened up by the change in legislative position (e.g. the “mainstreaming” of FISP), while other operators may feel that they are subject to unfair competition as a consequence of this.

#### *4.2.2 B6 SME consequences*

Interviewees did not provide specific foreseeable impacts on SMEs in relation to the repeal of PARNUTs; impacts are generally expected to be similar to those for operators as a whole (section 4.2.1). Despite this, some general information have been collected both on the current threats for SMEs competitiveness today and on the expectable most significant changes in the regulatory framework which could affect directly or indirectly this class of operators.

In general terms, it is worth noting that SMEs play a significant role in the FISP sector, especially in certain categories of products. For instance, whereas the market of RTD sportsdrinks is concentrated under few major players (e.g. Coca Cola, Pepsi), SMEs account instead for the majority of the market of supplement style sports nutrition products (see also section 3.2.1.4).

Although the SMEs importance may vary significantly across Member States (as indicated by case study findings), it is widely recognized by almost every category of interviewees that some specific features of FISP market affect smaller companies more than the rest of the market:

- Innovation is crucial in the sector, as detailed in section 3.2.3 and in the following section 4.2.3. Due to the limited resources that SMEs are able to invest, it is clear that in case of negative impacts on innovation of a new regulatory framework, these are likely to affect SMEs more than major players.
- Access to financing is a significant challenge for the SMEs that want to grow in a very innovative sector. The problem has been exacerbated by the enforcement of Regulation (EC) No 1924/2006 on health claims, since the high costs stemming from the procedure for

presenting dossiers for claim approval, and the high degree of uncertainty about a positive outcome of the same, often prevent SMEs from starting such process and from presenting dossiers.

- A general trend towards market consolidation has been cited by more than one interviewee; this can be seen as the response to increased efficiency in the market. More specifically, the nature of the industry results in the need for large technical structures for those companies that want to compete without being limited to secondary roles as third party or contract manufacturers. This technical structure typically covers multiple areas:
  - Scientific committee / experts to be involved both in product development and production.
  - High-level quality check measurements.
  - Manufacturing phase based on instruments for detection and dosage typical of the pharmaceutical sector.
  - Legal experts and consultants in order to understand different legal frameworks and implications related to new products and new markets.
- Multiple interviewees noted that one of the most limiting obstacles for SMEs in the EU market at present is the different regulations across Member States and in some cases the coexistence between national legislation and EU-level one. In this context, any simplification from a legal standpoint and any improvement in harmonization across countries would in all probability enhance the chances for effective intra-EU trade for smaller companies<sup>35</sup>. However, as seen in section 4.1.2, this simplification is far from guaranteed given that some six Member States appear likely to have national rules, and national rules in other, cross-cutting areas (e.g. caffeine content) may also persist.
- While the categories of cost identified in section 4.2.1.1 would impact both SMEs and larger players, certain interviewees believed that any necessity of reformulation could have a higher proportional (and significant) impact on SMEs than on larger players. As concluded in the previous section, any costs of relabeling was judged as a minor with minimal impact both on large players and SMEs.

#### 4.2.3 B5 Impacts on innovation

Operators consider innovation as an important economic driver of the sector (see also sections 3.2.3 and 4.1.1.1). Companies are aware that current and future stronger brands will be built on the basis of the capacity to innovate. Moreover, the inclusion of new targets of consumers and the specialisation of the traditional targets push the companies toward the necessity to innovate in order to attract them with new products that meet their new, sophisticated needs. In this light, unsurprisingly, several concerns about the impact on innovation of the repeal of the PARNUTs Directive have been collected from stakeholders. These concerns are mostly connected with the uncertainty about the introduction of new vertical legislation at national and EU-level. For this reason, even if it has not been possible to draw up an unequivocal cause-effect relationship between innovation and the post-2016 legal framework, the future uncertainty was generally identified as a factor with significant negative impact on innovation. Having said that, while almost all operators consider the absence of a clear position on the possibility to introduce whether or not a new legislation as

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<sup>35</sup> Larger players are already able to compete at EU level thanks to their more complex technical structure.

an obstacle to the innovation of the sector, the positions detected on the impact of a new legislation, or the absence of it, present a high degree of variety.

On the one hand, the repeal of PARNUTs without the introduction of a specific vertical legislation for FISP raises concerns from parts of the industry about innovation. The main concerns of this nature expressed by stakeholders are:

- **Ability to communicate the product and therefore the innovation:** innovation is directly linked with the possibility for the companies to be rewarded by the market with an extended number of consumers, attracted by new products, and/or with higher prices for innovative products. Communicating the innovation to the market is necessary to obtain the reward. Certain operators' major concerns for the future of innovation in the sector are associated with the possibility to communicate the scope and the functions of FISP after the end of PARNUTs. In fact, the possibility to use this type of statements is considered at risk after 2016. Instructions of use and current denominations (e.g. "pre-post-during exercise", "intended for sportspeople") are in fact one of the main tools of marketing (see section 3.3.3). Stricter constraints to the use of statements in the marketing of products are likely to make it more difficult for producers to communicate new ingredients and new formula, reducing the incentive to innovate (see also section 4.4.1.2).
- **Uncertainty associated with obtaining the authorization on new health claims:** in case such claim-like statements are not permitted anymore, unless the possibility to make a non-specific claim linked to a specific claim under Article 10(3) of Regulation (EC) No 1924/2006 exists for a certain product, the statement used, if considered to have an impact on the health, would fall under the scope of Regulation (EC) No 1924/2006. This piece of legislation will probably be the only possibility for operators to communicate on innovative products in terms of ingredients and formulas. In relation to the link between Regulation (EC) No 1924/2006 and innovation, two main difficulties have been identified by stakeholders:
  - The application process is considered too complex and expensive for the majority of individual operators. Only few operators can bear the high costs of the claim approval process and most of times big companies too do not have an in-house capacity to manage the process and they externalize this work to external, highly expensive, consultants. The other obstacle to the innovation originating from the application process of Regulation (EC) No 1924/2006 is that, apart from specific cases where protection of proprietary data is granted, claims are authorized for all to use. Therefore, while the small and medium enterprises are damaged by the high costs of the process, big companies, which can afford the costs, can be discouraged because they bear the full cost of the process but all the competitors benefit of a positive result. One stakeholder, in the context of the UK case study, provided details of their experience with an application for a health claim, and the difficulties that they perceived with the process (see case study annex).
  - The results of the process do not depend solely on the scientific opinion of EFSA. Regulation (EC) No 1925/2006 aims at ensuring the presence of a clear and fact-based cause-effect relationship. Some claims (e.g. the ones on caffeine) that have received a favourable opinion by EFSA in this respect have been put on-hold for further discussions after the request of a number of Member States of reconsidering

such approval in the more general policy context of reducing the health risks associated with an intake of caffeine by consumers. This has been identified by some operators as a factor that increases the degree of uncertainty on the outcome of the approval process and that prevents operators themselves from submitting dossier for the approval of health claims.

- **Uncertainty about the use of non-permitted nutrition claims:** several permitted nutrition claims under Regulation (EC) No 1924/2006 are currently used on FISP (e.g. high protein). However there are nutrition claims not present in the list of permitted nutrition claims under Regulation (EC) No 1924/2006, but which are widely used by FISP operators at present (e.g. high energy product) due to mandatory indication requirements under Directive 2009/39/EC. Operators expressed their concerns about their ability to communicate on products if the use of these nutrition claims were not be allowed. As general consequence, if the list of permitted nutrition claims will not be updated including these claims, the impossibility to communicate this information is considered by operators as an obstacle to the innovation; however stakeholders also noted a conflict in this respect in terms of nutrition claims suitable for sportspeople and those suitable for the general population.
- **Uncertainty at MS level:** companies operating in several EU Member State markets already face a number of barriers when trying to launch one product to suit all markets, because of differences in national legislation. After the repeal of the PARNUTs Directive, a possible scenario is the increasing of MS which decide to implement additional national rules. The introduction of differentiated national legislations will result in barriers of the market among countries (see section 4.1.2), which will reduce the market for the products and can result in a reduction of the investment in innovation.

Within such scenario, certain operators foresee a market with a still high level of innovation, but with such innovation not focusing on “substantial” aspects (e.g. launch of new ingredients and/or combinations of ingredients): the innovation would instead be concentrated around products with claims already approved, which would be innovated just for “less demanding” elements such as flavours, packaging and formats. On the other hand, the pace of the introduction of “substantial” innovations on new ingredients and/or formulas is at risk of decreasing.

On the other side of the collected opinions, other operators do not foresee negative impacts on innovation stemming from the enforcement of the new legislation and from the absence of a specific EU-level legislation on FISP. On the contrary, these operators believe that sector innovation will be at risk only if a more restrictive legislation is approved. Also these operators express their concerns on possible restrictions on the use of certain indications (notably those which are currently permitted under Article 9 of Directive 2009/39/EC) in marketing, but do not see a complete ban on the use of such important communication tools as a realistic scenario. Apart from the present moment of uncertainty, certain operators considered the introduction of a specific legislation on the FISP as potentially negative for the level of innovation of the sector. In this framework, the main threat to the innovation is the risk of an excessive regulation which, starting from a useful definition of products, can lead to an over-categorization. As products do not always fall into neat categories and given the diversity of products used, an over-categorization can have, as a consequence, a burden which would limit the launch of new products. Operators who share this common view consider that, as long as no specific legislation would be established for FISP, there would indeed be sufficient room for innovation. These operators also believe that, through industry collaboration (including between SMEs), the submission and eventual successful approval of

health claim dossiers would be possible<sup>36</sup>. From this perspective, the fall of FISP under horizontal rules of law is seen as an opportunity for innovation and not an obstacle.

#### 4.2.4 B3 Impacts on trade

Data from section 3.2.4 indicated that the EU's largest trading partner for FISP is the US (import).

Interviewees and case studies also provided some additional information on some trade related issues:

- Some third country operators use EU-based sub-contracted manufacturers for the production of FISP for the EU market, and hence facilitate compliance with relevant EU legislation (whether it be certain provisions of Directive 2009/39/EC / Regulation (EC) No 953/2009, or other horizontal rules). There was the perception that this tendency may have increased in recent years.
- There may be direct imports from Third Countries of FISP that do not conform to EU legislation. These FISP primarily reach EU consumers through direct sales channels (e.g. internet purchases), though in certain case study Member States it was believed that certain distributors may import and resell these products.

Overall, taking all evidence on trade and operator impacts into account, it seems likely that impacts on trade will generally be in line with those on operators outlined in 4.2.1. More specifically:

- Direct costs stemming from EU legislation are unlikely to change significantly; therefore EU based exporters are unlikely to be adversely affected by legislative compliance costs. That said, the possibility that the cost base of EU based exporters will change as an indirect result of other factors (notably any change in composition of products) cannot be entirely precluded. In the case that there were such changes to the costs base, there could be potential effects on the competitiveness of EU exports both through price and also through perceptions relating to compositional suitability of EU products for the needs of sportspeople (see section 4.2.1.2).
- As will be the case for EU based operators which sell their products in multiple Member States, third country operators will most probably be faced with different national rules in certain Member States. However, this is already the case to an extent (see section 4.1.2).
- Certain formulations of products which are currently permitted under Directive 2009/39/EC may not be permitted under other horizontal rules of food law. As is the case for EU based operators, this could either be due to certain national provisions (e.g. maximum levels of vitamins and minerals) or EU level provisions, most notably attaining minimum levels of fortification as required by Regulation (EC) No 1924/2006.

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<sup>36</sup> It should be noted that the collaborative submission of health claims dossier for claims relating to sport was only identified in one case; that outlined in the UK case study; therefore it is not clear to what extent e.g. SMEs may be able to obtain authorisation of a health claim.

- It is doubtful that the direct imported products which are not currently in compliance with EU legislation will be legal in the EU following the repeal of Directive 2009/39/EC. The legality of such products is only likely to change in very specific, theoretical cases; for example, if product contains a substance which is not included in the list of substances currently permitted for use in PARNUTs foods (Regulation (EC) No 953/2006), but also is not prohibited by EU or national legislation under other horizontal rules of food law<sup>37</sup>.

Certain interviewees identified some possible trade-specific impacts. These were:

- **Loss of the perceived quality assurance provided by specific EU legislation.** Certain interviewees noted that EU legislation can be perceived as a guarantee of quality in some Member States, and consequently exports of such products can benefit from the presence of legislation. Infant formula was provided as an example in the area of PARNUTs; one interviewee reported that operators can export up to 85% of their production to the Far East due to high demand from consumers in the region stemming from the guarantee of safety provided by specific EU legislation. However, certain factors should be borne in mind when considering this possible impact:
  - The limited information on trade does not suggest that levels of export of FISP by EU based operators are near the same level as those of infant formulae. It is possible that consumers are more sensitive about the safety of infant formulae than of FISP, in turn driving demand for EU-produced infant formula, though, it should be emphasized that no evidence to confirm this was identified during the course of the study. Furthermore, EU level provisions for infant formula are considerably more detailed than those for FISP<sup>38</sup>.
  - It is not clear to what extent demand for EU products from certain Third Country consumers is due to dedicated legislative provisions for specific categories of food, and to what extent it is due to general horizontal rules of food law. No evidence was identified to separate the importance of the two categories of legislative provisions.
- **Possible difficulties with the acceptance of FISP in the case of export to certain Third Countries.** As was noted in section 3.4.2.2, certain third countries require certification of compliance with EU legislation for FISP before they can be imported. However, as noted in the same section, the requirements of this accepted EU certification depend on the categorisation of food products as adopted by the third country itself (e.g. whether FISP are considered to be food supplements, PARNUTs, products, etc. by the third country's legislation). In summary, it is unclear to what extent any such third country requirements are contingent on the recognition of FISP as a legislative category in EU legislation (as per section 3.4.2.2 interviewees were unable to clarify this point).

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<sup>37</sup> This theoretical case assumes that the product containing the substance at present is considered to be placed on the market as sportsfood in accordance with Directive 2009/39/EC. In this case, the substance in question would change from being not permitted for use in a product placed on the market as sportfoods in accordance with Directive 2009/39/EC to a substance which is permitted for use in general food.

<sup>38</sup> Directive 2006/141/EC has historically regulated infant formula and this contained, inter alia, precise labelling and composition requirements. Under Regulation (EU) No 609/2013 this directive will be repealed, and the adoption of a delegated act for infant formula is foreseen by 20 July 2015.

### 4.3 Consumer impacts

#### 4.3.1 B8 Impacts on consumer choice and behaviour

##### 4.3.1.1 Consumer choice

In general terms, the uncertainty surrounding the legal framework for FISP and its interpretation at national level after 2016 makes difficult any prediction on changes in consumer choice and behaviour after the repeal of PARNUTs.

Feedback collected during interviews identified the potential threat of large scale reformulation of FISP currently on the market the most significant element which could impact consumer choice. The degree of formulation will ultimately be driven by two factors:

- **Composition criteria in Member States introducing national legislation.** As long as composition criteria are not too strict, no withdrawal nor reformulation will be necessary, thus preserving the possibility of choice.
- **Restrictions in other horizontal rules of food law** (either at EU or national level). As noted in section 4.4.1.2, certain rules affecting composition exist from which FISP placed on the market as sportsfood in accordance with Directive 2009/39/EC are currently exempt. Without adaptation of these rules, the reformulation or withdrawal of certain products will be required.

The large scale reformulation of products can be seen as a “worst scenario” from the producers’ standpoint. Evidence from the CA survey suggests that; widespread formulation is not likely; but some reformulation is. 59% of responding CAs believed that no reformulation was likely; 9% that limited reformulation was likely; and 41% that moderate reformulation was likely.

Regardless of the level of reformulation required, some other possible impacts on consumer choice after 2016 were identified by interviewees. It should be emphasized that these impacts are speculative.

- **Changes in the range of products available.** As previously noted, there is fair amount of evidence to suggest that the market may be pushing towards a wider product range as it becomes mainstream (see section 4.1.1.1). One way in which the post 2016 legal position was identified as interacting with this trend was through the possible emergence of products on the market using different ingredients in lower quantities than at present. For example, protein products present on the market at present may contain energy content as high as 90% protein (section 3.1.2.2), while the authorised health claim only requires 12% (section 3.3.4.2). Consequently, in the absence of the suitability provisions (article 3 of Directive 2009/39/EC), certain operators may be incentivised to produce FISP with significantly lower levels of protein. It should, however, be noted that such a practice is contrary to the industry’s perceived strengths of research and proven product effectiveness (section 3.2.2). Nonetheless that does not preclude the possibility that operators not currently active in the area of FISP may adopt such practices.
- **Reduced availability of niche products.** As noted in section 4.2.3, any potential disincentive in innovation could result in an establishment of products with authorized claims and in a

progressive reduction of the availability of smaller and niche products, thus limiting the consumer choice

- **Possible minor changes on the basis of the actual situation after 2016 in different Member States.** An interviewed provided an example of the French market where pharmacies are not allowed to sale foods for general consumption, in the case of the absence of an alternative legislation regulating FISP, the possibility to purchase such products in pharmacies would end; similar consideration also have been reported for Italy. Such changes may both impact consumer choice and consumer behaviour.

#### 4.3.1.2 Consumer behaviour

Similarly to consumer choice, also elements potentially affecting consumer behaviour are difficult to identify in advance and it is necessary to proceed by assumptions. In general terms, the importance of indications mandated by PARNUTs for producers have already been highlighted in Section 3.3.3; through the consumer survey it has been possible to check the importance for consumers of some of information reported in label.

While some information will reasonably always be present on labels (list of ingredients, warnings on potential overdose, side effects, etc.) regardless the legal framework in force, other secondary indications might be limited or excluded in absence of a specific regulation, namely the expected results or effects and specific consumption instructions (pre-during-post exercise, etc; see also section 4.4.1.2). Table 4.9 summarizes the percentage of consumers who declared that these two types information should never be missing on the label of FISP (see also the consumer survey annexe; separate annexe document).



**Table 4.8: Information that should never be missing on the labels of FISP**

Product categories	Expected results/effects			Consumption instruction		
	Sportspeople	Lifestyle users	Total consumers	Sportspeople	Lifestyle users	Total consumers
Total FISP	22%	14%	20%	24%	21%	23%
Sportsdrinks	21%	12%	18%	23%	22%	23%
Sport energy bars	22%	17%	21%	23%	17%	22%
Protein-based products	24%	17%	23%	27%	24%	26%
Performance boosting products	21%	14%	20%	23%	23%	23%

Source: Consumer survey

In general terms consumption instructions appear to be crucial for more consumers with respect to the expected results and effects; there is also a higher convergence of answers between sportspeople and lifestyle users for this kind of information. As imaginable, the perceived importance of this supplementary instructions increases in presence of more technical products (e.g. protein-based products).

Consequently, results from the consumer survey suggest that information on FISP labelling that is potentially at risk after 2016 at present play an important role in the purchasing behaviour. However, as noted in section 4.4.1.2, the degree to which this information is at risk depends on national CA interpretation and application of other horizontal rules of food law relating to labelling. While the indications mandated by Article 9 of Directive 2009/39/EC will no longer exist, Regulation (EU) No 1169/2011 requires all foods to provide instructions of use where it would be difficult to make appropriate use of the food in the absence of such instructions. Rules on claims also require the provision of all necessary information for consumers to ensure the appropriate use of the food, when such food bears a claim. The extent to which these can be used will depend on both the nature of the information which operators wish to provide, and the interpretation of the national CAs of these aforementioned provisions.

#### 4.3.2 *B9 Impacts on consumer protection*

The theme of the impact on consumer protection has generated a wide range of different stakeholders' views. In particular, divergent points of view emerged in relation to the necessity to regulate the FISP sector in order to enhance consumer protection.

First of all, it is necessary to specify that, from the interviews with operators and with CAs, different definitions of the group of consumers to protect have emerged. The main divergence on this point is related to the possibility to consider sportspeople as a vulnerable group and, consequently, a group with special nutrition needs. According to an interviewed national consumer association, sportspeople do not need to be targeted as a group of consumers with special needs, as they need the same types of nutrients needed by the general population, but in higher quantity. At the other end of the spectrum, a rather common opinion among producers is that the condition of use of the relevant products for the study in relation to physical activity can be assimilated to a condition of vulnerability, in which special needs should be considered, and this is reflected by the high level of certain nutrient present in FISP (see section 3.1.2). It was also noted by some Member State level stakeholders that the main aim of a specific legislation on FISP should be the protection of the general public rather than the specific group of sportspeople, and in this context the best way of protecting the general public from products which contain nutrients in levels which are unnecessary and potentially dangerous is considered the enhancement of the current legislation, rather than vertical specific legislation on FISP. This point of view should be considered in light of the recent extension of the target group of FISP consumers to people which are not sportspeople, but lifestyle users. Differences in the consumption patterns between the two groups (section 3.3.1.1) can be also considered as the basis for different needs in term of consumer protection. In particular, possible regulatory constraints in communicating to the consumers the effects and the instructions of use of products may especially affect the consumers that have limited access to other sources of information, in particular amateur sportspeople and lifestyle users. According to interviewees, even some groups of consumers of highly specialized products can be affected by the absence of information on the label: professional and semi-professional sportspeople that practice minor sports and are not part of a team are often not supervised by a sport nutrition specialist. Any lack of information on the effects of products and/or on instructions of use might lead to negative consequences for their health.

Given the above premises, different views have been collected in relation to the necessity of adopting a specific legislation on FISP, in order to enhance the protection of consumers.

A recurring opinion expressed by certain operators is that the consumer protection rules already in force at EU level are sufficient to ensure the protection of FISP consumers: as a consequence, consumers are unlikely to be endangered by the absence of a specific regulation for FISP. On the other hand, these consumers might be affected in case a more restrictive national legislation on FISP is introduced. According to such position, the legislation now in force at EU and national level is considered sufficient to ensure a good level of protection for all consumers in relation to the consumption of FISP. The introduction of specific legislation is not seen as a guarantee for increased consumer protection, while horizontal legislation on consumer protection is believed to ensure better protection than the potential introduction of vertical legislation specifically targeting FISP products.

On the other hand, certain operators considered that only specific, EU-wide rules can give consumers the protection they need. In the framework of such position, the following issues were identified by these operators as raising major concerns:

- **Information on the label:** the most serious consumer protection issue identified by interviewees was that of information which can be provided on product labels after 2016 (see also section 4.3.1.2). The indication of “food intended for sportspeople”, or similar indications of suitability for a particular nutritional use, are required by the PARNUTs directive. Indications on the label about the purpose for which FISP products are intended are also rooted in the PARNUTs directive and, once the directive will be repealed, there is a strong sense of uncertainty about the information items that will be allowed on the labels. In the case that no national legislations were eventually to be adapted, and that FISPs were to fall under other horizontal rules of food law, certain interviewees foresaw negative impacts on consumer protection stemming from the changes in product ranges and labelling indications. Furthermore, there were some concerns that, without adaptations to other horizontal rules in order to ensure that there is suitable information on the label, the risk of the general public using FISP products which contain nutrients in levels which are in conflict with the nutritional needs of the average person would be increased.
- **Food not intended for sportspeople marketed as FISP:** certain operators may try to push the boundaries of FISP by targeting sportspeople with products which are not properly tailored for sportspeople. Consequently, while this may result in a wider consumer choice, it may also have negative impacts on consumer protection.
- **The ability to indicate high energy on products, and to restrict the use of such wording (if eventually permitted) to FISP.** At present, certain FISP products placed on the market as sportsfood in accordance with Directive 2009/39/EC bear indications of high energy or similar. These indications are placed on the product under Article 9 of Directive 2009/39/EC. Such statements at present are not authorised nutrition claims under Regulation (EC) No 1924/2006 as they are not considered beneficial to the general population. Consequently, consumers will not be able to receive this information after the repeal of Directive 2009/39/EC. In the case such nutrition claims were to be permitted under other horizontal rules of food law, any changes to legislation would likely need provisions in order to ensure that high energy products for sportspeople can be labelled in a way to make it clear they should only be used by consumers with the corresponding needs.

In relation to the protection of consumers, other issues emerged during the study through interviews and case studies. These themes, illustrated below, are not directly linked with the changing of the legislative framework after 2016; however, they contribute to draw the full scenario of the situation related to FISP consumer protection in EU.

- Professional and semi-professional sportspeople are normally well informed in relation to ingredients and formula of products that they consume, and it is believed that the absence of a specific EU-level regulation will not affect them. A general agreement has been collected in relation to the importance of price factor as an access barrier to highly specialized products. High price and necessity to use such products frequently and in a continuous way is a barrier to the use of highly specialized products among the non-target group. The price factor has been described as a mechanism of protection of lifestyle consumers.
- Interviewed representatives of sportspeople engaged in professional competitions expressed their concerns in relation to the risk of inadvertent assumption of doping substances through consumption of FISP. Such consumer group deems essential a guarantee that consuming FISP

does not jeopardize their compliance with anti-doping rules in sport competition. For such athletes, transparent and certified information on product composition, enforcement of controls on introduction of illegal products in the EU, and proper training of personnel in retail outlets dealing with highly specialized FISP products are of paramount importance from a consumer protection standpoint, in order to avoid inadvertent doping. It was noted that there is a voluntary UK-based doping-free assurance scheme for operators (Informed Sport) which covers around 300 products, and a voluntary national programme (AFNOR) in France.

A general concern clearly emerged from interviews in relation to the necessity of proper addressing of issues related to online purchase of products imported from third countries, and provision of adequate information to consumers about the potential health risks and anti-doping implications deriving from consumption of products not in compliance with EU-level and national regulations.

#### 4.3.3 *B7 Impacts on price*

##### 4.3.3.1 Drivers of the price of FISP

According to interviewees, the main drivers of the price of FISP are:

- **Raw material price.** Certain ingredients can be considered similar to commodity products (though possibly with multiple price points based on quality – e.g. protein), with the ingredient available from multiple suppliers. However, it was noted for other ingredients that there may be just one supplier due to the costs of authorizing a novel food ingredient in the EU, and in this case the company may set a monopoly price (e.g. DSM – Meg 3, a special form of omega 3).
- **Innovation.** The research and development overhead of certain companies (including costs related to employing specialist personnel). The importance of this driver may change between companies.
- **Anti doping practices / HACCP obligations.** The cost of these have to be factored into the final price .
- **Packaging and brand equity.** These may enable certain companies to set slightly higher prices for their products.
- **VAT.** As was demonstrated in the case of the UK in 2012, any changes to VAT classifications may impact the price of the final product (see box below).

Beyond the specific example of VAT, legislation was not considered to be a driver of price at present. However one interviewee felt that, in the case any compositional requirements were introduced by national legislation, these would in turn become a key driver of price in the Member State in question.

#### **Box 1: Example of the impact of price: VAT in the UK**

VAT was introduced on sports nutrition products in the UK in the second half of 2012, resulting in a corresponding price rise. According to a combination of information from Euromonitor and case study interviewees, the reactions to this price rise was multi-faceted

- Some consumers tried to stock up in advance of the introduction of VAT, leading to a short term decline in sales after the price increase as consumers used stocks.

- Producers launched new products (most notably products in smaller volumes, for which the absolute increase is lower) in order to make the price increase less obvious to consumers.
- Promotions were used to try and keep consumer demand over the short term.
- Some cases of reformulation may have occurred in order that the product be classified as a food product rather than a sports nutrition product, and hence benefit from a 0% VAT rate.

The reactions of consumers, producers and retailers; i.e. attempts to combat the enforced price rise; suggest a certain level of price elasticity of demand over the short term.

Source: case study

One interviewee distinguished between drivers of price in the markets for sports nutrition products and sportsdrinks. Sports nutrition products were considered to generally be low volume / high price products, due to difficulties in scaling up production to industrial scales for the majority (an estimated 90%) of operators. The sportsdrinks on the other hand were considered to be higher volume products, and subsequently prices are lower. Evidence from section 3.1.3 confirms the assertions of this interviewee to an extent.

However, another interviewee believed that there was downward pressure on the price of FISP as a whole, and that gross margins were approaching that of other fast moving consumer goods. This downward pressure was attributed to a variety of factors including the movement to the mainstream of FISP products, the emergence of alternative ingredients and new methods of selling (including the supermarket channel) which place considerable downward pressure on prices.

In summary, evidence suggests that the drivers of price are primarily cost based, though packaging and brand equity may enable certain producers to charge a premium. Legislation is not currently considered a significant driver with the exception of VAT classification.

#### 4.3.3.2 Change in legal position and price

Certain interviewees felt that there would be no direct impact on price if FISP fall under other horizontal rules of food law after 2016 as prices are determined by costs and market factors (as outlined in the previous section); and that multiple price points were already opening up in the FISP market due to the presence on the market different qualities of product (often based on the use of different ingredients). However, other interviewees believed that there could be downward pressure on price stemming indirectly from regulation under other horizontal rules of food law. More specifically, as mentioned in section 4.3.1.1, these interviewees believed that without specific legislation, alternative FISP products which are less fit-for-purpose (for example, protein products with lower protein content which may also use lower quality protein) would emerge as direct competition to incumbent FISP products. These alternative products, which would likely be cheaper than existing products, would consequently place downward pressure on market prices as a whole. It should also be noted that the example of the UK demonstrates that any change in the VAT classification of FISP after 2016 stemming indirectly from the repeal of Directive 2009/39/EC may impact prices in

certain Member States. These impacts, which will depend on national product classifications for VAT, will be Member State specific.

In Member States that have specific legislation including compositional requirements (potentially DE, DK, FR and HU), these compositional requirements may become a key driver of price after 2016. The extent of these impacts will depend on national compositional requirements themselves which, at present, are unclear.

In summary, legislation at present would not appear to be a direct driver of price; costs and market factors are key. However, through the possible impact on the nature of products on the market (and hence the cost of production), legislation indirectly may impact price. The extent of this impact on price will depend on the extent to which the composition of FISP products on the market change after 2016, either in response to perceived new economic opportunities provided by the repeal of Directive 2009/39/EC, or due to the introduction of national legislation with compositional requirements.

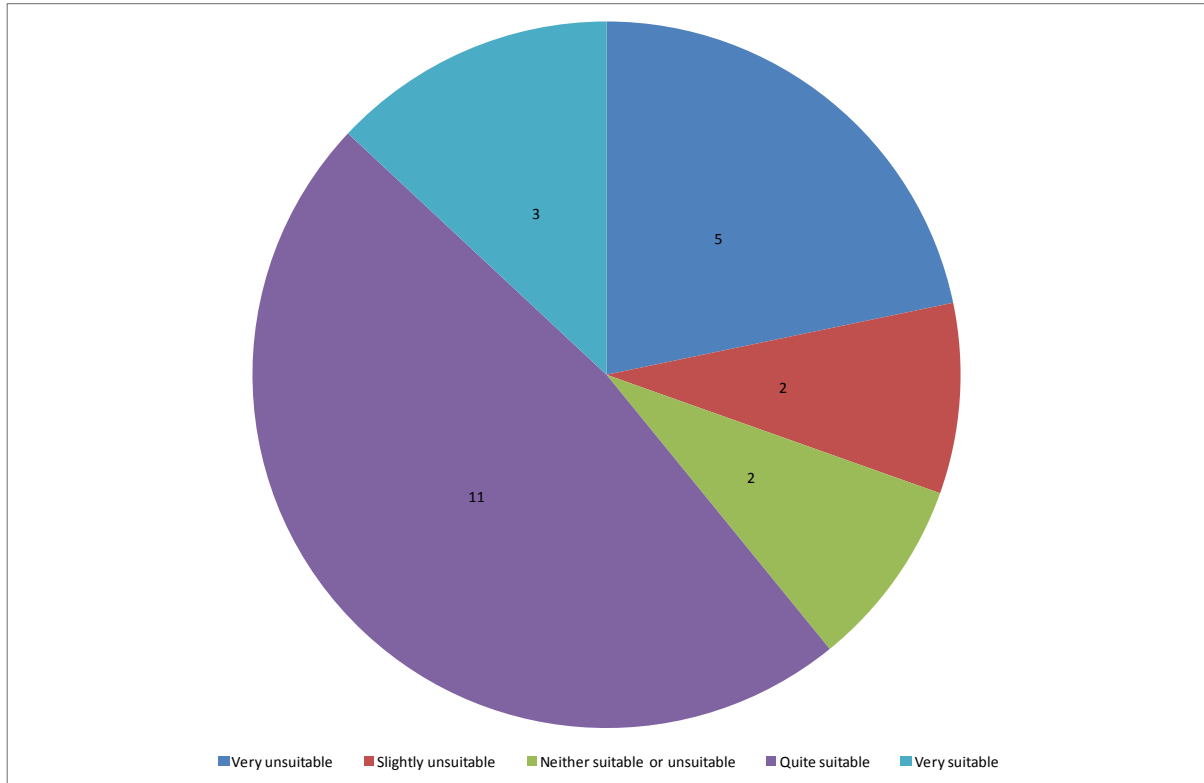
#### **4.4 Regulatory environment and competent authorities**

##### *4.4.1 B10 Impacts on the regulatory environment*

###### **4.4.1.1 Suitability of other horizontal rules of food law to regulate FISP**

Both CAs and interviewees were divided on the suitability of other horizontal rules of food law to regulate FISP products, with some interviewees and CAs of the view that other horizontal rules of food law are suitable and others that it is not. Figure 4-1 presents CA ratings of the suitability of other horizontal rules of food law for the regulation of FISP. A majority (61% of CAs) believed other horizontal rules to be either quite suitable or very suitable for the regulation of FISP.

**Figure 4-1: CA rating of the suitability of other horizontal legislation of food law for the regulation of FISP**



Source: CA Survey  
N=23

The main arguments identified for and against the suitability of other horizontal rules of food law are presented in Table 4.9.

**Table 4.9: Summary of arguments for and against the suitability of other horizontal rules of food law for the regulation of FISP.**

For (horizontal rules are suitable)	Against (horizontal rules are unsuitable)
<ul style="list-style-type: none"> <li>• The size of the FISP market is large and constantly growing, meaning that it is not possible to specially monitor this market; general rules should be used.</li> <li>• There is an existential question as to whether sportspeople need special food other than normal food or whether their needs are sufficiently different for FISP to constitute a separate group.</li> <li>• Experience shows that it is not possible to establish compositional requirements for the legal category of sportsfood.</li> <li>• Communications concerning foods intended for sportspeople can be covered by Regulation (EC) No 1924/2006; though it may sometimes be difficult to correctly frame the use of claims intended for sportsfood as this category is not defined.</li> <li>• Claims made for sportspeople should be scientifically substantiated in the same way as for foods for normal consumption.</li> <li>• Uniform information would be available to the consumer in line with that for other foods; though in some cases information may not be suitably adapted to sportspeople.</li> <li>• Regulations (EC) No 178/2002, 1924/2006, 1925/2006 and (EU) No 1169/2011 as well as Directive 2002/46/EC can deal with most safety, composition and labelling issues.</li> <li>• General food law has substantially evolved since first discussions on the regulation of sportsfood, (as shown by the aforementioned pieces of legislation) and so specific provisions are no longer needed.</li> <li>• International and voluntary standards, such as the world anti-doping agency code, can provide a suitable framework</li> </ul>	<ul style="list-style-type: none"> <li>• The qualitative and quantitative composition of FISP means they are significantly different from other food products.</li> <li>• FISP can be considered riskier products due to composition, the promotion of product by people without nutritional or scientific qualifications and their sale through non-mainstream outlets such as gyms, internet, etc.</li> <li>• Horizontal rules do not include sufficient provisions for confirming the suitability of such FISP for the specific needs of sportspeople.</li> <li>• Specific EU regulation is needed in order to protect public health. Due to composition, certain FISP can be a risk to consumers including children and adolescents; specific rules are therefore needed. Health claims and FIC may help control information, but national interpretations of these can vary. Other horizontal rules do not sufficiently control the safety / suitability of FISP.</li> <li>• The novel food procedure for new ingredients is long and complex.</li> <li>• Other horizontal rules do not provide sufficient opportunities for communication on FISP, consequently impacting both consumer protection and innovation. Notably there is no suitable legislation foreseen in other horizontal rules for enabling suitable communication on combinations of substances with synergistic effects.</li> <li>• Horizontal rules do not contain specific provisions for dealing with the presence of certain substances in FISP.</li> </ul>



For (horizontal rules are suitable)	Against (horizontal rules are unsuitable)
for addressing doping issues.	

Source: FCEC based on CA survey and interviewees

#### 4.4.1.2 Potential issues identified for FISP under other horizontal rules of food law

A range of potential issues with other horizontal rules for the regulation of FISP were identified during the course of the study based on the CA survey, case study findings and interviewees. These potential issues can be broadly divided into three groups:

- **Potential issues with other horizontal rules of EU food law.** These are potential issues which have been linked to EU law and for which there are potential impacts regardless of national interpretation.
- **Potential issues stemming from national interpretation of other horizontal rules of EU food law.** These are potential issues which have been linked to EU law, but for which there is a degree of subjectivity depending on interpretation of the EU level law. Consequently there may either be no issue, minor issues or more significant issues depending on the interpretation of Member State CAs.
- **Potential issues stemming from other rules of national food law.** These are issues which have been identified which are caused by the existence of certain provisions at national level. These national provisions may be linked to certain pieces of EU legislation.

Findings based on the CA survey, case study findings and interviewees are presented in more detail below under the three headings identified above.

#### Potential issues with other horizontal rules of EU food law.

- **Fortification:** it was noted that for sportsdrinks, the minimum fortification levels required under Regulation (EC) No 1925/2006 may not be reached if the electrolyte composition contains small parts of magnesium, calcium and potassium in order to mirror the content of sweat (see section 3.1.2.1). Currently Article 1 (3) of Regulation (EC) No 1925/2006, together with the PARNUTs status of sportsfood placed on the market in accordance with Directive 2009/39/EC enables these substances to be used in sportsdrinks in smaller amounts.
- **Labelling:** Regulation (EU) No 1169/2011 requires the indication of *salt* rather than *sodium* on label. For carbohydrate-electrolyte drinks, it is important to be able to communicate on sodium rather than salt. However, according to Article 7 of Regulation (EC) No 1924/2006: “the amount(s) of the substance(s) to which a nutrition or health claim relates that does not appear in the nutrition labelling shall also be stated in the same field of vision as the nutrition information”. This provision may therefore provide the possibility for the indication of sodium on the label.

There are no obligations for the provision of suitable warnings on the composition of products (e.g. the high level of certain nutrients such as protein) in other horizontal rules of food law<sup>39</sup>. The provisions of Directive 2009/39/EC requiring the indication of suitability were perceived to the provision of such information at present.

- **Claims:** the suitability of two specific authorized health claims was questioned.
  - Firstly, the claim for *protein* which requires a minimum 12% of the energy of a food to be protein. It was noted that protein energy value in high protein FISP products can exceed 80% in some cases (see section 3.1.2.2), suggesting that the current threshold for use of the claim is too low for the case of FISP.
  - Secondly, the recently authorized *carbohydrate* claim refers to recovery, while most products based on carbohydrates are designed for consumption before or during exercise (see section 3.1.1.1). Furthermore, as was the case with protein, the carbohydrate content of certain FISP products is not sufficiently reflected in the conditions of use of the claim; products with small quantities of carbohydrates can use the claim.
  - Furthermore, some interviewees expressed concerns about the on-hold *caffeine* claim, given that certain other soft drinks (including energy drinks) contain caffeine, and hence may be able to make sports related claims if conditions of use are not strict enough. As the caffeine claims remains on hold at the time of writing, these concerns cannot be confirmed or negated.

Finally, certain interviewees expressed concerns about: (1) the absence of conditions of use for claims (both existing, and those to be authorised in the future) restricting their use to products which are intended for sportspeople; (2) how claims with conditions of use limiting them to sportsfoods can, in fact be restricted to sportsfood in the absence of an EU level definition; and (3) the possibility for operators to obtain the authorisation of new claims for various different reasons (see also section 4.2.3 for this final point)

- **Nutrient profiles.** While nutrient profiles<sup>40</sup> have not yet been adopted, various stakeholders noted that the specific composition of FISP (see section 3.1.2) could cause issues in the case that nutrient profiles are adopted and exceptions are not made for FISP. Estimates from Germany suggested that up to 85% of FISP could be impacted if nutrient profiles were not adapted.

## **Potential issues stemming from national interpretation of other horizontal rules of EU food law**

- **Labelling:** various stakeholders felt that instructions of use provided at present for products placed on the market in accordance with Directive 2009/39/EC may not be possible under Regulation (EU) No 1169/2011 on food labelling, as any reference to exercise or sports may

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<sup>39</sup> Such provisions do exist in Regulation (EU) 1169/2011 for caffeine. It may be possible to introduce such provisions for other substances through conditions of use for authorised health claims.

<sup>40</sup> Article 4 of Regulation (EC) No 1924/2006 foresees that nutrient profiles should be established and that only products compatible with those profiles can bear claims. However, nutrient profiles have not yet been adopted.

be considered a claim under Regulation (EC) No 1924/2006. However, Article 27 of Regulation (EU) 1169/2011 lays down an obligation for all foods to provide instructions for use which ensure appropriate use of the food. Furthermore, for products bearing claims, Articles 5 (3) and 10 (2) of Regulation (EC) No 1924/2006 lay down a series of general principles to ensure adequate consumer information in relation to these claims. There is consequently a degree of subjectivity with this issue. Ultimately it is up to national authorities to apply the rules, but there are legislative provisions for operators that could use to try to justify the provision of instructions with certain references to sport and exercise.

- **Food supplements:** various stakeholders (including CAs) expressed concerns with regards to the possibility for certain FISP to be accepted as food supplements. These concerns stem from the definition of a food supplement according to Article 2 (a) of Directive 2002/46/EC : *‘food supplements’ means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities<sup>41</sup>*. More specifically, these concerns were as follows:
  - **Format of the product.** Certain stakeholders felt that the majority of FISP will not be acceptable as food supplements due to their format. While bars and RTD products appear to quite clearly fall outside the definition provided, there is greater subjectivity with the case of powders. Some stakeholders believed that powders sold in large volume containers could not be considered as food supplements as they cannot be considered to be marketed in dose form; however if sold in smaller containers they may be acceptable as food supplements.
  - **Composition of the product.** Some stakeholders expressed concerns that the nutrients in some FISP would be compatible with the concept of a nutrient for food supplements; the point of view of these stakeholders was that macronutrients such as protein would not be consistent with the definition of nutrients in Directive 2002/46/EC (article 2 (b) ). While the definition of a nutrient provided by this article does limit nutrients to vitamins and minerals, article 2 (a) also includes a provision for other substances with a nutritional or physiological effect. Other pieces of community legislation such as Regulation (EU) 1169/2011 and Regulation (EC) No 1925/2006 also contain broader definitions of a nutrient.

However, in the case that a FISP product is not accepted as a food supplement by a Member State, it would still theoretically be possible to place the product on the market as fortified food. That said, there are two potential issues with this. Firstly, products placed on the market as fortified foods are not subject to the mandatory labelling provisions outlined in Article 6 of

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<sup>41</sup> Article 2 (a) of Directive 2002/46/EC

Directive 2002/46/EC. Secondly, evidence from case studies suggested that the placing on the market of products as fortified foods may be both rare and difficult in certain Member States.

### **Potential issues stemming from other horizontal rules of national food law.**

- **Fortification:** there may be an issue with fortification using certain substances in certain Member States. For example, in Germany, amino acids are not authorized for use in normal foods; only for use in PARNUTs foods (under Regulation (EC) No 953/2009). It was noted that a more complete harmonized list of authorized and banned substances for fortification at EU, together with maximum levels could address this issue; though it should also be noted that this issue stems from provision adopted at national level rather than EU level.
- **Food supplements:** in the absence of community level provisions, some Member States have adopted national level provisions for the maximum levels of vitamins and minerals in food supplements. Consequently, certain FISP may face compositional challenges due to the maximum permitted levels of vitamins and minerals. However, based on the major ingredients identified in section 3.1.2, it is likely that the impact of such maximum levels will be limited.

#### 4.4.1.3 Legal clarity after 2016

As was the case with the suitability of other horizontal rules of food law, interviewees were divided on the legal clarity that would be provided after 2016. The national situation in Member States will also play a role in the degree to which clarity would be provided after 2016; both any national legislation on sportsfood, and the national interpretation of certain other horizontal rules of food law (see above) will impact the degree of legal clarity. Certain adaptations to EU level rules (see previous section) may also assist legal clarity.

In general, interviewees believed that a final decision on the legislative position of FISP at EU level would provide a degree of certainty and hence clarity; interviewees generally agreed that there had been a fairly high degree of uncertainty stemming from the lack of clarity relating to the future position of FISP products, which had in turn impacted investment and innovation decisions of some operators. However, certain interviewees also warned that regulation of FISP under other horizontal rules of food law could still provide uncertainty given that Member States may, at a later date, decide to adopt national legislation; and in the case that a number of Member States take this path, there will once more be pressure for specific EU level provisions on the regulation of sportsfood. Not all interviewees shared this viewpoint, however.

Finally, there was a general consensus among interviewees (regardless of the degree of legal clarity they believed that would be provided after 2016) that any decision made to in relation to the regulation of FISP should be a long term one; therefore providing a predictable environment for operators, and hence a degree of legal clarity.

#### 4.4.2 *B11 Impacts on Competent Authorities (CAs)*

##### 4.4.2.1 CA enforcement

Evidence from case studies suggests that CA enforcement controls are presently performed as part of wider controls on food and similar products. Consequently no significant changes are expected to the nature of controls after 2016. Evidence from the CA survey corroborated this

to an extent; 41% of CAs did not foresee any changes to enforcement practices after 2016, and 18% only minor changes. However, some eight Member States (36% of respondents) did foresee moderate changes and one Member State foresaw major changes (Table 4.10).

**Table 4.10: likely changes to CA enforcement practices after 2016 due to any changes in legal position.**

Same legal position / no change foreseen	Different legal position but no change foreseen	Minor changes	Moderate changes	Major changes
BE	DE	DK	AT	EL
CY	FR	HR	EE	
IE	IT	PT	HU	
LU		SE	LT	
MT		NL		
UK		PL		
		RO		
		SI		
<b>6</b>	<b>3</b>	<b>4</b>	<b>8</b>	<b>1</b>

**Key to colour code based on legislation position**

Colour code	Legislative position
	No specific rules for sportsfood / covered by other horizontal rules
	Existing national legislation kept
	Existing national legislation amended or replaced
	New

Note: legislative positions based on the conclusions of section 4.1.2.1

Source: FCEC based on CA survey and case studies

In the Member States where changes to enforcement were foreseen and explanation of changes in enforcement procedures were identified, the following issues were identified:

- CA which is responsible for controls will change once FISPs are not classed as dietetic foods (EL).
- Some products will have to be re-notified as food supplements (PL).
- The focus of CAs during controls may change (NL).

Finally, according to the findings of the case studies, the perception of the extent to which the new legal position of FISP would help or hinder controls by Member State CAs will vary between Member States. In some case study MS, it was felt that there would be no complication to complete controls in the absence of specific provisions (e.g. UK). In others Member States, it was felt that the absence of a single piece of legislation for the category of FISP under other horizontal rules of food law could make enforcement more difficult (e.g. FR, DE; though it should be noted that national legislation will probably be introduced in both of these Member States). That said, as noted in 4.4.1.3, a final decision on the legislative position of FISP at EU level would provide a degree of certainty and hence clarity; and this could also benefit CA enforcement.

#### 4.4.2.2 Other burdens

Other than enforcement, the other change which was identified for CAs related to notification. For CAs with notification requirements for sportsfood placed on the market in accordance with Directive 2009/39/EC, the burden of managing notification for these products would disappear after 2016 (with the exception of Estonia which indicated the intention to introduce a notification procedure). However, as was noted in e.g. Italy, it is expected that certain FISP will be notified as food supplements after 2016, and some Member States also have notification procedures for fortified food; consequently there may be little actual change in the burden for CAs with regard to notification.

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