



European Commission
Directorate General for Health and Food Safety

Study on food intended for Sportspeople

Annexes

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

Submitted by:

FCEC

Contact for this assignment:

Dr Dylan Bradley



Agra CEAS
Consulting

Arcadia
INTERNATIONAL 


VAN DIJK
MANAGEMENT CONSULTANTS

CIVIC
CONSULTING

EUROPEAN COMMISSION

Directorate-General for Health and Food Safety
Directorate E — Food and feed safety, innovation
Unit Directorate E.1 — Food information and composition, food waste

Contact: sante-consult-e1@ec.europa.eu

*European Commission
B-1049 Brussels*

Study on food intended for Sportspeople

Annexes

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

Prepared by Agra CEAS Consulting

Project Leader: Dr Dylan Bradley

CONTACT DETAILS

E-mail: Dylan.Bradley@ceasc.com

Project Team

Agra CEAS Consulting

John Nganga
Dr Dylan Bradley
Dr Maria Christodoulou

Arété

Alberico Loi
Enrica Gentile
Mario Gentile
Serena Berisio

***Europe Direct is a service to help you find answers
to your questions about the European Union.***

Freephone number (*):

00 800 6 7 8 9 10 11

(*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

LEGAL NOTICE

This document has been prepared for the European Commission however it reflects the views only of the authors, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

More information on the European Union is available on the Internet (<http://www.europa.eu>).

Luxembourg: Publications Office of the European Union, 2016

ISBN 978-92-79-56815-2
doi: 10.2875/846312

© European Union, 2016

CONTENTS

1	CASE STUDY: FRANCE	4
1.1	Theme 1: current market for sportsfood.....	4
1.1.1	National rules (A13)	4
1.1.2	Sportsfood products on the market	6
1.1.3	Operators	8
1.1.4	Consumers, distribution and marketing	12
1.2	Evolution of the market after 2016	17
1.2.1	B1 general evolution	17
1.2.2	B4 impacts on competitiveness and operator costs.....	18
1.2.3	B5 Innovation.....	19
1.2.4	B6 SME consequences.....	19
1.2.5	B7 Price.....	20
1.2.6	B8 Consumer choice and behaviour; B9 consumer protection.....	20
1.2.7	B10 Regulatory	20
1.2.8	B11 Competent Authority	21
2	CASE STUDY: GERMANY	23
2.1	Theme 1: current market for sportsfood.....	23
2.1.1	A13 National rules	23
2.1.2	Sportsfood products on the market	25
2.1.3	Operators	27
2.1.4	Consumers, distribution and marketing	30
2.2	Evolution of the market after 2016	36
2.2.1	B1 general evolution	36
2.2.2	B4 impacts on competitiveness and operator costs.....	37
2.2.3	B5 Innovation.....	37
2.2.4	B6 SME consequences.....	37
2.2.5	B7 Price.....	38
2.2.6	B8 Consumer choice and behaviour; B9 consumer protection.....	38
2.2.7	B10 Regulatory	38
2.2.8	B11 Competent Authority	41
3	CASE STUDY: ITALY	42
3.1	Theme 1: current market for sportsfood.....	42
3.1.1	A13 National rules	42
3.1.2	Sportsfood products on the market	45
3.1.3	Operators	47
3.1.4	Consumers, distribution and marketing	50
3.2	Evolution of the market after 2016	55
3.2.1	B1 general evolution	55
3.2.2	B4 impacts on competitiveness and operator costs.....	56

	3.2.3	B5 Innovation.....	56
	3.2.4	B6 SME consequences.....	56
	3.2.5	B7 Price.....	56
	3.2.6	B8 Consumer choice and behaviour; B9 consumer protection.....	57
	3.2.7	B10 Regulatory	57
	3.2.8	B11 Competent Authority	58
4		CASE STUDY: UK	59
	4.1	Theme 1: current market for sportsfood.....	59
	4.1.1	National rules (A13)	59
	4.1.2	Sportsfood products on the market	60
	4.1.3	Operators	63
	4.1.4	Consumers, distribution and marketing	66
	4.2	Evolution of the market after 2016	71
	4.2.1	B1 general evolution	71
	4.2.2	B4 impacts on competitiveness and operator costs.....	72
	4.2.3	B5 Innovation.....	72
	4.2.4	B6 SME consequences.....	73
	4.2.5	B8 Consumer choice and behaviour; B9 consumer protection.....	73
	4.2.6	B10 Regulatory	73
	4.2.7	B11 Competent Authority	74
5		CASE STUDY: SPAIN.....	75
	5.1	Theme 1: current market for sportsfood.....	75
	5.1.1	A13 National rules	75
	5.1.2	Sportsfood products on the market	75
	5.1.3	Operators	80
	5.1.4	Consumers, distribution and marketing	82
	5.2	Evolution of the market after 2016	86
	5.2.1	B1 general evolution	86
	5.2.2	B4 impacts on competitiveness and operator costs.....	89
	5.2.3	B5 Innovation.....	89
	5.2.4	B6 SME consequences.....	89
	5.2.5	B7 Price.....	89
	5.2.6	B8 Consumer choice and behaviour; B9 consumer protection.....	89
	5.2.7	B10 Regulatory	90
	5.2.8	B11 Competent Authority	90
6		SURVEY: CONSUMER SURVEY RESULTS	91
	6.1	Question 2 – Prevalence of FISP consumption	91
	6.2	Question 4 – Sport activity	95
	6.3	Question 5 – Practiced sports.....	96
	6.4	Question 6 – Consumption habits	98
	6.5	Question 7 – Reasons behind consumption	100
	6.6	Question 8 – Retail channels.....	103
	6.7	Question 9 – Aspects influencing purchasing behaviours.....	105

6.8	Question 10 – Information on labels	108
6.9	Question 11 – Information on labels (2)	110
6.10	Question 12 – Trust in claims.....	112
6.11	Question 13 – Influence of claims in purchasing	115
6.12	Question 14 – Foods other than FISP	118
6.13	Question 15 – Reasons behind consumption of foods other than FISP	120
6.14	Question 16 – Expenditure	121
6.15	Description of the population: Questions 17 – 25	123
6.16	Full consumer survey questionnaire	133
6.16.1	Part A – First screening.....	133
6.16.2	Part B – Second screening	135
6.16.3	Part C – Consumption circumstances/reasons	135
6.16.4	Part D –Reasons behind consumption/purchase	136
6.16.5	Part E – Expenditure	139
6.16.6	Part F – General/Socio-demographic	139
7	SURVEY: COMPETENT AUTHORITY SURVEY RESULTS.....	141
7.1	Introduction to survey and replies	141
7.2	National legislation in place	141
7.2.1	MS with legislation	141
7.2.2	Nature of national legislation.....	142
7.2.3	Impact of national legislation.....	144
7.3	Soft rules	148
7.4	Products on the market.....	149
7.4.1	Total number of products on the market.....	149
7.4.2	Notified products on the market	150
7.4.3	Products placed on the market as sportsfood in accordance with Directive 2009/39/EC which may not be suitable for sportspeople	150
7.5	Claims	152
7.5.1	Change in practices after 2012.....	152
7.5.2	Use of authorised health claims relevant for FISP products.....	155
7.5.3	Use of unauthorised claims	156
7.5.4	Use of generic statements	162
7.6	Post 2016.....	163
7.6.1	Suitability of EU general food law for the regulation of FISP	163
7.6.2	Post 2016 legal situation	167
7.6.3	Impacts of post 2016 situation	168

1 CASE STUDY: FRANCE

1.1 Theme 1: current market for sportsfood

1.1.1 National rules (A13)

1.1.1.1 Legislation in place

A national order from 1977 (Arrêté du 20 juillet 1977 pris pour l'application du décret du 24 juillet 1975 sur les produits diététiques et de régime) regulates dietic products including sportsfood in France. Chapter 3 – dietetic products for effort is the main section of relevance for sportsfood. It covers:

- **Categories of sportsfood** (Article 49); two categories are defined:
 - Food products which are both balanced in terms of their protein, fat and carbohydrate content and their provision of protective substances (category 1).
 - Food products of which the composition is predominantly carbohydrates or fats but in which there is a balance between the provision of calories and protective substances (category 2).
- **Compositional requirements** (Articles 50 and 51);
 - Category 1: protein calorie provision of 13-17%; carbohydrate calorie provision of 50-60%; fat calorie provision of 27-33%; required amounts of vitamins B1, B6, C, Calcium and magnesium.
 - Category 2: Carbohydrate calorie provision of at least 60% and required amounts of vitamin B1 or minimum fat calorie provision of 33% and required amounts of vitamins B1 and B2.
- **Labelling requirements** (Article 53 and 54)
 - Sale denominations of “balanced for effort” (category 1) and “balanced for effort” plus “balanced for provision of carbohydrates / fat” (category 2).
 - Statement of the purpose of the product and the intended use.

There are other chapters of the 1977 order which could be of interest for FISP (e.g. chapter 2: "slimming products intended for diets with a certain protein requirement"). However, these chapters, while potentially interesting for FISP products, are not specifically intended for sportsfood products and no evidence was uncovered to suggest that they were widely used by such products.

A non-obligatory anti-doping standard was introduced in France in 2012 by AFNOR.

It was noted that other national legislation not directly relating to FISP may be of relevance; most notably that maximum levels for vitamins and minerals, and also for caffeine have been adopted in France. Caffeine in conjunction with synephrine is not permitted in France.

1.1.1.2 Legislative methods of placing products on the market

While the 1977 order does exist, several interviewees indicated that the categories and criteria are not strictly enforced at present as the order is considered too old. The 1977 order has not been updated as the authorities have been waiting to see what is decided at EU level before taking a decision on national legislation. Interviewees reported that, following the development of the SCF categories in 2001, operators were informally told by authorities that

as long as the product conforms to the description and criteria of one of the SCF categories the product could be placed on the market as sportsfood according to Directive 2009/39/EC. That said, evidence suggests that products which are high in carbohydrates (including carbohydrate electrolyte drinks, which interviewees confirmed generally conform to the definition of category 2 sportsfood products) generally try to respect the carbohydrate and vitamin B composition criteria and are placed on the market under this categorisation.

It was noted that there are other ways of placing food intended for sportspeople (FISP) on the market in France, notably:

- As food supplements.
- As fortified foods or other foods for normal consumption.

Interviewees were divided on the extent to which FISP are placed on the market using these methods. Some interviewees believed it was rare (indeed only likely for certain products which are very close to food supplements in nature). However, other interviewees believed FISP were commonly placed on the market under other legislative frameworks due to the categories in French legislation or the nature of the product which may represent a food supplement. Most notably, food supplements legislation was identified as a way of placing powdered products in small packages (e.g. 30g protein supplements) on the market, and an interesting way for the placing of the market of more innovative ingredients (e.g. creatine) which do not fit with the categories in the national 1977 order. Fortified foods were identified as a possible way of placing larger volume powdered products (e.g. 500g) on the market.

On balance, evidence suggests that FISP are placed on the market as food supplements to an extent, but less commonly as normal or fortified foods. In the case that a product is placed on the market as a food supplement, it is necessary to notify the Competent Authority¹. Fortified foods which comply with the Regulation (EC) No 1925/2006 do not need to be notified; other fortified foods do².

1.1.1.3 Impacts of national legislation

Some interviewees felt that French legislation created no burden for operators at present due to the absence of a notification procedure for products placed on the market as sportsfoods according to Directive 2009/39/EC, and due to the more flexible approach which has been taken with the national legislation. Indeed, some interviewees saw the national legislation as a positive factor for operators as the legislation and better controls may be perceived to have a positive impact on the image of FISP produced in France. However, there was one

¹ If the product conforms to food supplements legislation, then it is just necessary to send an email/letter with a label of the product to DGCCRF. If the product contains an ingredient that has not been authorised, it is necessary to send a notification request which include: proof that the product is in accordance with national provisions and on the market in another MS as well as information on ingredients. The CA then has 2 months to refuse the product. The French authorities are in the process of preparing an electronic version of the notification process.

² It was clarified that there are very few notified fortified foods, and that these are predominantly energy drinks with caffeine or taurine.

interviewee who believed that the current situation created legal uncertainty for operators due to the various possible ways of placing products on the market and lack of clarity around them. This interviewee noted that, in the absence of clarity and in order to assure a certain level of security, operators may choose to notify FISP as food supplements.

As previously noted, fortification of carbohydrate rich products with vitamin B1 is widespread due to the composition requirements in national legislation. However, this was not considered to be an issue by operators.

While national labelling provisions go beyond the provisions of Directive 2009/39/EC (notably the use of specific sale denominations), on balance they do not result in labelling significantly different from that permitted under Directive 2009/39/EC to have a significant impact on consumer protection or information.

No other impacts of national legislation were identified by interviewees.

1.1.2 Sportsfood products on the market

1.1.2.1 A1 Products on the market

Number of products

No single source of the number of FISP products on the French market was identified, and counting the number of products faces the same challenges as highlighted in the main report. Evidence suggests that there are probably in excess of 3000 FISP products. This is based on the following:

- In 2012, according to information provided by interviewees over 50 brands of FISP products were identified on the French market. While the number of products per brand varies significantly, discussions with operators suggested an average number of around 30-50 products per brand.
- According to one interviewee, annual innovation is considered to represent around 5% of the French market³. Over the period 2012-2014 there was an average of 223 new FISP products launched per year according to information from interviewees based on data from the Innova database.

There is no meaningful way of estimating the number of products by category; however, information on the importance of each category in terms of value based on Euromonitor data is in Table 1.1 below.

Table 1.1: Importance of main categories of FISP in France

Category	2014 Value EUR m	% of total	Forecast annual growth rate 2013-18
Protein products	70.3m	55%	2.3%

³ This figure is slightly below the EU level range provided by interviewees of 8-12%.

Performance boosting products	34.7m	27%	2.1%
Sportsdrinks	22.6m	18%	2.1%
Total	127.6m		2.2% nutrition only

Source: Euromonitor

Most common sub-categories, formats and varieties

Interviewees were not able to provide quantitative data on the sub-categories under each category. However, qualitative comments were provided as follows:

Protein: evidence suggests the powder format to be the most important, followed by bars and RTD; there are also a small number of gels, cakes or crisps. While pure protein remains most popular, there are an increasing number of products which combine protein and carbohydrates for recovery.

Performance boosting products: energy bars are the most important sub-category, followed by energy gels and concentrates. Supplement style products make up the remainder of the category. The gel and concentrate sector, however is more innovative than the bars sector.

Sportsdrinks: the sector is less developed than in many other Member States. In terms of format, powder is comparatively more popular in France than in other Member States. The reason cited for this was portability.

Across all categories it was noted that low concentrate / natural versions of some products have been launched in recent years to target more wellness orientated consumers.

1.1.2.2 A2 Ingredients

Protein: the most common ingredients of protein products are different types of protein, namely:

- Whey
- Casein
- Egg protein
- Soya protein

The levels of protein tend to be very high; typically 80% or more of product composition. As noted above, there is an increasing trend towards the inclusion of carbohydrates with protein in some products in this category for the function of recovery. Some products may also contain vitamins to assist with the metabolism of protein; single amino acids; or caffeine to aid recovery.

Performance boosting products: for *energy bars and gels*, the most common ingredients are:

- Carbohydrates

- Vitamin B1

It should be noted that, due to French legislation, most energy bars and gels contain both these ingredients. Other vitamins may be added in some cases.

In terms of *supplement* style products, the following were identified.

- Creatine and other stimulants.
- Individual amino acids, vegetable extracts or specific nutrients with an impact on the nervous system.

Sportsdrinks: sportsdrinks contain the traditional carbohydrate-electrolyte combination. As with energy bars and gels, due to French legislation products in this category are generally fortified with vitamin B1.

1.1.2.3 A3 Price

No price data was identified at national level or provided by interviewees. However, Euromonitor contains price data for certain major brands in France. Prices for products considered representative of each category are provided in Table 1.2.

Table 1.2 Price of FISP products in France (2014, EUR)

Category	Average size	Average price	Price per unit
Protein – powders	925g	38.28 EUR	4.14EUR / 100g
Performance boosting – gels	86g	6.05 EUR	1.75 / 25g
Sportsdrinks	625ml	1.65 EUR	0.26EUR / 100ml

Source: FCEC based on Euromonitor; average of 5 randomly selected

1.1.3 Operators

1.1.3.1 A6 Market structure

Value of the market

According to national French industry estimates, the market for sports nutrition and drinks was worth approximately 75m EUR in 2014. It was noted that there is no panel data on internet and sport shop sales; hence this figure is an industry estimate. Data from Euromonitor puts the market at EUR 127.6m in 2014, suggesting the industry estimate may be slightly on the low side.

According to national French industry estimates, the market has grown at a compound annual growth rate (CAGR) of 3.5% since around 2005; Euromonitor data suggest growth over the last year of 5% for sports nutrition products and 1.3% for sportsdrinks. The key driving factor identified for this increase in sporting activity in France (an estimated 2/3 of the population

completed regular sporting activity of some kind⁴ in 2010), with three key factors contributing to this:

- Development of sport infrastructure.
- Increase in the number of sports clubs.
- Propagation of the number of gyms and fitness centres (a six-fold increase in 6 years).

This has led to the emergence of certain consumer groups (more details in section 1.1.4.5). It was noted that some evidence suggests that the French are, on average, more active than the EU average.

The main threats to the industry are considered to be connected to the broader economic situation in France (purchasing power and the economic climate). An absence of consumer belief of product claims and consumer understanding of products are other possible threats.

Structure of the chain and characteristics of operators

There are approximately 50 major brands of FISP products in France. The major operators in the sector, including the three largest operators, are French. That said there are some operators on the market that are based in other Member States such as Germany, the UK and Poland. There are some US operators (see section 1.1.3.3).

As is the case for the wider EU sportsfood market, the chain can be broken down into manufacture, branding and retail. An overview is provided in Table 1.3.

⁴ In addition to the fitness work-outs and the normal individual and team sports, this included activities and sports such as: walking, horse riding, dance, petanque and table tennis.

Table 1.3: Overview of types of operators present on the French market

Company background	Comments	Common roles	Examples
Dietetic / food supplement specialist	Uses knowhow from these sectors to enter sports nutrition	<ul style="list-style-type: none"> • Sub-contracted manufacture • Branding • Manufacture and branding 	Nutrition et Sante, Nutribio
Sports nutrition specialist	Only produces sports nutrition products	<ul style="list-style-type: none"> • Manufacture, branding and retail 	Overstim.s (Diète Sport)
Specialist producer and distributor of sports goods	Uses distribution network	<ul style="list-style-type: none"> • Branding and retail 	Decathlon

Source: FCEC based on interviewees and desk research

The size of operators varies. From a sample of 8 companies met during the case study, 4 (50%) classed themselves as SMEs. The majority of the companies considering themselves SMEs were sub-contracted manufacturers, though there was also one operator covering from manufacture to retail. From the same sample of operators, all eight operators reported that they sell products both inside France and on other EU markets. Some of these operators; performing both sub-contracted manufacture and branding; noted that their clients (either brands or retailers) required that their products be sellable in multiple Member States.

Table 1.4 shows the latest available concentration ratios for sports nutrition operators. The sports nutrition industry shows a high level of concentration. The third column displays the concentration ratio from 2009.

Table 1.4: Concentration ratio of branded sports nutrition operators in France (2013)

Concentration ratio (CR)	Combined market share 2013	Combined market share 2009
CR-4	66.2%	65.0%
CR-8	84.6%	80.3%

Source: FCEC based on Euromonitor

Data enabling the calculation of CR-4 and CR-8 ratios for the importance of sportsdrinks operators has thus far, not been identified. However, estimation of the importance of the main three brands is provided in Table 1.5. Together they account for an estimated 88% of the market (i.e. CR-3 = 88%).

Table 1.5: Main brands of sportsdrinks in France

Brand	Estimated % of total sportsdrinks market (2013)
Isostar (Nutrition et Sante)	34%

Gatorade (PepsiCo)	33%
Powerade (Coca Cola)	21%

Source: FCEC based on Euromonitor

1.1.3.2 A10 Innovation

The main drivers of innovation were noted as:

- **Consumption format**; this was noted as a particular driver for carbohydrate based products, with the emergence of many gels and bars. It was also noted that sachets have played a significant role in terms of innovation for sportsdrinks in France.
- **Taste and flavours**; innovations in this area increase consumer acceptability and can help attract lifestyle users and occasional sportspeople to products. Lower concentrated / more natural versions have been a recent driver for launches of some products.
- **Quality and effectiveness of products**; most notably, improvement in manufacturing techniques (filtering and purification of proteins in particular) have been a major driver in the protein category.
- **New sports / increased popularity of certain sports**; new products will be designed to address the needs of these new or increasingly popular sports.
- **Increased sporting activity among the French population**; see section 1.1.3.1.

In recent years, there have been several new entrants into the market. They tend to position themselves quite specifically in terms of their products and/or target consumer (e.g. specialisation in nutrition for a certain sport).

Table 1.6 shows the number of new FISP products launched in France for the period 2012-14. As can be seen in the table, the majority of new product launches related to powder products.

Table 1.6: New FISP products launches in France, 2012-2014

Year	Powders	Supplements	Bars	Drinks RTD	Protein RTD	Others inc gels	Total
2012	16	16	18	7	1	20	78
2013	138	52	9	4	3	19	225
2014	213	59	44	18	9	44	367

Source: Innova, provided by interviewees

1.1.3.3 A8 Trade

No precise data on trade was identified. However, according to interviewees there is considerable import from the US. While the largest producers in terms of market share are French, a significant number of producers by number are American; roughly half of the 30 largest brands in France are from the US. No other third country is present among the largest brands.

While historically these American products have been imported directly rather than manufactured in France, interviewees suggested that recently there has been increasing interest in using French-based subcontractors to manufacture the products in France. There are also some large import "platforms"; these introduce US FISP products into the EU through a single EU-based operator in one Member State (e.g. Netherlands) who subsequently sells these products to traders in different Member States for onward sale to distribution outlets. It was noted that this method of import may have some issues as the local (French based) traders may receive the products with labelling in English and for which the composition is not known. The products may therefore not be considered fully in compliance with EU law; however these products also are difficult for Competent Authorities to take action against. While the operator introducing the product into the EU through the import platform should know the composition of the product imported, in reality it would appear this is not always the case. Finally, some interviewees felt that products from third countries and Member States that do not comply with French provisions can be found on the French market.

While there are some exports to third countries, evidence suggests that these are not particularly significant, at least at present. It was however noted that in some neighbouring dietetic areas such as infant formulae, exports from France to Asia have been high in recent years as trust in local production is low and manufacture in the EU is seen to provide a seal of guarantee.

1.1.4 Consumers, distribution and marketing

1.1.4.1 A7 Distribution channels

The main distribution channels identified in France along with their importance and characteristics are presented in Table 1.7.

Table 1.7: Main distribution channels in France

Channel	Comments	Importance
Specialised large sports shops (e.g. Decathlon)	A natural connection between sport and nutrition products. Well positioned for members of the general public performing sports activity.	Interviewees: most important channel by volume; 75% of sales CS: 26% of respondents
Online sales	Two sub-channels: <ul style="list-style-type: none"> • Direct from manufacturer (of which level of usage and importance varies by operator). • Specialist on-line. Can facilitate direct contact with customers. Used by most major brands to some extent.	Interviewees: 2nd most important channel by volume; probably in excess of 15% and growing. CS: 5% of respondents
Pharmacies and parapharmacies	Pharmacies are restricted as to which products they can sell in France. Dietetic products are among them. May be seen as more trustworthy by	Interviewees: 3rd most important channel by volume <10% of sales

	certain consumers.	CS: 9% of respondents
Multiple retailers (e.g. Carrefour)	Only targeted by certain brands. Traditionally in France a product cannot be sold in both pharmacies and multiple retailers (though this is changing).	Interviewees: Least important channel, <5% of sales by volume CS: 42% of respondents

Source: FCEC based on interviewees (data provided from a 2012 report/survey); and consumer study (CS).

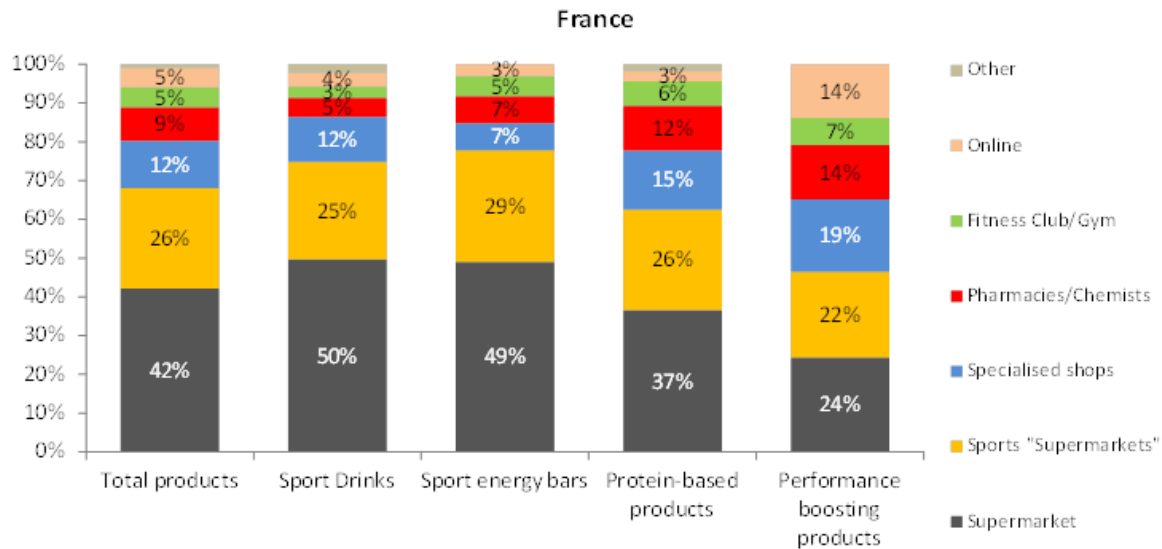
The table displays a difference between the importance of certain distribution channels (specialised large sports shops and supermarkets) by volume according to interviewees, and the number of consumers reporting the use of distribution channels in the consumer survey. These differences can be largely explained by the following:

- The information provided by interviewees was based on a report/survey dating from 2012 while the consumer survey was carried out in early 2015.
- While the survey/report including sportsdrinks as a whole, it is understood that two major brands, Powerade and Gatorade, were not included.
- Consumer survey figures are based on the number of consumers, while industry figures are based on the importance of volume.

In summary the combined data sources would suggest that specialised sports shops and multiple retailers are the largest two distribution channels.

The full results of the consumer survey distribution channel findings for France are displayed in Figure 1-1. While multiple retailers are very important for the distribution of sportsdrinks and energy bars, their importance is significantly lower for protein based products and performance boosting products. This broadly coherent with interviewee comments that, with the exception of sportsdrinks, FISP are not presently widely sold through more general retail outlets such as multiple retailers, grocery stores and fast food service outlets. Sportsdrinks, however, were considered to frequently use these distribution channels, and one interviewee noted that dedicated fridges of sportsdrinks can be found in some such outlets. The same interviewee added that, while most other categories of FISP at present are not sold in mainstream outlets, this is likely to change in the future given this has been a trend in other Member States such as neighbouring Spain.

Figure 1-1: distribution channels in France by product type according to consumer survey



Source: consumer survey

An additional channel of “grey” internet sales; that is to say direct sales of products from third countries which do not comply with French legislation was identified.

1.1.4.2 A11 Marketing techniques

Sponsoring of sports events and/or endorsement by certain famous sportsdrinks or clubs are important for some brands. Larger brands in particular were reported to use endorsement or sponsoring, while brands of all sizes may sponsor events of different types. Communication through specialised press was reported as a common marketing technique. Only one case of the use of mainstream media for advertising was identified during discussions with operators met during the course of the study; the most likely reason for this is the prohibitive cost of this advertising channel. Point of sale sampling was identified as a marketing tool used by some operators.

Certain interviewees noted that communication on FISP products through more informal channels; internet forums and word of mouth; was widespread. The nature of such communication makes it difficult (if not impossible) to control.

In the particular case of sportsdrinks, dedicated, branded fridges of these products were reported to be found in certain mainstream outlets such as grocery stores or sandwich shops.

Certain producers may indicate the respect of certain anti-doping norms such as that from the *Association Française de Normalisation (AFNOR)* on their packaging. This may be done for reasons of marketing. The anti-doping norms may have had a positive impact on the credibility of some products.

1.1.4.3 A5 Claims

As noted in section 1.1.1.1, there are certain labelling criteria in the national legislation which provide the opportunity for an indication of the denomination of sale and a statement of

purpose and intended use. Example indications identified by interviewees include (translated from the French):

- Sportsfood
- Sportsdrink / drink for sport / isotonic sportsdrink / recovery drink
- Sports bar
- Gel energy / power gel
- Endurance / effort / performance
- Designed for endurance sport
- Weight gain

Interviewees did not agree on the extent to which these indications were restricted to only products complying with the compositional criteria of the 1977 order. While one interviewee believed that only products fulfilling these criteria used these indications, other interviewees suggested that these indications may also be found on other products adhering to the SCF categories (see 1.1.1.2).

FISP products placed on the market as food supplements bear the indication “food supplement product based on substance X”

In terms of the use of health claims authorised under Regulation (EC) No 1924/2006, the examination of product labels provided by operators in the context of the case study interviews and an examination of products for sale on the market showed that the claims for carbohydrate electrolyte drinks and protein can be found on products fulfilling the claim conditions. Furthermore, claims relating to certain vitamins and minerals (for example vitamins B1, B2, PP and B6 for energy metabolism; vitamins B2, PP, C and B6 for fatigue reduction) could also be found.

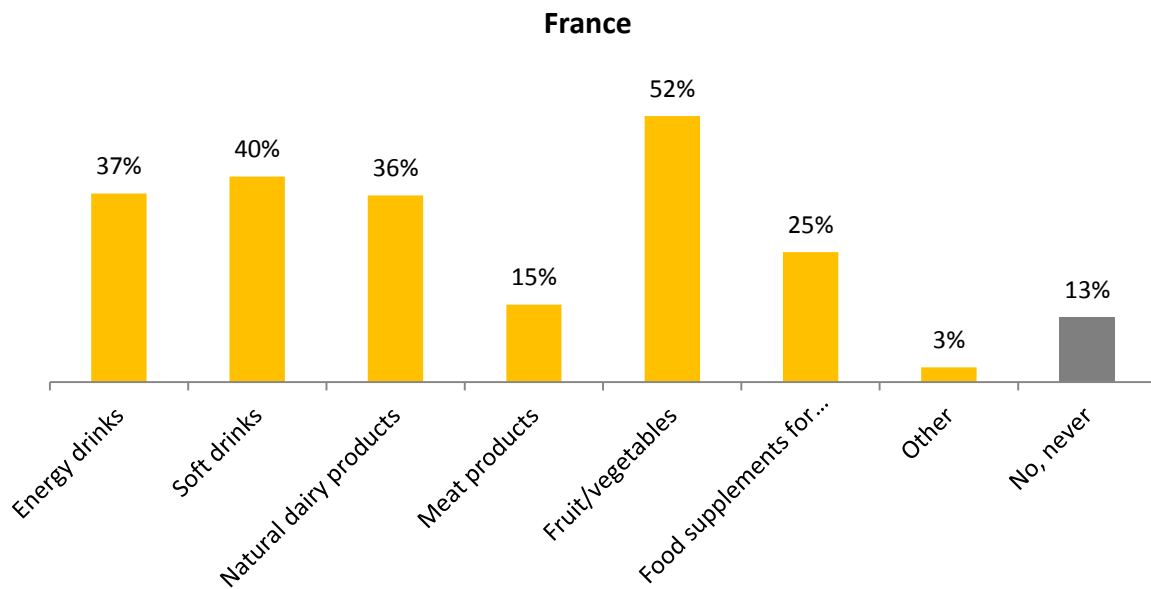
Operators (including sub-contracted manufacturers) interviewed in the course of the case study had varying perceptions about the extent to which FISP products were reformulated following the entry into force of the list of claims in order to use certain authorised claims. Half of the operators interviewed that were active in 2012 reported that reformulation had taken place to a moderate extent, while the other half reported that there was no reformulation. In summary, the extent to which reformulation took place varied from operator to operator (and in the case of sub-contracted manufacturers, from client to client). This was also confirmed as the likely case by certain interviewees.

1.1.4.4 A4 Foods not intended for sportspeople

With the exception of some energy drinks, foods other than FISP have not targeted sportspeople in France. It was noted that certain products such as pasta and cereal bars may be used by sportspeople due to the energy they can provide.

Evidence from the survey of consumers suggested that 87% of sportspeople use foods other than FISP in relation to sporting activity. The most common of these are fruit and vegetables (52%) followed by soft drinks (40%) (see Figure 1-2).

Figure 1-2: Use of foods other than FISP in relation to sports activity by sportspeople



Source: consumer survey

1.1.4.5 Consumers

According to interviewees, the main groups of consumers in France are:

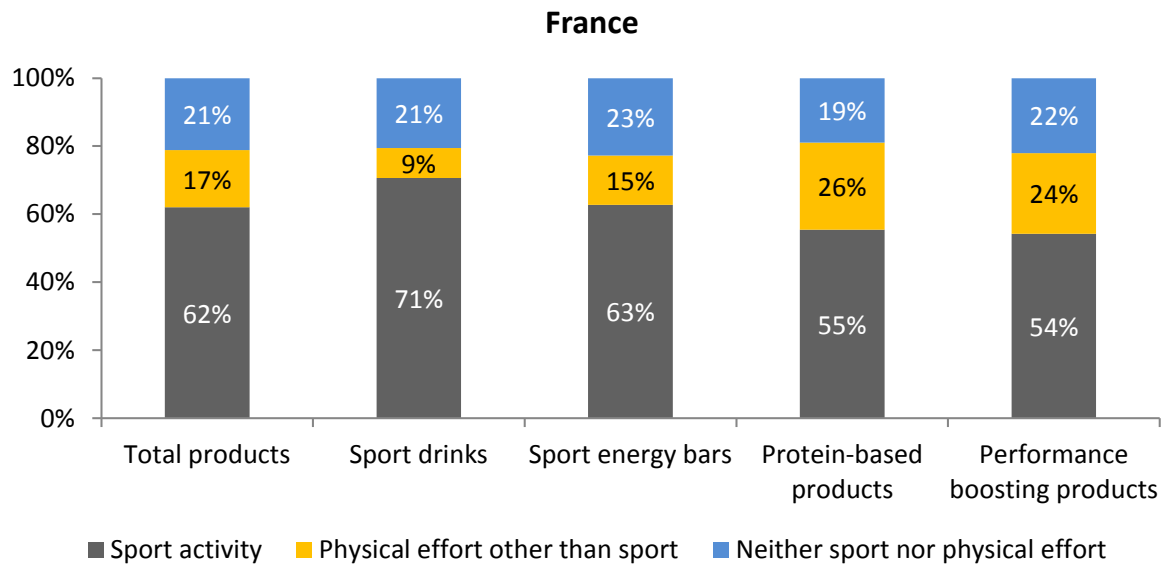
- Sportspeople:
 - Body builders aiming for muscle mass growth.
 - Athletes (professional or semi professional), looking for products to improve their performance or endurance.
 - Occasional sports users who are primarily interested in improving their physical condition and appearance.
- Lifestyle users:
 - Wellness consumers who are very attentive to their lifestyle and use sports nutrition products as a method of healthy nutrition.

A certain amount of this sporting activity is accounted for by consumers who want to improve their appearance. This group of consumers makes a particularly interesting target group for manufacturers. Occasional sport participants and wellness motivated users are an interesting target groups, and certain versions of products may target these consumers (see above).

However, there was a belief from one interviewee that certain products such as sportsdrinks were now being widely consumed by the general public. This was perceived to be dangerous to public health as the contents of such products (e.g. high levels of sugar), though suitable for sportspeople, are in opposition with the nutritional needs of the general public. The younger generation, including teenagers, were seen as been more likely to consume such products outside the context of sporting activity, and hence particularly at risk to health issues such as obesity which can result from the excessive consumption of nutrients such as sugar that are found in these products.

Figure 1-3 displays consumption habits of FISP consumers by product category according to the consumer survey. Results show that, in all cases, consumers who use products neither in relation with sport or physical activity are a minority.

Figure 1-3: consumption habits of FISP consumers in France by product category



Source: consumer survey

1.2 Evolution of the market after 2016

1.2.1 BI general evolution

In the case that no legislation is adopted at EU level, it is most likely that new national legislation will be introduced in France (source: CA survey). The basis for this is that it is believed the main aims of ensuring food safety and consumer protection can be best fulfilled through specific legislation, and the 1977 order currently in force is outdated. The majority of interviewees were potentially in favour of national legislation in such a situation, though one interviewee was against it.

Any regulation would need to be thoroughly discussed between various ministries; finance and fraud (DGCCRF), health, sport and agriculture; as well as potentially stakeholders; before the scope could be decided. However, it is likely that legislation would cover the following areas:

- Labelling;
- categorisation (possibly: (1) carbohydrate-electrolyte drinks and carbohydrate based products; and (2) protein; though expert input would be required prior to the development of any categorisation), and;
- compositional criteria.

It is possible that a notification procedure could be introduced for certain products which do not adhere to the categorisation or criteria for sportsfood adopted in any future legislation,

while those which adhere to the criteria or categorisation could potentially circumvent this obligation (as is currently the case in France for fortified foods).

It was noted that a major challenge with any definition of sportsfood in legislation is that it is sufficiently precise to avoid problems at the borderlines of the category. A definition would have to define both what is considered sportsfood and what is not. In the particular case of France, given that some FISP products are placed on the market as food supplements at present, it would probably be necessary to perform a one-off sorting of the products on the market. The choice of how to place a product on the market; as sportsfood under specific legislation or supplement; would belong to operators, as long as the relevant rules are respected. If the relevant rules were not respected, products would probably not be accepted in the category (as is the case at present with certain products placed on the market by operators as food supplement but which are not accepted as such by the competent authority).

Certain interviewees noted that, with potentially different legislation in different MS, a plan for mutual recognition would be needed.

1.2.2 B4 impacts on competitiveness and operator costs

1.2.2.1 Assuming national legislation is introduced

The majority of interviewees saw positive impacts for operators from the impact of national legislation; more specifically:

- it would allow FISP products to benefit from a special status which would separate products falling under the legislation from other products on the market;
- it would provide clarity in terms of the method of placing on the market (as noted above this is not the case at present as there are several different ways of placing products on the market), and;
- as long as any compositional criteria set out in national law are not too strict, there would be no adverse impact on formulation.

The main negative impact perceived was the potential for a patchwork of different legislation across EU Member States, which would in turn result in operators having to comply with various different labelling and compositional requirements. Given that many French-based operators are active in more than one Member State (see section 1.1.3.1), it was considered likely that there would be significant impacts from this internal market distortion.

1.2.2.2 If no national legislation were to be introduced

In the absence of national legislation (i.e. in the case that FISP were to fall under other horizontal rules of food law, the following issues for operators were identified at national level:

- There would be underhand competition in the area of FISP from other operators advertising products as being intended for sportspeople. The basis for this affirmation was article 2 (2) of Directive 2009/39/EC which prohibits the labelling of foodstuffs for normal consumption⁵ from being presented as if they were dietetic foods. A certain stakeholder also commented

⁵ As specified in the directive.

that, at present general food products will not use the indication “product for sportspeople” through the use of article 10 (3) of Regulation (EC) No 1924/2006 on health claims due to the existence of article 2 (2) in Directive 2009/39/EC.

- A consequential reduction in quality of some products; for example, in the case of protein based products, the ability to use the authorised health claims for protein and muscle mass at thresholds of 12% of product energy value would result in products on the market targeting sportspeople with levels of protein significantly lower than those found in dedicated FISP products at present.
- Potential difficulties for operators to submit sports nutrition products dossiers for the authorisation of new health claims.

On balance, evidence suggests that the majority of operators have not yet made any adjustments to their products in view of the expected repeal of PARNUTS legislation and removal of the category of sportsfood. However, one interviewee reported that some operators may have changed the position of their products in view of the expected change of the legal position of FISP at EU level.

1.2.3 B5 Innovation

It was noted by certain interviewees that, while categories in legislation would be useful for defining products, if too restrictive they would limit innovation as products do not always fall into neat categories.

Future uncertainty was identified as a factor with significant impacts on innovation. It was noted that, the current situation, which remains unclear in France (both due to uncertainty as to what action will eventually be taken at EU level, and uncertainty about the precise nature of any provisions at French level) has negative impacts on innovation, and will continue to have negative impacts until there is certainty. According to one operator interviewed in the context of the study, a minimum of 1 year is required to bring a new product to market (potentially longer if the product is more complex in composition) and consequently innovation was challenging at present given the uncertain outlook which could not guarantee returns on investment.

1.2.4 B6 SME consequences

Certain interviewees believed that national legislation would benefit interviewees in the sense that it would provide legal clarity. In the case that a notification system is only imposed for sportsfood products which do not comply with legislative requirements, and not for all sportsfood products (see section 1.2.1), there is unlikely to be a significant burden on SMEs from notification. Indeed some SMEs may already be placing FISP products on the market as food supplements, and hence notifying the competent authority of their products, and the burden of this notification process was perceived to be minimal.

Similarly, if reformulation is not widespread due to any new national rules (also see section 1.2.1), there would be no consequent adverse burden for SMEs.

1.2.5 B7 Price

None of the interviewed stakeholders felt to be in a position to make considerations on potential impacts on the price of products stemming from the introduction of national legislation.

1.2.6 B8 Consumer choice and behaviour; B9 consumer protection

Various interviewees noted that any national regulation would be introduced on the basis of consumer protection, and subsequently would be expected to have positive impacts in this respect. As already mentioned (section 1.2.1), as long as composition criteria are not too strict there would not be widespread reformulation or withdrawal. Subsequently, consumer choice should not be adversely affected.

However, one interviewee noted that the first aim of any legislation should be the protection of general consumers, and not specifically of consumers of FISP given the high level of nutrients which can be found in certain FISP products and their negative effects on health if not consumed in the context of sporting activity. This interviewee believed consumer protection would only be significantly enhanced if national legislation contained tight controls on the substances authorised in FISP, and the sale of such products were restricted to certain outlets which specifically target sportspeople.

Clarity with regards to the legal position of products; whether due national legislation or due to FISP falling under other horizontal rules of food law; was expected also to provide clarity with regards to the products for consumers.

One interviewee noted that, due to French national law, the repeal of PARNUTS could result in the inability of pharmacies to sell FISP products⁶. It is not clear whether any new national legislation would lift such a restriction, either directly or indirectly through the introduction of national legislation on sportsfood.

In the case that no national legislation were eventually to be adapted and FISP 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 cited in section 1.2.2.2 and the perceived deficiencies of other horizontal rules of food law identified in section 1.2.7.

1.2.7 B10 Regulatory

The intention of the competent authority to introduce national legislation, along with the support of certain parts of the industry indicates a feeling that other horizontal rules of food law, as they stand at present, are not suitable for the regulation of FISP in France. Particular insufficiencies identified include:

- The inability to sell high sodium and high carbohydrate products with suitable labelling indications.

⁶ The sale of foods for general consumption is not permitted in pharmacies in France (with certain specific exceptions).

- Issues relating to the extent to which instructions for use including words such as “exercise” and “sport” could be used on the labelling of FISP products.
- The limited degree of adaption of authorised health claims to the FISP products.
- The absence of provisions to guarantee the composition of products sold as FISP meet the needs of sportspeople.
- The absence of a list of banned doping substances.
- The absence of nutrient profiles and related conditions in order to avoid certain FISP products which are high in substances such as sugar from targeting the general population.

Nonetheless, certain interviewees agreed that, with modifications to address the points above, other horizontal rules of food law may be suitable for the regulation of FISP. That said, one stakeholder in particular felt that specific legislation was preferable given the long process which they expected amendments to the varying pieces of existing legislation to require.

On balance, the introduction of national legislation, if suitably designed, was considered to enhance legal clarity for FISP and was not expected to increase burdens for competent authorities or operators.

1.2.8 B11 Competent Authority

Controls are currently performed by departmental authorities as part of the wider food controls, the focus of which is determined at a national level. They cover places of manufacture and points of sale with the corresponding French department. Points of sale and places of manufacture which are based outside France cannot be controlled.

Controls of sportsfood products have not strictly adhered to the 1977 order in recent years given the degree of flexibility provided in terms of composition (see 1.1.1). Controls at present focus on the application of claims and general labelling legislation (e.g. misleading statements). While controls can prioritise specific areas (and it is possible that e.g. health claims will be a priority in next year's controls), in general terms the specialist nature of the FISP market means that it is difficult to consider it a high-priority market for checks. Furthermore, the high number of product lines makes it a difficult market to controls difficult for the authorities.

One interviewee commented that controls tend to focus on physical outlets with larger sales volumes, rather than smaller gyms and fitness suites; though the interviewee appreciated that controls of these outlets are not easy both due to the number of such outlets and their nature. This was confirmed to an extent by control bodies who have noticed an increasing hostility from some controlled specialist sports nutrition shops and gyms where the seller is often also a consumer of some of the FISP products for sale.

It was felt that the introduction of new national legislation for sportsfood after 2016 would be positive for the competent authorities and control bodies as there would be a clear legal framework for dealing with products. The method of determining areas to control and the controls themselves would not change; there would just be more legal clarity for the completion of market controls.

2 CASE STUDY: GERMANY

2.1 Theme 1: current market for sportsfood

2.1.1 A13 National rules

2.1.1.1 National legislation

There is no specific national legislation on sportsfood in Germany.

Directive 2009/39/EC is transposed in Germany through the *Diaetverordnung* (DiaetV). The DiaetV follows fairly closely the provisions set out in Directive 2009/39/EC. Food for intensive muscular effort is recognised as a type of dietetic food in the annexe to the DiaetV.

Some other national legislation with potential impacts for some FISP products was identified:

- There is a notification procedure for food supplements in Germany.
- There is national legislation on beverages containing caffeine (including energy drinks, which are not considered FISP).

There has been an appraisal of the definition and composition of sportsfood in Germany. This appraisal can be considered a form of non-legislatively binding rule; however, no interviewees made reference to this appraisal or its impacts during the course of the case study.

2.1.1.2 Legislative methods of placing products on the market

Three methods of placing on the market were identified in Germany. These were:

- dietetic food (sportsfood according to Directive 2009/39/EC);
- food supplement, or;
- fortified foods or other foods for normal consumption .

The choice of the method of placing on the market is the operator's, as long as the product complies with relevant legislation. In theory, it is possible to identify the method of placing on the market from the product label; for example, products placed on the market as sportsfood in accordance with Directive 2009/39/EC should bear an obligatory indication as outlined in Article 19 of the DiaetV⁷. However, it was noted that some products mix statements, and provide both indications for food supplements and for dietetic foods.

Certain (though not all) interviewees felt that there had been an increasing trend towards the placing on the market of FISP as food supplements. This trend was observed to have started in 2010 once it became clear that sportsfood may cease being a category of dietetic food in the future. This trend was explained by the following:

⁷ This article is similar to Article 9 of Directive 2009/39/EC

- Operators have tried to adjust to a future legislative situation where sportsfood may not be considered a dietetic food, and consequently have been testing new methods of placing on the market and the boundaries of these methods.
- According to the provisions of Article 11 (1) (c) of Directive 2009/39/EC products placed on the market as dietetic foods should theoretically have scientifically proven benefits (though this is no requirement to systematically check this). Placing products on the market as food supplements or foods for normal consumption can circumvent this issue.

The limited evidence available from interviewees suggests that about 50% of FISP products in Germany are placed on the market as sportsfood according to Directive 2009/39/EC, with the remainder placed on the market as food supplements (~25%) or foods for general consumption (~25%). It is important to note that these estimates are based on data provided by just a handful of operators, and that the method of placing on the market is understood to vary substantially from operator to operator.

It was noted by one interviewee that the placing on the market of fortified food products in Germany is particularly difficult (see section 2.2.7).

2.1.1.3 Impact of national rules

As there are no specific rules on sportsfood in Germany, there is no impact to report. However, interviewees did identify issues with the situation in Germany vis-a-vis that of other Member States. More specifically:

- Different Member States may have different interpretations of how products are positioned legally. Consequently, a product which is accepted as a sportsfood according to Directive 2009/39/EC⁸ in Germany may not be accepted as such in some other Member States, and may have to be placed on the market there as a food supplement instead. This can lead to labelling issues (i.e. products may have to have different labels due to the potentially different information on labels resulting from conflicting methods of placing on the market if a single label were to be used). The extent to which different labelling is necessary depends on the flexibility of the Member States involved with regards to this issue; Italy was cited as an example of a Member State which may consider some German products placed on the market as sportsfood according to Directive 2009/39/EC to be food supplements, and would not accept labelling on these products indicating them to be a dietetic sportsfood.
- The above issue may also impact exports; some third countries may not accept products with labeling (in different languages) which indicates the product is both to be a food supplement in one EU Member State and a dietetic sportsfood in another EU Member State.
- Differences in accepted composition or types of ingredients between Member States may result in the need to change product composition for different national markets. With regards to types of ingredients, creatine is an example; there are guidelines on the types of creatine accepted in sportsfood in Italy (as well as laws in third country Switzerland).

⁸ i.e. in accordance with Directive 2009/39/EC

It was also noted by interviewees that the absence of national legislation made the borderline between sportsfood according to Directive 2009/39/EC and some medicinal products, and between sportsfood according to Directive 2009/39/EC and food supplements rather blurred. This second point was at least partly demonstrated by the estimates for method of placing on the market provided in section 2.1.1.2.

2.1.2 Sportsfood products on the market

2.1.2.1 A1 Products on the market

Number of products

No data on the number of FISP products on the German market were identified. There is no notification for products placed on the market as sportsfoods according to Directive 2009/39/EC in Germany, and no interviewee felt able to provide a meaningful estimate as to the total number of products on the German market. According to one interviewee, three of the seven largest companies (which represent about 80% of the market by volume combine) each have 100-120 products including different flavours and formats. If it is assumed each of the seven largest companies have an average of 110 products, these 770 products represent approximately 80% of the German market. However it was noted that there are a multitude of smaller companies selling their products in significantly smaller volumes. According to the pareto principle⁹, there would consequently be around 4,000 products on the German market. Given that there are also many products for sale on the internet from operators based in other Member States or third countries, and that the German market is the second largest in Europe, it is possible that the number of products is higher than this.

While there is no meaningful way of estimating the number of products by category; however, information on the importance of each category in terms of value based on Euromonitor data is in Table 2.1 below. It should be noted that one interviewee believed the growth rate of the overall FISP industry is a bit lower than the EU average at around 2%; the weighted figure in Table 2.1 puts overall growth at 1.9%.

Table 2.1: Importance of main categories of FISP in Germany

Category	2014 Value EUR m	% of total**	Forecast annual growth rate 2013-18
Protein products	107	24%	9.0%
Performance boosting products	28.9	6%	8.5%
Sportsdrinks	316	70%	-1.4%*
Total	451.9		1.9% (weighted;

⁹ The pareto principle states that 20% of invested input is responsible for 80% of the results obtained.

Source: Euromonitor

* 2014-2019 forecasts

**Figures add up to more than 10 0 due to rounding

Main sub-categories and formats

Comments, and to the extent possible, estimates of the main sub-categories under each category are presented below. These are based on information provided by interviewees.

Sportsdrinks

- The majority; probably 80% of products; are carbohydrate electrolyte solutions.
- Low energy and moderated sodium drinks constitute the remainder.
- Format may be ready-to-drink (RTD) or powder.

Protein based products

- Approximately 50% of products in the category are protein only.
- The remainder are protein mixed either with carbohydrates, BCAA, individual amino acids such as l-carnatine or vitamins and minerals.
- Formats include powder, RTD and solid foods (notably bars).
- One interviewee noted a recent growth in products straddling the border between protein products and slimming products (e.g. body-shaping plus protein products).

Performance boosting products

- The majority of products in this category (60%+) are carbohydrates based products; either liquids/gels or bars.
- Creatine, BCAA and protein hydrosalates comprise approximately 20% of the category. Over half of these products are single ingredient, though there are some ingredient combinations as well. BCAA and combinations often come in powder format; the others in tablet/capsule or pill form.
- The remainder is made up of other, primarily single ingredient substances, based on the following substances: l-carnitine, caffeine and magnesium. Tablets, capsules and pills are the most common format. L-carnitine may be found in RTD form.

2.1.2.2 A2 Ingredients

Sportsdrinks

- Carbohydrates and electrolytes (primarily sodium) are the main ingredients.

Protein

- For powders, protein generally makes up over 70% of the dry matter. For protein enriched foods (i.e. bars and RTD), protein makes up at least 25% of the energy value of the product.
- Combinations of different proteins may be used in order to have a better effect than a single source of protein.
- Protein with carbohydrates are used in order to boost energy or help with strength.
- As noted in section 2.1.2.1, other ingredients such as BCAA, individual amino acids such as l-carnitine or vitamins and minerals may be combined with protein in some products.

Performance boosting products

- For energy boosting products, carbohydrates constitute at least 65% of total product energy.
- As noted in section 2.1.2.1, creatine, BCAA and protein hydrolysates, l-carnitine, caffeine and magnesium are the other main ingredients in this category.
- Creatine products contain creatine in volumes sufficient to ensure at least 0.08g of creatine per 1kg of bodyweight.

2.1.2.3 A3 Price

No price data was identified at national level or provided by interviewees. However, Euromonitor contains price data for certain major brands in Germany. Prices for products considered representative of each category are provided in Table 1.2.

Table 2.2 Price of FISP products in Germany (2014, EUR)

Category	Average size	Average price	Price per unit
Protein – powders	705g	23.79 EUR	3.37 EUR/100g
Performance boosting – gels	220ml	4.93 EUR	0.56 EUR/ 25g
Sportsdrinks	1607ml	1.28 EUR	0.08 EUR / 100ml

Source: FCEC based on Euromonitor; average of 5 randomly selected

2.1.3 Operators

2.1.3.1 A6 Market structure

Value of FISP market

According to data from Euromonitor, the market for sports nutrition and sportsdrinks was worth EUR 451.9m in 2014. No alternative data sources were identified during the course of the case study. The industry estimates that the industry has grown at around 2% per year in recent years. An increase in participation in sport was identified as a reason for industry growth; most notably the higher level of participation in physically demanding sports such as marathons (e.g. the number of people completing the Berlin marathon increased by 57% over the period 2008-14). The continued growth in sporting activity and different product positioning for different target groups appear to be the main opportunities for the FISP

market. Interviewees identified unfair competition from products not complying with legislation (both of EU and third country origin), and the doping issues as the major industry threats.

Structure of the chain and characteristics of operators

While a handful of large operators dominate the market, interviewees reported that there is a large (and growing number) of smaller companies which fall under the category of SMEs active in the market. The industry in Germany was therefore considered to be polarised, with the a few large operators, many small operators and very little between the two.

According to one interviewee, companies may either specialise in FISP or be active in neighbouring areas such as pharmaceutical products, slimming products or food supplements. The reason for this latter case is synergies in terms of the techniques and processes used in the industries. In some cases, the subsidiary may specialise in FISP, but the parent company may be active in a wider range of food or functional food related areas.

The level of integration of operators was reported by interviewees to vary between companies, with operators performing one or more of the manufacture, branding and sale roles. However, on balance evidence from interviewees suggests there is a fairly high level of integration; 41 of the significant 57 operators identified by one interviewee were active in more than one part of the chain; primarily both production and sale. Sub-contracted manufacture was identified as primarily being used in the case of private label FISP products.

Table 2.3 and Table 2.4 show the latest available concentration ratios for sports nutrition and sportsdrinks operators respectively. While the sports nutrition industry shows a high level of concentration, the sportsdrinks industry is less concentrated. There is also a high presence of private label operators¹⁰ in the sportsdrinks industry (they represent an estimated 38% of the total market for sportsdrinks).

Table 2.3: Concentration ratio of branded sports nutrition operators in Germany (2014)

Concentration ratio	Combined market share 2014	Combined market share 2010
CR-4	57.9%	62.6%
CR-8	78.1%	85%

Source: FCEC based on Euromonitor

Table 2.4: Concentration ratio of sportsdrinks operators in Germany (2014)

Concentration ratio	Combined market share 2014	Combined market share 2009
CR-4	42.2%	41.8%
CR-4 + other private label	63.2%	63.0%

¹⁰ Retail operators selling products under their brand that have been produced by subcontracted manufacturers.

Source: FCEC based on Euromonitor

2.1.3.2 A10 Innovation

Interviewees believed that annual innovation represented between 5-8% of the German market for FISP. Innovation in Germany was considered not just to be the development of new products, but also changes and improvements to existing products. The dynamic target group of customers expects innovation. The different needs of different athletes were also considered to drive innovation, and also to have contributed to increasing difficulty in terms of categorisation of products for sportspeople.

Two operators interviewed during the course of the study reported that the development time for new products is typically 1-2 years. The precise time needed depends on the complexity of the product. In the case of significant technical or regulatory challenges (e.g. the inclusion of caffeine in the latter case), the development period can exceed 2 years.

2.1.3.3 A8 Trade

No quantitative data on trade in FISP was identified during the course of the case study.

The following markets were reported as significant export markets by interviewees:

- Switzerland (which has a specific law on sportsfood; this is in the process of being updated)
- Russia (prior to sanctions)
- Turkey
- Norway (requires certification that a product imported from Germany is on the German market and in compliance with the law)
- Australia (interest in EU products due to the absence of use of genetically modified ingredients; there is national legislation on sportsfood in Australia)
- Middle East (a small but growing export market)

The extent to which German based operators export varies between operators. One major operator reported exporting 60% of its German production. However, interviewees did not consider this level of export to be representative of German FISP operators as a whole. Most large operators are understood not to export to such a high level; and one interviewee noted that many smaller operators may only sell products at a local level (not even at a national level) and subsequently will not export at all.

In terms of imports, the primary source third country identified was the US. Two forms of import were identified:

1. Import through local partners based in the EU who act as subsequent distributors.
2. Direct to consumer imports through US based companies selling products over the internet.

While no substantial concerns were expressed about the first form of import, interviewees considered the second form to be dubious. It was felt that many products imported this way were not in compliance with EU or German law.

Food supplements as a whole were reported to be generally imported from China; some sports supplements may be among these imports.

2.1.4 Consumers, distribution and marketing

2.1.4.1 A7 Distribution channels

Information on the distribution of FISP identified during the course of the case study is presented in Table 1.7. In the context of drug stores, sports shops and supermarkets, it was noted by interviewees that private label products are becoming increasingly common.

Table 2.5: Main distribution channels in Germany

Channel	Comments	Importance
Internet	Fast growing channel; both specialist (i.e. dedicated sports nutrition shops) and general (e.g. Amazon). Operators may be based in DE, other EU MS or third countries.	Interviewees: top four channel, ~ 20% by value (market share possibly as high as 50% for protein and performance categories) CS: 9% of respondents
"Drogerie" (drug stores chains)	Stores selling health, beauty and pharmaceutical products. Examples: DM, Rossmann. Smaller producers do not use this channel (they cannot meet demand). Drug stores sell on line as well.	Interviewees: top four channel, ~25% by value CS: see text
Sports/ fitness clubs and gyms	Includes a new emerging channel of self service machines (see below)	Interviewees: top four channel, ~30% by value CS: 13% of respondents
Sports shops	Examples: Sportscheck, Intersport	Interviewees: top four channel ~25% by value CS: 13% of respondents
Supermarket	Smaller producers do not use this channel (they cannot meet demand). Supermarkets are selling some products on line.	Interviewees: not yet mainstream CS: 42% of respondents
Chemists	May be popular with smaller companies.	Interviewees: considered to account for a very low proportion of distribution CS: 6% of respondents
Special events	Examples: pre-marathon fairs. Both sampling and purchase may occur. Popular with smaller companies.	Interviewees: no information

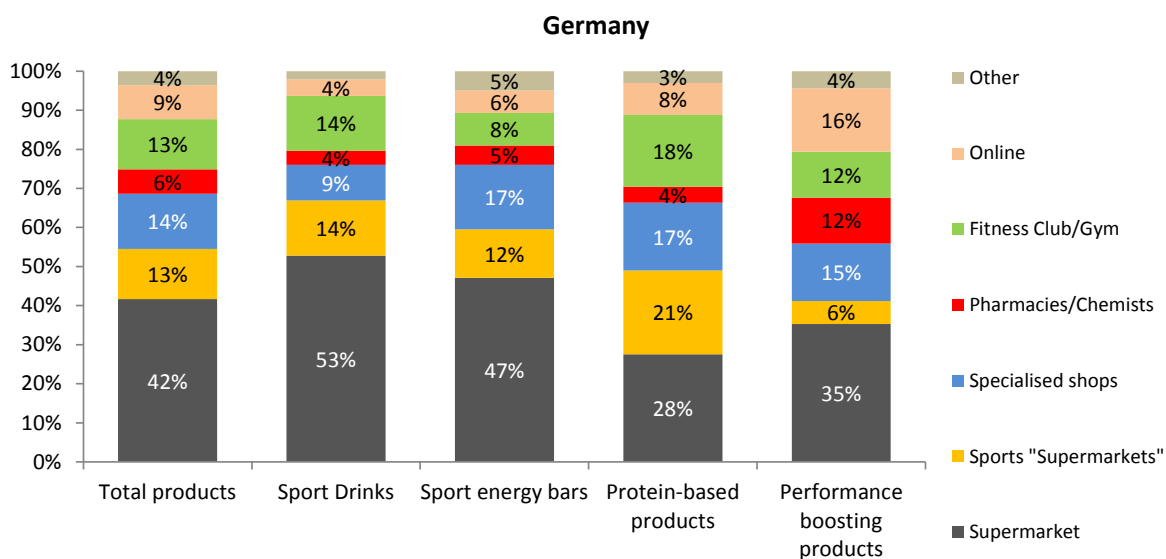
Source: FCEC based on interviewees and consumer survey (CS)

The table displays a difference between the importance of certain distribution channels (notably supermarkets) by volume according to interviewees, and the number of consumers reporting the use of distribution channels in the consumer survey. These differences can be largely explained by the following:

- The consumer survey did not include the Germany-specific channel of “Drogerie” (drug store chains), which are generally not found in other Member States. These drug stores chains bridge the categories of pharmacy and supermarket as a wide range of food and hygiene products can be found in them. In the absence of drug stores from the survey, it is considered likely that a significant proportion of consumers purchasing FISP in drug stores chains indicated supermarkets.
- Consumer survey figures are based on the number of consumers, while industry figures are based on the importance of volume.

The full results of the consumer survey distribution channel findings for Germany are displayed in Figure 2-1. The importance of supermarkets for distribution of sportsdrinks, and of the online channel for performance boosting products are worth noting.

Figure 2-1: distribution channels in Germany by product type according to consumer survey



Source: consumer survey

As noted in Table 1.7 above, an emerging method of selling sports nutrition products in German fitness clubs and gyms is that of self service machines (see Figure 2-2). According to one interviewee, these machines have been around for approximately two years. It was noted that there is a potential danger for the consumer from these machines as consumers can effectively mix their own drinks (including choosing higher levels of concentration) and the resulting drink is served in a cup. The product consequently does not appear to be in compliance with the definition of a pre-packaged foodstuff outlined in article 1 of Directive 2000/13/EC. One interviewee believed that products from these machines are placed on the

market as sportsfoods according to Directive 2009/39/EC (although this Directive only applies to pre-packed food).

Figure 2-2: Sports nutrition vending machine



Source: <http://www.astepahead.nl/> accessed 1/5/2015, based on information provided by interviewees

2.1.4.2 A11 Marketing techniques

According to interviewees, the following marketing techniques for marketing FISP are used in Germany:

- Exclusivity agreements with certain sports clubs (i.e. only a certain product can be used in the club).
- Sponsoring of sports clubs or teams.
- Endorsement by athletes.

- Specialist press advertising.
- "Nutritional schooling", whereby a representative of a company explains nutritional needs and how products can fit with this.
- Word-of-mouth advertising.
- Internet communication (including the use of internet forums).

The last two methods of communication on FISP products were considered by interviewees to be problematic for competent authorities to control. In the context of claims legislation and controls by competent authorities, these methods of communication fall into a grey area. There is generally no record of word of mouth advertising. The control of information on the internet is already challenging (see section 2.2.8), and information exchanged on internet forums either may not originate from the operator in question, or may not be traceable to them.

Recently there has been some TV advertising of FISP products, but this is understood not yet to be a significant form of advertising.

One interviewee noted that serious sportspeople will often rely on advice from trainers and nutritionists, meaning that the product labels are not as important for them.

2.1.4.3 A5 Claims

According to interviewees, authorised health claims which are relevant for sportspeople are widely used on FISP products in Germany. In addition to the seven authorised claims of direct relevance to FISP, it was noted that the claim on magnesium in relation to muscle function is commonly used.

There were mixed views on communication of substances without authorised health claims at present in Germany. One stakeholder believed that, if the product is placed on the market as a dietetic food, there may be the mention "with substance X", and that FISP products placed on the German market as food supplements would not bear particular indications of their suitability for sport. This interviewee felt that there is a certain reliance on the knowledge of the consumer in the absence of a suitable authorised health claim for a substance. However, another interviewee noted that some products can be found on the market with indications such as "dietary supplements for athletes", and that product names may be used to provide an indication of the direction of the action (e.g. "pre-work out booster" or "NO booster"). While further information may not be found on the label of such products, it may be present on product advertisements or websites.

There is some use of article 10(3) of Regulation (EC) No 1924/2006 in Germany in order to enable the use of non-specific sports related claims through the use of an authorised health claim. Interviewees noted two different cases:

- Products which are clearly intended for sportspeople (and may even be put on the market as sportsfoods according to Directive 2009/39/EC) using article 10 (3) for legal security; it was considered an extra security on top of any transitional brand protection under article 28 of the same regulation and purpose statements permitted under article 9 of Directive 2009/39/EC (for products placed on the market as dietetic foods).

- Products which may be considered to not be designed specifically for sportspeople. One example provided was that of an alcohol free beer which used the vitamin C claim in order to make the connection to sport. This product also uses sponsoring of sports events and endorsement by sportspeople in order to raise its profile among sportspeople. It was noted that certain products primarily intended for children (e.g. fruit purees) may also use this practice to target sportspeople.
- Certain tenuous links may be made between authorised claims and non-specific claims on products. One interviewee provided the example of a product which used the claim on zinc “Zinc contributes to normal metabolism of fatty acids” in order to facilitate the use of the non-specific claim “Fat burner”.

Interviewees reported that, following the entry into force of the list of authorised health claims in 2012, some FISP were reformulated or fortified in order to make them compatible with the health claims regulation. This included reformulation in order to support non-specific claims through article 10 (3) as outlined above. Relabelling of FISP was reported as widespread following the entry into force of the list of authorised claims due to the rejection of certain health claims.

Issues with the provision of information on labels / use of claims

Certain issues with information provided on product labels or the use of claims on FISP were identified by interviewees. More specifically:

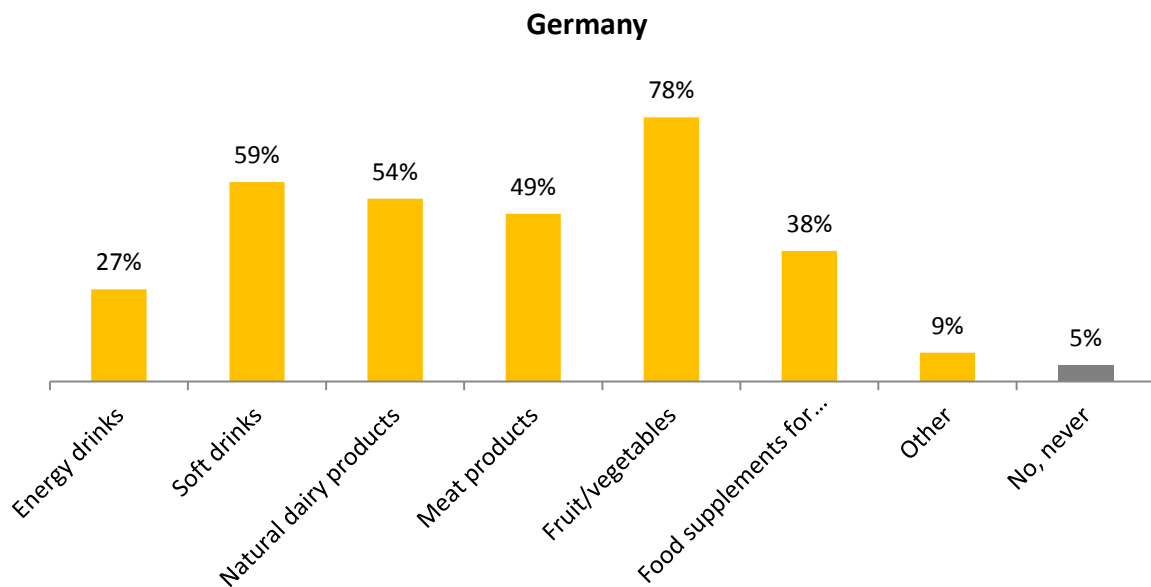
- Certain carbohydrate-electrolyte drinks do not meet the conditions required for use of the authorised health claims. Such products can be found labelled as carbohydrate-electrolyte drinks, but without the claim on the label.
- While there are no low carbohydrate or zero carbohydrate claims approved under health claims legislation, some FISP products with such mentions can be found.
- The name or description of some products may suggest benefits in the English language, despite the absence of an authorised health claim to facilitate the use of a non-specific under article 10(3) of Regulation (EC) No 1924/2006. One example is a product labelled “Body shape”. The language of the claim implied by this description can make it difficult for competent authorities to take action as it is necessary to for the competent authority to examine, on a case by case basis, whether the implied claim is understood by a majority of German consumers. If the implied claim is not understood by a majority of German consumers, it may be argued by the operator that there is no need to remove the English language description with the implied claim from packaging as it is not relevant to German consumers.
- Certain imported products from the US can be found with only a limited translation of the label and claims or suggested benefits in the English language (see also the previous point).

2.1.4.4 A4 Foods not intended for sportspeople

Interviewees did not identify any particular foods other than FISP which are commonly used by sportspeople in Germany. That said, evidence from the consumer survey indicates that some 95% of sportspeople use foods other than FISP in relation with sporting activity. Fruit

and vegetables are most commonly used (78% of respondents), followed by soft drinks (59%) and natural dairy (54%) (see Figure 2-3).

Figure 2-3: Use of foods other than FISP by sportspeople in Germany in relation to sports activity



Source: consumer survey

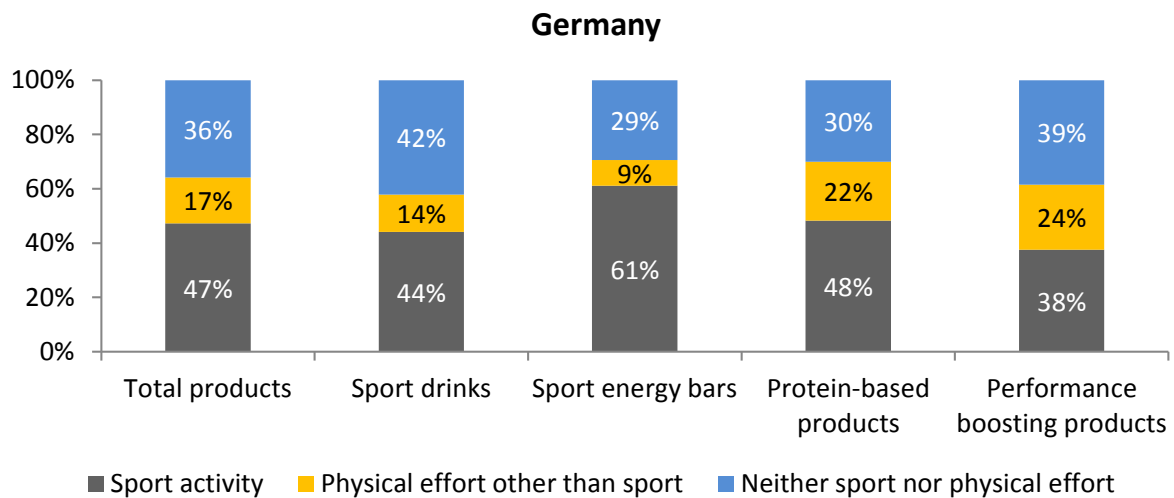
2.1.4.5 Consumers

According to interviewees, the main consumers of FISP products in Germany are primarily sportspeople, more specifically:

- High performance sportspeople or participants in sports requiring intensive muscular effort (e.g. marathons).
- Bodybuilders / fitness studio clients; according to Winters et al (2008), 76% of fitness studio clients in the German state of Nordrhein-Westfalen who train twice or more per week use FISP products (34% of them buy them from the fitness studio directly, and 22% based on the recommendation of their trainer).
- Recreational sportspeople.

Figure 2-4 displays consumption habits of FISP consumers in Germany by product category according to the consumer survey. There is a significant minority of consumers who use FISP in relation to non physical or sporting activity; particularly in the case of sportsdrinks.

Figure 2-4: consumption habits of FISP consumers in Germany by product category



Source: consumer survey

2.2 Evolution of the market after 2016

2.2.1 BI general evolution

In the absence of specific legislation on sportsfood at EU level after 2016, it seems most likely that national legislation will be adopted. While this is not yet certain, it does seem highly likely given that all major stakeholders; the federal ministry, the Bundeslaender, the industry and consumer organisations; are in agreement, and believe that legislation (either at EU or national level) for sportsfood is needed. However, the preference of all stakeholders is for EU legislation (on the basis of consumer protection), and in view of this no information on the likely areas covered by any national legislation was provided in the competent authority survey. That said, based on the views of stakeholders met during the course of the case study, there would likely be pressure for any national legislation to cover the following areas:

- Definition and / or categorisation
- Labelling
- Composition or substances authorised / banned for use in sportsfood products

In the absence of EU wide legislation after 2016, considerable impacts on the internal market were expected by interviewees; though some of these impacts exist already (see section 2.1.1.3). It was noted that many products on the German market contain multi-language labels, demonstrating that they are sold in several Member States and hence will be impacted by internal market distortions.

Given the uncertainty relating to the provisions for sportsfood (if any) which would be introduced in Germany after 2016, the remainder of section 2.2 focuses primarily on the impacts which would occur if FISP were to fall under other horizontal rules of food law after 2016.

2.2.2 *B4 impacts on competitiveness and operator costs*

The main impacts noted by interviewees in the case that sportsfood falls under other horizontal rules of food law in Germany after 2016 were:

- Internal market impacts, leading to the need for relabeling for different Member States. As already noted in sections 2.1.1.3 and 2.2.1 this issue already exists.
- Negative impacts on innovation (see section 2.2.3).
- The continued absence of legal clarity FISP in Germany. It was noted by one interviewee that the level of in clarity surrounding FISP in Germany was higher than in other Member States, as demonstrated by the fifty or so cases relating to the legal position of FISP which have been brought before judges in Germany since the 1990s¹¹. This process of seeking legal clarity from judges was also noted to be costly for operators. It was felt that if no legislation was adopted, this lack of legal clarity would persist and in the absence of the recognition of the category of sportsfood (and with the prospect of additional future cases relating to the legal position of sportsfood), legal clarity could potentially worsen.
- Unfair competition from certain (primarily internet based) operators; such operators will fill any gaps in the market resulting from the disappearance from the market of certain products for sportspeople (as identified in section 2.2.6).
- Relabelling, reformulation or withdrawal of existing products in order to remove mentions permitted under the DiaetV and reformulate or remove from the market any products which may not comply with the new legal framework.
- Possible difficulties for obtaining certification for export to certain third countries in the absence of the official recognition of sportsfood as a category of products (see also section 2.1.3.3).

2.2.3 *B5 Innovation*

One interviewee believed that there had been negative impacts on the development of new products in recent years stemming from the uncertainty regarding the future legal position of sportsfood. It was also noted that there have been some corporate sales of businesses in the area which may or may not be connected to the uncertainty in the sector (e.g. during the last year, Powerbar has been sold by Nestle and Lucozade by Glaxosmithkline).

Going forwards, it is likely that the impacts on the range of products outlined in section 2.2.6 will also impact the rate and nature of innovation in the sector.

2.2.4 *B6 SME consequences*

One interviewee believed that changes in laws and the absence of legal clarity generally impact SMEs more greatly than other operators due to the smaller number of staff (including

¹¹ These cases have covered a wide range of areas, including: the definition of sportsfood / borderline products (most notably the border with medical products); the legal position of certain products (e.g. whether or not they are dietetic foods; the placing of the market of products from other MS; and communication on certain products or substances).

the absence of staff dedicated to such areas). It was also noted by the same interviewee that the lack of clarity can more greatly affect new product development and reformulation among SMEs. No further specific impacts of the future situation on SMEs were identified.

2.2.5 *B7 Price*

None of the interviewed stakeholders felt to be in a position to make considerations on potential impacts on the price of products after 2016.

2.2.6 *B8 Consumer choice and behaviour; B9 consumer protection*

Some stakeholders expressed concerns that the range of products on the German market could be impacted after 2016. More specifically:

- The limitation on amino acids (and derivatives) in foods would lead to the disappearance of FISP with amino acids (unless legislative changes were made).
- 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 absence of any specific provisions covering doping substances after 2016 was considered to be a consumer protection issue by one stakeholder. This stakeholder cited the death of a consumer in Sweden due to the presence of a doping substance in a sports nutrition product as an example of the risk for consumers of doping substances in the absence of suitable provisions. It should, however, be noted that doping substances are not covered by provisions at present in Germany, so there will be no change from the status quo in this respect; that said, there have been national discussions on the introduction of anti-doping measures. The other major consumer protection issue identified by interviewees was that of information which can be provided on product labels after 2016 (see also section 2.2.7.).

2.2.7 *B10 Regulatory*

Interviewees provided a variety of comments relating to possible issues that FISP in Germany would face in the case that it is not considered a dietetic food after 2016 and no specific national legislation on sportsfood were to be adopted.

General issues

- Amino acids and derivatives are not authorised for use in food in Germany; they are legally considered to be equivalent to food additives, and therefore a national authorization would be need to use them. However, Regulation (EC) No 953/2009 allows for amino acids to be used in dietetic foods; hence the existence of FISP products with amino acids on the German market at present. If FISP falls under other horizontal rules of food law after 2016 however, the use of amino acids in FISP in Germany would be effectively prohibited. According to interviewees, it would appear unlikely that national legislation in Germany would be changed in order to allow the use of amino acids in food after 2016.
- Creatine and carnitine are considered food additives in Germany, and can only be used in certain authorised cases if exceptions are applied for.

- There is no legal definition of sportsfood in EU legislation. The inclusion of such a definition was felt necessary by one interviewee in order to avoid the misuse of the status of “sportsfood” by generic products after 2016.

Food supplements legislation

- The view of several stakeholders in Germany is that products with high levels of macronutrients such as protein are not likely to be accepted as food supplements in Germany as they are not considered to be compatible with the national interpretation of the food supplement definition.
- The same stakeholders believed that certain sports nutrition products in powdered form for making up into shakes may not be considered food supplements due to a combination of the nutrients they contain (e.g. 100g protein 60g carbohydrates and 5g fat). Consequently they may be considered a normal food after 2016, and hence indicated as “a protein concentrate with vitamins and sweeteners for the creation of a cold drink”.
- The absence of maximum levels was seen as a particular issue for some nutrients which may be present in quantities several times above the commonly accepted upper limit in certain FISP products. One example provided was nicotinic acid (a B vitamin).

Novel foods legislation

- The novel food status of certain ingredients (according to Article 1 (2) (a)-(f) of Regulation (EC) No 258/97) was considered to be not easily identifiable in many cases. Furthermore, a substance may be considered novel in one context (e.g. sportsfood) but not in another e.g. food supplements based on the provisions set out in Article 1 (2) (f) of Regulation (EC) No 258/97. While both of these issues already exist, it is unclear as to whether the disappearance of the category of dietetic sportsfood from legislation, and the regulation of FISP under other horizontal rules of food law may cause issues in this respect.
- The definition “food or food ingredient with new or intentionally modified primary molecular structure” is not legally defined. For example, in the case of creatine there are products marketed with alternative “innovative” forms of creatine, the novel food status of which is unclear.
- Connected to the issue of novel foods, the knowledge of the local level control authorities of the novel food status of ingredients and novel food legislation may not be sufficient for market controls due to the complexity and ambiguity surrounding the issue of novel foods. This is an existing problem.

Fortified foods

- National authorisation is needed in Germany in order to place a product on the market as a fortified food; consequently there would be a considerable burden for operators wishing to place FISP products on the market as fortified foods in Germany¹².
- Annexe III to Regulation (EC) No 1925/2006, while theoretically a good tool for regulating the substances which cannot be used in FISP, only contains two substances at present.
- Certain substances are not clearly authorised for use in fortified foods (e.g. amino acids in the case of Germany; see above). Such substances would need to be authorised, however in order to avoid their misuse in general food it would be necessary to introduce a definition (see above) or demarcation criteria.

Health claims and food information for consumers (FIC)

- Certain stakeholders believed that instructions of use containing words such as “sport” or “exercise” (e.g. “for use after exercise”) would be construed as claims in Germany. That said, there is clearly a degree of dependence on the interpretation of the competent authorities.
- There is no authorisation of substance or maximum levels connected to the authorisation of claims; consequently, health claims do not deal with safety but only with effects, creating a consumer protection issue.
- The possibility to use mentions such as “physical performance” in conjunction with certain substances such as BCAA or caffeine, which at present are permitted under the labelling provisions of the DiaetV, will be lost.
- Warnings on the presence of certain substances may be beneficial for consumer protection for certain substances which are commonly used in FISP such as creatine (such a warning exists for caffeine in Annexe 3 of Regulation (EU) 1169/2011).
- Nutrient profiles were identified as a possible future issue which, if not adjusted to take into account the nature of FISP, would affect the ability of around 60% of products to use nutrient claims, and 85% to use health claims (industry figures). This would consequently have significant impacts on both the range of products on the market and the ability of products to communicate (including the use of trademarks and product names under Article 1 (3) of Regulation (EC) No 1924/2006).
- One interviewee expressed concerns about the extent to which health claims and FIC legislation can be used to control the promotion of certain ingredients without authorised claims through channels such as advertisements or the internet. It should be noted that this was identified as an issue which already exists, and hence it does not seem likely the situation would worsen of the situation after 2016.

¹² Regulation (EC) No 1925/2006 only regulates vitamins and minerals; while provisions for the regulation of other substances are foreseen in the Regulation, these substances are not yet subject to the provisions of the regulation. National provisions continue therefore to exist for other substances. In Germany, additives, as defined by § 2 para. 3 sentence 2 of the German Food and Feed Code remain prohibited and need a special authorisation for use in foods. Consequently, additives and equivalent substances such as minerals, trace elements and vitamins A and D as defined by the above article of the German Food and Feed Code need special authorisation when used to fortify foods.

2.2.8 *B11 Competent Authority*

Market control is the responsibility of the Bundeslaender, which controls operators (producers, wholesalers, retailers and internet retailers) on their territory. Controls take place as part of wider controls on food and cosmetics.

Internet controls are co-ordinated at national level; websites and the physical location of internet sellers are checked centrally; though the Bundeslaender have responsibility for the control of internet based operators on their territory. In theory, operators selling by internet should already be registered, though this is not always the case, and some internet operators may only provide PO Box addresses which makes physical controls difficult. In the case that a product is identified for sale from an operator based in another MS or a third country, the federal authorities will contact the authorities of the Member State or third country about products which are not deemed to be in compliance. Only German language internet websites which allow payment in euros and delivery to Germany are checked; though there are also some borderline cases which will be checked; for example adverts from foreign operators in English for products which are available for purchase on ebay.de.

Further statistics on internet trade were provided by interviewees:

- In the general area of food and cosmetics, around 40% of operators selling by internet are not registered. Often operators do not know about the requirement to register.
- Roughly 1/4 of operators selling food or cosmetic products by internet do so over market place sites such as ebay or amazon. If asked, both ebay and amazon are fairly co-operative in terms of quickly taking down listings of unaccepted products.
- Roughly 1/3 of operators are based outside Germany.

Interviewees do not believe that the nature of controls themselves are likely to change after 2016 if there is no legislation for sportsfood at EU level (i.e. they will remain a part of wider controls for food and cosmetics). However, in the case no legislation is adopted at German level, issues with the legal clarity for controlling authorities would remain and they were expected to have a continued and possibly greater negative impact on the effectiveness of controls. It is already considered difficult to control food supplements based on the existing legislation, and it was felt that this would become more difficult if more borderline FISP products started being sold as food supplements after 2016. One interviewee concluded that under horizontal legislation, control authorities may not have the necessary power to act due to legal uncertainty.

In the case that national legislation were to be introduced, there would be a one-off burden for the Bundesinstitut fuer Risikobewertung (the Federal risk management institute), which would be required to obtain scientific risk analysis input on ingredients, their maximum levels and the composition of FISP products (the definition of sportsfood is considered a risk management issue).

3 CASE STUDY: ITALY

3.1 Theme 1: current market for sportsfood

3.1.1 A13 National rules

The product categories which are relevant for the study are covered in Italy by a number of national provisions. The most important is the Legislative Decree D.L.vo 111/1992 which transposed formerly Directive 1989/398/CE and then Directive 2009/39/CE.

However, there are other national rules of interest for sportsfood:

1. “Food supplements” (Dir. 2002/46/CE), including those targeting sportspeople, are covered by Legislative Decree D.L.vo 169/2004.
2. Fortified foods targeting sportspeople are directly covered by European Regulation 1925/2006/EC.
3. Any other type of food targeting sportspeople but not falling under the previous legislation is covered by Legislative Decree D.L.vo 109/92, which contains provisions on labelling, presentation and advertising of general food products (implementation at national level of Directives 359/89/CE and 396/89/CE).
4. Decree of the Ministry of Health, 09/07/2012, which disciplines the use of ingredients of vegetable origin in food supplements (including those targeting sportspeople): Annex I features a positive list of allowed ingredients, with the related conditions of use.
5. Italian Law n. 376 of 14/12/2000 disciplines health protection in sport activity and contrast to doping. This law is generally considered very strict and forbids the inclusion of any ingredient included in the list of doping substances of the World Anti-doping Agency (WADA), in all products (except medical ones). In this framework, it is not possible to use any of the substances reported on the WADA list as ingredients in products intended for sportspeople manufactured in Italy.

Legislative Decree 111/1992, which transposes the PARNUTs Directive, identifies dietetic foods as products which address the need of a specific target of consumers, among which sportspeople. All the products regulated through the PARNUTs should be easily distinguishable from foods for normal consumption¹³ and their composition should be functional to the nutritional aim of the target of consumers. Finally, the consumer target should be clearly indicated on the label. Regarding sportsfood, the full statement “dietetic food for sportspeople” has normally been replaced by a more synthetic statement: “for sportspeople”, not considered as an authorised claim under the Claims Regulation.

The Ministerial Circular of 5th November 2009 clarified further elements needed to properly identify food supplements, dietetic foods and fortified foods. In particular, a clear distinction has been reported between food supplements and certain categories of products:

¹³ As specified by Directive 2009/39/EC.

1. **Food supplements** are intended for consumption in small quantities and do not have relevant caloric contribution. These products are regulated by Dir. 2002/46/CE (transposed in Italy by Legislative Decree 169/2004).
2. **Protein supplements, energy supplements and mixed products** with relevant caloric contribution are not considered as food supplements in Italy: in this light such products have to report nutritional information on the label. Generally, these products target particular nutritional uses and consequently fall under the PARNUTS directive, however in case they are not aimed to satisfy the special nutritional needs of specific groups of people and they are fortified with mineral, vitamins and other substances they fall under Regulation 1925/2006.

Notification Procedure

Ministerial Circular n.4075 of the 6th March 2008 (which replaced a previous Circular dating back to 2000) regulates the notification procedure for the following categories of products:

- Foods for particular nutritional uses (among which food intended for sportspeople).
- Food supplements.
- Fortified foods.
- Novel foods.

Producers willing to market products falling under such categories must inform the Ministry of Health and transmit to the competent office (Office IV, with responsibilities over special foods, food supplements and novel foods) a facsimile of the label of the product, whose compliance with legislation in force is verified. The Ministry of Health checks the following aspects:

- a. Possible presence of prohibited ingredients.
- b. Compliance with legislation concerning labelling.
- c. Absence of claims concerning therapeutic properties and compliance of nutrition and health claims (if present) with Reg. 1924/2006 and Reg. 432/2012.

In particular the Office IV is in charge of the notification procedure. It is estimated that around 70% of total annual working hours of Office IV staff (13 units: 1 Head of Office; 4 technicians; 3 administrative officers; 4 administrative support personnel; 1 grant student with support functions) are dedicated to activities related to the notification procedure, i.e. analysis of facsimiles of labels and support to operators for proper interpretation of the relevant provisions.

Figures on total number of products notified under the different categories are as follows:

1. “Foods intended to meet the expenditure of intense muscular effort, especially for sportspeople”: 1,442 (cumulated total since 1995) / 17 (total for 2014 only).
2. Food supplements (including also those not targeting sportspeople): 76,690 (cumulated total since 1995) / 5.013 (total for 2014 only).
3. Fortified foods (including also those not targeting sportspeople): 1,592 (cumulated total since 2008) / 259 (total for 2014 only).

One of the most significant changes in national legislation covering the sportsfood has been the abolition of the authorization procedure originally foreseen by D.L.vo 111/1992 (Articles 7 and 8) also for “Foods intended to meet the expenditure of intense muscular effort, especially for sportspeople”. Article 28 of Italian Law n. 14 of 03/02/2003 repealed the authorization procedure and left in place only the notification procedure of such products to the Ministry of Health, which constitutes at present the essential element of Italian legislation covering “sportsfood”, in as much as it covers also food supplements targeting sportspeople and fortified foods (Reg. 1925/2006/EC allows Member States to implement notification systems).

The main aim of the notification system is not to control compliance of the products with all the relevant legislation, but to monitor placement of products on the market.

Operators can market products immediately after the notification has been sent to the competent office. Moreover, operators that do not notify the products only incur in an administrative fine, and the product can remain on the market (unless other violations are ascertained).

Evidence collected through the interviews with operators highlighted that the notification procedure is not seen as a burden for the companies. The cost of notification for companies is rather limited: a fee of 160 Euros per notified product label. No reason has been identified which may lead companies to non-compliance with the notification procedure. Operators reported that generally all the products placed legally on the Italian market have been notified.

Illegal and counterfeit products

Both operators and CA reported that the notification procedure has the important advantage to help to contrast the diffusion on the Italian market of illegal FISP products (including imported ones). In fact, all notified products are recorded in a register. The Ministry of Health has access to the register and can easily check if a product on the market has been recorded. As consequence, the CA can immediately identify non-recorded products, which are likely to be illegal products.

Italian Ministry reported of other instruments used to contrast the diffusion of illegal products:

- An ad hoc anti-counterfeiting group set up by the Ministry of Health, by *Nuclei Antisofisticazione* (anti-counterfeiting unit) of *Carabinieri* guards, and by AIFA (Italian Agency for Pharmaceuticals).
- USMAF offices (*Uffici di sanità marittima, area e di frontiera*) of the Ministry of Health, dealing with health protection related to sea and air transport and to customs: these are especially important for what concerns contrast to import of illegal products.

3.1.2 Sportsfood products on the market

3.1.2.1 A1 Products on the market

In terms of number of products, no exact data are available, but one of the most important online retailers in Italy reports that approximately 10,000 different references and 200 brands are available on their website.

Not considering sportsdrinks, the most relevant products cited are:

- Proteins (in all different formats, noticing that in recent years a growing role is played by egg-based products as well as meat protein and vegetal ones)
- Branched Chain Amino Acid (BCAA)
- Energizing gels
- Oats (both flour and rolled oats)
- Multivitamin products

Weights of different macro-categories of products in terms of value are reported in Table 3.1 below.

Table 3.1: Importance of main categories of FISP in Italy

Category	2014 Value EUR m	% of total*	Forecast annual growth rate 2013-18
Protein products	38.2	11%	3.6%
Performance boosting products	45.6	13%	2.1%
Sportsdrink	273.8	77%	-7.2%
Total	357.6		2.8% nutrition only

Source: Euromonitor

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

3.1.2.2 A2 Ingredients

The most common ingredients reported by a major online retailer based in Italy are:

Protein

- Whey protein hydrolysate
- Casein
- Dipeptides (both synthetic and by hydrolysis of plant proteins)
- Soy protein or other vegetable protein

Performance boosting products

- Carbohydrates powder (maltodextrin, starch e.g. vitargo etc ...), to be reconstituted in water
- Creatine in all forms (not only monohydrate, often as a different salt or with various methods of tampon or delivery)
- Caffeine
- Nitrate
- Glutamine
- Arginine (also AKG and other salt forms)

Sportsdrinks

- Carbohydrates
- Vitamins and minerals

Others

- Probiotics
- Enzymes

No specific combinations of the above listed ingredients have been provided by interviewees, with the exception of probiotics and enzymes, often associated with proteins.

Additional insights have been collected with reference to sodium phosphate and carnitine, which seem to be rather uncommon as ingredients for products marketed in Italy.

3.1.2.3 A3 Price

No price data was identified at national level or provided by interviewees. However, Euromonitor contains price data for certain major brands in the Italy. Prices for products considered representative of each category are provided in Table 4.2.

Table 3.2 Price of FISP products in the Italy (2014, EUR)

Category	Average size	Average price	Price per unit
Protein – powders	990g	31.31 EUR	3.16 EUR / 100g
Performance boosting – gels	38g	1.65 EUR	1.10 EUR / 25g
Sportsdrinks	583ml	0.89 EUR	0.15 EUR / 100ml

Source: FCEC based on Euromonitor

Key drivers for products prices vary on the basis of which level of the supply chain is taken into account:

- For producers, the most relevant part of variable cost is the ingredient, especially for new products where the molecule producer is in a temporary monopoly position; another important role is played by packaging costs, as innovation in packaging is particularly important for consumers.

- According to retailers, two main drivers explain changes in prices, both of them referring to imported products: transport costs and variations in exchange rates (in the period Dec 2014 – Jan 2015 both elements increased, with a significant impact on final prices).
- For domestic products, no significant oscillations in prices are reported.

An example of unexpected price growth is reported about whey proteins: in recent years the price of this ingredient boosted because of increasing demand for powder milk from China; operators reacted by developing products based on substitute sources of protein (eggs, meat and vegetables).

As for prices across different retailers, no significant differences were detected, with some exceptions:

- Supermarkets usually are able to offer slight discounts for mass market products (e.g. sportsdrinks).
- Usually fitness centers and gyms have higher retail prices due to their supplying policy (sometimes directly from other retailers).
- For the online channel, aggressive pricing strategies are often applied for the most common products, with the objective to attract consumers on the online stores and to also sell side products.

Finally, according to both producers and retailers, the price elasticity of demand is quite low. Especially for new products/molecules, consumers are in general extremely informed and aware of differences between products and prefer to pay a premium price for the specific products they look for. For commodities products the situation is quite different, with more price competition but also in this case there is a relevant portion of consumers preferring to pay for quality (one interviewed operator reports that for many customers one of the most important aspects of the product is the brand of the producer of the ingredient, and if it is trusted in the community or not).

3.1.3 Operators

3.1.3.1 A6 Market structure

A distinction generally accepted within the Italian market is between sportsdrinks – representing the largest part of the market and quite concentrated in a short list of products marketed by global players (e.g. PepsiCo with Gatorade brand, CocaCola with Powerade, etc.) and sports nutrition, with a wide range of products spanning from protein bars to powder and non-protein products. Italian producers of FISP are mostly SMEs. Enervit, the most important operator and the biggest Italian company with 52 million Euros of turnover and 170 employees, is positioned slightly above the upper limit of SMEs definition, while the other Italian companies are below. Finally, several multinational companies are important players in the Italian market, and some of them operate in Italy through national subsidiaries.

For sportsdrinks, the situation is rather different. The market environment is entirely composed of big multinational companies (e.g. Coca-Cola, PepsiCo) which have a specialised range of sportsdrinks.

According to Euromonitor data, the Italian market for FISP was worth 357.6m EUR in 2014. The market is heavily weighted towards sportsdrinks, though this category has shrunk in

recent years, while sports nutrition has grown. Forecasts for the two markets are divergent as well, with an expected Compound Annual Growth Rate (CAGR) for sports nutrition of 3% in the 2013-18 period, and an expected annual decrease for sportsdrinks of 8% in 2014-19¹⁴.

In terms of market composition, protein products account for approximately 45% of the whole sports nutrition market in terms of value, while non-protein products (mainly creatine, energy bars, carbohydrates, BCAA, etc.) represents the remaining 55%. Within the protein category, the most relevant products are powders and bars (17% and 9% of the total market, respectively) which are also the most fast-growing, with CAGR in the 2008-13 time span of 8%.

Concentration ratios for the Italian sports nutrition segment are reported in Table 3.3 below. In general, the sector is highly concentrated, with the top three players accounting for more than 60% of the total market.

Table 3.3: Concentration ratio of branded sports nutrition operators in Italy (2014)

Concentration ratio (CR)	Combined market share 2014	Combined market share 2010
CR-4	68.8%	70.7%
CR-8	84.6%	86%

Source: FCEC based on Euromonitor

A similar consideration is valid for sportsdrinks. The CR4 in 2011 was 71%; it increased to 77.9% in 2014. CR8 in 2011 was 76%; it increased to 90.1% in 2014. The top three players now account for 73% of the market (Table 3.4).

Table 3.4 –Concentration ratio of sportsdrinks operators in Italy (2014)

Concentration ratio	Combined market share 2014	Combined market share 2011
CR-4	77.9	71%
CR-4 + other private label	90.1%	76%

Source: FCEC based on Euromonitor

The structure of the supply chain for FISP appears to be quite definite, with large operators engaged in the production of ingredients (which mainly occurs abroad) as well as of final products, and with small/medium specialised retailers coexisting with large supermarkets. Sub-contracting in the production phase is used especially by retailers which place on the market private label products; in general, its importance is likely to be greater for smaller producers.

Among the few significant examples of vertical integration across Europe, the following are noteworthy:

¹⁴ Source: Euromonitor

- UK-based ingredient producer Glambia, which developed its own brand for consumer products.
- France-based retailer Decathlon, which developed its own brand for consumer products.
- Italy-based producer Enervit which acquired 70 specialized stores (Vitamin Store).

In general terms, producers need a complex structure to manage critical stages of the process:

- Quality tests.
- Scientific department.
- R&D department.
- Detection and dosage tools.
- Communication to consumer (especially experts able to understand the legal framework and allowing the company to operate accordingly).

The above aspects represent the largest part of investments and fixed costs for producers, which explain on one hand the relatively high average size of players, and on the other the main barrier to entry for competitors.

Margins for producers are significantly different with respect to the retail channel, with lower margins through supermarkets and higher margins through specialized stores.

Finally, a SWOT analysis¹⁵ has been drafted on the basis of the interviews held with retailers and producers.

Strengths

- Sector with high margins.
- High-growth market thanks to the diffusion of a healthy culture across countries.
- Specialized niche, although with increasing competition.

Weaknesses

- Competition with illegal products imported from third countries (especially for “muscle products” sold through the online channel).
- Lack of enforcement in the current legislation both at national and European level.
- Need of recurring investments in innovation and marketing to preserve market shares.
- Current claim regulation does not guarantee returns comparable with risks and costs associated to the approval procedure.

¹⁵ 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.

Opportunities

- Fast-growing segment of population involved in semi-competitive sport activity (running, cycling, etc.)
- New transversal product categories targeting lifestyle users (vegan, organic, cosmetics).

Threats

- Post-2016 scenario in which no specific legal framework is envisaged for sportsfood.
- Market-related risks from possible “block” of the possibility to use labelling indications as required by article 9 of Directive 2009/39/E, sports images and sports indications on labels and packaging.

3.1.3.2 A10 Innovation

Evidence from interviews suggests how important innovation is for the sector, giving the opportunity to players to:

- respond to the continuous request from consumers for more performing products;
- tackle unfair competition from imported illegal products;
- maintain high margins by offering new and better products every year; and,
- enhance bargaining power with big retailers.

Also in subsectors where innovation in ingredients and combinations is minimal (e.g. sportsdrinks), every year new flavours, special editions and new packaging/bottles are introduced.

3.1.3.3 A8 Trade

In general terms, the most important import/export route is from US to Italy: US products have a strong reputation in the sector and specialised consumers closely follow the innovation of US market. Because of more flexible legislation certain US products may contain substances and formulas not legally available on the EU market. Some of these products enter the EU market illegally, generally through the online channel. On the other hand, exports from Italy to US are negligible, since Italian (and in general European) producers base their products on domestic legal limitations and are often not attractive outside the EU.

As for intra-EU trade, an important exporter is Germany, which is broadly perceived as a high-quality producer. Italian producers export their products in a few EU countries where the market is more developed (France, UK, Germany and Spain). An interesting market for Italian producers is Sweden, where there are no large-scale local producers but the number of consumers is believed to be rapidly increasing.

3.1.4 Consumers, distribution and marketing

3.1.4.1 A7 Distribution channels

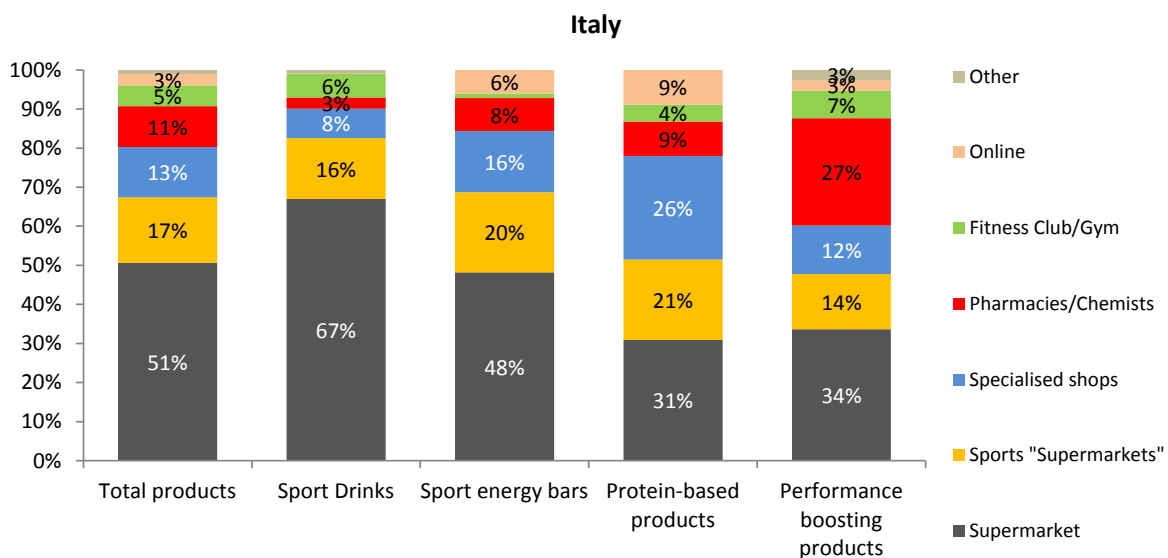
The Italian retail market is based on the channels outlined in Table 3.5. Figure 3-1 displays the full results of the consumer survey distribution channel findings.

Table 3.5: Distribution channels of FISP in Italy and their importance

Channel	Comments	Importance (% of consumers)
Supermarket	Main channel for less specialised products (e.g. sportsdrinks)	CS: More than the half of FISP is sold through supermarket channel
Sport supermarket	Example: Decathlon	CS: Second place for importance; particularly important for protein-based products
Specialised shops	Shop specialised in products for sports nutrition	CS: 13% of consumers use this channel to buy FISP.
Pharmacies/Chemists	Stores selling pharmaceutical and health products	CS: Very important for products to boost performance (26%)
Fitness clubs/gyms	Small corner shops in fitness clubs and in gyms	CS: More important for boosting products (9%) and protein-based products (4%)
Online	Both specialist (i.e. dedicated sports nutrition shops) and general (e.g. Amazon) websites.	CS: Fast growing channel but the least important for the moment.

Source: consumer survey (CS)

Figure 3-1: distribution channel in Italy by product according to the consumer survey



Source: consumer survey

The growing importance of online sales has been acknowledged by all interviewed operators; all the major manufacturers have well-developed and interactive websites, with the objective of allowing consumers to easily identify new products, and more in general the most suitable products for their needs (e.g. possibility to select the practised sport, the necessity to consume before-during-after exercise, nutritional needs, etc.).

It is interesting to note that in recent years some “physical” retailers based in Italy have started to move towards the online channel: often these retailers have experienced difficulties, due to the different KPIs¹⁶ and marketing techniques between the two channels.

3.1.4.2 A11 Marketing techniques

Marketing techniques differ significantly between the sportsdrinks and the sports nutrition segments. In the sportsdrinks arena, global players largely use “classic” media as television, endorsement by famous sportspeople and appealing packaging: these techniques imply large investments which are compatible only with big global players. On the other hand, medium-sized companies operating in the FISP sector (both as producers and retailers) use the following list of media:

- **Event organization/sponsorships:** this is by far the most important channel because it allows both to approach specific segments of the population (e.g. amateur and/or professional sportspeople) and to establish – also through dedicated happenings and parties organized in the context of larger sports events – a personal and trusted relationship with customers.
- **Web marketing/key word advertising:** also this channel allows direct advertising to specific targeted groups.
- **Specialized magazines:** these still play a role in marketing, not only for “classic” advertising, but also through the offering of new products to the editor by retailers, requesting for a test and a review (which is much more powerful for the consumer in comparison with an advertisement).

It is worth noting that, although not properly a marketing technique, the web monitoring of forums and social media has critical importance; it is commonly recognized that word of mouth is often the true driver of consumer choices: monitoring reactions to the launch of new products and feedback on offered services is therefore crucial for operators, it being understood that this “channel” is in no way controllable by companies through marketing techniques.

3.1.4.3 A5 Claims

Different insights on the use of claims in the Italian market have been collected through interviews; **for producers, the importance of approved health claims by EFSA is in general terms not central**, for the following reasons:

- Complexity and costs related to the approval procedure. This implies that few producers have enough resources to apply for new claims and the remaining operators simply utilize the already approved ones.

¹⁶ Key Performance Indicators: a set of quantifiable measures that a company or industry uses to gauge or compare performance in terms of meeting their strategic and operational goals.

- Many examples (glucose, sucrose, sodium, caffeine) have been provided of claims which were generally substantially valid for EFSA with regards to sportspeople, but which have been rejected on the ground of their contrast with general guidelines for food consumption for the general population.

The above reasons have resulted in a **general preference of producers for claim-like statements** (e.g. “energetic”, “for sportspeople”, purpose-related statements, etc.) which are legal in the Italian regulatory framework, thanks to provisions concerning implementation of art.9 of directive 2009/39/CE.

Retailers represented a slightly different scenario, where consumers at almost any level of sport activity reach in a short timeframe a very high level of awareness and expertise on different substances and their effect (but also on how they interact, on which is the best diet to enhance the results, etc.); as a consequence, consumers’ interest for labelling information is limited to ingredients, to the brand of the ingredient producer and to nutritional value. Also in this case, health claims appear not so important for consumer information, while specific claim-like information¹⁷ such as “pre-during-post exercise” instructions of use are still deemed important.

In light of the above evidence, it seems that for the Italian market approved health claims play a secondary role as marketing tools (basically producers limit themselves to use the approved ones, with minimal reformulations – if any – in order to meet composition criteria, and they do not usually submit requests for new claims) in comparison with claim-like statements, which are generally considered essential for product definition and consumer targeting. No evidence was found to suggest that there was widespread reformulation following the entry into force of the list of health claims in order to use certain authorised claims.

As for foods other than FISP, examples were provided on honey and walnuts products reporting claim-like statements and imagery related to sport activity, in some cases citing collaborations with doctors and nutritionists (in potential contrast with Reg. 1924/2006, art.12c.).

3.1.4.4 A4 Foods not intended for sportspeople

A brief list of examples of foods other than FISP has been provided by interviewees:

- Walnuts
- Honey
- Dry fruit mixes
- “Raw products”: products (e.g. bars) with raw/barely processed ingredients

In general terms, these products more or less directly connect the consumption to the idea of sport and healthy life; most of the time in potential conflict with the current legislation.

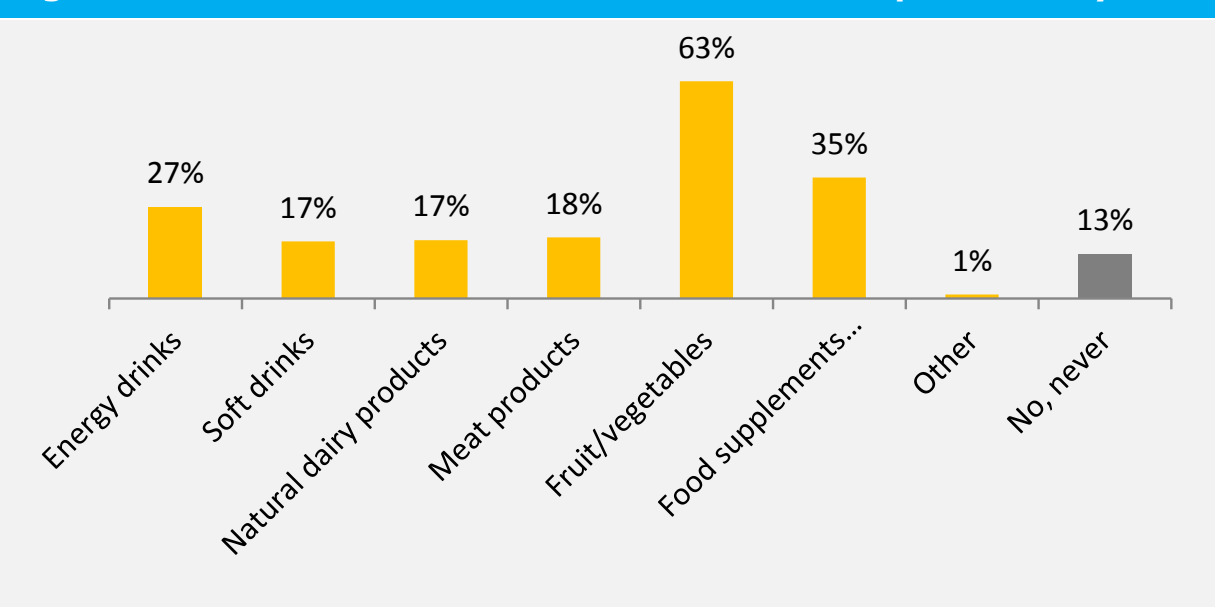
¹⁷ Allowed under the implementation of Article 9 of Directive 2009/39/EC.

Energy drinks are also cited among the most common products not developed for sportspeople but which more and more often are associated to energy and sports by consumers.

As a general rule, producers who offer both FISP and food other than FISP (e.g. cereal bars), are focused on maintaining separate these categories as much as possible in order to avoid misunderstanding in consumers, and to target different population segments.

Some data on foods not specifically targeted for sportspeople and consumed in the context of sport activity have been collected through the consumer survey. Results for Italy show that only 13% of respondents declare not to consume such products to support their sport activity; on the other side, fruit and vegetables and food supplements for overall good health (i.e. not specifically designed for sport) are the most relevant categories (with a prevalence of 63% and 35% of total responses, respectively); consumption of energy drinks is also quite common, with 27% of total responses.

Figure 3-2: Foods other than FISP in relation to sport activity¹⁸



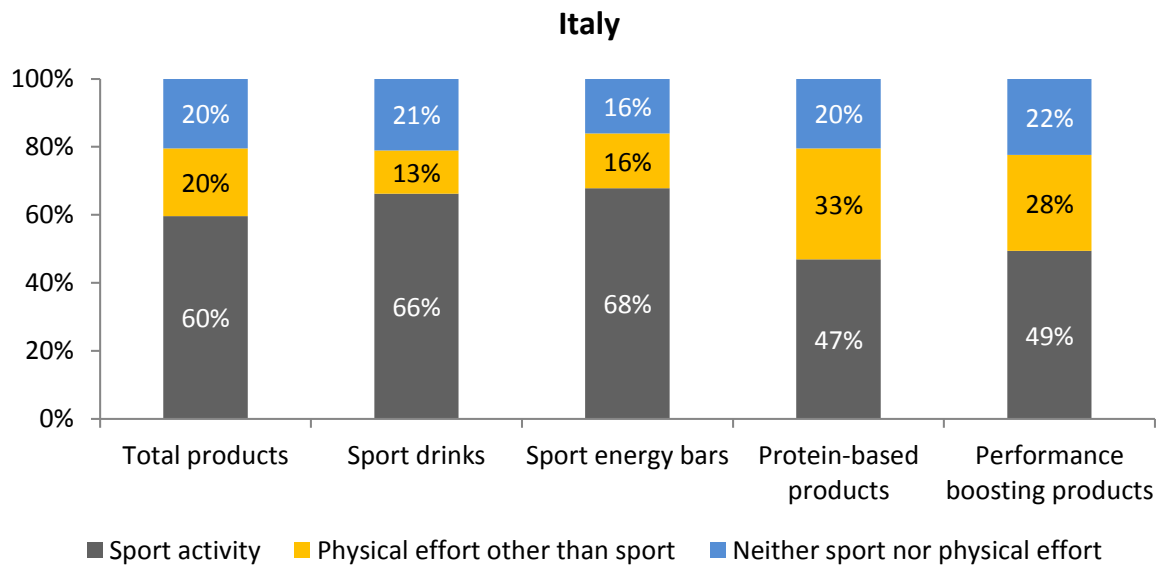
Source: Survey AgraCEAS -Aretè for DG SANTE

3.1.4.5 Consumers

Figure 3-3 displays consumption habits of FISP products by product category according to the consumer survey. In all cases, consumers using products in relation to neither sports nor physical activity are a minority. However it is worth noting that there is a substantial proportion of consumers using protein based products in relation to physical effort other than sport.

Figure 3-3: Consumption habits of FISP consumers by category in Italy

¹⁸ For details on consumer survey, please refer to § 3.3.5 of Interim Report



Source: consumer survey

3.2 Evolution of the market after 2016

3.2.1 BI general evolution

In general terms, being the post-2016 scenario not completely defined, interviewees provided different feedback on the basis of the envisaged scenarios they have in mind.

The Italian CA does not foresee specific national legislation after 2016, envisaging FISP as being regulated by other horizontal rules of food law; in this context, it is considered that producers will likely notify and market FISP products as food supplements or as fortified food products. On the other hand, although both legal status and relevant legislation for sportsfood products could change, no significant reformulation or withdrawal of products is expected by the Italian CA for the Italian market.

As for producers, they developed a **“worst-case” scenario** which enabled them to emphasize the potential effects on the market stemming from **“mechanical” application of horizontal rules of food law** to FISP, without any specific exception.

- One of the main concerns raised by producers refers to use of **claim-like** statements after the end of PARNUTS. As already reported, use of approved health or nutrition claims appears to be rather limited in the Italian market, while statements like “sport product”, “for sportspeople”, “to be assumed pre-during-post exercise”, etc. play a central role in product marketing. The use of these statements is today allowed under the Directive 2009/39/CE but their future is considered by interviewees to be uncertain in case no specific regulatory framework for sportsfood is adopted.
- Another concern refers to potential **prohibition of some ingredients** (today allowed) if included in Annex III of CE Regulation n. 1925/2006. For these substances the turning point could be the difference between consumption in a controlled and restricted context (i.e. physical activity) rather than widespread consumption by the general population.

- Finally, potential adoption of nutritional profiles could limit future utilization of health and nutrition claims in FISP (for instance in the case of products with high content of glucose or sodium) when the “dietary product” definition under PARNUTS will come to an end.

For all these reasons, producers would definitely favour a legislation allowing a categorization similar to the one used under PARNUTS; in terms of **minimal expectations** with respect to the future scenario, these could be summarized as follows:

- a. Products and ingredients allowed today should not be banned (and hence withdrawn or reformulated).
- b. Use of claim-like statements should still be possible.
- c. Possibility to use images of sports activities on labels should be kept.
- d. Possibility to use the “for sportspeople” statement should be kept.

3.2.2 B4 impacts on competitiveness and operator costs

The most significant risks for competitiveness refer to the above expectations (see section 3.2.1) with regards to the future legal framework for FISP. Producers highlighted that the potential prohibition of use for claim-like statements and for product categorization related to sport could “block” the market and worsen the clarity of communication to consumers. Additional risks relate to the application of horizontal rules of food law which - by a way of example - through annex III of CE guideline n.1925/2006 could declare illegal substances already approved and available on the market, but which could not be suitable for the general population. In general, uncertainty about proper interpretation of legislation is likely to increase, and this could also have side effects on competitiveness and operator costs.

3.2.3 B5 Innovation

Considerations by the interviewed Italian stakeholders on potential impacts of the new regulatory framework on innovation are in line with the ones made by EU-level stakeholders. Stricter constraints to the use of claim-like statements in the marketing of products are likely to make it more difficult for producers to communicate effectively to consumers the functions and properties of new ingredients, combinations of ingredients and products, thus reducing the incentive to true innovation. Innovation would hence tend to focus on non-substantial aspects like flavours, formats etc.

3.2.4 B6 SME consequences

The evidence collected so far has not highlighted specificities for Italy concerning impacts on SMEs under the new regulatory framework. The greater exposure of SMEs (due to their limited resources) to risks related to innovation, especially if stricter enforcement of the claims regulation will prevent the use of claim-like statements in product marketing, has been highlighted also for Italy.

3.2.5 B7 Price

None of the interviewed stakeholders felt to be in a position to make considerations on potential impacts on the price of products stemming from the new regulatory framework.

3.2.6 B8 Consumer choice and behaviour; B9 consumer protection

In the course of two interviews, a common fear emerged that the absence of specific vertical legislation for “sportsfood” under the new regulatory framework at EU level - and in particular the lack of a regulatory ground for linking the composition of a product to the effects which can be achieved through its consumption - might result in less information for the consumer, and/or less clarity in such information. Consumers looking for specialist products might face greater challenges in identifying them, especially in the case of a proliferation of products targeting sportspeople only through a generic reference to “sports”.

Some Italian producers fear the occurrence of a “worst case scenario” where the use of most of the claim-like statements customarily used in the marketing of FISP in Italy (from “product for sportspeople”, to pre-during-post effort instructions of use, to statements like “energetic”, “carbohydrate-based” etc.) will be impossible, with negative impacts in terms of information to consumers. It is worth noting that the interviewed Italian producer organisation deems that even if sportspeople cannot be considered a category of “intrinsically vulnerable consumers”, they consume products in vulnerable conditions (e.g. under physical effort) which - without proper management – can lead to more or less severe health issues for them.

Another potential health risk for consumers is that the Ministerial Circular 5th November 2009, which regulates the distinction between food supplements and protein and energetic supplements, has its legal basis on the PARNUTS Directive, and its future is uncertain after 2016. The risk for the consumers is related to the absence, within the Circular, of mandatory requests of indications on the energy value for food supplements. After the repealing of the PARNUTS Directive, the category of “protein and energetic supplements” foreseen by the Circular and rooted in the PARNUTS Directive will fall, and a growing number of notifications of products with high energy value as “food supplements” is expected. The Italian CA does not exclude to draft a new legislation; however, during the transitional period, or in the absence of a new legislation, products with high energy value could be marketed without clear indications on the label.

However, given the current trend towards notification as food supplements of products which would probably have been notified as “foods intended to meet the expenditure of intense muscular effort, especially for sportspeople” in the past, there is the risk that some of such products - whose content in fats, proteins and carbohydrates can be substantial, with remarkable caloric provision – are assumed in significant quantities by consumers who are totally unaware of the related risks, due to the absence of nutritional information on the label.

3.2.7 B10 Regulatory

The Italian Ministry of Health would see with favour the introduction of EU-level legislation defining in an unambiguous way few key categories of specialist products targeting sportspeople, putting aside the ambition to cover with specific vertical legislation the entire, extremely wide array of products more or less explicitly targeting sportspeople. This might help to prevent an uncontrolled proliferation of conventional products (and especially supplements) which target sportspeople just by virtue of claim-like statements making just a generic reference to “sports”, but actually not designed for the specific needs of sportspeople.

The Ministry of Health expressed its concerns about the possibility that ingredients commonly used in FISP could be used as ingredients for food not normally targeting sportspeople. However, according to the CA, in order to ensure protection of the consumers and consistency with the rules already in place, new uses of these ingredients should require the authorization under the Novel Food Regulation as already happens, under the same regulation, for certain ingredients that are firstly used exclusively in food supplements and later used in other foods.

According to the Italian CA, the introduction of new national legislation covering sportsfood after 2016 is not on the agenda. National legislation in force at present is likely to be kept also after 2016, inasmuch it is not in conflict with EU-level legislation.

3.2.8 B11 Competent Authority

According to interviewees, significant changes in the administrative burden for the CA and FBOs stemming from the new regulatory framework in force after 2016 are unlikely. The overall number of notifications is unlikely to change significantly: there will probably be a further shift of notifications from the “foods intended to meet the expenditure of intense muscular effort, especially for sportspeople” category (which already sees very few notifications) to the “food supplements” category, a process which has actually already been under way for some time in Italy (a growing number of specialized products targeting sportspeople have indeed been notified as food supplements).

Finally, in terms of controls, the Italian CA today controls at central level all the notified labels, to verify if specific labelling requirements and composition are met; under the assumption that current FISP products will be preferably notified as food supplements or as food added with vitamins and minerals, the CA’s control activity would go on with no significant differences with respect to current situation.

4 CASE STUDY: UK

4.1 Theme 1: current market for sportsfood

4.1.1 National rules (A13)

There are no specific national rules for sportsfood in the UK and there has never been a notification procedure for the category.

Directive 2009/39/EC is transposed in the UK through various, primarily vertical regulations pertaining to the different categories of dietetic food. There are different regulations for each of the UK's four countries. A result of the approach to the transposition of the Directive 2009/39/EC is that there is no single, clear reference in UK legislation recognising foods intended to meet the expenditure of intense muscular effort as a type of PARNUTS food.

According to interviewees, in the absence of specific legislation, the UK view is that sportsfood can be considered PARNUTS products and PARNUTS purpose statements on food are acceptable, however in general terms FISP should conform to requirements of general food law (GFL). It was noted that some FISP products may be placed on the market as food supplements, in line with the legislative definition. There is no notification process for food supplements in the UK.

Some national rules or provisions of indirect relevance to certain FISP were identified, notably:

- **Nutrient profiles for advertising to children:** in the UK, nutrient profiles are used to determine which foods can and cannot be advertised to children. As sportsdrinks and some sports nutrition products typically contain moderate amounts of sugar and sodium (“salt”) for functional reasons, they cannot be advertised to children. One stakeholder felt this can create the incorrect perception that sportsdrinks are unhealthy when in fact they are designed for a specific use and are formulated in line with scientific recommendations and with conditions of use for authorised health claims.
- **Regulations on food in schools:** sportsdrinks cannot be sold in schools in England, as the majority of drinks are prohibited. Once again, one stakeholder felt this restricted access of teenagers engaged in sporting activities to suitable products.
- **Hybrid front of pack labelling scheme:** A voluntary colour-coded front of pack nutrition labelling system exists in the UK. This can be an issue for FISP due to the levels of some nutrients, which would be marked as red (e.g. salt and sugar in sportsdrinks) when in fact they are appropriately formulated for their purpose. Furthermore the labelling excludes protein which is an interesting nutrient for sportsdrinks. While this system is voluntary, so companies can choose not to use it, there may be consumer mistrust of products which do not use this labelling. Many major operators have committed to using this labelling, but some have also taken the decision to exclude sportsdrinks from their commitments because the colour-coding and the Reference Intakes (RIs) are not necessarily relevant for sportsdrinks (who may have different nutrition requirements versus the general population) or reflective of the purpose of a FISP. This tool was considered inappropriate by one stakeholder as it is a “one size fits all” approach which does not take into account the specific characteristics of FISP.

4.1.2 Sportsfood products on the market

4.1.2.1 A1 Products on the market

Number of products on the market

No interviewees were able to provide an overview of the total number of FISP products on the market. In the absence of a notification system, centralised market monitoring and market studies into the number of products, no meaningful way of estimating the total number of products was identified. Furthermore, interviewees noted some difficulties in estimating the number of products on the market given issues such as internet trade and different varieties / formats (see also main report). However, it can be concluded that the number of products on the UK market is several thousand based on the following:

- Interviewee perception that the number of operators is in the hundreds, and there is increased specialisation in certain sports leading to a larger number of products.
- The number of products stocked by specialised retailers such as Holland and Barrett, GNC or SNUK is in the hundreds (and some cases thousands). By way of example, GNC UK lists 432 sports nutrition products, and many of these are products from brands which are not stocked by competing specialised retailers.

With the exception of sportsdrinks, no meaningful estimates of the number of FISP products by category were identified. However, in the particular case of sportsdrinks, one interviewee estimated that there are 50 products, based on the fact that there are 7 major brands, each with approximately 7 different products (including differentiations by flavour). Another interviewee however felt that this was likely to be a gross underestimate; the interviewee agreed that while the major brands hold the vast majority of the sportsdrinks market, there are a large number of small niche brands which would greatly increase the number of products on the market.

The importance of each category in terms of volume based on Euromonitor data is displayed in Table 4.1 below.

Table 4.1: Importance of the main categories of FISP in the UK

Category	2014 value EUR m	% of total	Forecast annual growth rate 2013-18
Protein products	295.7	40%	9.7%
Performance boosting products	146.7	20%	8.6%
Sportsdrinks	289.3	40%	-11.3%
Total	731.7		9.3% nutrition only

Source: Euromonitor

* Percentages add up to 101% due to rounding

Most common sub-categories, formats and varieties

Comments, and to the extent possible, data and estimations regarding the importance of different sub-categories and formats are below.

Protein

- Protein only products (which tend to be in powder form) are the mainstay of the category.
- Mass gainers, which include carbohydrates, are probably the next most important category.
- Growth in the mainstream market has seen an increasing number of recovery products comprising protein and carbohydrates in particular. Recovery products are interesting not just for “non-traditional” users of protein products such as runners.
- The more mainstream the product, the more likely the use of ready to drink (RTD) or bar formats.

Performance boosting products

- Energy bars and gels are fairly widely used.
- Pre-work out products, which use a creatine or caffeine base to combine various ingredients are considered to be a growing segment. Emerging products in this category are targeting new areas such as endurance sports and may come in various forms such as RTD.
- Individual ingredient supplements, which generally come in tablet or pill form, target educated consumers.

Sportsdrink

- Over 90% of products are sold in RTD form, almost exclusively 500ml bottles. The remainder is sold in powder or concentrated liquid form.
- The vast majority of drinks (80%+) are carbohydrate-electrolyte solutions. The “light” market (products with lower levels of carbohydrates and marketed for less intense exercise) is believed to account for 4% of the market, and carbohydrate only drinks the remainder.

Borderline products

An interesting borderline case with some vitamin and mineral supplements were identified in the UK. Certain supplements were identified as edging into the sports areas, through the legitimate use of claims, following the entry into force of the list of authorised health claims. One such example of such products can be found at: <http://www.vitabiotics.com/>¹⁹. The key elements underpinning the targeting of sportspeople are:

- Endorsement from certain sportspeople.

¹⁹ Accessed 21/4/15

- Identification of sportspeople as one of the possible target groups for this product. By way of example, one vitamin c supplement from this company identifies the following population groups as targets for the product²⁰:
 - People requiring immune support.
 - *Athletes and sportspeople.*
 - Over 50s.
 - Those with hectic lifestyles.

4.1.2.2 A2 Ingredients

Protein: protein was identified as the main ingredient, with carbohydrates also found in many products. Whey protein is understood to remain the dominant protein type in the UK, though it was noted that various alternative sources such as pea protein were also emerging (see also section 4.1.3.2).

Performance boosting products: carbohydrates, creatine, amino acids and caffeine are common ingredients. While products in this category are predominantly single-ingredient, the sub-category of pre-work out products (which combines creatine or caffeine with other ingredients such as single amino acids) is growing in popularity.

Sportsdrinks: the key ingredients are water, carbohydrates and electrolytes, particularly sodium. Historically some sportsdrinks have contained different electrolytes in the same proportions as they are found in sweat (sodium, potassium, calcium, magnesium). A few products may also contain other functional ingredients such as vitamins, caffeine and protein (caffeine and protein were identified as added to niche products, and present in 20% or less of sportsdrinks on the UK market).

4.1.2.3 A3 Price

No price data was identified at national level or provided by interviewees. However, Euromonitor contains price data for certain major brands in the UK. Prices for products considered representative of each category are provided in Table 4.2.

Table 4.2 Price of FISP products in the UK (2014, GBP)

Category	Average size	Average price	Price per unit
Protein – powders	1083g	44.27 GBP	4.09 GBP / 100g
Performance boosting – gels	54g	1.41 GBP	0.66 GBP / 25g
Sportsdrinks	500ml	1.35GBP	0.27 GBP / 100ml

Source: FCEC based on Euromonitor; average of 5 randomly selected

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 from interviewees, the reactions to this price rise was multi-faceted:

²⁰ <http://www.vitabiotics.com/ultra/vitamin-c/> accessed 21/4/15

- 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.

4.1.3 Operators

4.1.3.1 A6 Market structure

Value of the market

As noted in section 4.1.2.1, data from Euromonitor puts the UK market at 731.7m EUR in 2014. Sports nutrition grew at an annual rate of 16.5% p.a. over the period 2008-13, and is expected to grow at a slower rate of 9.3% p.a. going forwards to 2018. Sportsdrinks contracted by 1.1% p.a. over the period 2008-13, and going forwards to 2018 the market is expected to contract more rapidly at 11.3% p.a.

A major driver of the sports nutrition and drinks market in the UK in recent years was considered to be the increase in popularity of certain sports; most notably following the 2012 London Olympics. Long distance cycling and marathons were identified as particular cases in point. The sportsdrinks industry, however, has suffered in recent years, and is expected to continue suffering due to increased awareness among UK consumers about sugar intake. While on one hand this has provided the opportunity for light versions of sportsdrinks, evidence suggests that manufacturers have not adapted well to the situation; as seen in section 4.1.2.1, light products make up only a small part of the market (estimated 4%). It should be noted that light products are unlikely to fulfil the criteria for use of the carbohydrate-electrolyte claims.

Structure of the chain

Information provided by interviewees suggested that major UK based operators are mainly of a size which is larger than that of an SME; of the major 17 UK based operators identified by interviewees, only one was considered an SME. It is possible that this is a consequence of the rapid growth of the UK market over recent years which has resulted in the EU's largest market. That said, one interviewee noted that there are SME operators in the sports nutrition segment, though the interviewee was not able to provide data to back this. The likely presence of SMEs in the sector is corroborated by interviewee perception that the number of operators may be in the hundreds (section 4.1.2.1) and given the high concentration ratios of the industry (Table 4.3), it would appear likely that there are many SMEs which are sharing a small proportion of the UK market.

Among the major identified operators, the level of integration also appears lower; of the aforementioned 17 operators:

- 9 are retailers only.
- 2 are product manufacturers only (branded or contracted).
- 1 is an ingredient manufacturer only.

Consequently, only 5 operators are present in multiple parts of the chain (ingredient manufacture and manufacture - 2; retail and manufacture – 3). In addition to the 17 UK based companies identified above, one US Company, one Canadian company and one Irish company were identified as having significant direct presences in the UK market. Various companies, most notably from the US were identified as having indirect presence on the UK market (i.e. distribution to retailers or internet retail only).

The concentration ratios of branded sports nutrition (excluding drinks) operators in the UK are displayed in Table 4.3. The third column displays the concentration ratios from 2009.

Table 4.3: Concentration ratio of branded sports nutrition operators in the UK (2014)

Concentration ratios	Combined market share 2014	Combined market share 2010
CR-4	55.2%	61.8%
CR-8	70.2%	78.45

Source: FCEC based on Euromonitor

While concise comparable data has not thus far been found on CR-4 and CR-8 ratios for the sportsdrinks industry, it is understood from interviewees that Lucozade, Gatorade (Pepsico) and Powerade (CocaCola) dominate the market, holding a market share of over 90% between them (i.e. CR-3=90%). The largest of the three operators in the UK is Lucozade.

In summary, a significant difference was noted between the producers of sportsdrinks and sports nutrition:

- **Sportsdrinks:** there are 6 or 7 major sportsdrinks manufacturers on the UK market. The companies are larger and tend to operate cross-border (e.g. Lucozade - UK and Ireland in particular; PepsiCo-Gatorade - 5 EU MS; Coca Cola Powerade across the EU).
- **Sports nutrition:** manufacturers tend to be comparatively smaller in size with a wide range of lower volume products. There are a large number of these smaller companies. There is some use of sub-contracted manufacture; particularly for private label brands.

4.1.3.2 A10 Innovation

There was overwhelming agreement among interviewees that the FISP sector in the UK is innovative. However, no specific figures to quantify innovation in the UK were identified. The following drivers for innovation in the sector were identified:

- **New target markets stemming from the increase in interest in certain sports.** Some products may also target the broader area of extreme activities (e.g. military, emergency services, heavy manual labourers).

- **New product forms.** This is a particular driver for producers who try to offer new products to support certain activities or sports (e.g. gels for triathletes). In the category of protein products, RTD products were identified as having gained popularity in recent years in the UK (most notably among gym-goers) leading to the launch of many new products. This popularity and trend in product launches was expected to continue into the near future.
- **New science about the efficacy of ingredients,** e.g. fast release vs slow release proteins.
- **New substances or combinations of certain substances which are intended for specific functions.** One recent example of this is beetroot juice. A version of this which uses the word "sport" and makes statements on the importance of nitrate (despite the absence of an authorised health claim) can be found for sale in Holland and Barrett (<http://www.hollandandbarrett.com/shop/product/james-white-drinks-beet-it-sport-60004927>²¹).
- **New / alternative ingredients.** In the particular case of the UK, the emergence of products using different types of protein such as egg or pea was identified, with the consequence that protein products of various different types of protein at different price points could be found on the market. This is probably at least partly due to the high price of whey protein in the UK in recent times.
- **New product flavours or pack sizes.**

In summary, over the short term, innovation tends to be driven by new flavours and pack sizes. Over the long term, innovation is driven by science, research and development.

4.1.3.3 A8 Trade

While no data on trade was identified, the following qualitative information on trade was provided by interviewees:

- **Sportsdrinks:** there is no substantial third country trade in sportsdrinks due to the bulky nature of RTD products.
- **Sports nutrition products.** A significant part of protein products may be produced by US companies; these may, in some cases, produce in the US and export products to the UK. Imports into the UK of US products were considered to be considerably facilitated by the mutual language shared by the two countries. The direct-to-consumer import of certain products from the US which are not in compliance with EU legislation is believed to occur; such products can be purchased on US based websites and shipped to the UK. The majority of "bulky" FISP products are most likely made in the UK/EU due to the product nature. Ingredients for protein products made in the EU are most likely originating from inside the EU; most notably, Ireland. It was noted that the end of milk quotas may have impact on the availability of protein for the production of sports nutrition products.

²¹ Accessed 21/4/2015

4.1.4 Consumers, distribution and marketing

4.1.4.1 A7 Distribution channels

Once again, differences were noted between the sportsdrinks and sports nutrition market.

Sportsdrinks are primarily sold through physical outlets as they are not suited to distance trade. Supermarkets were considered an important outlet.

Sports nutrition: Figures for distribution by a major UK based operator which focuses primarily on sports nutrition (rather than drinks) and is considered representative of the sports nutrition industry were provided by one interviewee. These are displayed in Table 4.4, along with additional information uncovered during the course of the case study.

Table 4.4: distribution channels of sports nutrition products in the UK

Channel	Further comments	% of distribution by value
Internet	Can be further sub-divided into specialist and mass (e.g. amazon). Mass has gained popularity in recent years.	38%
Specialist sports nutrition		34%
Multiple retailers and convenience stores	Of increasing importance for sports nutrition	15%
Gyms and fitness centres		7%
Pharmacies		4%
Sporting goods shops		2%

Source: FCEC based on interviewees

Further comments were provided as follows:

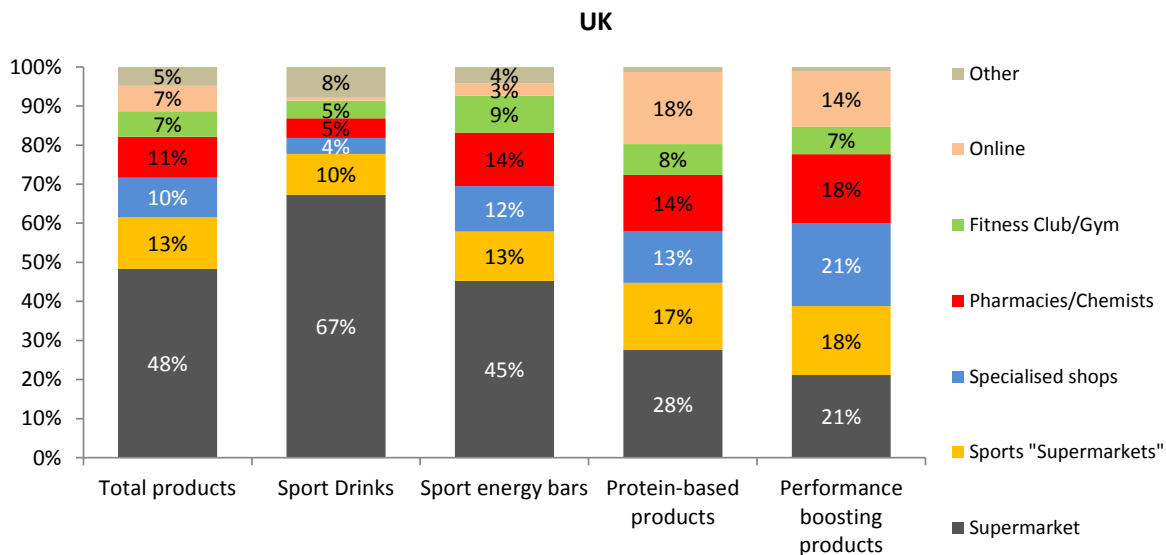
- High volume protein powder products are often sold through physical sales channels due to their size, and these products are particularly common in gyms.
- Smaller supplement-style products on the other hand are often sold by internet, and there is a concern in relation to regulatory compliance of products sold by internet particularly those originating outside the EU.

Findings of the consumer survey with regards to distribution channels are displayed in Figure 4-1. The findings, which relate to the number of consumers indicating that they use a purchase channel, are broadly coherent with the evidence provided by interviewees. Results worth noting include:

- The higher importance of supermarkets for the distribution of sportsdrinks
- The importance of the internet and specialist shops for protein and performance boosting products.

- The fairly small role played by gyms and fitness centres.

Figure 4-1: distribution channels in the UK by product type according to consumer survey



Source: consumer survey

Finally, one interviewee felt that the distribution of illegal black market products may take place over the internet and through some sports centres / gyms as “under the table” trade; though no solid evidence exists to corroborate this.

4.1.4.2 A11 Marketing techniques

Advertising and written press were identified as the most important marketing channels by interviewees. The use of radio and TV was deemed to be lower than for normal food products; most likely due to the cost implications. Personal recommendations from professionals; magazine or blog articles; and other internet sources of information were considered to also be important.

One interviewee believed that there was a fair amount of “feel good” marketing surrounding the FISP industry. This was considered to facilitate the targeting of the general population. Marketing is unlikely to be of high importance to elite athletes, as the majority of these will rely on dedicated nutritionists for the determination of dietary intake.

According to interviewees, methods such as word of mouth and business-to-business leaflets may be used to communicate some information about FISP which is not on the label. Most notably, personal trainers in gyms may be relied on for information on products.

4.1.4.3 A5 Claims and labelling

Evidence from interviewees and field observations indicates that FISP are typically placed on the market as sportsfood products in accordance with Directive 2009/39/EC. Labels contain instructions for use and words such as "sport". Examples include:

- "Consume before / during / after sport / exercise / workout / training"
- "for endurance exercise".

One interviewee felt that there is sometimes a lack of clarity regarding what is or is not a sportsfood product according to Directive 2009/39/EC and this can further complicate interpretation of labelling for enforcement bodies, in turn creating some uncertainty for operators.

According to information from interviewees on the use of authorised health claims, and based on field observations:

- The carbohydrate-electrolyte claim is used by sportsdrinks products which meet the requirements.
- The protein claim is often used by sports nutrition products with the required level of protein. Some sportsdrinks have added protein and may use this claim. Products fulfilling the criteria of the creatine claim are also likely to use it.
- Claims relating to some other vitamin and mineral substances will be used if the criteria are fulfilled (e.g. claims for muscle function; energy yielding metabolism; nervous system).

It is understood from one interviewee that the UK authorities have taken a strict line on the interpretation of claims legislation, typically ruling against the use of wording that deviates from that included in the register of authorised health claims, even though a level of flexibility is allowed by legislation.

Business-to-business communication was considered an issue with claims legislation in the context of FISP. While health claims applies to all commercial communication (Article 1 (2) of Regulation (EC) No 1924/2006), it is not clear whether or not this includes some business-to-business communication such as leaflets and word-of-mouth and to what extent it is possible for the competent authority to take action in this area.

Reformulation following the entry into force of health claims

As was noted in section 4.1.2.1, following the entry into force of the list of health claims, there has been an interesting case of certain food supplement products using certain claims in order to explicitly include sportspeople among the target groups. The claims used were identified to primarily pertain to:

- Vitamin c and the immune system during/after exercise
- Various vitamins and minerals and their impact on muscle function, an energy yielding metabolism or the immune system.

One interviewee felt that in some cases the supplements may just have been relabelled, while in other cases reformulation or the introduction of new products occurred.

In terms of FISP, no evidence was uncovered to suggest that fortification was widespread following the entry into force of the list of authorised health claims in 2012.

Experience with the submission of health claim dossiers

One interviewee reported having submitted a dossier for a health claim in relation to an FISP product, which was ultimately rejected. From this experience, the interviewee picked up on the following difficulties in the health claims application process:

- A high level of investment is required for researching, creating and submitting health claim dossiers; the exact level of investment depends on the nature of the claim (i.e. whether specific scientific research needs to be performed or whether existing research can be used).
- There are some difficulties in communication. The EFSA review process could benefit significantly from improved dialogue/communication so that requirements and information needs are clear and applicants can respond to requests effectively.
- The rationale for rejection was not entirely clear in the case of this dossier, hence the interviewee did not know whether or not it was worthwhile resubmitting a dossier.

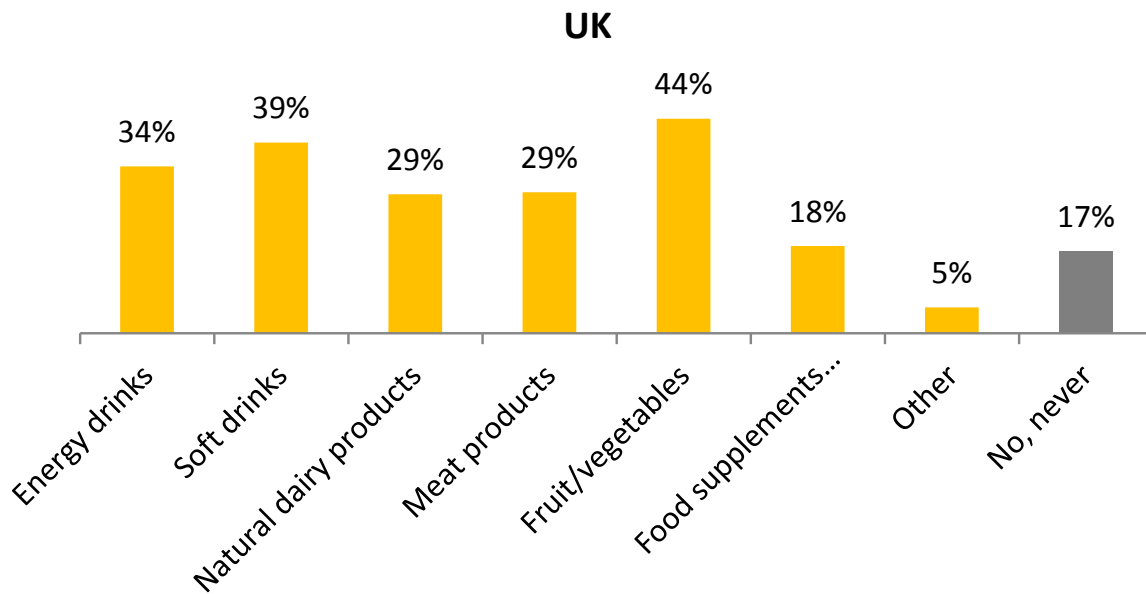
In addition to issues with the scientific assessment part of authorisation, it was noted that certain claims may become undone due to political considerations. For example, claims relating to sodium, carbohydrates and caffeine may be considered unsuitable as they are against the needs of the general population. The interviewee in question felt it important that the specific needs of sportspeople are taken into account in this context. Finally it was noted that it may be difficult to obtain authorised claims for more complex products containing more than one ingredient.

4.1.4.4 A4 Foods not intended for sportspeople

A number of high sugar foods are traditionally considered a source of energy for certain physical activities. One particularly popular one used in outdoor sports is Kendal mint cake.

According to results from the consumer survey, 83% of sportspeople use foods other than FISP in relation to sporting activity. The most common of these are fruit and vegetables (44%) followed by soft drinks (39%) (see Figure 4-2).

Figure 4-2: Use of foods other than FISP in relation to sports activity by sportspeople



Source: Consumer survey

According to one interviewee, the price differential, on a nutrient supply basis, between FISP products and foods other than FISP providing the same nutrient has effectively disappeared in recent years in the UK. For example, the price, per-gram of protein for protein-based FISP products, compared to the per-gram price of high protein foods other than FISP (such as dairy or meat) was considered to be similar nowadays. However, no concrete data was provided to confirm this assertion.

4.1.4.5 Consumers

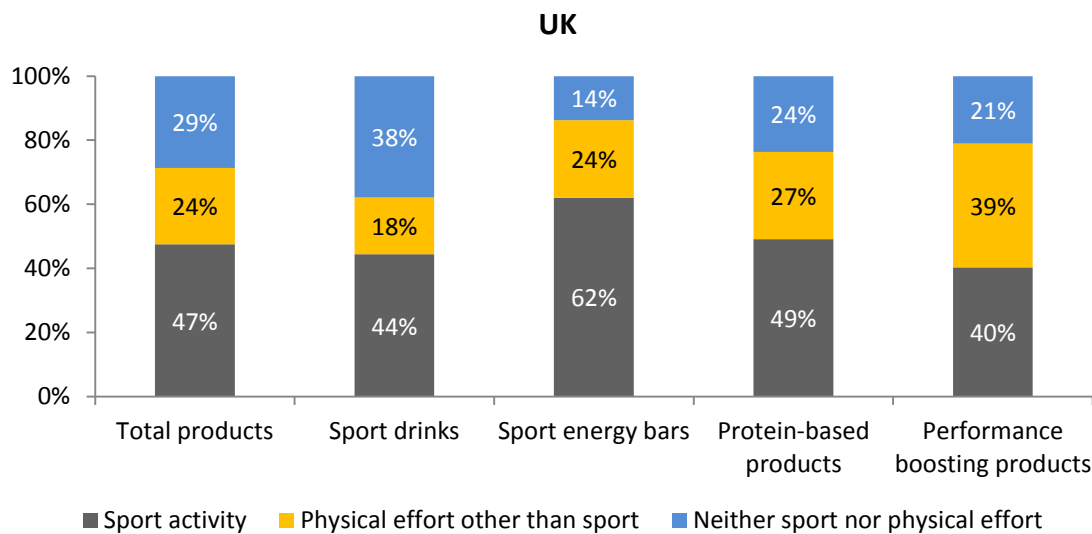
Interviewees felt that the range of consumers of FISP in the UK is wide, and, on balance, that the industry is becoming mainstream. More specific comments were made on the following groups of consumers:

- **Sportspeople**
 - **Body builders and muscle mass intense sportspeople.** Some protein and supplement style products may be widely used by aesthetically motivated body builders, as well as by sportsdrinks who participate in sports where muscle mass is an advantage (e.g. rugby, sprinting).
 - **High level athletes.** It was noted that high level athletes were likely to have their own dedicated nutritionists who control dietary intake. While their nutritional needs are outside the normal, it was noted by one interviewee that the high level athletes form a very small part of the general population.
- **Lifestyle / other users**
 - **Health and wellbeing motivated consumers.** These were considered to make up a significant proportion of sports nutrition product consumers.
 - **People engaged in extreme physical activities other than sport.** Users may not be sportspeople but rather people involved in extreme physical activities of some kind;

for example the military, emergency services or manual labour. The claims used on FISP products are also relevant to these groups.

Figure 4-3 displays consumption habits of FISP consumers by product category according to the consumer survey. The proportion of consumers who use products neither in relation to sport activity or other physical effort varies between product categories. It is particularly high (38%) in the case of sportsdrinks.

Figure 4-3: consumption habits of FISP consumers by product category in the UK



Source: consumer survey

4.2 Evolution of the market after 2016

4.2.1 BI general evolution

The most likely is that no specific legislation will be introduced in the UK, and so FISP will fall under other horizontal rules of food law (source: CA survey). The UK policy at present is to avoid introducing more legislation than necessary and current policy is to not legislate without good reason. That said, it is understood that the UK will look at the report to the Council and European Parliament before taking a final decision. There is also a degree of uncertainty about the future direction in view of the UK general election that took place in May 2015.

According to interviewees, the present situation has some harmonisation-related issues. However, in the case that the PARNUTS framework is repealed and some Member States keep national legislation, this problem of EU- wide harmonisation could be further accentuated. While all interviewees identified internal market impacts, one interviewee expressed particular concerns regarding the possible internal market impacts; more specifically:

- Any national legislation which provides an advantageous position in relation to labelling indications permitted on a national market may produce two significant issues. Firstly, whether or not products from a Member State which permits such labelling will be accepted on other Member State markets is unclear. Secondly, operators producing and selling on that specific Member State market will be advantaged vis-a-vis those which are sending their products to this market from another Member State (unless the labelling of these products sent from other Member States is specifically changed in order to take advantage of the labelling possibilities provided by the Member State of destination).
- Some operators which are present in multiple Member States and the absence of harmonisation could adversely impact operating practices. This was felt to be a particular issue for the sportsdrinks industry which is cross border in nature.

4.2.2 B4 impacts on competitiveness and operator costs

In general interviewees felt that the repeal of PARNUTS should, in theory, create a more level playing field for operators, given that the degree to which FISP differ from normal foods is not clear. There may be some changes in the method of marketing of FISP products, though it is hard to say in advance to what extent.

However, certain issues for operators were identified:

- Significant relabelling was considered likely due to the presence on labels of instructions, descriptions and denominations in accordance with the PARNUTS directive which would no longer be permitted.
- Certain formulation issues with carbohydrate-electrolyte drinks would be likely; more specifically, there has been a historical practice of using electrolytes in sportsdrinks in the same concentration as they are found in sweat, but these levels may be below the minimum levels required by Regulation (EC) No 1925/2006 on fortification. At present, PARNUTS products can use these lower levels due to "without prejudice" provisions.
- A suitable transition period is required for whatever replaces PARNUTS; the present timeframe of July 2016 is too short given the continued uncertainty regarding the future position of FISP.

4.2.3 B5 Innovation

While one interviewee saw opportunities for innovation under other horizontal rules of food law as the sports nutrition market would continue to become more mainstream, another expressed concerns with the possible impacts on innovation under such a framework. More specifically, it was noted that the health claims application process is not easy. If the instructions and denominations which are used at present (see section 4.1.4.3) are not accepted under other horizontal rules of food law (and consequently considered to be health claims in the future and as such need to pass through the health claims process) it will be difficult for operators to communicate on innovative products. In the absence of the ability to communicate on the ingredients of FISP products (which was perceived by this interviewee to provide a licence to operate), the investment required and uncertainty associated with obtaining new claims for FISP products could act as a barrier which discourages innovation.

4.2.4 *B6 SME consequences*

In the case that the health claims authorisation process does prove to be a barrier to innovation, interviewees felt that SMEs would be adversely impacted, and consequently have little impact to innovate. Beyond this (still hypothetical) impact, no other specific impacts on SME were identified.

4.2.5 *B8 Consumer choice and behaviour; B9 consumer protection*

Article 9 of Directive 2009/39/EC requires that the designation under which a product is sold is accompanied by an indication of its particular nutritional characteristics. There was concern from one stakeholder that in the absence of the PARNUTS framework directive, instructions, descriptions and denominations relating to sport or exercise could be (mis)-interpreted as health claims, and hence it would not be possible to provide this information to consumers.

Changes to legislation may be needed in order 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.

Views on the impact on consumer choice were conflicting and largely in line with the opposing views identified in terms of impacts on innovation. One interviewee believed that the range of products would continue to grow under other horizontal rules of food law as sports nutrition becomes mainstream. On the other hand, another interviewee felt that with limited ability to communicate and incentive to innovate, it is likely that established products with authorised health claims will remain on the market (provided nutrient profiles do not affect this), but less established, smaller products may disappear and new product launches may reduce; resulting in an overall reduction of consumer choice.

4.2.6 *B10 Regulatory*

Most stakeholders in the UK considered other horizontal rules of food law to be suitable to regulate FISP. However, a few areas of general food law which may need to be modified in order were identified:

- There may be an issue around the composition of certain FISP products. It may be possible to address these through derogations under Regulation (EC) No1925/2006 on fortified foods as far as addition of vitamins and minerals.
- It will be necessary to enable the labelling of high energy FISP products in a way which indicates that they are only intended for certain consumers with the need for them.
- The replacement of sodium with salt (under the FIC regulation) is not compatible with the aim of communication on sportsdrinks.
- At present, health claims legislation was perceived not to be designed to fully deal with FISP products, as witnessed by difficulties with claims which are perceived not to be in the interest of the general population. Without “sportsfood” as a defined legislative category, it may be difficult to limit certain health claims only to foods intended for sportspeople.
- It may be difficult to legislate for and control all segments of the FISP industry in the same way. For example, the control of third country based internet sales was considered to be a

significant challenge which affects the supplement style industry, but does not impact the sportsdrinks industry.

According to one interviewee, the power already exists to deal with dangerous products, therefore specific legislation on FISP is not required.

Finally, one interviewee felt that whatever is decided in legislative terms for FISP, it is important that the legislative changes made look at the longer (e.g. 20 year) situation rather than what is likely to be on the market in the next 5 years.

4.2.7 B11 Competent Authority

Competent Authority (CA) responsibility in the UK is limited and administration is partly devolved to the various countries of the UK (the Department of Health, which deals with health issues in England, takes the overall policy lead and represents the UK in the EU). Surveillance and enforcement is performed by local authorities, and as a result, can vary. Controls at present are intelligence led, and controls on products placed on the market as sportsfood according to Directive 2009/39/EC will take place as a part of general food market monitoring (i.e. there are not specific controls). However, certain types of control or categories of product may be targeted if intelligence suggests there may be non-compliances; for example, it is possible that health claims in certain points of sale may be a target of a certain control program.

Controls on internet sales are performed by a FSA-BIS²² joint venture e-commerce group which is led by one specific local authority. Once again, monitoring by this group is intelligence led, and it covers the whole area of food products. Action can be taken against UK based internet operators (e.g. sales stopped) if a product is found not to be in compliance. However, for internet operators based in third countries, no concrete action can be taken; it is only possible to inform the consumer that the product is dangerous.

In view of the above, the method of enforcement, and the burden on the competent authority and enforcement authorities resulting from FISP is not expected to change after 2016 with the repeal of the PARNUTS directive.

²² Food safety authority; and Business, innovation and skills

5 CASE STUDY: SPAIN

FORENOTE: in accordance with the offer, Spain was included in this study as a partial case study; it is therefore not fully comparable to the other case studies.

5.1 Theme 1: current market for sportsfood

5.1.1 *A13 National rules*

In Spain, food intended to meet expenditure of intense muscular effort must comply with general conditions established by the Royal Decree 1809/1991, which still constitutes the reference national regulation for transposition of Directive 2009/39/EC into Spanish law.

5.1.2 *Sportsfood products on the market*

5.1.2.1 *A1 Products on the market*

It has not been possible to identify the number of products present on the Spanish market; however, a desk research has been performed on websites of three major players in the Spanish market (i.e. Weider Nutrition, Nutrition & Sante Iberia and Quamtrax Nutrition – as reported in table 2.4). On the basis of this research, it has been possible to collect some general data on FISP products, on the main categories and on the number of references for the above mentioned players (please note that total market share for these players is around 48% of the Spanish FISP market).

Product categorization for the cited players is reported in the table; whenever possible, the same product categories have been placed side-by-side, in order to facilitate comparisons between different product ranges. Categories indicated in the table are not directly comparable with product categories defined for the purposes of the study, because each operator uses its own categorisation for commercial purposes.

Table 5.1 – Products offered by the top-three market players, Spain

Weider Nutrition	Nutrition & Sante Iberia	Quamtrax Nutrition
Amino acids (18 products)		Amino Acids (5 products)
Bars (12 products)	Energy bars / energy cakes (15 + 1 products)	Bars (7 products)
Carbohydrates (4 products)		
Creatine (3 products)		
Depurative (1 product)		
Energetic (4 products)		
Gel (6 products)	Gel (11 products)	
Isotonic (3 products)	Powder - isotonic (10 products)	
Joint Protectors (2 products)		
Other products (3 products)		
Pre-Workout (3 products)		
Pro-Hormonal (3 products)		
Proteins (15 products)	Proteins (8 products)	Proteins (10 products)
Recovery (2 products)		
Sportsdrink (6 products)	Sportsdrink (8 products)	Sportsdrinks (2 products)
Volume gainers (2 products)		
Weight control (11 products)		Weight gainers / reducers (2 + 8 products)
	Supplements (3 products)	
	Tablets (8 products)	
		High performance (4 products)
		Oats (5 products)

Total 98 products	Total 64 products	Total 43 products
--------------------------	--------------------------	--------------------------

Source: FCEC based on desk research

The main categories of products reported during interviews are the following:

1. Carbohydrates-electrolyte solutions
2. Protein concentrates and high protein products
3. Carbohydrate – rich energy products
4. Supplements

A breakdown of the value of sales by main products categories is reported in Table 5.2.

Table 5.2: Importance of the main categories of FISP in Spain

Category	2014 value EUR m	% of total	Forecast annual growth rate 2014-1198
Protein products	21.7	4%	26.9%
Performance boosting products	30.1	6%	11.6%
Sportsdrinks	439.5	90%	-5.8%
Total	491.3		18.0% nutrition only

Source: Euromonitor

* Percentages add up to 101% due to rounding

The most common products of the FISP sector in Spain are sportsdrinks. In 2014, the category accounted for about 90% of the value of the total market of sport nutrition.

Within the protein product category, protein bars accounted for about 40% of the total of the value of sales of the category, with CAGR in 2009 - 2014 period of 11.3%; market forecasts reveal that the remarkable growth of protein bars in the market should be far from an end.

In the 80s, weight gainer products were common in Spain, but their popularity strongly decreased during the last years.

5.1.2.2 A2 Ingredients

The most common ingredients for the main product categories marketed in Spain are listed below:

Sportsdrinks

- Carbohydrates – sucrose, dextrose, maltose, fructose, maltodextrin and glucose syrup
- Minerals – sodium, potassium, citrates, bicarbonates, chlorides, calcium and magnesium
- Vitamins – mainly vitamin B1

Most common combinations:

- Sugars + sodium
- Sugars + maltodextrin + sodium + potassium
- Sugars + sodium + potassium + calcium + magnesium + vitamin B1

Proteins

- Whey protein
- Calcium and sodium caseinates
- Soy protein isolate
- Egg albumin
- Milk proteins (whey, casein or mixed)
- Other protein sources
- Carbohydrates – lactose, sucrose, maltodextrin
- Vitamins and minerals

As per most common combinations, the above source of protein can be often found as unique source of protein concentrates or isolated

Most common combinations:

- Milk proteins + carbohydrates
- Milk proteins + carbohydrates + vitamins + minerals
- Other proteins source + carbohydrates + vitamins + minerals

Performance boosting products

- Creatine
- Caffeine
- Carnitine
- BCAA
- Leucine
- Arginine
- Other AAs
- HMB (metabolite from Leucine)
- Hydrolyzed collagen
- Glucosamine
- Chondroitin
- Hyaluronic acid
- Bicarbonates and citrates
- Flavonols
- Bromeline
- Coenzym Q10

- Ginseng

Although most of these ingredients are usually marketed alone, the most common combinations are:

- BCAA + glutamine
- Collagen + glucosamine + chondroitin + hyaluronic acid
- Citrulline + arginine + ornithine

The composition may vary significantly according to the form in which they are marketed.

Table 5.3: Product ingredients and most common combinations, Spain

Ingredients			
<u>Bars</u>	<u>Gels</u>	<u>Drinks</u>	<u>Tablets</u>
Cereals	Sugars (glucose syrup, maltodextrin and fructose)	Maltodextrin	Dextrose
Sugars	Fruit purée	Sucrose	Fructose
Milk derivatives	Fruit juice	Vitamins	Vitamins
Vitamins	Dried fruits	Sodium	Minerals
Vegetable oils	Vitamins		
Dried fruits	Caffeine		
Nuts			
Cocoa			
Most common combinations			
<u>Bars</u>	<u>Gels</u>	<u>Drinks</u>	<u>Tablets</u>
Cereals + sugars + milk derivatives + vegetables oils + dried fruits + vitamins	Sugars + fruit purée + fruit juice + vitamins	Maltodextrin + vitamins	All ingredients in combinations
Cereals + sugars + milk derivatives + nuts + vitamins	Sugars + dried fruits + vitamins	Maltodextrin + sucrose + vitamins + sodium	

Above combinations + cocoa	Above combinations + caffeine		
-------------------------------	----------------------------------	--	--

5.1.2.3 A3 Price

Prices for products considered representative of protein and sportsdrinks categories are provided in Table 5.4.

Table 5.4 Price of FISP products in Spain (2014, EUR)

Category	Average size	Average price	Price per unit
Protein – powders	957g	25.41 EUR	2.66 EUR / 100g
Sportsdrinks	832ml	0.74 EUR	0.09 EUR / 100ml

Source: FCEC based on Euromonitor; average of 5 randomly selected

Even if it has not been possible to identify average prices for all categories, prices of specialized products (e.g. proteins, supplements) are perceived as higher than prices for products that target general consumers. Such perception can be considered as a barrier to the extension of consumption of such products among recreational and lifestyle users, but also a form of consumer protection from the use of certain types of products not intended for recreational and lifestyle users.

Spanish consumers are price-sensitive and their demand for low price products is high. The economic downturn has probably exacerbated this attitude. The entrance on the FISP market of private labels, at least for product categories that target general consumers, has pushed price competition further. This is particularly evident in relation to sportsdrinks, which decrease in sales value more than in sales volume (-4.9% in value and -2.0% in volume, 2009-14). Promotion policies by large-scale retailers and a strong competition with private labels have further moved competition in the sportsdrinks segment on price.

5.1.3 Operators

5.1.3.1 A6 Market structure

In 2014 the market for sports nutrition in Spain grew by 2%, reaching a value of about Euro 52 million, while sportsdrinks market value decreased by 6% for a total value of about Euro 440 million.

In terms of forecasts, the FISP market is expected to increase in the 2014-19 period at a Compound Annual Growth Rate (CAGR) of 3.4%, while a decrease is estimated for sportsdrinks, with a negative CAGR in the same period of approximately 3.3%.

Within the sports nutrition market, protein products represent the most relevant category, with a total value in 2014 of about Euro 22 million (42% of the total); non-protein products (e.g. creatine, energy bars, carbohydrates, BCAA, etc.) account for Euro 30 million.

The concentration ratios of branded sports nutrition (excluding drinks) operators in Spain are displayed in Table 5.5. The third column displays the concentration ratios from 2009. The sector is less concentrated than other case study Member States.

Table 5.5: Concentration ratio of branded sports nutrition operators in Spain (2014)

Concentration ratios	Market share (value term) 2014	Market share (value terms) 2010
CR-4	52.8%	50.8%
CR-8	62.1%	57.9%

Source: Euromonitor

The sector of sportsdrinks is much more concentrated: the first three operators account for the 90.8% of the market share. The CR4 in 2014 was 92%, and it has not changed since 2010.

Additional information about the number of operators comes from the general sanitary register, where:

- 289 companies are registered for selling dietetic sportsfoods
- 757 companies are registered for selling food supplements (this includes food supplements for sportspeople)

Taking into account the fact that the Spanish market for sports nutrition and sportsdrinks is dominated by few large multinational players, it is plausible to assume that most of the companies present in the general sanitary register are SMEs.

It is worth noting that one of the interviewed players estimates a market value for Spain significantly different in terms of size, with a lower limit of Euro 150 million (considering both sports nutrition and sportsdrinks). In the same way, its estimates for the relative weights of different product categories deviate from what reported above (carbohydrates-electrolyte: 42%, protein products: 19%, carbohydrate products: 12% and supplements: 27%).

5.1.3.2 A10 Innovation

No data on the Spanish industry innovation rate could be collected. However, innovation in flavours and in packaging for the sportsdrinks products is reported to be frequent. Manufacturers that invest in this kind of innovation and in marketing and communication can resist to the competition with private label products, which are by now widely present in the Spanish market for FISP.

On the other side, innovation in terms of new ingredients is particularly concentrated in the area of supplements.

5.1.3.3 A8 Trade

No quantitative trade data are available for the category. However, the main import and export flows involve the following countries:

Import from:

- EU: France, Italy, Belgium, Germany, Netherlands and UK
- Extra-EU: United States, especially for supplements

Export to:

- EU: Portugal, UK, France, Italy, Netherlands, Belgium, Germany, Czech Republic, Poland and Malta
- Extra-EU: Latin America, Morocco, Dubai and United Arab Emirates.

5.1.4 Consumers, distribution and marketing

5.1.4.1 A7 Distribution channels

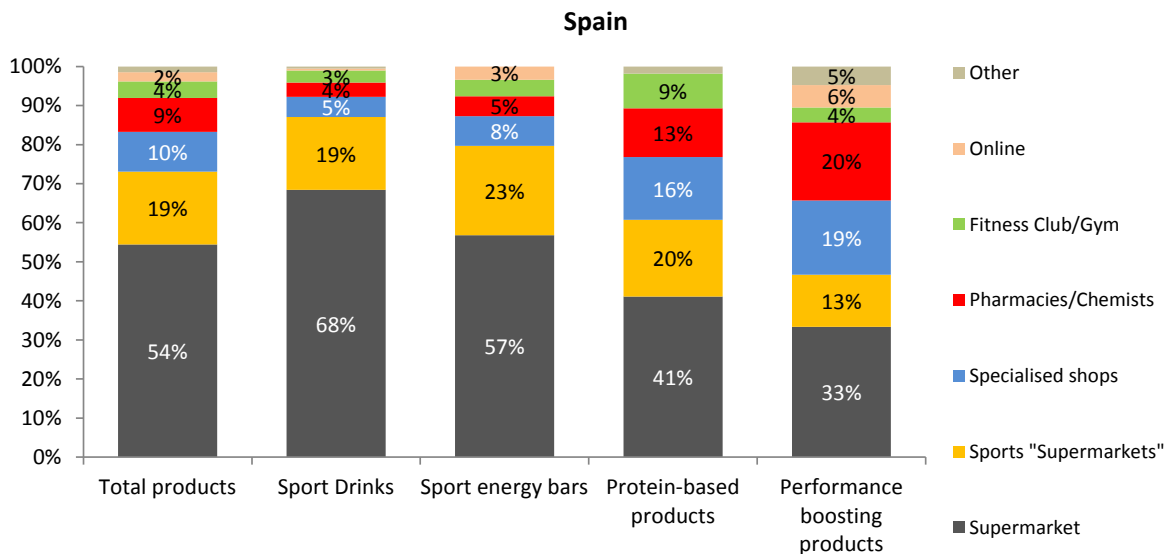
FISP products are available on the Spanish market through the channels displayed in Table 5.6. Full findings of the consumer survey with regards to distribution channels in Spain are presented in Table 5.6.

Table 5.6: distribution channels of FISP in Spain

Channel	Comments	Importance
Supermarket	Main channel for less specialised products (e.g. sportsdrinks) and new channel for private label specialised products	More than the half of FISP is sold through the supermarket channel. Private labels are growing in importance
Sport supermarket	Example: Decathlon and other sport supermarket with their own private labels.	At the second place for importance, particularly important for energy bars
Specialised shops	Shops specialised in products for sport nutrition	10% of consumers use this channel to buy FISP, mainly performance boosting products
Pharmacies/Chemists	Stores selling pharmaceutical and health products	Very important for products to boost performance (20%) and protein-based products (13%)
Fitness clubs/gyms	Small corner shop places in fitness clubs and in gyms	More important for boosting products (9%) and protein-based products (4%)
Online	Both specialist (i.e. dedicated sports nutrition shops) and general (e.g. Amazon) websites.	The least important channel for the moment.

Source: interviewees and consumer survey

Figure 5-1: distribution channels in Spain by product type according to the consumer survey



Source: consumer survey

It is difficult to estimate the weight of each channel on the overall FISP market. However, the performance of private labels is very strong in the sportsdrinks segment, revealing the importance of the supermarket channel in this product category. Mercadona's (Spanish leading large-scale retailer) own label of sportsdrinks accounts for 14.6% of all volume sales for such category and for 9.7% of all sales in value. Carrefour's own label accounts for 3.4% of overall sales volume and 2.3% of overall sales value. Private label sportsdrinks are usually positioned in the low part of the price scale.

The increasing volume of protein bars sales has also been driven by the supply of such products as private labels.

The internet has been reported as a rapidly growing distribution channel, in particular in relation to specialised products. Around half of products that target body builders, athletes and fitness enthusiastic consumers are sold through the internet. On the other hand, sportsdrinks are rarely purchased online.

5.1.4.2 All Marketing techniques

Products that target pro and semi-pro athletes and body builders are promoted mainly through the following channels:

- Specialized printed magazines
- Internet
- Sponsorship of sport events

Product endorsement by sport champions is a widely used marketing technique to present new products to the market.

In general, the most common information items reported on labels are the following: sportsfood, sport nutrition, sport bar, gel energy/power gel, before/during/after instructions of

use, designed for endurance sport, endurance/effort/performance/power/resistance, recovery, hydration, and pictures of sportspeople (or sports).

5.1.4.3 A5 Claims

In general terms the use of claims is not widespread in the Spanish sport nutrition industry. A potential explanation for this is the possibility to use different communication techniques to communicate the products, e.g. the use of sport pictures on the label. Moreover, the consumers which use more specialised products (e.g. proteins) are already well aware of what kind of products they need, with no necessity to refer to the claims.

More in detail, carbohydrates-electrolytes solutions appear to be the category which less utilizes approved health claims related to endurance, performance and water absorption, mainly because they do not fulfil the composition requirements of Regulation 432/2012; in the same way, the use of the approved claims for Vitamin C is not common.

On the other hand, approved claims for creatine are more common in supplements labels, as well as approved claims for proteins (muscles and bones), which can be utilized by any product being a source of proteins (<12% energy); this last aspect in particular makes it difficult for not well informed consumers to understand the difference between products fulfilling just the minimum requirements, on one side, and protein concentrates and high protein products, on the other side.

Additional considerations on the use of claims emerged during interviews refer to the need – generally accepted among operators – of having in the labels specific mandatory statements for sportsfoods (how to use the product, appropriate moment for use, etc.), besides approved health claims which are usually intended for foods for normal consumption.

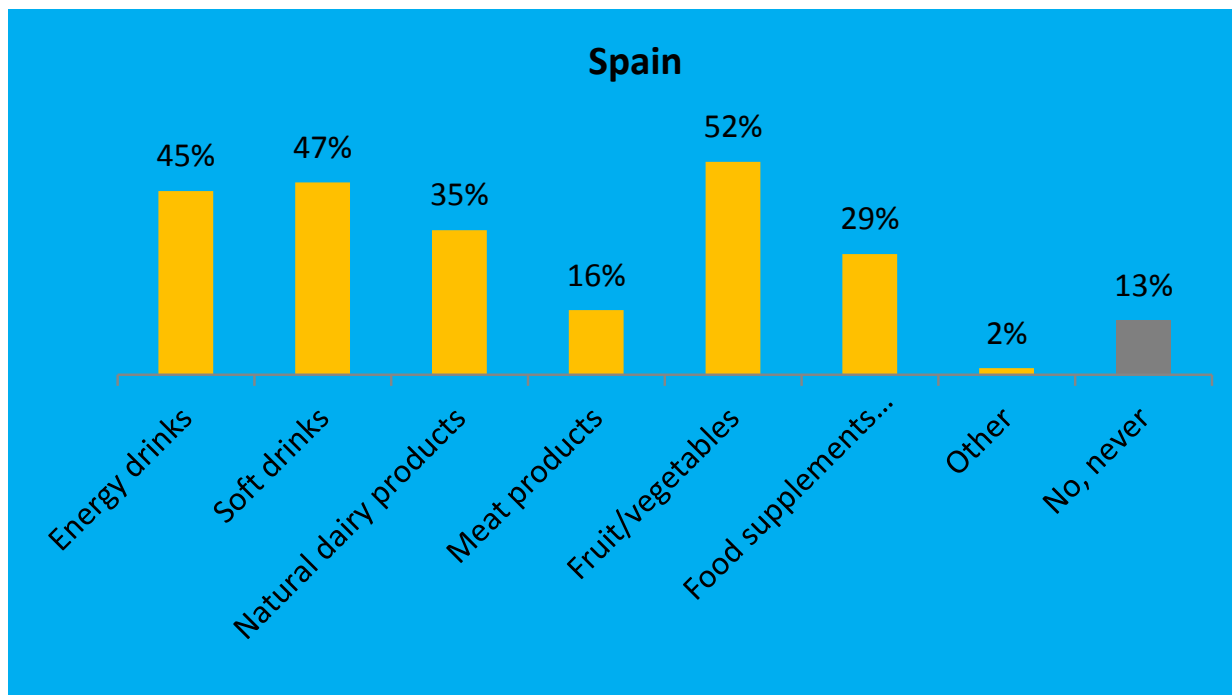
Considerations made during interviews suggest that the use of claim-like statements for FISP (e.g. “intended for sportspeople”) which are currently allowed under the indication requirements of Article 9 of Directive 2009/39/EC should not be regulated by an *ad hoc* EU regulation or directive after 2016. Any claim should be approved under the regulation (EC) n. 1924/2006 on Nutrition and Health Claims.

5.1.4.4 A4 Foods not intended for sportspeople

Advertising of certain products for normal consumption associates such products to sport activities. Some water brands target sportspeople, highlighting the necessity of re-hydrating the body after physical effort. Other companies associate their products to the general concepts of vitality and activity, even if not specifically in relation to sport practice.

Figure 1.1 shows results of the consumer survey in relation to foods other than FISP usually consumed during sport activity.

Figure 5-2 - Foods other than FISP used in relation to sport activity



Source: Survey AgraCEAS -Areté for DG SANTE

The consumption of energy drinks is widespread among sportspeople in Spain: 45% of respondents declared to consume such products in relation to sport activity. This is the higher percentage across the five Member States in which the survey has been carried out. Evidence collected reported that advertising techniques of such products explicitly target sportspeople: the most common brands sponsor racing teams and/or sport events.

5.1.4.5 A12 Consumers

There is a general division of the market between two groups:

- Athletes, bodybuilders and fitness enthusiasts, which consume mainly specialized products (e.g. proteins and supplements);
- Recreational and lifestyle users which are mainly interested in sportsdrinks.

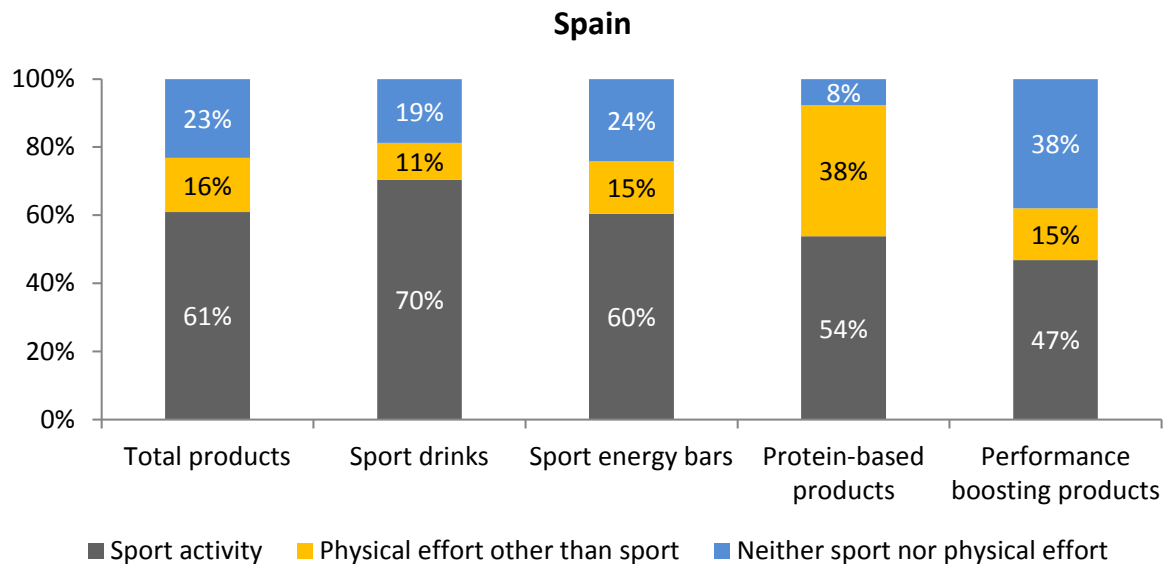
The incidence of lifestyle users is increasing. In particular, a growing consumption of sportsdrinks occasionally not related to physical activities has been reported. Sportsdrinks are replacing soft drinks to some extent, and are widely consumed in coffee shops. A possible reason for this is the increasing innovation on the taste of such products and the perception, among consumers, that sportsdrinks are healthier than soft drinks, because the former contain less sugar and are fortified with vitamins and minerals.

Lifestyle and recreational users have been identified as the fastest growing group of consumers. A major cause of such process is the increasing consideration of the role of nutrition in relation to wellbeing and health.

On the opposite side of consumer patterns stand body builders, athletes and people practising fitness very frequently. Such consumer group is very well informed in relation to the ingredients and the formula of the consumed products, and has a higher level of purchasing capacity in comparison with lifestyle and recreational users.

Figure 5-3 displays consumption habits of FISP consumers by product category in Spain. In most cases consumption of FISP products is connected to sport activity. There is a high level of usage of protein products in relation to physical activity other than sport, and of performance boosting products neither in relation to sport or other physical activity.

Figure 5-3: Consumption habits of FISP consumers in Spain by product category



Source: FCEC

5.2 Evolution of the market after 2016

5.2.1 BI general evolution

With the exception of Royal Decree 1809/1991, no specific National Legislation is currently regulating the FISP sector. Certain groups have called for specific legislation for FISP; most notably, the *Consejo superior de Deportes* (High sports council) and certain operators have called for such legislation. However, at present it seems unlikely that national legislation will be introduced in Spain in the near future. Nonetheless, there is still some uncertainty over this point.

Due to the uncertainty on some elements of the post-2016 regulatory framework, most interviewees were unable to envisage a specific scenario and to comment its impact on the sector; however, one of the interviewees tried to summarize the potential impact of the end of PARNUTs and the consequent application of EU Regulation 609/2013 and 1924/2006 without any specific provision for sportsfood products.

In Table 5.7 the main concerns relative to this scenario are summarized, with the important limitation that they reflect just the producers' viewpoint.

Table 5.7: Relevant issues in the post-2016 scenario, Spain

Topic	Current regulation	Possible regulation post 2016	Comments
General <ul style="list-style-type: none"> • Sportsfood category • Mandatory description of characteristics • Claims / composition / instruction of use 	<ul style="list-style-type: none"> • Directive 2009/39 (PARNUTs) • Regulation 609/2013 (FSG) 	<ul style="list-style-type: none"> • Regulation 609/2013 (FSG) 	Concerns on: <ul style="list-style-type: none"> • What will happen to the "sportsfood" category • How provision of information to consumers will be managed
Sportsfood definition and categorization	<ul style="list-style-type: none"> • Directive 2009/39 (PARNUTs) • Regulation 1924/2006 (NHC) 	<ul style="list-style-type: none"> • Regulation 1924/2006 (NHC) 	<ul style="list-style-type: none"> • Potentially no definition and recognition of the category of sportsfood could be held, with products being defined only through authorised health claims • Concerns about the use of non-authorised nutritional claims
Mandatory instructions <ul style="list-style-type: none"> • Before/during/after • Recovery • During the effort Product denominations targeting consumers (e.g. "sportsfood", "for sportspeople", "hydration drink", etc.)	<ul style="list-style-type: none"> • Directive 2009/39 (PARNUTs) • Regulation 1924/2006 (NHC) 	<ul style="list-style-type: none"> • Regulation 1924/2006 (NHC) 	<ul style="list-style-type: none"> • Potentially prohibited if considered as non-authorised health claims • It would be crucial to insert specific instructions of use for FISP in the Food Information Regulation (FIR) • It would be crucial to insert the legal product denomination "sportsfood" in the FIR

<p>Compulsory statements due to specific nutritional characteristics (e.g. "high in carbohydrates", "high in energy", "with sodium", "isotonic", "rich in proteins", "rich in vitamins/minerals", etc.)</p>	<ul style="list-style-type: none"> • Directive 2009/39 (PARNUTs) • Regulation 1924/2006 (NHC) 	<ul style="list-style-type: none"> • Regulation 1924/2006 (NHC) 	<ul style="list-style-type: none"> • Potentially prohibited if considered as non-authorized nutritional claims for the general population • It would be necessary to adapt authorised claims without specific requirements to the sportspeople needs • It would be necessary to compile a list of health and nutritional claims specific for FISP
<p>Authorised claims (e.g. "proteins contributes to a growth/maintenance in/of muscle mass", etc.)</p>	<p>Regulation 1924/2006 (NHC)</p>		<ul style="list-style-type: none"> • These claims are authorised for foods for general consumption without any nutritional composition adaptation to sportspeople • It would be necessary to limit the use of these claims to FISP
<p>New claims previously rejected as not suitable for the general population (e.g. Sodium, Glucose)</p>	<p>Regulation 1924/2006 (NHC)</p>		<ul style="list-style-type: none"> • It would be necessary to compile a list of health and nutritional claims authorised for FISP only

5.2.2 B4 impacts on competitiveness and operator costs

In general terms, competitiveness of operators could be damaged by relevant differences in approaches to regulation post 2016. As far as FISP is concerned, only an EU level regulation is believed to guarantee comparable conditions for competitors across Europe; national legislations adopted by Member States could result in trade barriers, with limitations to exports towards other Member States, differences in notification procedures and taxes and even different approaches to general issues (i.e. categorization of supplements).

One of the interviewed stakeholders in particular would welcome a centralized notification/registration procedure, which through the issuance of certificates of free sale could facilitate exports.

5.2.3 B5 Innovation

No specific elements concerning potential impacts on such aspect emerged from the investigations carried out for the case study.

5.2.4 B6 SME consequences

No specific elements concerning potential impacts on such aspect emerged from the investigations carried out for the case study.

5.2.5 B7 Price

No specific elements concerning potential impacts on such aspect emerged from the investigations carried out for the case study.

5.2.6 B8 Consumer choice and behaviour; B9 consumer protection

There is no shared view in relation to the impact on all consumers. Specific considerations can be made for the different consumer groups.

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. On the other hand, these consumers might be affected in case a more restrictive national legislation on sportsfood is introduced. Regarding the protection of general consumers, 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 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.

Certain operators consider sportspeople as a nutritionally vulnerable group of population, with specific needs that differ from those of general population.

5.2.7 B10 Regulatory

At this stage the Spanish CA does not express the intention to regulate at Member State level the sector after the repeal of PARNUT. The Spanish CA declared that FISP products need to be regulated at EU level.

Another stakeholder stated its favour for the introduction of a specific EU Regulation, whose main contents should be:

- Definition of sportsfoods (including supplements)
- Composition general requirements by categories of products (if possible)
- Mandatory statements (different from claims) and disclaimers
- Dosage
- Anti-doping
- EU Centralized notification/registration procedure
- No trade barriers to export products

On the other side, main concerns are related to:

- The possibility to inform the consumer about composition and instruction of use of the product after the repeal of PARNUTs directive.
- The absence of harmonization at EU level that will lead to differences among Member States and, as final consequences, trade barriers and no free competition among operators.

According to one stakeholder, a vertical legislation will not increase the level of consumer protection.

5.2.8 B11 Competent Authority

No specific elements concerning potential impacts on such aspect emerged from the investigations carried out for the case study.

6 SURVEY: CONSUMER SURVEY RESULTS

A total number of 4,503 people were contacted in the framework of the consumer survey across 5 EU countries, and specifically: UK, France, Germany, Italy and Spain. Table 6.1 shows the distribution of the total respondents among the five countries.

Table 6.1: Survey contacted people and respondents

	UK	France	Germany	Italy	Spain	Total
Total contacted people	428	1,378	882	1,224	591	4,503
Consumers	244	362	415	246	360	1,627
Completed ²³	243	243	247	246	242	1,221
Non-consumers	187	977	453	1,005	248	2,870

Source: Survey AgraCEAS -Areté for DG Sante

In the following sections, data are analysed on the basis of the relative questionnaire question, while general information on population are reported in the last section²⁴.

6.1 Question 2 – Prevalence of FISP consumption

“Which of the following sportsfood products have you consumed in the last year?”

Prevalence of FISP consumption

The average prevalence²⁵ of FISP consumption within the sample is 36.3% (1,633 consumers²⁶ out of 4,503 respondents). This overall percentage of FISP consumers includes respondents declaring to consume the following four macro-categories of products:

- Sportsdrinks (e.g. Gatorade, Lucozade, Powerade, etc.);

²³ Out of the total 1,627 respondents who declared to have consumed FISP products during the last year, 1,221 surveys were completed and therefore this last number, with the only exception of prevalence of consumption calculation, has been taken into account for all the following data processing.

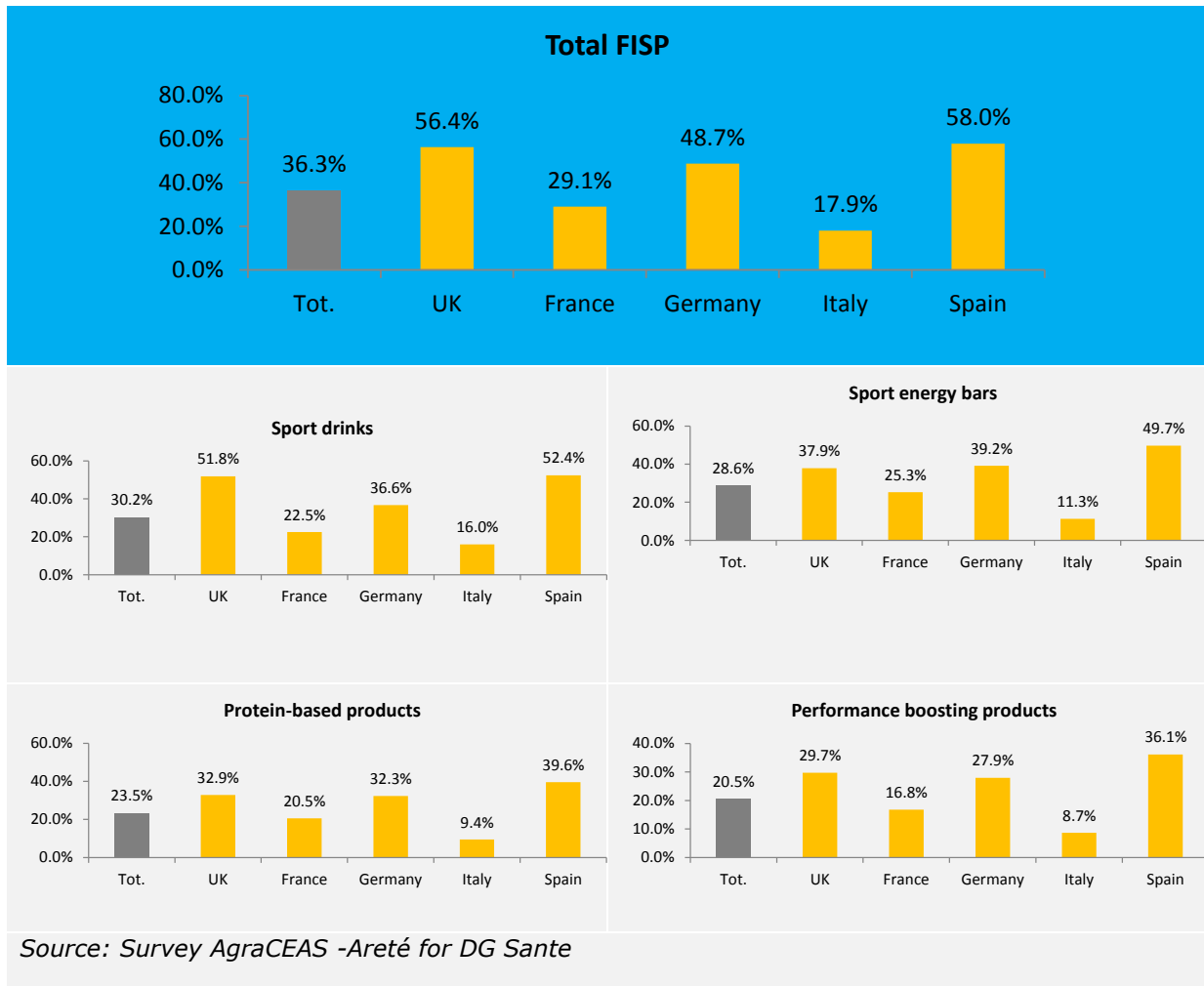
²⁴ Results for questions n.3 have not been reported since the question was only necessary for data elaborations (i.e. understand the two most important product categories for each respondent); similarly, results for questions n. 21 and n. 23 have not been reported since they were only used for “sanity checks” in the survey answers.

²⁵ In the present study FISP consumers are defined as subjects who have been consuming FISP at least once over the last year, so prevalence of FISP consumption was calculated on the basis of this assumption.

²⁶ The difference between 1,627 consumers reported in Table 6.1 and the 1,633 consumers used for the calculation of prevalence of consumption relies in the application (to the second total) of specific weights to take into account demographics differences across Member States.

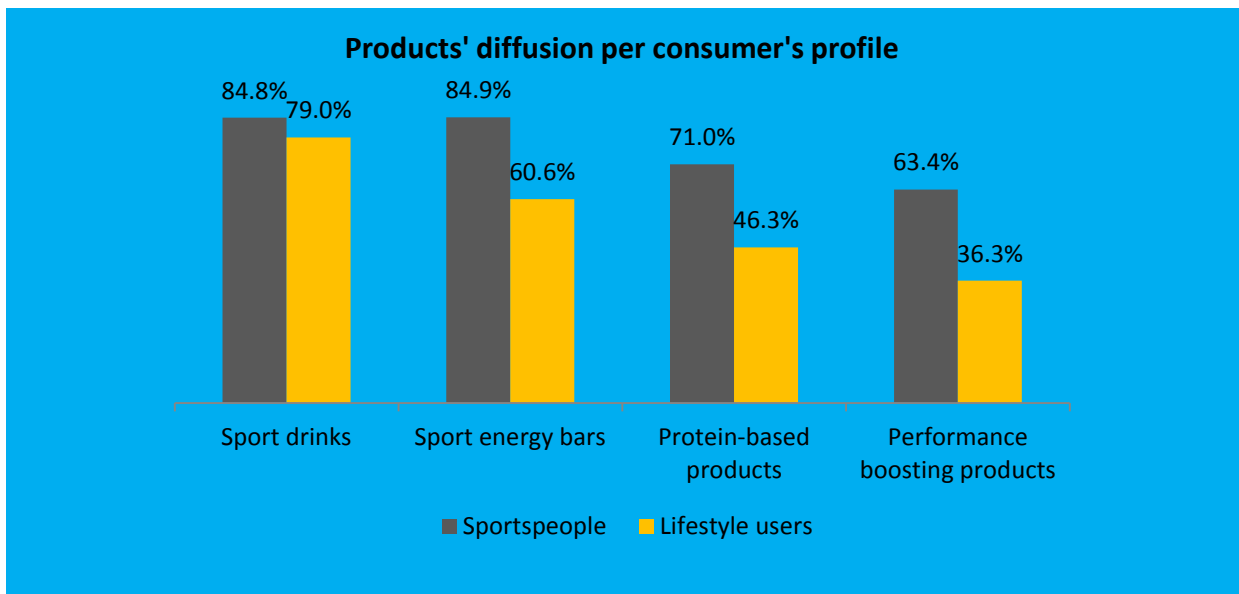
- Sports energy bars;
- Protein-based products (protein bars and products with high concentration of proteins);
- Performance boosting products (products with high concentration of carbohydrates/amino acids, all-in-one sportsfood products, creatine, carnitine, branch chain amino acids and other food supplements).

Figure 6-1: Prevalence of FISP consumption



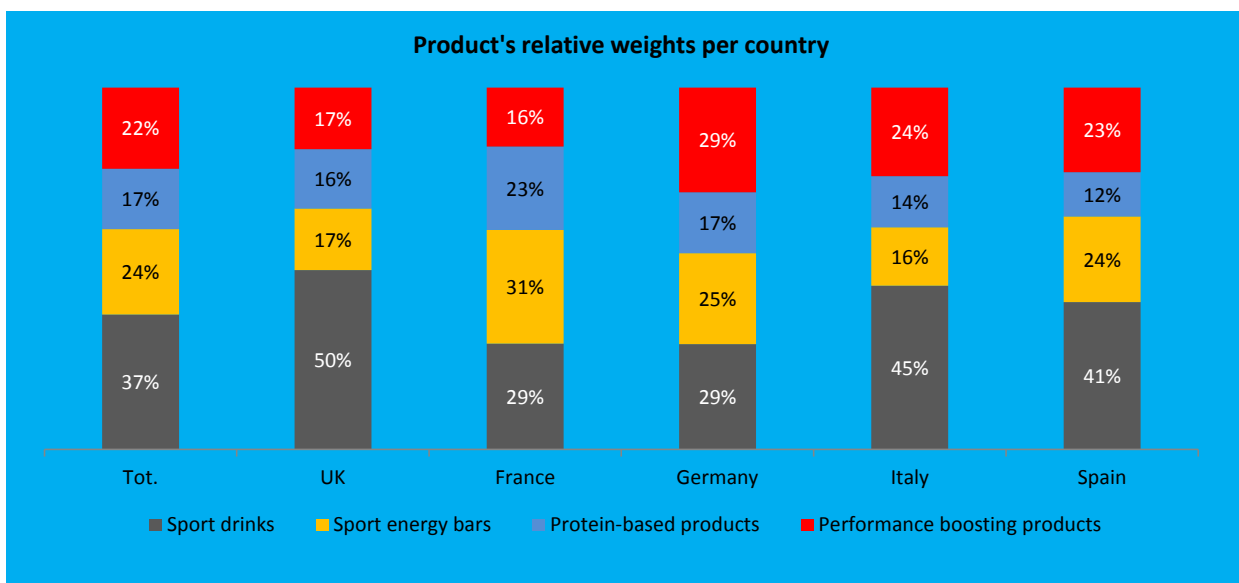
In most of the following analysis, the total population of eligible targets (people who declare to have consumed at least one FISP product during the last year) has been split between “sportspeople” – consumers of FISP who declare to practice sports at least once a week – and “lifestyle users” - consumers of FISP who declare not to practice sport at all or to practice sport less than once a week.

Figure 6-2: Products' diffusion among sportspeople and lifestyle user consumers



Source: Survey AgraCEAS-Areté for DG Sante

Figure 6-3: Products' relative diffusion by Member State

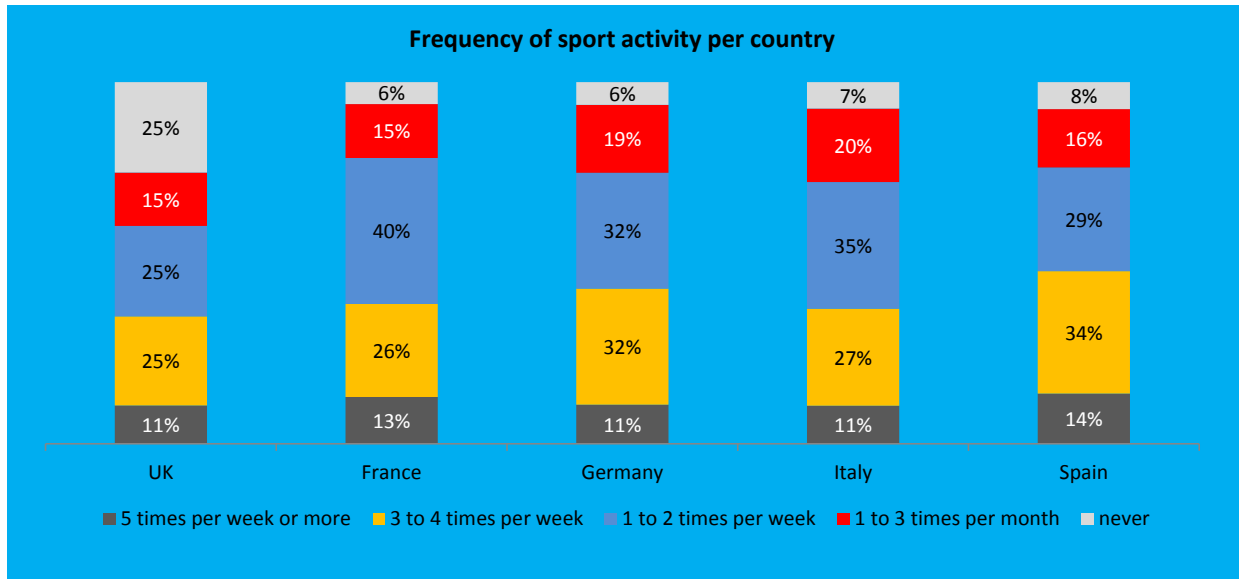


Source: Survey AgraCEAS-Areté for DG Sante

6.2 Question 4 – Sport activity

“How often have you played sport in the last month?”

Figure 6-4: Frequency of sport activity



Source: Survey AgraCEAS-Areté for DG Sante

6.3 Question 5 – Practiced sports

“Which sport do you play/do?”

Figure 6-5: Most commonly played sports

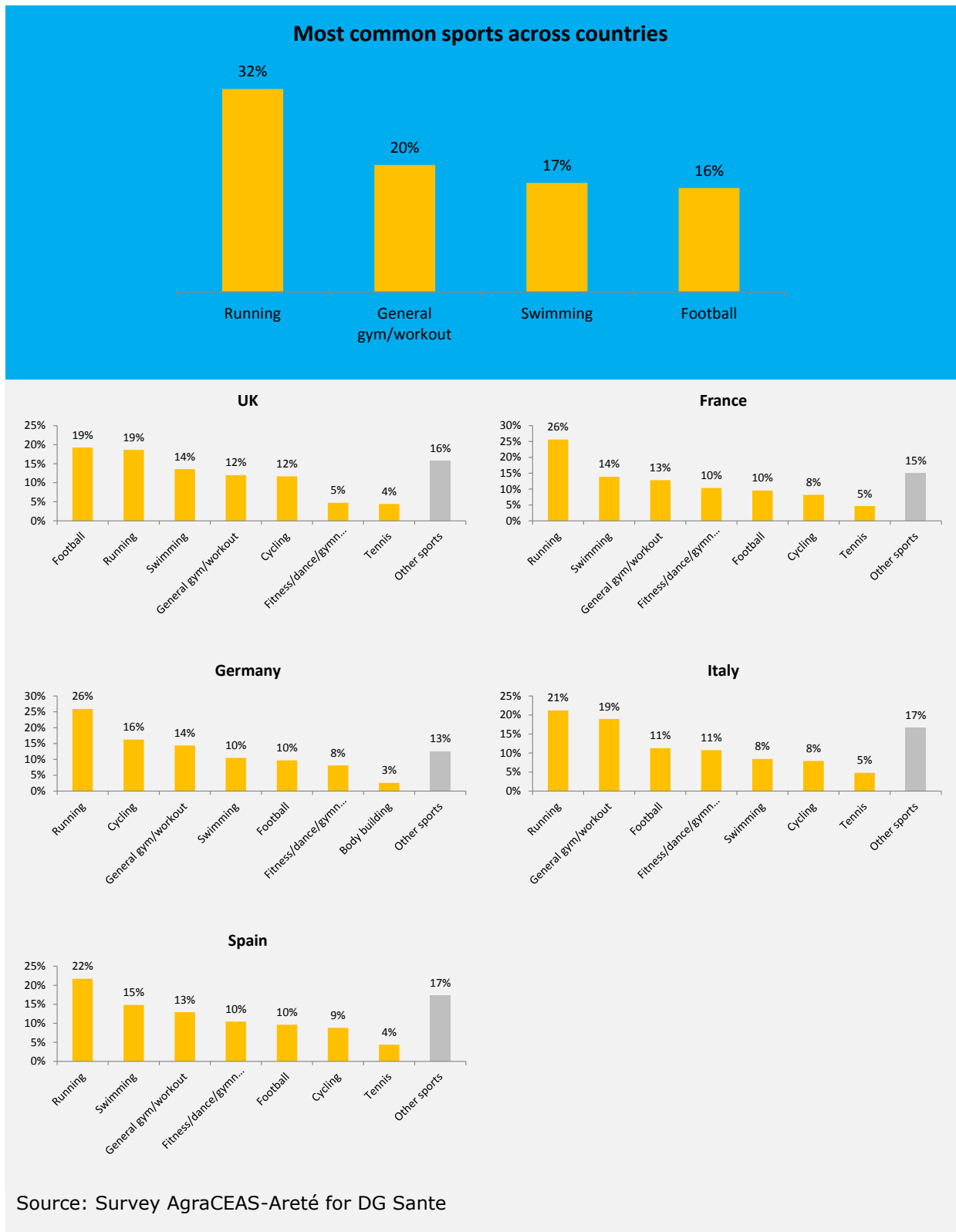
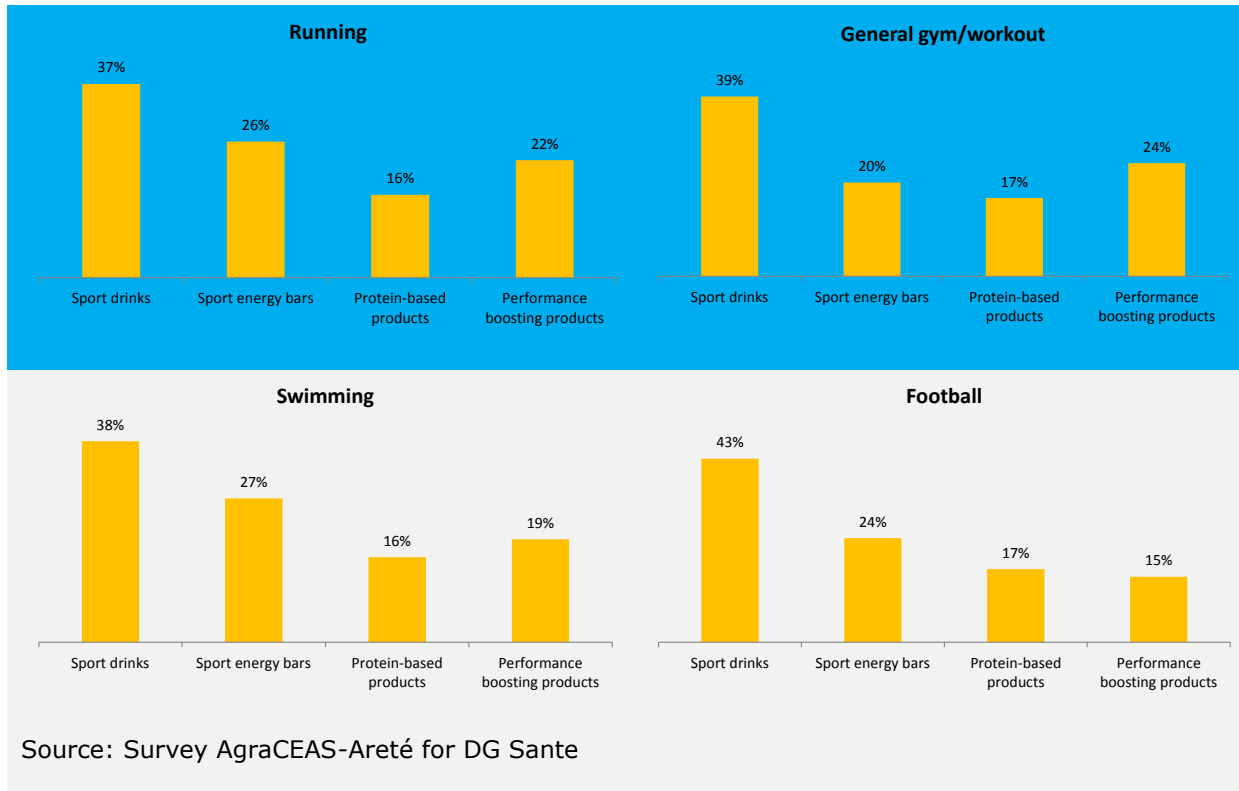


Figure 6-6: Product's relative weights across most common sports



6.4 Question 6 – Consumption habits

“Is your consumption of [SELECTED PRODUCTS], on average, more related to ...”

Figure 6-7: Distribution of respondents on the basis of consumption habits

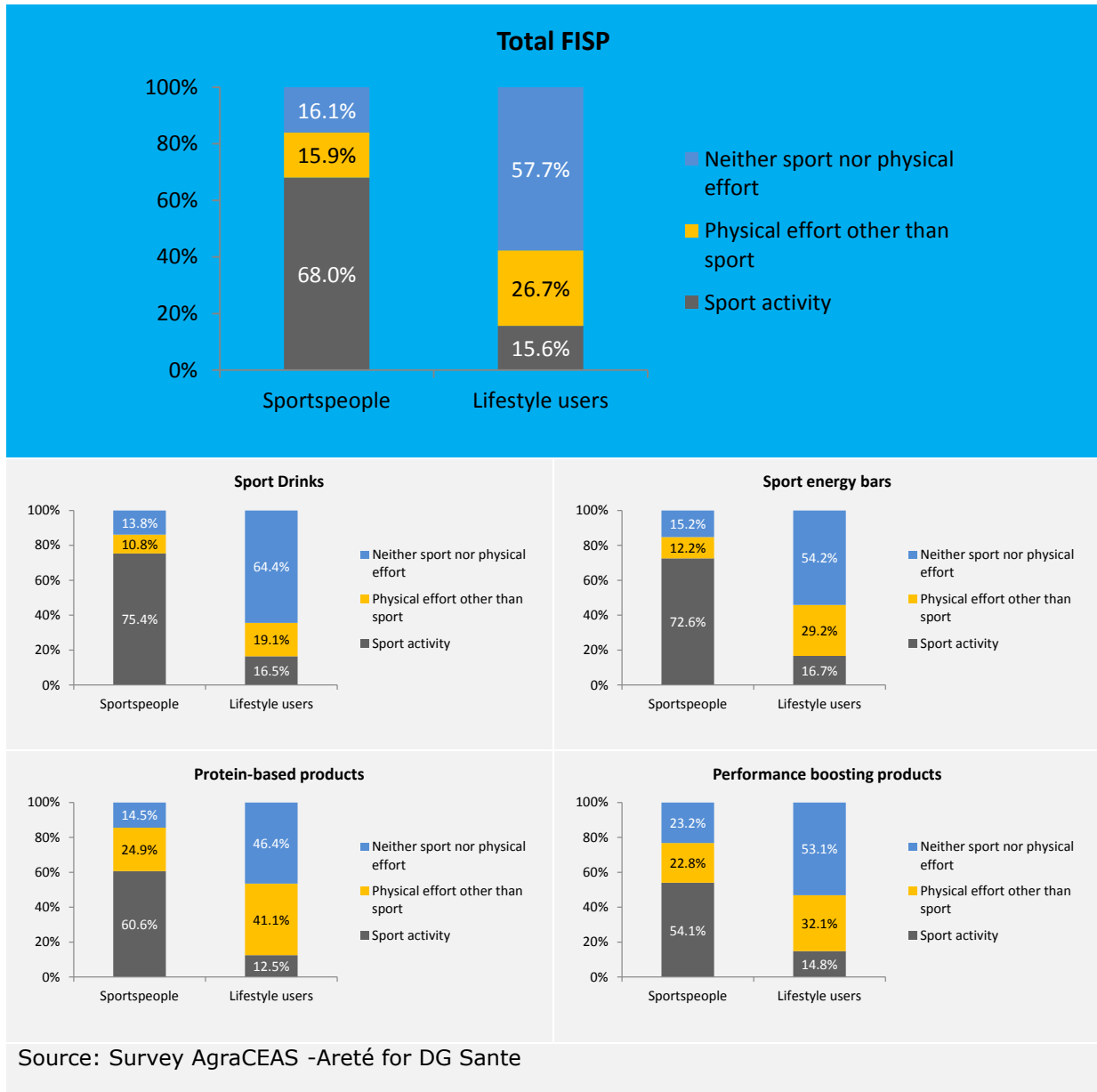
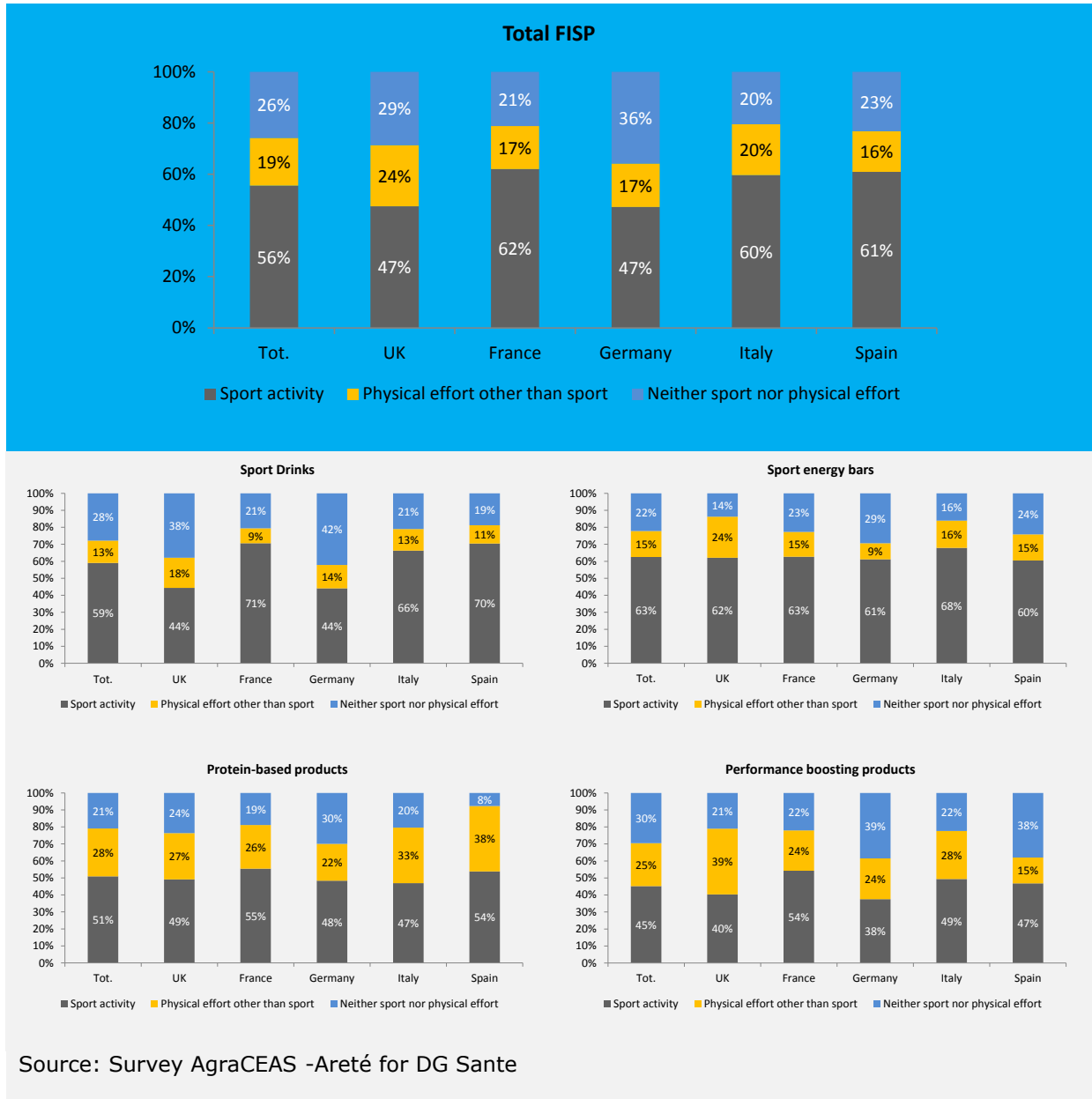


Figure 6-8: Consumption habits: breakdown by products across Member States



6.5 Question 7 – Reasons behind consumption

“Which are the two main reasons behind your consumption of [SELECTED PRODUCTS]?”

Figure 6-9: Reasons behind consumption, for sportspeople and lifestyle users

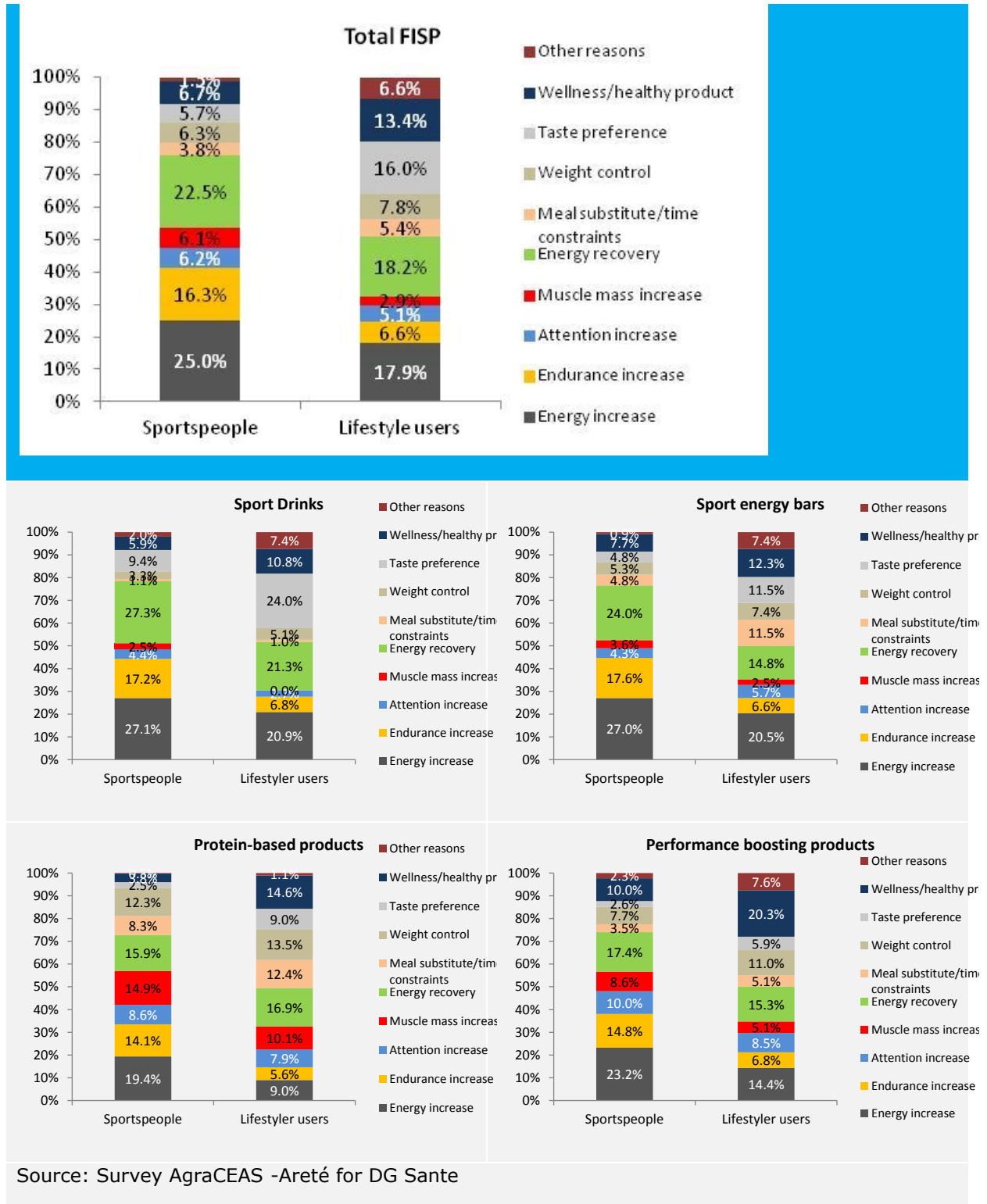
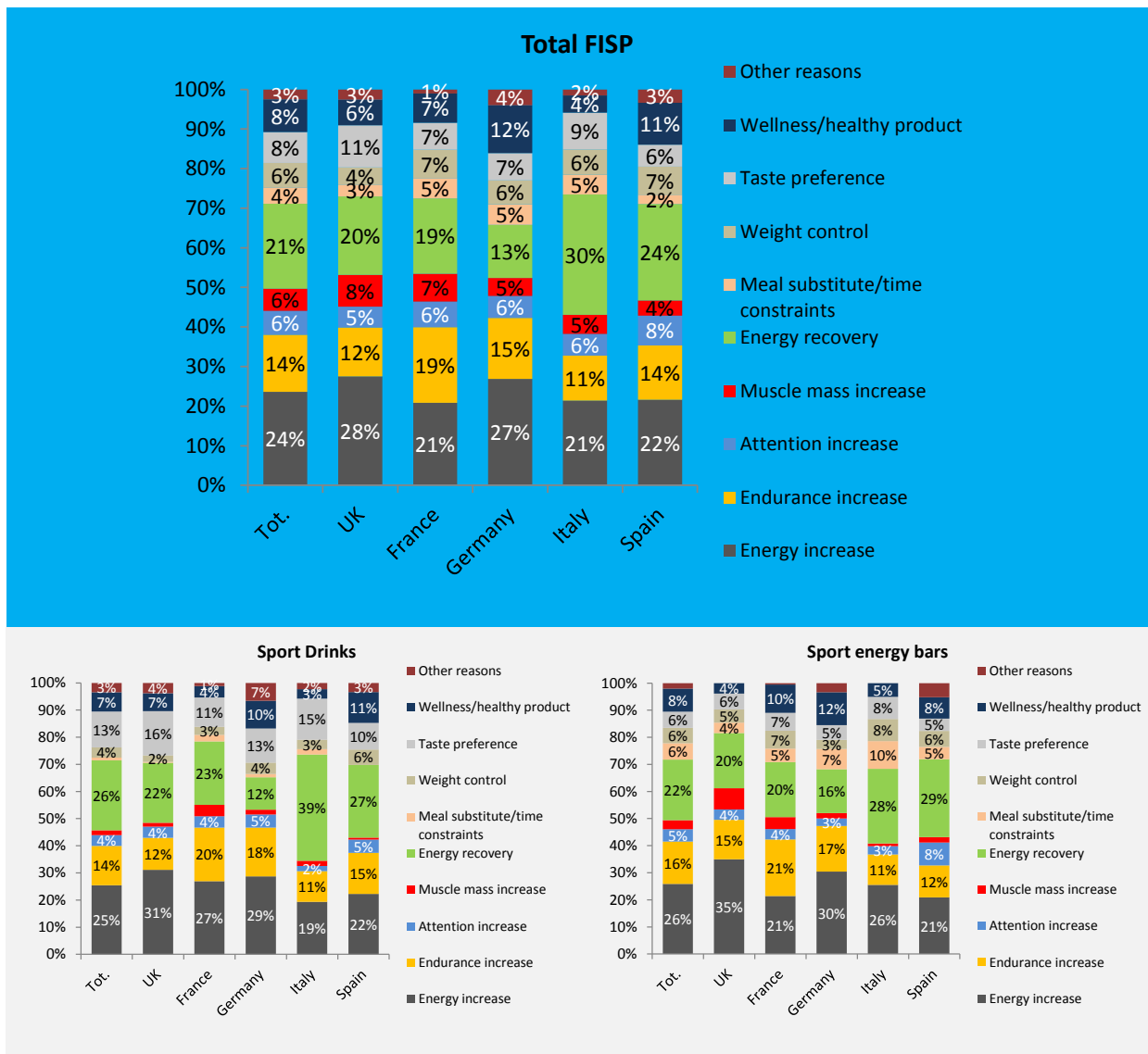
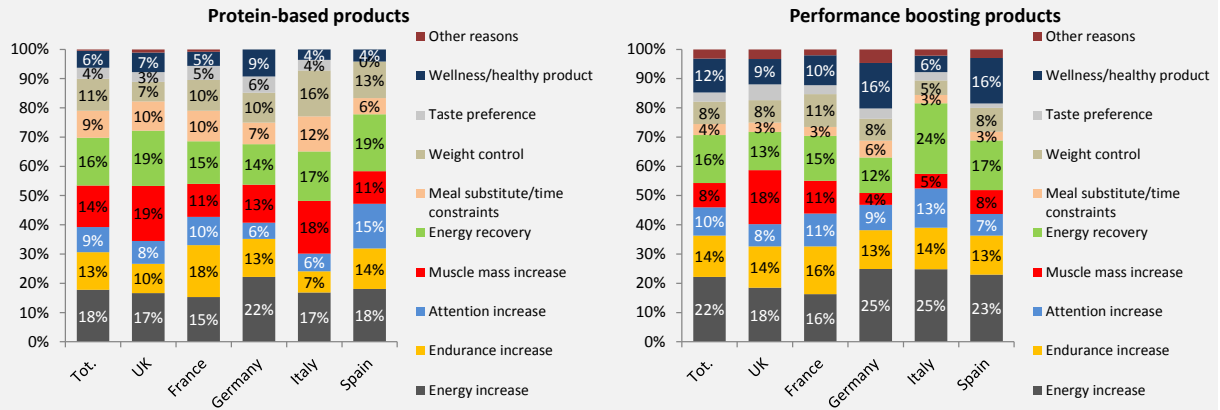


Figure 6-10: Reasons behind consumption by Member States





Source: Survey AgraCEAS -Areté for DG Sante

6.6 Question 8 – Retail channels

“Where do you usually purchase [SELECTED PRODUCTS]?”

Figure 6-11: Retail channels, for sportspeople and lifestyle users

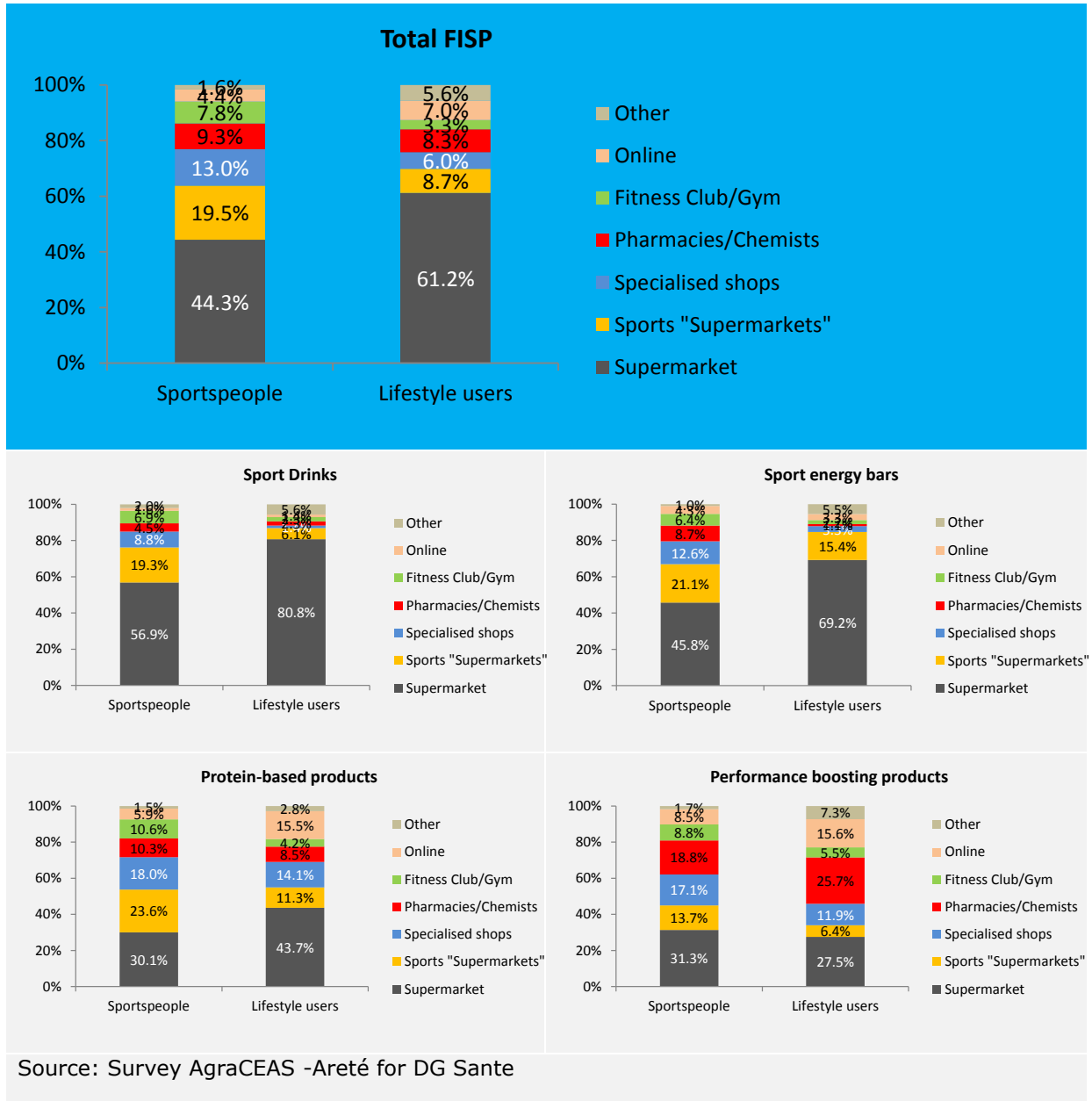
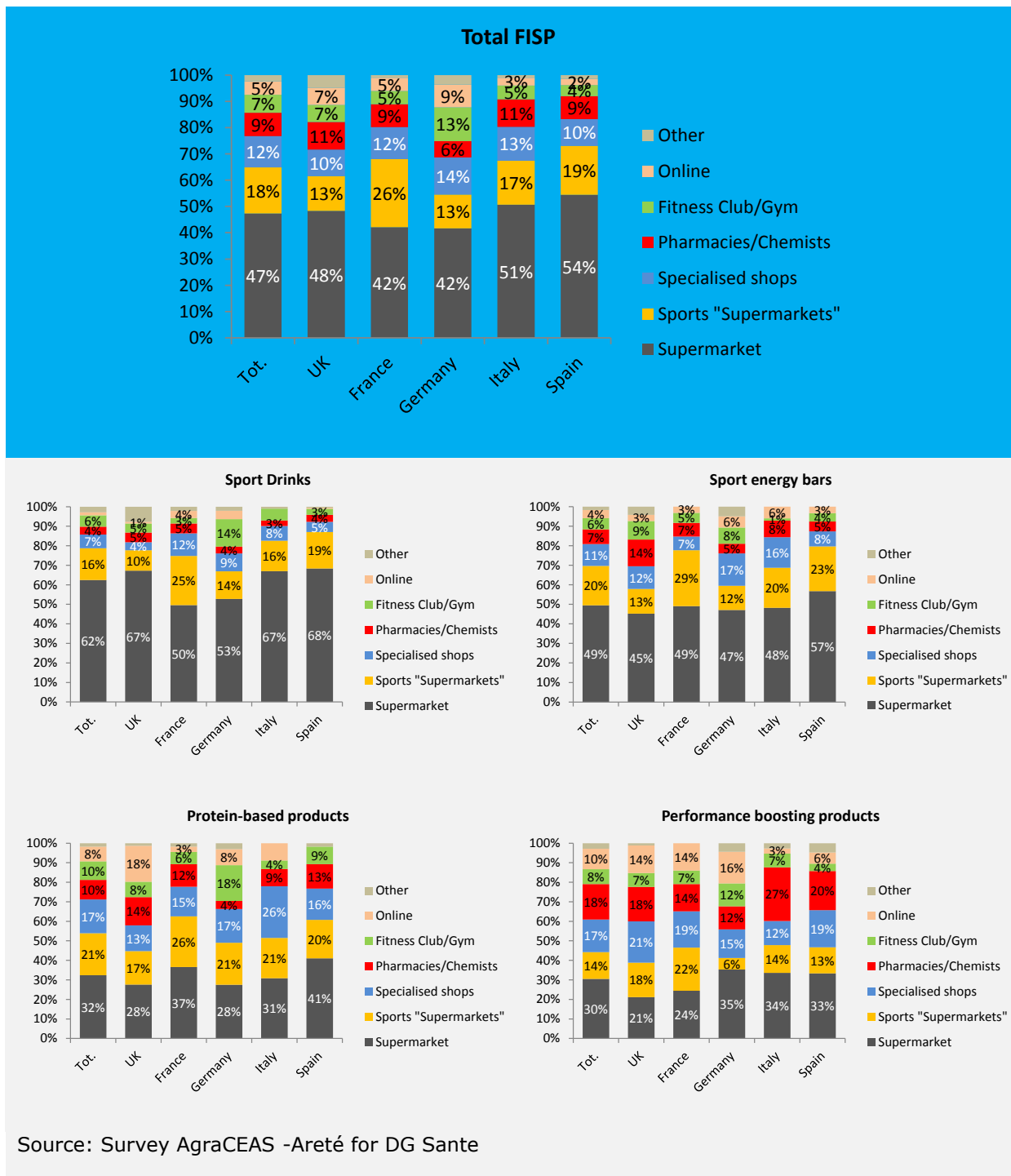


Figure 6-12: Retail channels by Member States



6.7 Question 9 – Aspects influencing purchasing behaviours

“When you buy [SELECTED PRODUCTS], what is the importance of the following aspects for you?”

Figure 6-13: Purchasing behaviours: important aspects



Table 6.2: Purchasing behaviours: important aspects for different products

<i>Sport Drinks</i>	Sportspeople			Lifestyle users		
	<u>Very Important</u>	<u>Important</u>	<u>Not so important</u>	<u>Very Important</u>	<u>Important</u>	<u>Not so important</u>
Expected results/effects	53%	38%	9%	21%	47%	32%
Quality of ingredients (e.g. healthy/natural products, etc.)	53%	41%	7%	35%	45%	20%
Presence of specific ingredient(s)	36%	49%	15%	14%	41%	45%
Ease of use	44%	49%	7%	35%	51%	14%
Practical aspects/convenience	39%	53%	8%	30%	54%	16%
Overall product composition for balanced sport nutrition	46%	42%	12%	19%	48%	34%
Price	43%	48%	9%	44%	44%	12%

<i>Sport energy bars</i>	Sportspeople			Lifestyle users		
	<u>Very Important</u>	<u>Important</u>	<u>Not so important</u>	<u>Very Important</u>	<u>Important</u>	<u>Not so important</u>
Expected results/effects	49%	43%	8%	25%	49%	26%
Quality of ingredients (e.g. healthy/natural products, etc.)	55%	42%	3%	40%	46%	14%
Presence of specific ingredient(s)	38%	52%	10%	17%	53%	31%
Ease of use	42%	51%	7%	29%	49%	22%
Practical aspects/convenience	42%	51%	7%	25%	57%	18%
Overall product composition for balanced sport nutrition	46%	50%	4%	19%	64%	17%
Price	39%	52%	9%	44%	44%	11%

Study on foods intended for sportspeople: Annexes
Food chain evaluation Consortium Lot 3 (FCEC)

<i>Protein-based products</i>	Sportspeople			Lifestyle users		
	<u>Very Important</u>	<u>Important</u>	<u>Not so important</u>	<u>Very Important</u>	<u>Important</u>	<u>Not so important</u>
Expected results/effects	54%	42%	5%	25%	64%	11%
Quality of ingredients (e.g. healthy/natural products, etc.)	58%	37%	5%	39%	54%	7%
Presence of specific ingredient(s)	36%	57%	7%	23%	55%	21%
Ease of use	41%	52%	6%	39%	57%	4%
Practical aspects/convenience	40%	50%	10%	29%	68%	4%
Overall product composition for balanced sport nutrition	48%	44%	7%	20%	70%	11%
Price	40%	49%	11%	45%	50%	5%

<i>Performance boosting products</i>	Sportspeople			Lifestyle users		
	<u>Very Important</u>	<u>Important</u>	<u>Not so important</u>	<u>Very Important</u>	<u>Important</u>	<u>Not so important</u>
Expected results/effects	66%	30%	4%	49%	43%	8%
Quality of ingredients (e.g. healthy/natural products, etc.)	61%	35%	4%	40%	54%	6%
Presence of specific ingredient(s)	43%	49%	8%	25%	64%	10%
Ease of use	39%	53%	8%	31%	59%	10%
Practical aspects/convenience	38%	54%	8%	30%	59%	11%
Overall product composition for balanced sport nutrition	47%	46%	7%	24%	64%	11%
Price	42%	49%	9%	44%	47%	9%

Source: Survey AgraCEAS -Areté for DG Sante

6.8 Question 10 – Information on labels

“Which are for you, among the following, the most important information reported on the label of [SELECTED PRODUCTS]?”

Figure 6-14: Most important information on labels by product type

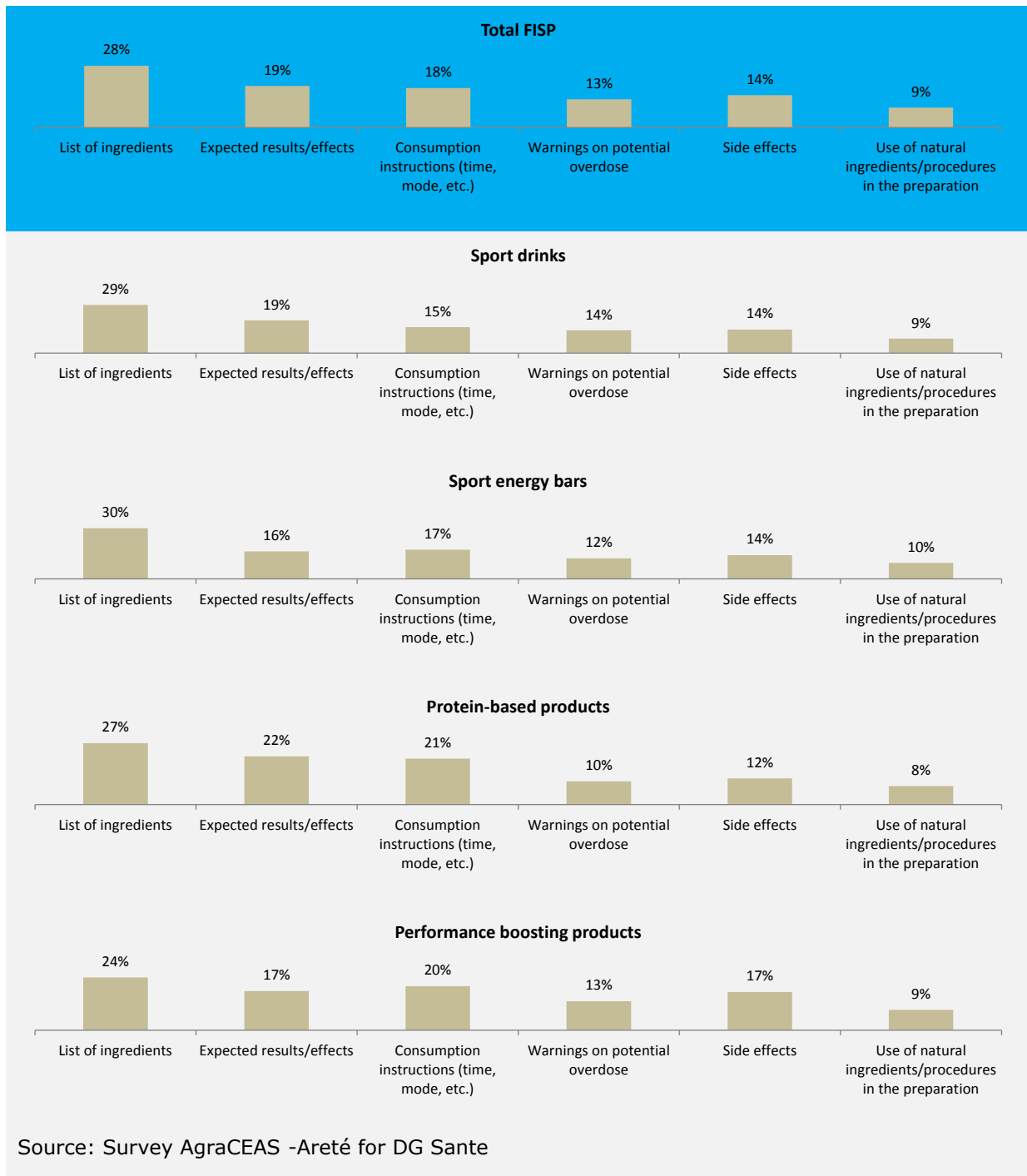
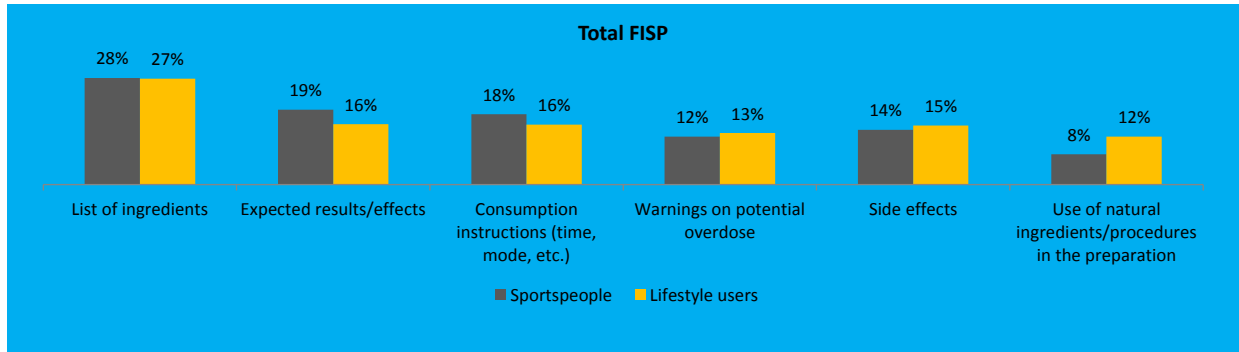


Figure 6-15: Most important information on labels for sportspeople and lifestyle users



Source: Survey AgraCEAS -Areté for DG Sante

6.9 Question 11 – Information on labels (2)

“Which of the following information should never be missing for you on the label of [SELECTED PRODUCTS]?”

Figure 6-16: Information on labels by product type (2)

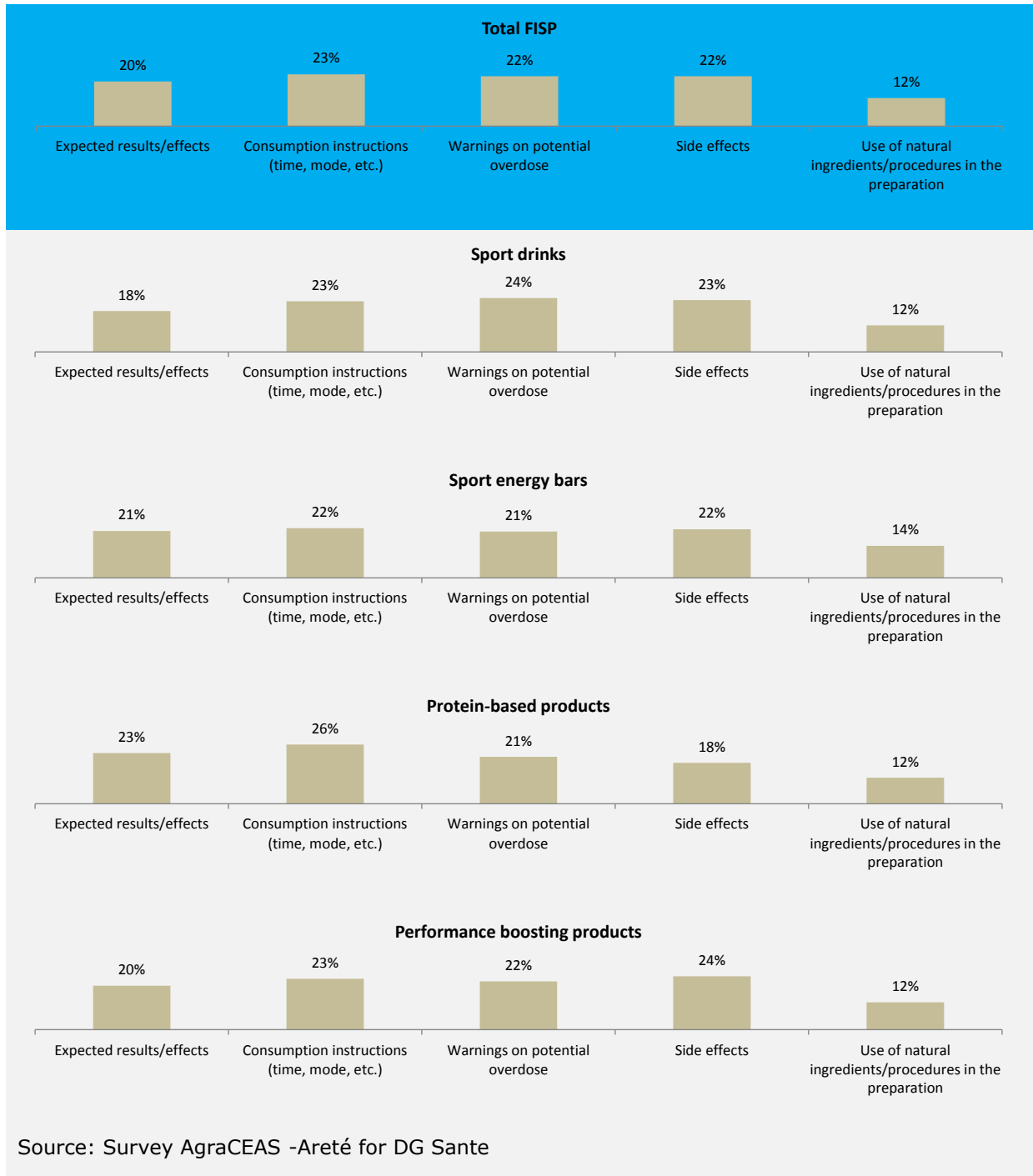
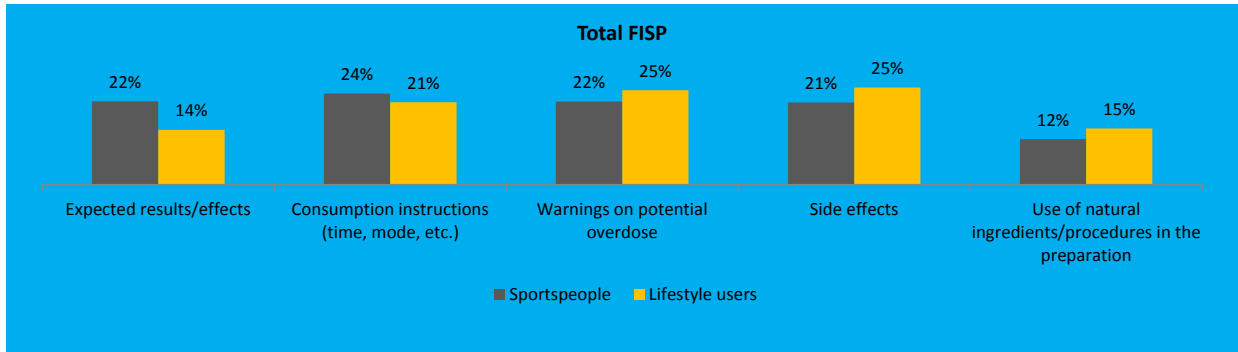


Figure 6-17: Information on labels (2) for sportspeople and lifestyle users



Source: Survey AgraCEAS -Areté for DG Sante

6.10 Question 12 – Trust in claims

“How much do you trust the following claims on the label of sportsfood/sportsdrink products?”

Table 6.3: Trust in authorized / non-authorized claims by Member States

Authorized Claims highlightd in light blue

Total Countries	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	43.1%	47.5%	9.4%
Creatine can help enhance physical working capacity at fatigue threshold	40.7%	49.1%	10.2%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	53.2%	40.5%	6.2%
Glucose contributes to normal energy-yielding metabolism during exercise	53.7%	39.5%	6.8%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	40.2%	50.9%	8.8%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	36.3%	52.1%	11.6%
Whey protein essential amino acids aid muscle maintenance and growth	44.5%	45.5%	10.0%
Protein contributes to a growth in muscle mass	54.5%	36.9%	8.5%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	42.2%	48.1%	9.7%
United Kingdom			
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	43.2%	49.0%	7.8%
Creatine can help enhance physical working capacity at fatigue threshold	37.4%	53.9%	8.6%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	52.7%	39.1%	8.2%
Glucose contributes to normal energy-yielding metabolism during exercise	52.7%	39.1%	8.2%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	43.2%	45.3%	11.5%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	42.0%	44.4%	13.6%
Whey protein essential amino acids aid muscle maintenance and growth	46.5%	41.6%	11.9%
Protein contributes to a growth in muscle mass	51.0%	37.4%	11.5%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	37.9%	49.8%	12.3%
France			
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	43.6%	42.8%	13.6%
Creatine can help enhance physical working capacity at fatigue threshold	41.6%	43.2%	15.2%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	56.0%	36.6%	7.4%
Glucose contributes to normal energy-yielding metabolism during exercise	56.4%	35.8%	7.8%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	39.5%	50.6%	9.9%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	37.9%	50.6%	11.5%
Whey protein essential amino acids aid muscle maintenance and growth	48.6%	43.2%	8.2%
Protein contributes to a growth in muscle mass	56.0%	32.9%	11.1%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	44.0%	43.6%	12.3%

Study on foods intended for sportspeople: Annexes
Food chain evaluation Consortium Lot 3 (FCEC)

<i>Germany</i>	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	37.2%	55.1%	7.7%
Creatine can help enhance physical working capacity at fatigue threshold	37.7%	52.2%	10.1%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	48.2%	45.3%	6.5%
Glucose contributes to normal energy-yielding metabolism during exercise	44.5%	47.8%	7.7%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	39.3%	51.0%	9.7%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	23.1%	59.9%	17.0%
Whey protein essential amino acids aid muscle maintenance and growth	49.4%	42.5%	8.1%
Protein contributes to a growth in muscle mass	50.6%	41.3%	8.1%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	36.8%	53.0%	10.1%

<i>Italy</i>	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	40.7%	48.0%	11.4%
Creatine can help enhance physical working capacity at fatigue threshold	38.2%	50.8%	11.0%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	51.6%	43.1%	5.3%
Glucose contributes to normal energy-yielding metabolism during exercise	54.5%	39.8%	5.7%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	35.4%	56.5%	8.1%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	37.0%	53.7%	9.3%
Whey protein essential amino acids aid muscle maintenance and growth	33.7%	53.3%	13.0%
Protein contributes to a growth in muscle mass	57.3%	35.0%	7.7%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	41.5%	49.2%	9.3%

<i>Spain</i>	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	50.8%	42.6%	6.6%
Creatine can help enhance physical working capacity at fatigue threshold	48.8%	45.5%	5.8%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	57.9%	38.4%	3.7%
Glucose contributes to normal energy-yielding metabolism during exercise	60.7%	34.7%	4.5%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	43.8%	51.2%	5.0%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	41.7%	51.7%	6.6%
Whey protein essential amino acids aid muscle maintenance and growth	44.2%	47.1%	8.7%
Protein contributes to a growth in muscle mass	57.9%	38.0%	4.1%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	50.8%	44.6%	4.5%

Source: Survey AgraCEAS -Areté for DG Sante

6.11 Question 13 – Influence of claims in purchasing

“When you buy a product how important is the influence of the following claims on the label of sportsfood/sportsdrink products?”

Table 6.4 – Influence of authorized / non-authorized claims in product purchasing by Member States

Authorized Claims highlightd in light blue

Total Countries	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	42.9%	43.8%	13.3%
Creatine can help enhance physical working capacity at fatigue threshold	42.0%	45.0%	12.9%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	45.6%	43.3%	11.1%
Glucose contributes to normal energy-yielding metabolism during exercise	45.6%	44.1%	10.3%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	38.9%	47.7%	13.4%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	39.8%	45.7%	14.5%
Whey protein essential amino acids aid muscle maintenance and growth	42.0%	43.9%	14.1%
Protein contributes to a growth in muscle mass	46.1%	39.2%	14.7%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	43.5%	41.6%	14.9%
United Kingdom	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	42.0%	40.7%	17.3%
Creatine can help enhance physical working capacity at fatigue threshold	36.6%	48.1%	15.2%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	39.5%	42.4%	18.1%
Glucose contributes to normal energy-yielding metabolism during exercise	43.6%	42.0%	14.4%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	42.8%	37.9%	19.3%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	39.1%	40.7%	20.2%
Whey protein essential amino acids aid muscle maintenance and growth	44.0%	36.6%	19.3%
Protein contributes to a growth in muscle mass	44.9%	35.8%	19.3%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	37.9%	40.3%	21.8%

France	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	44.9%	43.2%	11.9%
Creatine can help enhance physical working capacity at fatigue threshold	48.1%	39.9%	11.9%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	51.0%	39.9%	9.1%
Glucose contributes to normal energy-yielding metabolism during exercise	50.6%	40.7%	8.6%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	37.9%	48.1%	14.0%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	45.3%	40.3%	14.4%
Whey protein essential amino acids aid muscle maintenance and growth	47.7%	41.6%	10.7%
Protein contributes to a growth in muscle mass	48.1%	38.7%	13.2%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	47.7%	37.9%	14.4%

Germany	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	35.6%	48.6%	15.8%
Creatine can help enhance physical working capacity at fatigue threshold	33.2%	49.8%	17.0%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	43.7%	43.3%	13.0%
Glucose contributes to normal energy-yielding metabolism during exercise	40.5%	47.0%	12.6%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	38.1%	47.0%	15.0%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	31.6%	50.2%	18.2%
Whey protein essential amino acids aid muscle maintenance and growth	40.5%	42.9%	16.6%
Protein contributes to a growth in muscle mass	46.2%	38.1%	15.8%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	37.2%	44.1%	18.6%

Italy	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	41.5%	43.9%	14.6%
Creatine can help enhance physical working capacity at fatigue threshold	43.1%	43.9%	13.0%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	45.9%	43.5%	10.6%
Glucose contributes to normal energy-yielding metabolism during exercise	39.8%	50.4%	9.8%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	31.3%	55.7%	13.0%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	38.6%	48.8%	12.6%
Whey protein essential amino acids aid muscle maintenance and growth	35.8%	48.4%	15.9%
Protein contributes to a growth in muscle mass	43.1%	43.5%	13.4%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	45.9%	41.9%	12.2%

Study on foods intended for sportspeople: Annexes
Food chain evaluation Consortium Lot 3 (FCEC)

<i>Spain</i>	<u>Very Much</u>	<u>Not much</u>	<u>Not at all</u>
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	50.8%	42.6%	6.6%
Creatine can help enhance physical working capacity at fatigue threshold	49.2%	43.4%	7.4%
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	47.9%	47.5%	4.5%
Glucose contributes to normal energy-yielding metabolism during exercise	53.7%	40.1%	6.2%
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	44.6%	49.6%	5.8%
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	44.6%	48.3%	7.0%
Whey protein essential amino acids aid muscle maintenance and growth	42.1%	50.0%	7.9%
Protein contributes to a growth in muscle mass	48.3%	40.1%	11.6%
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	48.8%	43.8%	7.4%

Source: Survey AgraCEAS -Areté for DG Sante

6.12 Question 14 – Foods other than FISP

“In relation to sport activity, do you ever consume products which are not specifically marketed for sports activity? If yes, which?”

Figure 6-18: Foods other than FISP used in relation to sport activity

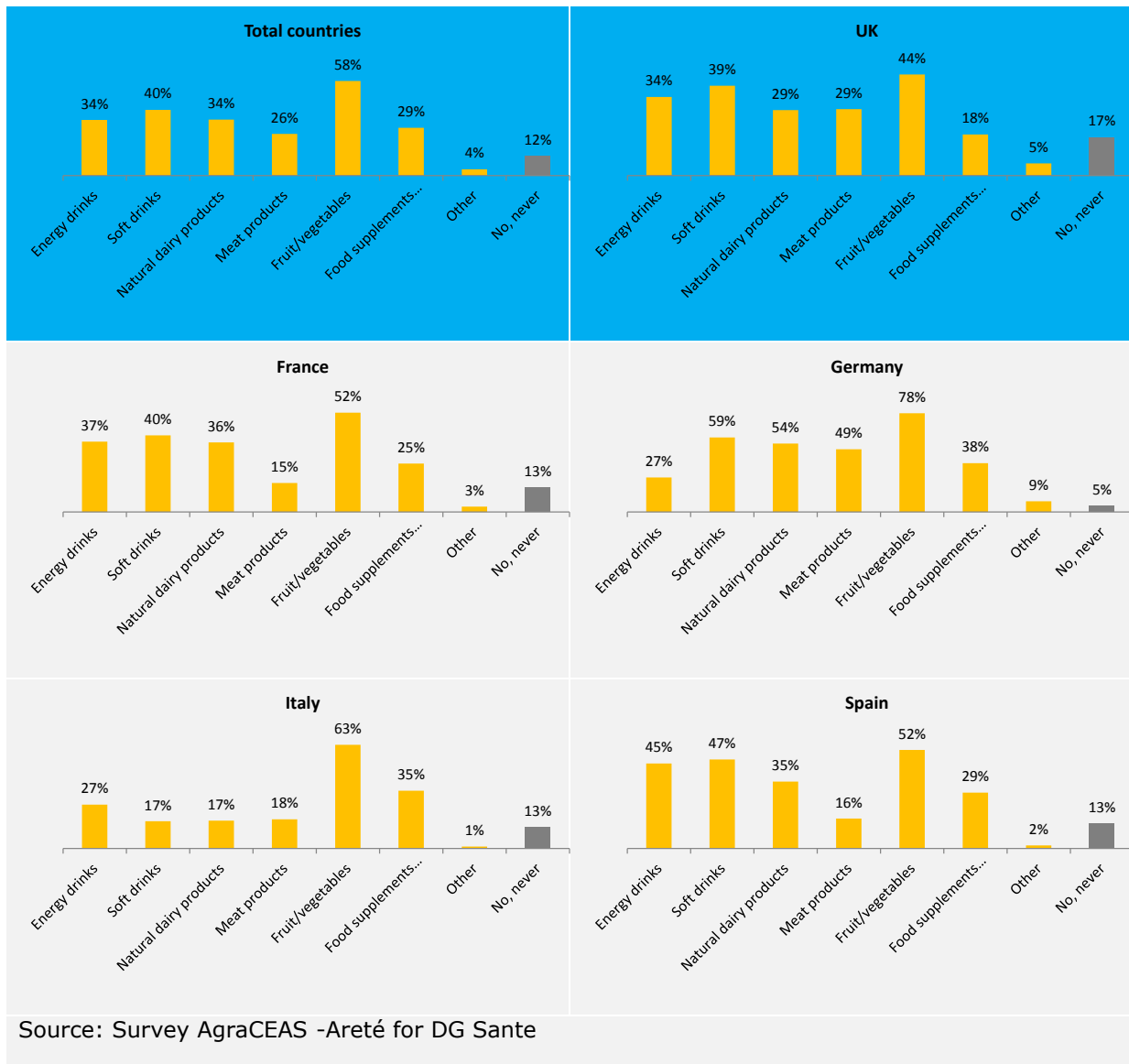
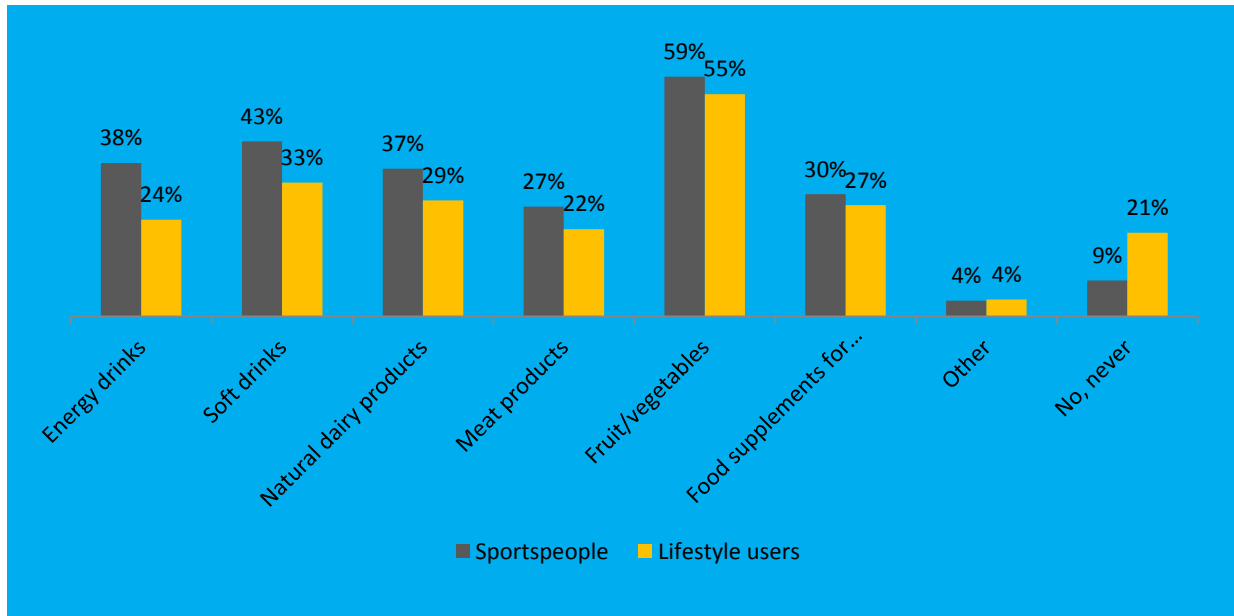


Figure 6-19: Foods other than FISP used in relation to sport activity, for sportspeople and lifestyle users

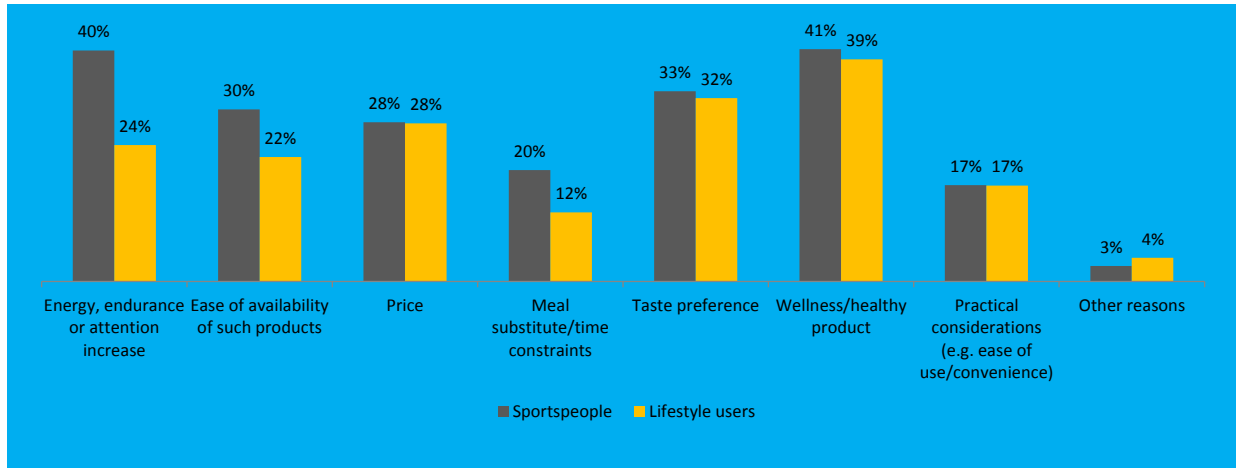


Source: Survey AgraCEAS -Areté for DG Sante

6.13 Question 15 – Reasons behind consumption of foods other than FISP

“Why do you purchase these other food products in relation to sporting activity?”

Figure 6-20: Foods other than FISP used in relation to sport activity, reasons behind consumption, for sportspeople and lifestyle users

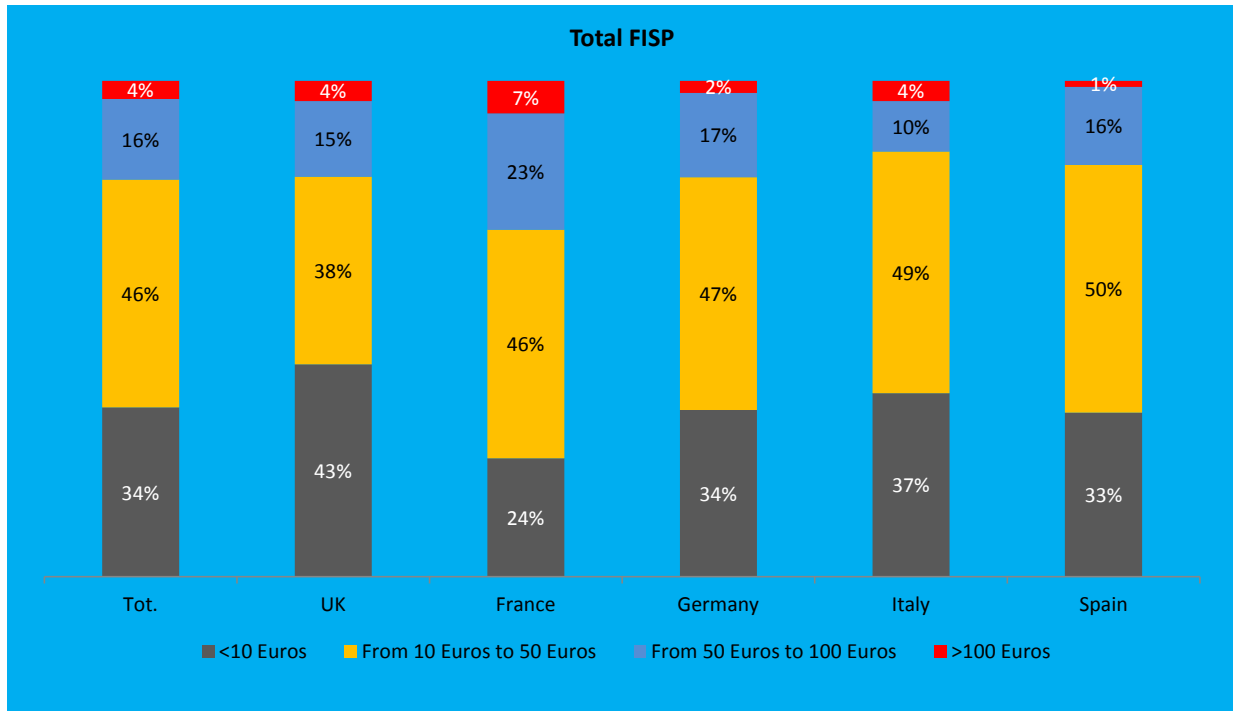


Source: Survey AgraCEAS -Areté for DG Sante

6.14 Question 16 – Expenditure

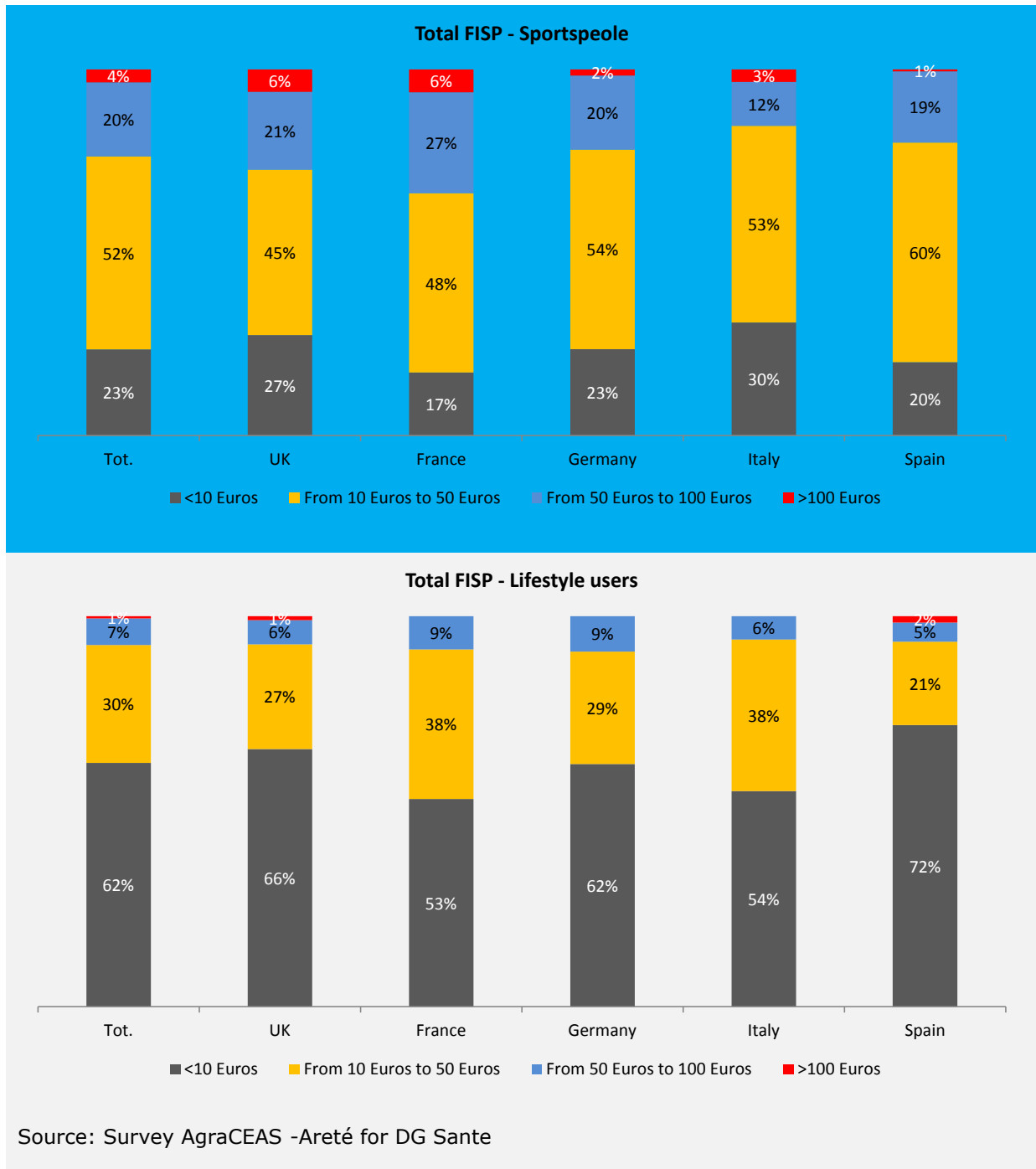
“With reference to the general “sportsfood” category, how much do you spend, on average, in a month?”

Figure 6-21: General expenditure and breakdown by Member State



Source: Survey AgraCEAS -Areté for DG Sante

Figure 6-22: General expenditure and breakdown by Member State, for sportspeople and lifestyle users



6.15 Description of the population: Questions 17 – 25

Question 17

Gender

Table 6.5: Gender composition by Member State, for sportspeople and lifestyle users

		Total Countries		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Male		56.6%	59.2%	49.5%
Female		43.4%	40.8%	50.5%
		UK		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Male		55.4%	58.2%	51.4%
Female		44.6%	41.8%	48.6%
		France		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Male		63.0%	65.0%	52.5%
Female		37.0%	35.0%	47.5%
		Germany		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Male		57.6%	60.7%	48.4%
Female		42.4%	39.3%	51.6%
		Italy		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Male		52.0%	54.9%	44.8%
Female		48.0%	45.1%	55.2%
		Spain		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Male		53.4%	54.3%	50.5%
Female		46.6%	45.7%	49.5%

Source: Survey AgraCEAS -Areté for DG Sante

Question 18

Age

Table 6.6: Age distribution by Member State, for sportspeople and lifestyle users

	Total Countries		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
15-24	16%	19%	9%
25-39	32%	35%	24%
40-54	32%	31%	33%
>55	20%	15%	34%

	UK		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
15-24	23%	26%	20%
25-39	30%	39%	18%
40-54	23%	21%	25%
>55	24%	15%	37%

	France		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
15-24	21%	25%	2%
25-39	33%	34%	26%
40-54	29%	29%	32%
>55	17%	13%	41%

	Germany		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
15-24	14%	17%	4%
25-39	27%	30%	19%
40-54	37%	36%	40%
>55	22%	17%	37%

Study on foods intended for sportspeople: Annexes
Food chain evaluation Consortium Lot 3 (FCEC)

	Italy		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
15-24	9%	10%	7%
25-39	36%	39%	28%
40-54	40%	38%	47%
>55	14%	13%	17%

	Spain		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
15-24	13%	16%	6%
25-39	33%	33%	32%
40-54	31%	34%	24%
>55	22%	17%	37%

Source: Survey AgraCEAS -Areté for DG Sante

Question 19

“Level of education: how old were you when you finished studies?”

Table 6.7: Level of education by Member State, for sportspeople and lifestyle users

	Total Countries		
	<u>Totale</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
<15 years old	4.3%	3.3%	7.1%
16 to 19 years old	40.6%	38.0%	47.8%
>20 years old	45.2%	47.2%	39.6%
still student	9.9%	11.5%	5.6%
UK			
	<u>Totale</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
<15 years old	7.0%	3.9%	11.3%
16 to 19 years old	47.1%	42.1%	54.1%
>20 years old	37.4%	44.0%	28.1%
still student	8.6%	10.0%	6.5%
France			
	<u>Totale</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
<15 years old	3.2%	2.3%	8.4%
16 to 19 years old	28.4%	26.0%	40.9%
>20 years old	59.5%	61.2%	50.7%
still student	8.9%	10.6%	0.0%
Germany			
	<u>Totale</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
<15 years old	5.3%	4.4%	7.7%
16 to 19 years old	63.3%	66.3%	54.8%
>20 years old	24.2%	20.8%	34.0%
still student	7.2%	8.5%	3.5%
Italy			
	<u>Totale</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
<15 years old	5.3%	5.3%	5.4%
16 to 19 years old	29.2%	27.7%	33.0%
>20 years old	53.8%	53.8%	53.7%
still student	11.7%	13.2%	7.9%
Spain			
	<u>Totale</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
<15 years old	0.9%	1.2%	0.0%
16 to 19 years old	33.7%	28.4%	50.2%
>20 years old	51.7%	54.9%	41.8%
still student	13.7%	15.5%	8.0%

Source: Survey AgraCEAS -Areté for DG Sante

Question 20

Profession

Table 6.8: Profession distribution by Member State, for sportspeople and lifestyle users

	Total Countries		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Self-employed	10.6%	10.8%	10.2%
Manager	7.4%	8.3%	4.9%
Employee	40.0%	42.6%	33.0%
Manual worker	8.2%	8.3%	7.9%
Soldier	0.7%	0.7%	0.7%
Professional sportsman	0.5%	0.5%	0.4%
Unemployed	11.6%	9.0%	18.8%
Retired	10.0%	6.9%	18.3%
Student	11.0%	12.9%	5.9%

	UK		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Self-employed	9.8%	10.8%	8.5%
Manager	15.0%	18.4%	10.2%
Employee	31.0%	35.8%	24.2%
Manual worker	10.4%	10.8%	10.0%
Soldier	0.6%	0.0%	1.5%
Professional sportsman	1.1%	1.8%	0.0%
Unemployed	12.7%	6.5%	21.4%
Retired	6.1%	1.1%	13.1%
Student	13.3%	14.9%	11.2%

	France		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Self-employed	4.9%	5.2%	2.9%
Manager	10.7%	11.3%	7.3%
Employee	44.8%	47.2%	32.2%
Manual worker	5.7%	5.6%	6.2%
Soldier	1.8%	2.2%	0.0%
Professional sportsman	0.0%	0.0%	0.0%
Unemployed	10.0%	9.7%	11.4%
Retired	13.5%	8.5%	40.0%
Student	8.6%	10.3%	0.0%

Study on foods intended for sportspeople: Annexes
Food chain evaluation Consortium Lot 3 (FCEC)

	Germany		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Self-employed	9.1%	9.4%	8.4%
Manager	5.9%	7.0%	2.7%
Employee	41.7%	43.4%	36.7%
Manual worker	10.5%	11.7%	7.1%
Soldier	0.2%	0.3%	0.0%
Professional sportsman	0.0%	0.0%	0.0%
Unemployed	6.2%	3.6%	13.7%
Retired	14.7%	9.9%	28.5%
Student	11.7%	14.7%	2.9%

	Italy		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Self-employed	18.2%	20.4%	12.7%
Manager	2.1%	2.3%	1.5%
Employee	37.4%	37.2%	37.6%
Manual worker	8.2%	8.1%	8.7%
Soldier	0.8%	0.6%	1.2%
Professional sportsman	0.2%	0.3%	0.0%
Unemployed	15.5%	11.9%	24.5%
Retired	6.0%	5.8%	6.6%
Student	11.7%	13.5%	7.2%

	Spain		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Self-employed	12.9%	11.2%	18.2%
Manager	2.3%	3.1%	0.0%
Employee	44.5%	46.0%	39.6%
Manual worker	6.1%	6.2%	5.7%
Soldier	0.0%	0.0%	0.0%
Professional sportsman	1.1%	0.8%	2.3%
Unemployed	14.9%	13.4%	19.6%
Retired	8.1%	7.0%	11.4%
Student	10.1%	12.3%	3.1%

Source: Survey AgraCEAS-Areté for DG Sante

Question 22

“Do you live in a...”

Table 6.9: Area of residence by Member State, for sportspeople and lifestyle users

		Total Countries		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Urban area		76.6%	79.1%	69.9%
Rural area		23.4%	20.9%	30.1%
		UK		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Urban area		75.6%	81.0%	68.1%
Rural area		24.4%	19.0%	31.9%
		France		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Urban area		74.4%	73.4%	79.6%
Rural area		25.6%	26.6%	20.4%
		Germany		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Urban area		69.0%	73.0%	57.2%
Rural area		31.0%	27.0%	42.8%
		Italy		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Urban area		77.6%	79.9%	71.9%
Rural area		22.4%	20.1%	28.1%
		Spain		
		<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Urban area		88.1%	91.3%	78.2%
Rural area		11.9%	8.7%	21.8%

Source: Survey AgraCEAS -Areté for DG Sante

Question 24

“Are you a regular smoker?”

Table 6.10: Regular smokers by Member State, for sportspeople and lifestyle users

	Total Contries		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Smoker	33.5%	33.8%	32.7%
Non - smokers	66.5%	66.2%	67.3%
UK			
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Smoker	31.0%	28.3%	34.7%
Non - smokers	69.0%	71.7%	65.3%
France			
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Smoker	31.7%	32.9%	25.5%
Non - smokers	68.3%	67.1%	74.5%
Germany			
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Smoker	40.0%	39.4%	41.8%
Non - smokers	60.0%	60.6%	58.2%
Italy			
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Smoker	21.0%	20.9%	21.3%
Non - smokers	79.0%	79.1%	78.7%
Spain			
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Smoker	42.7%	44.5%	37.0%
Non - smokers	57.3%	55.5%	63.0%

Source: Survey AgraCEAS -Areté for DG Sante

Question 25

“In the last month, how often have you consumed alcohol?”

Table 6.11: Alcohol consumption by Member State, for sportspeople and lifestyle users

	Total Countries		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Every day	7.0%	7.2%	6.7%
4 to 5 times per week	8.2%	8.6%	7.3%
2 to 3 times per week	20.9%	21.8%	18.3%
once a week	22.0%	23.7%	17.4%
1 to 3 times per month	23.2%	22.2%	26.1%
never	18.6%	16.6%	24.2%

	United Kingdom		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Every day	5.5%	7.1%	3.3%
4 to 5 times per week	13.3%	15.4%	10.5%
2 to 3 times per week	21.7%	21.2%	22.3%
once a week	19.3%	17.8%	21.4%
1 to 3 times per month	18.5%	17.5%	20.1%
never	21.7%	21.1%	22.5%

	France		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Every day	10.8%	10.8%	10.6%
4 to 5 times per week	9.4%	8.7%	13.1%
2 to 3 times per week	22.3%	22.0%	24.0%
once a week	24.5%	24.6%	23.9%
1 to 3 times per month	16.4%	17.3%	11.9%
never	16.7%	16.7%	16.6%

	Germany		
	<u>Total</u>	<u>Sportspeople</u>	<u>Lifestyle users</u>
Every day	3.5%	2.7%	5.9%
4 to 5 times per week	3.4%	3.1%	4.2%
2 to 3 times per week	18.8%	19.4%	17.0%
once a week	23.6%	26.2%	15.8%
1 to 3 times per month	30.9%	31.5%	28.9%
never	19.9%	17.1%	28.2%

	Italy		
	Total	Sportspeople	Lifestyle users
Every day	7.6%	8.6%	5.1%
4 to 5 times per week	7.6%	10.1%	1.5%
2 to 3 times per week	16.3%	18.2%	11.6%
once a week	21.4%	25.2%	11.9%
1 to 3 times per month	27.3%	20.5%	44.2%
never	19.8%	17.4%	25.7%

	Spain		
	Total	Sportspeople	Lifestyle users
Every day	7.6%	6.1%	12.1%
4 to 5 times per week	7.6%	7.8%	7.1%
2 to 3 times per week	25.0%	28.0%	15.8%
once a week	20.8%	23.2%	13.6%
1 to 3 times per month	23.7%	23.5%	24.3%
never	15.3%	11.5%	27.0%

Source: Survey AgraCEAS-Areté for DG Sante

6.16 Full consumer survey questionnaire

The Food Chain Evaluation Consortium (FCEC) is carrying out a study on consumer behaviour and consumption of certain food products on behalf of the European Commission.

Please answer the questions below.

6.16.1 Part A – First screening

- 1) Which of the following products have you consumed in the last year?

<i>In grey: eligible target</i>	5 times per week or more	3 to 4 times per week	1 to 2 times per week	1 to 3 times per month	less than 1 time per month	never
Fruit/vegetables/dry fruit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Energy drinks (e.g. Redbull, Burn, Monster ...)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Soft drinks (e.g. Coca-cola, Fanta, Pepsi ...)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Sportsdrinks (e.g. Gatorade,	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Other supplements (e.g. caffeine, vitamins and minerals specifically for sport)	□	□	□	□	□	□
---	---	---	---	---	---	---

3) Which of the following products have you consumed more often in the last year?
(Please select **no more than 2 options**)

(list of products selected in Q2)

- Sportsdrinks (e.g. Gatorade, Lucozade, Powerade)
- Sports energy bars
- Protein bars (protein only or combined with other substances such as carbohydrates)
- Sportsfood products with high concentration of proteins
- Sportsfood products with high concentration of carbohydrates/amino acids (e.g. gel, powder)
- All-in-one sportsfood products (e.g. proteins + carbohydrates + vitamins)
- Creatine, carnitine and/or branch chain amino acids
- Other sport supplements (e.g. caffeine, vitamins and minerals specifically for sport)

6.16.2 Part B – Second screening

4) How often have you played sport in the last month?

- 5 times per week or more (=> Q5)
- 3 to 4 times per week (=> Q5)
- 1 to 2 times per week (=> Q5)
- 1 to 3 times per month (=> Q5)
- never (=> Q6)

5) Which sport do you play/do?

(Please select **only the two you most commonly play**)

- Running
- Football
- Athletics
- Cycling
- Body building
- Martial arts/combat sports
- Swimming
- Tennis
- Basketball
- Volleyball
- Fencing
- Fitness/dance/gymnastics
- General gym/workout
- Other

6.16.3 Part C – Consumption circumstances/reasons

(set of questions to be asked for each of the 1-2 product categories identified at question 3)

6) Is your consumption of [PRODUCT CATEGORY 1/2], on average, more related to ...

- Sport activity
- Physical effort other than sport (e.g. work)
- Neither sport nor physical effort (e.g. convenience, weight control, etc.)

7) Which are the two main reasons behind your consumption of [PRODUCT CATEGORY 1/2]?
(Please select **no more than 2 options**)

- Energy increase
- Endurance increase
- Attention increase
- Muscle mass increase
- Energy recovery
- Meal substitute/time constraints
- Weight control
- Taste/preference
- Wellness/healthy product
- Other reasons

8) Where do you usually purchase [PRODUCT CATEGORY 1/2]?
(Please select **no more than 2 options**)

- Supermarket
- Sports “supermarkets” e.g. Sports Direct
- Specialised shops
- Pharmacies/Chemists
- Fitness club/Gym
- Online
- Other

6.16.4 Part D –Reasons behind consumption/purchase

(9, 10, 11: set of specific questions to be asked for each of the 1-2 product categories identified at question 3)

9) When you buy [PRODUCT 1/2], what is the importance of the following aspects for you?

	Very Important	Important	Not so important
Expected results/effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality of ingredients (e.g. healthy/natural products, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Presence of specific ingredient(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Practical aspects/convenience	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Overall product composition for balanced sport nutrition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Price	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10) Which are for you, among the following, the most important information reported on the label of [PRODUCT 1/2]?

(Please select **all the options that fit**)

- List of ingredients
- Expected results/effects

- Consumption instructions (time, mode, etc.)
- Warnings on potential overdose
- Side effects
- Use of natural ingredients/procedures in the preparation

11) Which of the following information should never be missing for you on the label of [PRODUCT 1/2]?

(Please select **all the options that fit**)

- Expected results/effects
- Consumption instructions (time, mode, etc.)
- Warnings on potential overdose
- Side effects
- Use of natural ingredients/procedures in the preparation

(12, 13, 14, 15: set of general questions to be asked to each respondent in the eligible target, irrespective of the 1-2 product categories identified at question 3)

12) How much do you **trust** the following claims on the label of sportsfood/sportsdrink products?

	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Creatine can help enhance physical working capacity at fatigue threshold	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Glucose contributes to normal energy-yielding metabolism during exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carbohydrate-electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Whey protein essential amino acids aid muscle maintenance and growth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Protein contributes to a growth in muscle mass	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13) When you buy a product how important is the **influence** of the following claims on the label of sportsfood/sportsdrink products?

	Very Much	Not much	Not at all
Creatine increases physical performance in successive bursts of short-term, high intensity exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Creatine can help enhance physical working capacity at fatigue threshold	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive physical exercise leading to muscle fatigue and the depletion of glycogen stores	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Glucose contributes to normal energy-yielding metabolism during exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carbohydrate -electrolyte drinks help reduce the perception of effort/fatigue, making you feel better during exercise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Whey protein essential amino acids aid muscle maintenance and growth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Protein contributes to a growth in muscle mass	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Product specially manufactured on the basis of the specific nutritional needs of sportspeople	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14) In relation to sport activity, do you ever consume products which are not specifically marketed for sports activity? If yes, which?

(Please select **all the options that fit**)

- Energy drinks
- Soft drinks
- Natural dairy products
- Meat products
- Fruit/vegetables
- Food supplements for overall good health
- Other

15) Why do you purchase these other food products in relation to sporting activity?

(Please select **all the options that fit**)

- Energy, endurance or attention increase
- Ease of availability of such products
- Price
- Meal substitute/time constraints
- Taste preference
- Wellness/healthy product
- Practical considerations (e.g. ease of use/convenience)
- Other reasons

6.16.5 Part E – Expenditure

(this question is referred to the general “sportsfood” category, i.e. the whole range of products listed at question n. 2)

- 16) With reference to the general “sportsfood” category (which includes energy bars, sportsdrinks, products with high concentration of carbohydrates/proteins, creatine, caffeine pills etc. ...), how much do you spend, on average, in a month?
- <7 pounds
 - From 7 pounds to 35 pounds
 - From 35 pounds to 70 pounds
 - From 70 pounds to 140 pounds
 - >140 pounds

6.16.6 Part F – General/Socio-demographic

The interview is nearly completed. We kindly ask you to answer to some final questions about you to help us to analyse the results

- 17) Gender
- Male
 - Female
- 18) Age
- 15-24
 - 25-39
 - 40-54
 - >55
- 19) Level of education: how old were you when you finished studies?
- <15 years old
 - 16 to 19 years old
 - >20 years old
 - still student
- 20) Profession
- Self-employed
 - Manager
 - Employee
 - Manual worker
 - Soldier
 - Professional sportsman
 - Unemployed
 - Retired
 - Student
- 21) Does your job require a particular physical effort? (e.g. warehouse worker, house mover, construction worker, professional sportsman, etc.)
- Yes
 - No
- 22) Do you live in a...
- Urban area
 - Rural area
- 23) In the last month, how often have you consumed fruits or vegetables?

- Every day
- 4 to 5 times per week
- 2 to 3 times per week
- once a week
- 1 to 3 times per month
- never

24) Are you a regular smoker?

- Yes
- No

25) In the last month, how often have you consumed alcohol?

- Every day
- 4 to 5 times per week
- 2 to 3 times per week
- once a week
- 1 to 3 times per month
- never

7 SURVEY: COMPETENT AUTHORITY SURVEY RESULTS

7.1 Introduction to survey and replies

The survey of competent authorities was run on-line from 9 March 2015 to 16 April 2015 (extended to 30th April for certain Member States) following approval of the questionnaire by the steering group. The questionnaire was sent to contact points in EU-28 Competent Authorities (CAs) identified by DG SANTE. Competent Authorities were requested to complete the questionnaire on-line, but a .pdf version of the questionnaire was also provided to allow them to consult internally prior to submitting their replies on line. Several follow up reminder messages were sent in order to maximise replies. 23 of 28 Member States replied, and one Member State provided limited written information. The final status of replies is Table 7.1.

Table 7.1: Member States response to the CA survey

Completed	Limited written information provided	No response
AT, BE, CY, DK, DE, EE, EL, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO*, SE, SI, UK	BG	CZ, ES, FI, SK
23 MS	1 MS	4 MS

* Three replies from different services were received in Romania. These replies were validated and cross checked to form a single reply for the MS.

It should be noted that, while CAs were requested to complete the online version (which was set up in a way to guide the respondent through the questions, with certain questions requiring answers), some seven Member States completed the .pdf version, in some cases with the omission of replies to certain questions which were obligatory in the online version. For questions in which data is aggregated (i.e. individual Member States are not listed), the number of respondents is indicated (*N=number*).

7.2 National legislation in place

7.2.1 MS with legislation

CAs were asked whether there is national legislation covering the placing on the market of FISP in their Member State. Results are displayed in Table 7.2.

Table 7.2: National legislation covering the placing on the market of FISP in the EU-28

MS with legislation	MS without legislation
BG	AT
DK	BE
EE	CY
FR	DE
HU	EL
IT	HR
PL	IE
PT	LT
RO	LU
	LV
	MT
	NL
	SE
	SI
	UK
9 Total	15 Total

7.2.2 Nature of national legislation

7.2.2.1 Areas covered by national legislation

CAs of Member States with national legislation were asked about the areas covered by this legislation. Results are displayed in Table 7.3.

Table 7.3: Areas covered by national legislation

MS	Notification	Authorisation	Definition	Composition	Labelling	Marketing	Outlets	C
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	
Tot	5	1	2	3	6	1	

Note: information on areas covered was not provided by BG

Further relevant information on provisions by area, where provided, is identified below:

Notification

- **PL:** electronic notification form.
- **PT:** forwarding of label.

Definition

- **FR:** products contain the components of protein, carbohydrate, fat, vitamins, minerals and other biologically important substances in easily available form to cover the increased nutrient requirements, and their compositions and the documented analytical results contribute to the indicated purpose on the base of expert opinions.

Composition

- **DK:** safety evaluation of new additions of nutrients (vitamins, minerals and other active substances e.g. caffeine, glucuronolactone, amino acids) prior to marketing of products.
- **FR:** provisions on the levels of certain macro and micronutrients (see arrêté du 20 juillet 1977, article 50 and 51).

Labelling

- **FR:** indications as set out in the arrêté du 20 juillet 1977, articles 53 and 54.
- **HU:** provisions similar to those under article 9 of Directive 2009/39/EC.
- **PL:** provisions similar to those under article 9 of Directive 2009/39/EC.
- **PT:** notification requirement comprises the forwarding of a model label.

7.2.2.2 Similarity to other national legislation

While most Member States either believed that their legislation was not similar to that of another Member State, or did not know, two Member States believed their legislation to be similar:

- **HU:** believed that the absence of notification was similar to the situation in the majority of MS.
- **RO:** believed national legislation to be similar to that in Hungary (though the areas covered by the respective legislations imply that similarities may be limited - Table 7.3).

7.2.3 Impact of national legislation

7.2.3.1 Overall rating of impacts

Competent authorities were asked to rate the impact of national legislation for FISIP in their Member State on a number of factors. Results are presented in Table 7.4. On average, national legislation was considered to have positive impacts on consumer protection and CA enforcement, and neutral impacts elsewhere.

Table 7.4: Rating of impacts on a different areas (1=strongly negative, 5=strongly positive)

Area of impact	Average	DK	EE	FR	HU	IT	PL	PT	RO
Internal market	3.0	2.0	3.0	2.0	3.0	4.0	3.0	3.0	4.0
TC market access	3.0	2.0	2.0	3.0	3.0	5.0	3.0	3.0	3.0
Competitiveness	2.6	2.0	2.0	3.0	3.0	3.0	3.0	2.0	
Innovation	3.0	2.0	3.0	3.0	3.0	3.0	3.0	3.0	4.0
SMEs	2.7	2.0	2.0	3.0	3.0	4.0	3.0	2.0	
Price	2.7	2.0	3.0	3.0		3.0	3.0	2.0	
Consumer protection	4.0	5.0	4.0	3.0	3.0	5.0	5.0	3.0	4.0
Legal clarity	2.9	3.0	2.0	2.0	4.0	5.0	3.0	2.0	2.0
CA enforcement	3.6	4.0	2.0	4.0	4.0	4.0	5.0	4.0	2.0
Other	3.0				3.0	3.0			

Competent authorities were also asked to justify the ratings of their impacts. These comments are organised by CA rating in Table 7.5.

Table 7.5: Comments on impacts of national legislation

Area	Negative (1, 2)	Neutral (3)	Positive (4, 5)
Internal market	Notification / authorisation obligation (DK) National rules not applied elsewhere (FR)	Absence of national rules on notification or composition means little impact (HU)	Impact of national legislation minimal without nutritional rules (PT)
TC market access	Notification / authorisation obligation (DK) TCs not aware of notification obligation (EE)	Absence of national rules on notification or composition means little impact (HU)	Legislation gives clarity (IT)
Competitiveness	Fee for safety evaluation of additions of new nutrients (DK) Injunctions placed on no-notified products (EE) Small tax for notification (PT)	Labelling costs similar to that of other foods with nutrition declaration (HU)	
Innovation	Fee for safety evaluation of additions of new nutrients (DK)	No specific compositional requirements in national legislation (HU)	
SMEs	Fee for safety evaluation of additions of new nutrients (DK) Bureaucratic burden (EE)	Absence of national rules on notification or composition means little impact (HU)	Legislation gives clarity (IT)

	Small tax for notification (PT)		
Price	Fee for safety evaluation of additions of new nutrients (DK) Small tax for notification (PT)	Notification is free of charge (EE)	
Consumer protection		No specific compositional requirements in national legislation (HU)	safety evaluation of additions of new nutrients (DK) Unsafe products can be stopped (EE) CA can check labels for misleading info; label contains consumer info (IT) Notification allows the detection of unauthorised substances (PL) Notification enables market monitoring (PT)
Legal clarity	As no legal definition of sportsfood it is not clear which products must be notified (DK) No definition of sportsfood (PT)		National definition and labelling provisions can exclude some products from category (HU) Clear rules about presentation and notification (IT)
CA enforcement	Higher workload (EE)		Safety evaluation controls substances. Post marketing the legislation is enforced as a part of the normal product control (DK). Notification process facilitates monitoring (PT)

			Clear market monitoring procedure (PL)
--	--	--	--

Note: in the case of France, the main comment provided was that the rules are not strictly applied as dispositions are obsolete, therefore there is little impact.

7.2.3.2 Operator and CA burdens; operator costs; and CA enforcement

Member States were asked about the burden of national legislation on (a) FBOs and (b) the national CA. Results are presented in Table 7.6. The burden on FBOs was generally perceived to be light, and on CAs to be neutral.

Table 7.6: Burden of national legislation on (a) FBOs and (b) the national CA (scale: 1 = very heavy, 5 = very light*) and costs for FBOs

MS	FBO burden	FBO costs identified	National CA burden
DK	4.0	Notification free; ingredient authorisation on unauthorised nutrients	4.0
EE	3.0	Notification free; possible costs for labelling changes	3.0
FR	5.0	None identified	5.0
HU	4.0	Labelling cost similar to that of other foods	3.0
IT	5.0	Notification cost of 160.20 EUR per label	2.0
PL	3.0	Notification free. However, authorities can investigate if a notified product is covered by authorisation, and in that case the notifier is responsible for the cost of a scientific opinion.	2.0
PT	3.0	Notification costs	3.0
RO			3.0
Average	3.9		3.1

Note: scale reversed from original scale in question to ensure consistency of presentation in survey results

In terms of controls, market controls on FISP are part of broader food product controls in DK, EE and PL, and part of controls of PARNUTS foods in HU. Other Member States did not provide details on methods of enforcement.

7.3 Soft rules

CAs reported the soft rules outlined in Table 7.7.

Table 7.7: Soft rules

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		

7.4 Products on the market

7.4.1 Total number of products on the market

CAs were asked about the number of FISP products on the market (independent of the method of placing on the market, in accordance with the definition of FISP adopted for this study) and the evolution of the number of products since 2011. Data provided by CAs is presented in Table 7.8. 16 Member State CAs were unable to provide any data on the number of products currently on the market.

Table 7.8: number of FISP products on the market and their evolution since 2011

MS	Total	Sportsdrinks	Muscle strengthening	Performance boosting	Other	Evolution since 2011
AT						about the same
BE						about the same
BG	>1015	No data	725	290		
CY	~2550	~50	1500	1000		large decrease
DE						slight increase
DK						large increase
EE						about the same
EL	~1000					
FR	1000					slight increase
HR	>350	>50	>150	>150	No data	slight increase
HU						large increase
IE	>1050	>80	>750	>170	>50	slight increase
LT						about the same
LU						about the same
LV						
MT	695	25	300	170	200	about the same
NL	1050	130	500	250	170	
PT						large increase
SE						large increase

UK						about the same
----	--	--	--	--	--	----------------

7.4.2 Notified products on the market

CAs were asked about the number of FISP products notified under Directive 2009/39/EC and the evolution of the number of notified products since 2011. Data provided by CAs is presented in Table 7.9.

Table 7.9: number of notified FISP products on the market and their evolution since 2011

MS	Total	Sportsdrinks	Muscle strengthening	Performance boosting	Other	Evolution since 2011
EE	1422					slight increase
EL	~1000					strong increase
IT	1442					slight decrease
LT						about the same
LV	433					
MT		0	0	0	0	about the same
PL*	2604	507	988	711	398	strong increase
PT	177	19	109	49		strong increase
RO	172**					slight increase

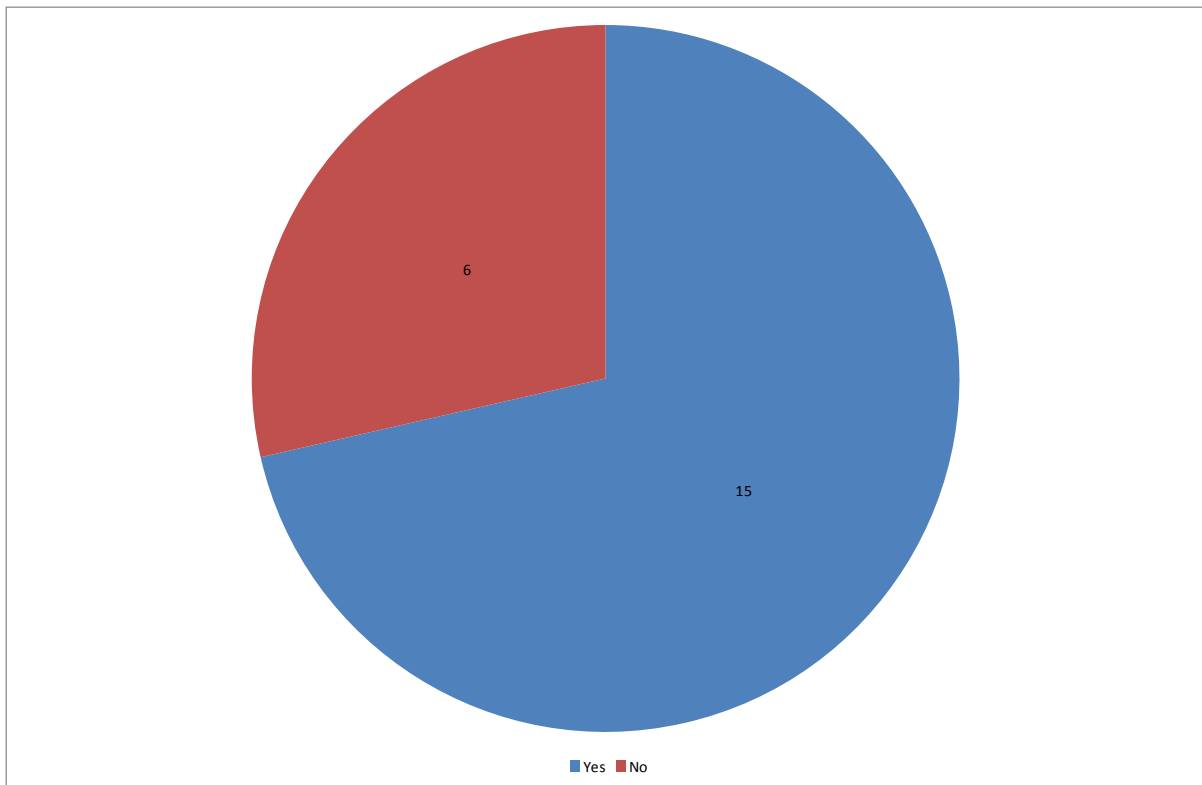
* Between 2009-14

** All PARNUTS products, not just FISP

7.4.3 Products placed on the market as sportsfood in accordance with Directive 2009/39/EC which may not be suitable for sportspeople

CAs were asked if there any FISP products on their national markets which are placed on the market as sportsfood in accordance with Directive 2009/3/EC but about which there are doubts as to whether the product can really be considered as suitable for sportspeople. Of the 21 Member States which replied, 15 answered yes (Figure 7-1).

Figure 7-1: Products placed on the market as sportsfood in accordance with Directive 2009/39/EC which may not be suitable for sportspeople



N=22

A wide range of examples of such products was given by MS. These are listed below. In addition to the list of examples, certain Member States considered any product which does not fall inside the categories set out in the SCF (2001) report to fall in the category of products unsuitable for sportspeople. Other Member States noted that the absence of a legislative definition of sportsfood made it difficult to identify such products.

- Certain soft and energy drinks.
- Focus drinks (e.g. aptonia) which are water, flavour and sweeteners.
- Certain carbohydrate bars.
- Certain “high protein” products in bar form.
- Certain products containing botanicals (e.g. Paunsinystalia yohimba Pierre ex. Beille) or DHEA; or containing combinations of several botanicals or preparations of botanicals, or containing high doses of free amino acids and other substances.
- Products containing the following substances:
 - omega 3 fatty acids.
 - Fibre.
 - alpha-Ketoglutarat.
 - Glucosamine/Chondroitin for joints.
 - Glutamate as a *Power Booster*.
 - Isolated amino acids such as BCAA, Citrullin, Ornithin, L-Arginine and Beta-Alanine.
 - Creatine-derivates or Tribulus terrestris.

- L-Carnitine in conjunction with linoleic acid, colostrum, alpha-lipoic acid, pyruvate, tribulus terrestris, Maca, serenoa, citrus aurantium, Guarana, green-tea extract, CLA, taurine as fat burners.
- Green-tea extract, Citrus aurantium, Guarana, Curcuma longa as fat burners.
- Quercetin, plant extracts on the basis of diuretics for body definition.
- Agmatine, Edysterone, raspberry ketone, novel creatine bonds, Higenamin (Acenitum-ingredient), Methylstenbolon, Yohimbe-bark extract, Cordyceps Sinensis.
- Some products which were notified under Directive 2009/39/EC may contain unauthorized novel food ingredients (for example plant Tribulus terrestris which is authorized only in food supplements) or very high amounts of vitamins, caffeine (more than 500 mg per daily dose), herbal ingredients in therapeutic doses. These products can be considered medicines.
- Some pre-workout products specifically targeting sportspeople which include botanical substances (e.g. Dendrobium and Rhododendron extract) caffeine etc. for which the usefulness and the suitability for the target group might be questioned.

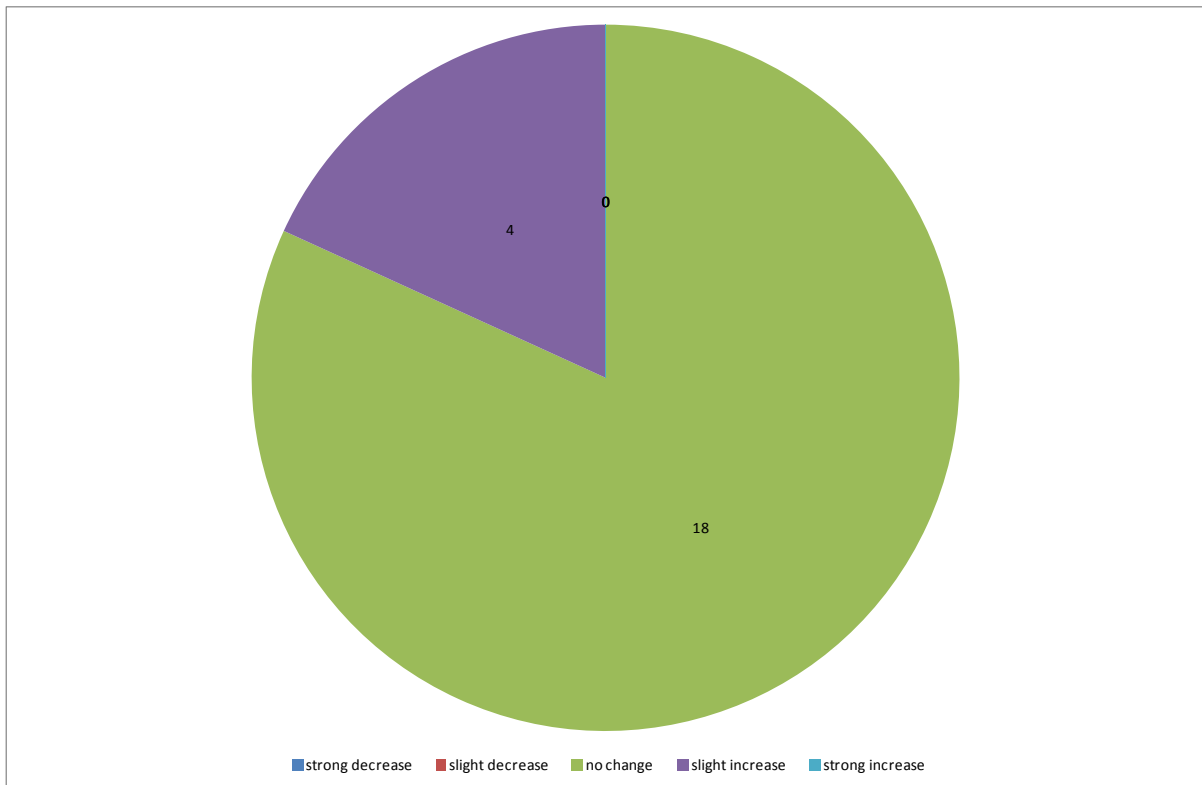
Finally, it was also noted that there are many sports foods imported from other English speaking countries are freely available to purchase on the internet which do not comply with EU law.

7.5 Claims

7.5.1 Change in practices after 2012

CAs were asked about the change in the number of foods intended for sportspeople fortified in certain substances or nutrients for which claims have been authorised following the entry into force of health claims legislation. Results are presented in Figure 7-2. The average rating of 3.2 / 5 suggests there was no significant change.

Figure 7-2: Change in the number of foods intended for sportspeople fortified in certain substances or nutrients for which claims have been authorised

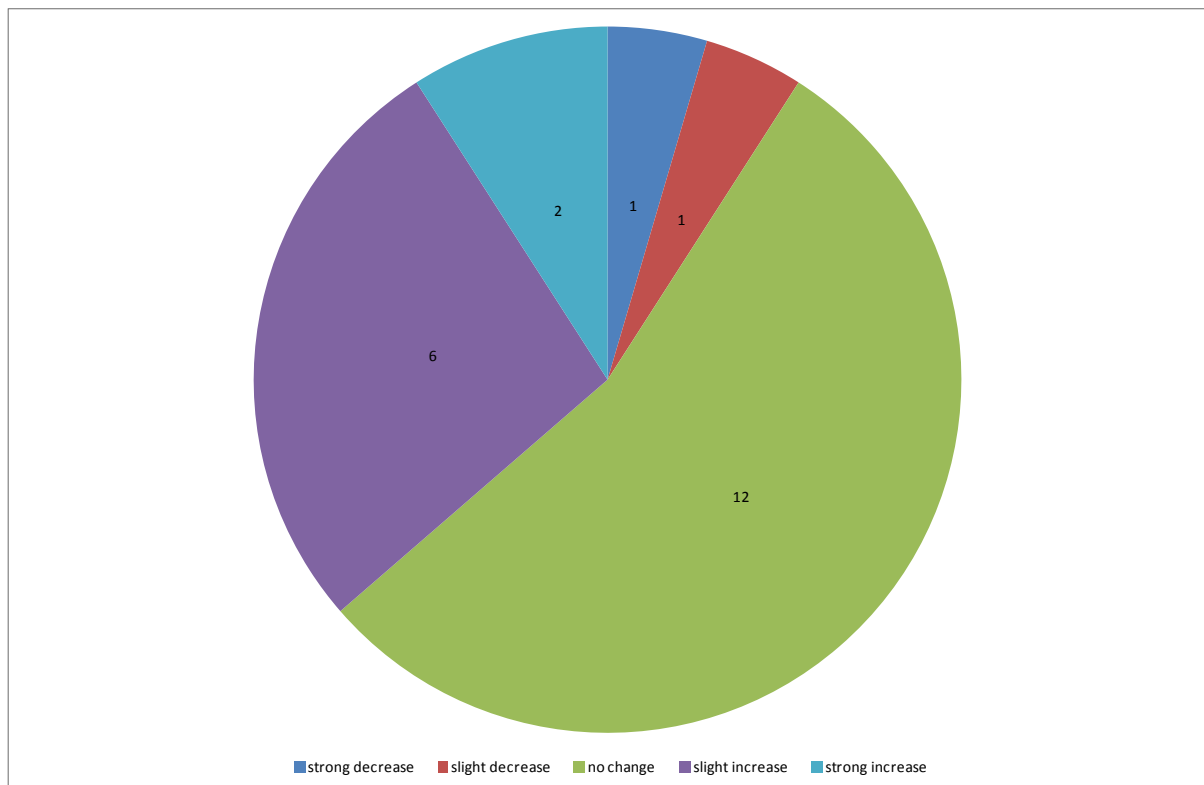


N=22

CAs were asked about changes in the use of claims in the marketing of FISP following the entry into force of health claims legislation. Results are presented in Figure 7-3. The average rating of 3.3 / 5 suggests there was no significant change. Exceptions with notable explanations include:

- **HR (slight increase):** there was previously a mandatory notification procedure for claims; the removal of this has led to an increase in the use of claims.
- **LV (slight decrease):** as a large number of previously used health claims were not authorised, these claims disappeared.
- **SE (strong increase):** operators are well acquainted with claims legislation and consequently have used as many claims as possible leading to a strong increase in the use of claims. However, the use of some unauthorised claims (most notably by internet or by word of mouth) can be found and is particularly high among smaller operators.

Figure 7-3: Changes in the use of claims in the marketing of FISP following the entry into force of health claims legislation

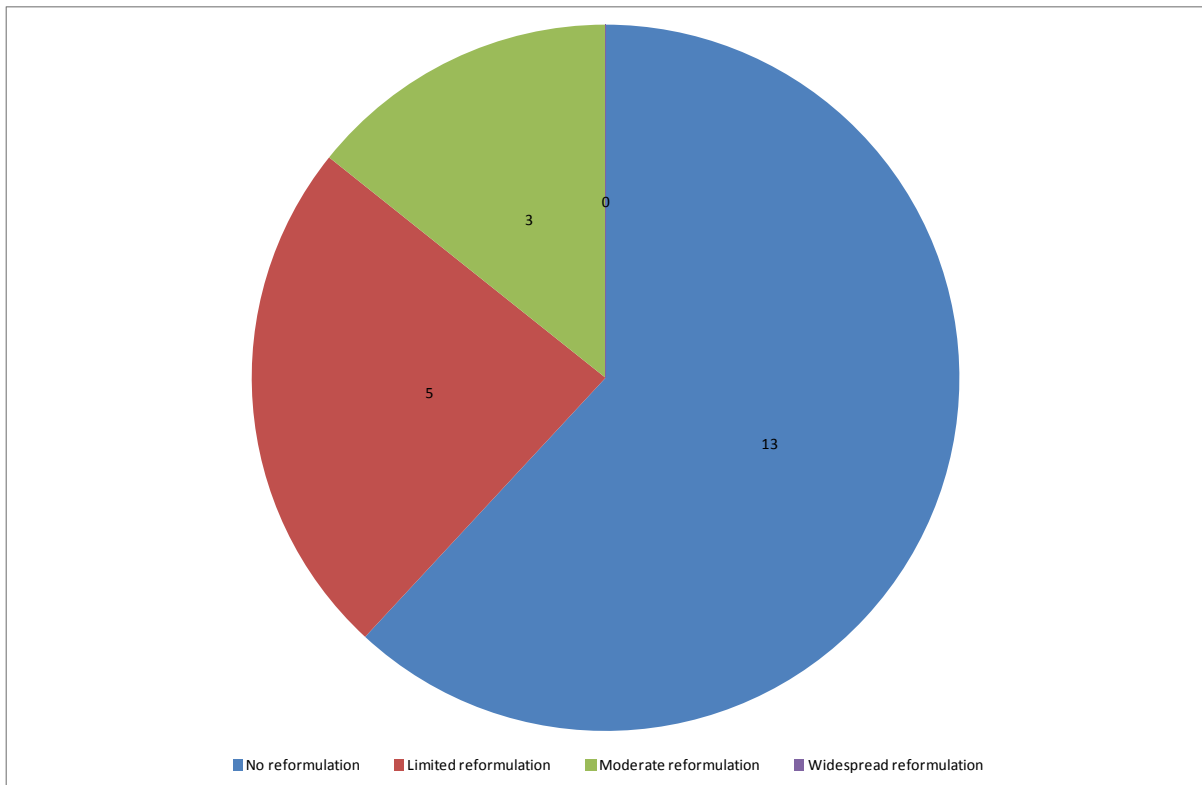


N=22

CAs were asked to what extent foods other than FISP were reformulated after the entry into force of health claims legislation in order to use sports related claims. Results are presented in Figure 7-4. The average of 1.5 / 4 suggests that there was no to limited reformulation. Exceptions with notable comments include:

- **FR (moderate reformulation):** there is the impression that the classification of sportsfoods as a dietetic food partly prevents such reformulation and marketing at present.
- **IE (moderate reformulation):** normal foods - such as milk are now fortified with protein and some micronutrients e.g. vitamin D to use claims.
- **SE (moderate reformulation):** milk fortified with protein has appeared on the market bearing health claims related to protein and muscle mass. Some products are now marketed in additional ways as they can make claims related to protein content (e.g. quark which used to be a product marketed for baking and cooking is now also sold for immediate consumption with claims on protein; it is often flavoured).

Figure 7-4: Extent to which foods other than FISP were reformulated after the entry into force of health claims legislation in order to use sports related claims

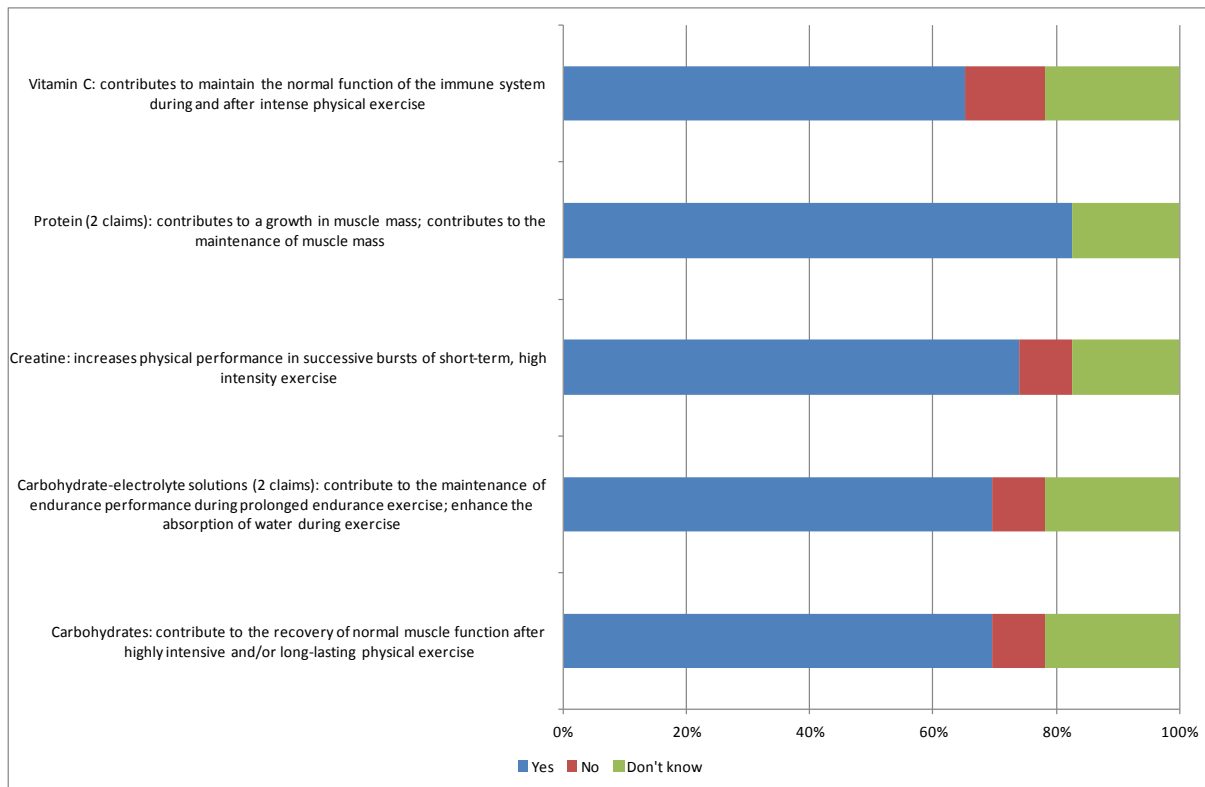


N=21

7.5.2 Use of authorised health claims relevant for FISP products

CAs were asked if certain authorised health claims had been identified as used on FISP. Results are displayed in Figure 7-5. The majority of CAs had identified the use of all health claims on FISP. The claim most widely identified as used was that of protein; the least widely used claim was that of vitamin C.

Figure 7-5: use of authorised health claims on FISP



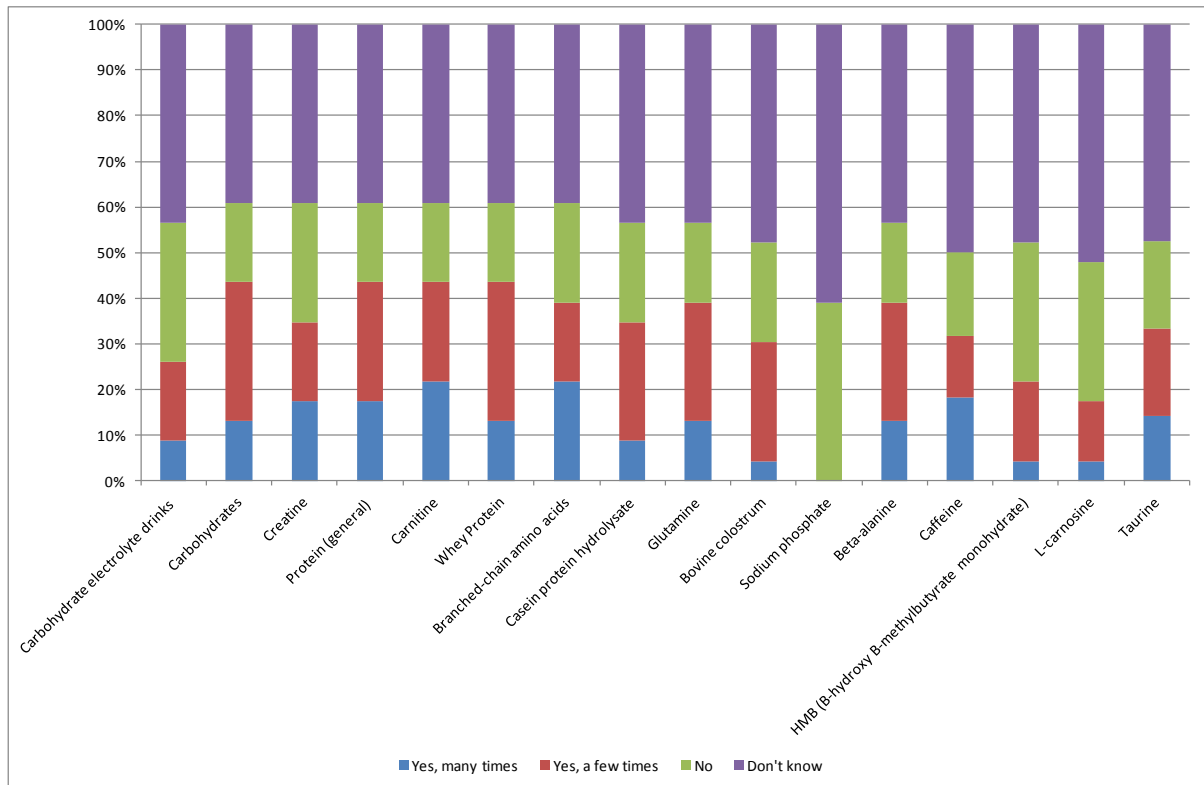
N=23

7.5.3 Use of unauthorised claims

CAs were asked if the use of unauthorised health claims had been identified as used on FISP in relation to certain substances²⁷. Results are displayed in Figure 7-6. Generally, 40% or more of respondents did not know if unauthorised claims had been used. Of respondents who had information on the use of unauthorised claims, prevalence varied by substance. BCAA, carnitine and protein were identified as the substances for which unauthorised health claims targeting sportspeople are most commonly found. No use of unauthorised claims for sodium phosphate was identified. Bovine colostrum, HMB and l-carosine were the substances for which unauthorised health claims targeting sportspeople are least commonly found.

²⁷ This list of substances was determined on the basis of rejected health claim applications relevant to sportsfood, and was approved by the steering group.

Figure 7-6: Identification of the use of unauthorised claims in order to target sportspeople



N=23; except caffeine (N=22) and taurine (N=21)

CAs were asked to provide further details of the unauthorised claims that they have observed. One Member State identified the use of the term “food for sportspeople” as an unauthorised claim used in relation to the majority of substances. Other unauthorised claims identified by respondents are presented below. Information in quotation marks refers to examples of complete claims (generally translated) which were provided. Many (but not all) of these unauthorised claims appear to relate to information on the internet or product promotional material rather than on the product label. Some information provided outlined the function to which the substance was commonly linked in unauthorised claims without providing precise claim statements; this information is indicated under *functions* and is not provided in quotation marks.

Carbohydrate-electrolyte solutions

- “Carbohydrate-electrolyte drinks contain electrolytes, which helps to improve your liquid absorption and reduce the possibility of your muscles cramp.”
- “Nourishing drink based on vitamins and minerals, restorative and hydrating effect on the body (especially in the states of exhaustion and after consuming alcohol) / innovative, specially prepared formula to reduce alcohol and toxins from the body.”
- **Function:** recovery.

Carbohydrates

- “Carbohydrate blend quickly replenishes muscle glycogen.”
- **Functions:** *muscle mass / muscle builder, muscle fuel / fast energy for muscles, muscle tone, energy / high energy.*
- References to release of carbohydrates and the glucaemic index.

Creatine

- “Preparation diet supplemented with creatine, which by micronization is easily digestible and well absorbed into skeletal muscle cells. The system is converted to creatine phosphate as a source of energy for protein synthesis and contraction of muscle fibres. This results in a marked increase in the strength and resilience and improves fitness and muscle endurance. Creatine increases physical performance in the case of successive short, very intense physical exercise.”
- “Possibly the most effective supplement for maximum strength and mass.”
- “Responsible for muscle growth, strength and recovery.”
- **Functions:** *release of energy, muscle function, strength, muscle volume, train muscle for maximum performance, enhance body stores of creatine, accelerates recovery, endurance and power, immediate energy production, improvement in power and/or training results, synthesis of ATP, increase power, muscle rebuild.*

Protein

- “Enables the fastest possible acquisition of muscle mass and strength.”
- “Prevent unwanted muscle breakdown, speed up recovery, reduces risk of heart disease, amino acid mix helps gain muscle mass.”
- **Functions:** *muscle growth, rebuild muscles, mass gain.*
- Use of protein and characteristics in the name of the product, e.g. “ultra-filtered whey protein.”

Carnitine C

- “Other than enhancing athletic performance and promoting cardiovascular health, L carnitine can help with obesity. With regular exercise carnitine can cause a significantly greater weight loss, improves fat burning, increase performance, natural energy boost, fat oxidation.”
- “Allows the transportation of fatty acids and is converted into energy increase fat burning by 70% assist in weight loss.”
- “Acetyl L - Carnitine helps in losing weight and improves mental alertness.”
- “L - carnitine - stimulates the metabolic fats, making them easier to use, as sources of energy. Its effects are weight loss aids. The main function of L - Carnitine is to help transport long-chain fatty acids, which burned inside the cell provide energy (thus reducing fat).”
- “For the better burning of fats, particularly during cardio vascular exercise.”
- “L-carnitine plays an essential role in burning fat and the production of energy.”
- “L-carnitine has been added in order to avoid a reduction in the rate of testosterone caused by daily stress, and to regulate androgen receptors which optimise the action of testosterone.”

- **Functions:** *fat burning, rebuild, resistance to fatigue, mental performance, role in muscle bioenergetics, performance and recovery.*

Whey protein

- “Prevents unwanted muscle breakdown, speed up recovery, trigger protein synthesis, burn fat; the natural components of whey help to enhance the body's production of glutathione which may provide dietary support to the immune system.”
- “100% Whey Protein - effectively supports muscle growth and regeneration.”
- “Whey protein concentrate - is a complex of soluble proteins naturally found in cow's milk whey, which stimulates growth and immune processes of the body.”
- **Functions:** *muscle growth, recovery, fat burning.*

BCAA

- “Supplementation of amino acids promotes regeneration, stimulates muscle development and prevents the breakdown of muscle cells. Amino acids contribute to the repair of human tissue.”
- “BCAA to build and maintain muscle.”
- “BCAA to protect and fuel lean muscle tissue during high intensity exercise.”
- “BCAAs offer N retention, immune system support and improved endurance performance.”
- “L-Leucine is essential for the regulation of muscle protein synthesis and building muscle.”
- “Reduce the formation of lactic acid, preserve glycogen stores and deliver more energy to exercise.”
- “BCAA, like all proteins, are essential for muscular construction.”
- **Functions:** *muscle growth, fuel for athletic performance, rebuild, repair, endurance, recovery, muscle maintenance.*

Casein-protein hydrolysate

- “Helps to avoid the body going into a state of catabolism (breaking down and using its own muscle tissue for energy). Help to facilitate training adaptations by providing a slow but sustained release of amino acids to the muscles to support growth and development. Slow digesting protein.”
- “Regeneration and slow release of vital nutrients and amino acids.”
- “Instant provision of amino acids. Boosts protein synthesis during and after exercise. Increases endurance and accelerates recovery during exercise. Increases nutrient absorption.”
- “Allows the continued production of muscles even during long periods without eating.”
- **Functions:** *slow digesting, rebuild, muscle growth, recovery.*

Glutamine

- “L-glutamine benefits the immune system and increases muscle development.”
- “Glutamine may enhance muscular growth and improve the rate of recovery between workouts through its anabolic and anti-catabolic properties. Glutamine is also suggested to play an important role in immunity; it provides the fuel for the immune system to produce antibodies and fight infections.”
- "L - glutamine used by athletes to improve muscle mass and strength,"
- "100% pure pharmaceutical glutamine, which is used to increase the optimum results';
- “Influence on the synthesis of protein, hydration of cells, and the secretion of growth hormone”
- ***Functions:*** *recovery, muscle mass.*

Bovine colostrum

- "< *Bovine colostrum-containing product*> contains components that in nature: strengthen the body's immune system, increase physical strength, exercise-induced increase recovery, improve the ability of the body to muscle growth, have a beneficial effect on the digestive system."
- ***Functions:*** *immune system, growth*

Sodium phosphate

- “Ensures the supply of important substances into the bloodstream²⁸”

Beta Alanine

- “Beta Alanine increases muscle endurance during training. Beta Alanine has a performance-enhancing effect.”
- “Beta Alanine works by increasing the buffering capacity of the muscle during high intensity exercise. This delays time to fatigue during high intensity exercise allowing athletes to train harder for longer. Using β -alanine is an excellent strategy for maximising training intensity and improving fitness, speed and strength.”
- "Beta Alanine decreases fatigue and helps in maintaining good shape."
- "Beta Alanine increases the training time, thanks to the delay fatigue."
- “Eliminates lactic acid, intensifies training, and avoids muscle aches.”
- “Increase strength and endurance in training.”
- “Helps with insomnia and improve sleep quality”.
- ***Functions:*** *hyperbolic energy, muscle endurance, against muscle fatigue, performance.*

²⁸ Respondent indicated that they had not identified unauthorised claims in relation to FISP but provided this example nonetheless.

Caffeine

- "Caffeine may spare muscle glycogen (carbohydrate), increase awareness, reduce the perception of exertion, increase resistance to fatigue and improve cognitive function during exercise. Caffeine may also provide a vigorous boost to athletes who feel lethargic or fatigued before or during exercise."
- "Caffeine contributes to increased alertness and improved concentration."
- "Caffeine for improved focus."
- "Caffeine is a substance that: increases performance during endurance sports, helps to remove fatigue, improves concentration and mental performance, increases the burning of stored fat, causes the muscles during work use fat as an energy source."
- "Accelerates the metabolism of fats."
- ***Functions: energy fat burner, alertness, energising effect.***

HMB

- "Resistance training in conjunction with HMB may improve protein synthesis. In addition HMB plays a role in decreasing protein breakdown during resistance training."
- "Reduce muscle damage during intense training."
- "HMB is a substance your body distinguished by the anti-catabolic and anabolic activity. HMB is used in strength sports and forcefully - endurance."
- ***Functions: decrease catabolism, muscle repair/recovery, muscle growth***

L-carnosine

- Supports an increase in the intensity of exercise. Strong anti-oxidant. Can help combat premature fatigue."
- "L-carnosine effectively affects the absorption of lactic acid produced in muscle cells during exercise. Faster getting rid of the lactic acid from the muscles allows for a longer and more intensive training, which in turn translates into faster training effects."
- ***Function: performance.***

Taurine

- "Taurine is an amino acid that functions electrically active tissue such as the brain and heart to help stabilize cell membranes. Athletic performance may also benefit from taurine because it acts as an insulin mimetic, thereby allowing better glucose deposition into the muscles."
- "Stabilizes the membrane, thereby facilitating the transfer of potassium, sodium, calcium and magnesium in the cells, and out of them."
- "Taurine helps to induce and regulate nerve impulses and maintain fluid balance. It is also important for the operation of vision and operation of the brain and nervous system, where, in conjunction with glycine and GABA acts as a neurotransmitter."

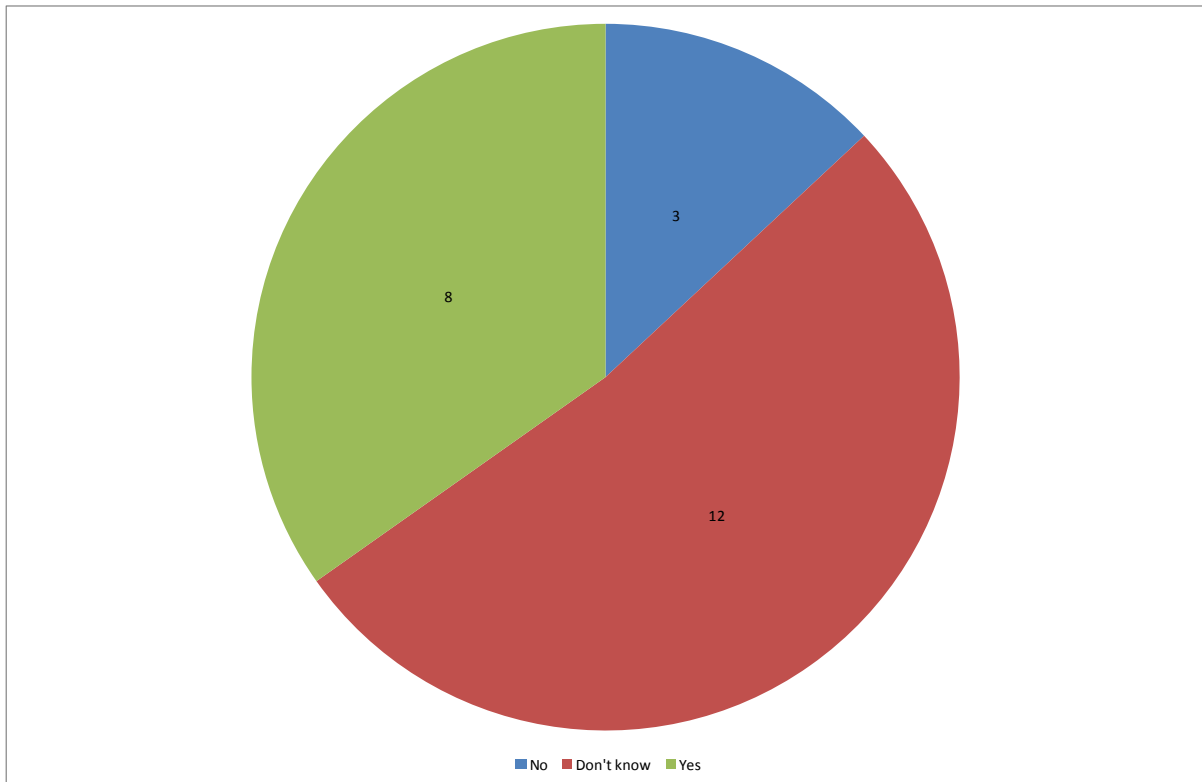
- "Taurine is an amino acid with anti-catabolic effect, it helps reduce cholesterol and nitrogen accumulates in the body. The use of taurine induces an increased secretion of the hormone, which is insulin, which lowers the blood sugar level, facilitates the transport of creatine and other amino acids into muscle cells, thereby increasing muscle strength."
- "Favours the production of energy which is an important fuel for muscles."
- "Maximum muscle development; increase resistance and endurance."
- **Functions:** *focus, muscle function, energy, regulate heartbeat, stability of cell membranes, increase action of insulin, improve glucose intolerance, enhance antioxidant levels.*

7.5.4 Use of generic statements

Respondents were asked if they had identified the use of other generic statements on the suitability of FISP. Results are presented in Figure 7-7. Just over a third of Member State CAs had identified the use of such statements. Examples provided include:

- Product names such as Honey Power, natural energy gel; products placed on the market under other horizontal rules of food law with names such as "sport crackers", "Nature's own sportsdrink".
- Use of words such as power, strength, performance, stimulators; notably on food supplements targeting sportspeople.
- Descriptions such as energizing product, joint protecting product, testosterone increase.
- Provision of information in image form.
- Claims on whole products rather than specific ingredients (no specific example provided).
- Use of terms: high quality [name of ingredient], high dose [name of ingredient].

Figure 7-7: use of other generic statements on the suitability of FISP



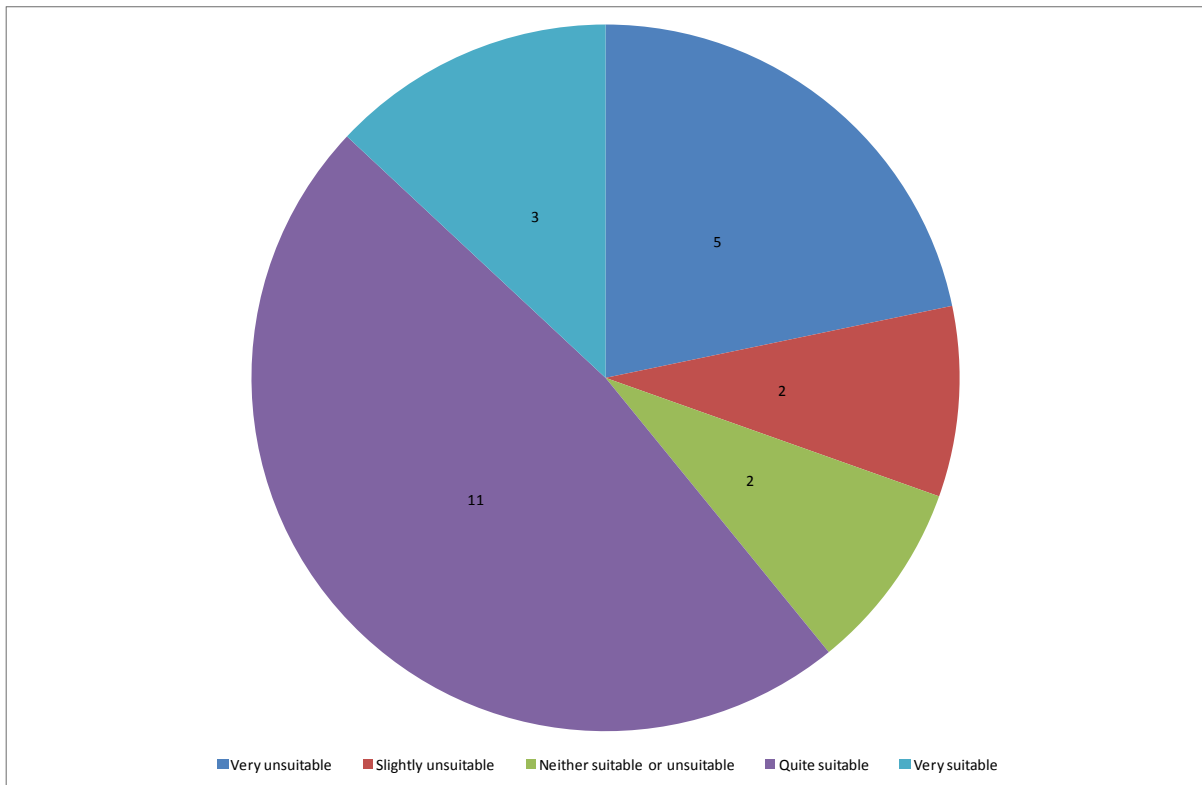
N=23

7.6 Post 2016

7.6.1 Suitability of EU general food law for the regulation of FISP

Respondents were asked how suitable EU general food law and secondary legislation under it (*other horizontal legislation of food law*) is for the regulation of FISP in the absence of specific provisions after 2016. Results are presented in Figure 7-8. Almost half of respondents considered it to be quite suitable. The average rating of 3.2 however suggests that, on balance, it is considered to be neither suitable nor unsuitable.

Figure 7-8: CA rating of the suitability of other horizontal rules of food law for the regulation of FISP



N=23

Respondents were also asked to explain their rating. Summaries of explanations, organised by rating (unsuitable, neutral, suitable) are presented in Table 7.10.

Table 7.10: explanation of ratings given in relation to the suitability of other horizontal rules of food law for the regulation of FISP

Very / slightly unsuitable	Neither suitable or unsuitable (neutral)	Very / slightly suitable
<ul style="list-style-type: none"> • Absence of a definition is historically damaging and will be damaging going forwards; it is unlikely there will be agreement on a definition. • The qualitative and quantitative composition of FISP means they are significant different from other food products. • 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. • Horizontal rules do not include sufficient provisions for confirming the suitability of such FISP for the specific needs of sportspeople. • 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 other horizontal rules do not sufficiently control the safety / suitability of FISP. 	<ul style="list-style-type: none"> • The composition of FISP is specific. The amounts of nutrients are significantly higher than in other products. • While EU General Food Law establishes general requirements for only safe food to be placed on the market, the specific composition of FISP means that provisions of the General food law (and secondary legislation) would be insufficient to an extent. 	<ul style="list-style-type: none"> • EU food law and the secondary legislation would be sufficient; partly as the term food for sport people is a highly debatable one (one respondent) and partly because PARNUTS legislation is not well adapted to FISP (one respondent). • There is an existential question as to whether sportspeople need special food other than normal food or whether their needs are sufficiently different to constitute a separate group. • Experience shows that it is not possible to establish compositional requirements for the legal category of sportsfood. • Communications concerning foods intended for sportspeople can be covered by Regulation (EC) No 1924/2006; though it may sometimes difficult to correctly frame the use of claims intended for sportsfood as this category is not defined. • Claims made for sportspeople should be scientifically substantiated in the same way as for foods for normal consumption. • 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 (one respondent). • Regulations (EC) No 178/2002, 1924/2006 and (EU)

- The novel food procedure for new ingredients is long and complex.
- There is no suitable legislation foreseen in other horizontal rules for combinations of substances with synergistic effects.

No 1169/2011 can deal with mostly of safety and quality issues.

- Some changes may be needed to annex 3 of Regulation (EC) No 1925/2006, and the maximum levels in vitamin and mineral supplements may need to be set.
- 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.

7.6.2 Post 2016 legal situation

7.6.2.1 Overall legal situation

Respondents were asked what is most likely to occur in their Member State after 2016 if no specific legislation for sportsfood is introduced at EU level. Results are presented in Table 7.11.

Table 7.11: legal position of FISP post 2016 by Member State

Existing national legislation kept	Existing national legislation amended or replaced	No specific rules for sportsfood / covered by other horizontal rules	Unable to answer – political decision required
BG	FR	AT	DE
DK	HU	BE*	IT
	EE*	CY	LT
		EL	
		HR	
		IE**	
		LU	
		LV	
		MT	
		NL	
		PL	
		PT	
		RO***	
		SE	
		SI	
		UK	
2	3	16	3

* EE indicated that no specific legislation would be introduced, but also indicated that a notification procedure for FISP would probably be introduced. The response has therefore been moved. BE indicated that existing legislation would remain, though there is no legislation at present, and for this reason the response has been moved.

** IE considered other horizontal legislation to be very unsuitable for the regulation of FISP, but was of the opinion that without EU provisions it will be difficult to regulate at national level.

*** RO indicated that existing legislation will remain but it will not be specific.

7.6.2.2 Post 2016 national legislation

Member States which indicated that new legislation for sportsfood would be introduced were asked about the likelihood of legislation by area. Results are presented in Table 7.12. National legislation seems most likely in the areas of notification, definition, composition and labelling. BG did not provide details of areas likely to be covered in its written response.

Table 7.12: likelihood of legislation by area (1 = very unlikely, 5 = very likely).

MS	Notification	Authorisation	Definition	Composition	Labelling	Marketing	Outlets	Other
EE	5	1	1	1	1	1	1	1
FR	2	1	5	5	4	4	1	
HU	5	1	5	5	5	3	3	3
LV*	4	2	4	4	4	2	2	
RO*	4	4	3	5	5	5	4	3

* LV and RO indicated in the previous question that FISP would be covered by other horizontal rules; nonetheless, ratings on the likelihood of legislation by area were provided and is presented in this table.

7.6.3 Impacts of post 2016 situation

7.6.3.1 Reformulation

Respondents were asked about the likelihood of reformulation in view of the potential change in legal position of sportsfood in their Member State. Results are presented in Table 7.13; the expected legal position of sportsfood by Member State is indicated by a colour coding (key underneath table).

Table 7.13: likelihood of reformulation in view of the potential change in legal position of sportsfood, by Member State

Same legal position / no reformulation	Different legal position but no reformulation	Limited reformulation	Moderate reformulation	Widespread reformulation
BE	AT	MT	DK	
CY	EE	SE	HU	
IE	EL		LT	
LU	FR		PL	
LV	HR		PT	
SI	IT		RO	

UK				
7	6	2	6	0

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
	Unable to answer – political decision required

Some respondents provided further comments on the issue. These are as follow:

- **AT:** while there will be no reformulation, it is expected that many existing claims on FISP will disappear with the changes of legal position.
- **DE:** the extent of reformulation will depend on legal position, which is unclear in Germany. However, some legal requirements (e.g. restrictions on amino acids) will lead to reformulation if FISP is regulated by other horizontal rules of food law.
- **DK:** Currently products following the legislation for particular nutritional use where the formulation does not comply with the conditions of use for the approved claims exist.
- **HR:** Products will have to change labelling, they will no longer can be labelled dietetic food. The term “food for sportspeople” will be considered a non-specific general claim which must be stated with approved claim.
- **HU:** new compositional rules will probably result in moderate withdrawal.
- **IT:** there is the hope/expectation that FBOs will market foods as food supplements or fortified foods.
- **MT:** there is little local manufacturing; the market depends on products from other MS / countries.
- **PL:** products currently classified as foods for particular nutritional uses meet the expenditure of intense muscular effort need not meet the requirements for vitamins and minerals laid down in the legislation for fortified foods. When the above group disappears, FBOs will have to adapt (e.g. some energy drinks with B vitamins).
- **PT:** mostly FISP are imported. Reformulation / withdrawal are expected, following enforcement actions.
- **SE:** the fact that sports foods will no longer be PARNUTS will change the legislative environment and to some extent this will have an impact on the companies; however there is no quantities evidence on this.

7.6.3.2 CA enforcement practices

Respondents were asked about the extent to which it will be necessary to change CA enforcement practices after 2016 due to any changes in legal position in their Member State. Results are presented in Table 7.14.

Table 7.14: 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		
6	3	4	8	1

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
	Unable to answer – political decision required

Some respondents provided further comments on the issue. These are as follow:

- **CY:** FISP are controlled in the same way as food supplements, and after 2016 are expected to fall under food supplement legislation so there will be no change.
- **DE:** controls take place at present as part of broader food controls so there will be no change.
- **EL:** CA responsible for controls will change unless product is considered a food supplement.
- **IT:** due to the expectation that products will be notified as food supplements, there will still be notification.
- **LV:** (no rating provided) it will depend on how products are placed on the market.

- **NL:** At present the CA is focused on products that go towards drugs and less on the nutritional composition.
- **PL:** controls will not change, but products will have to be re-notified as food supplements / fortified foods leading to a heavy administrative burden.

7.6.3.3 Impacts

Finally, respondents were asked to rate the impact of the post 2016 legal situation in their Member State on innovation, producers and consumer behaviour, protection and information. Results are presented in Table 7.15. The first column contains the average rating. Subsequent columns split out average ratings by expected legal position after 2016 (other horizontal rules of food law; national legislation; or unclear). Relevant comments provided by respondents are summarised for each case.

Table 7.15: impact of the post 2016 legal situation on: innovation; producers; and consumer behaviour, protection and information (1= strongly negative; 5= strongly positive).

Area	Average all	Other horizontal rules of food law		Specific national rules		Unclear (political decision required)	
		Average	Comments	Average	Comments	Average	Comments
Innovation	2.7	2.9	<p>BE (3): no change expected as legal framework same.</p> <p>IE (1): no legal framework to stimulate innovation.</p> <p>PL (2): any national level legislation on could cause difficulties for FBOs to introduce new products on the market and could disrupt the internal market.</p> <p>RO (4): legal clarity will enable innovation.</p> <p>SE (2) negative impact if health claims prevents foods from informing about nutritional properties.</p>	2.5	<p>DK (2): approval of claims time-consuming compared to status quo.</p> <p>EE (3): health claims and novel foods are more important pieces of legislation for innovation.</p>	2.3	DE (1): disruption of internal market will have negative impacts on innovation.
Producers	2.7	2.8	BE (3): no change expected as legal	3		2	DE (1): disruption of internal market from differing national rules.

Area	Average all	Other horizontal rules of food law		Specific national rules		Unclear (political decision required)	
		Average	Comments	Average	Comments	Average	Comments
			<p>framework same.</p> <p>IE (1): no legal framework to guide SMEs. Barriers to trade likely due to different national rules across the EU.</p> <p>PL (2): possible difficulties to introduce new products on the market and possible internal market distortions.</p> <p>RO (4): clarity about notification.</p> <p>SE (2): SMEs impacted if cannot inform about nutritional properties.</p>				Adverse impact of this on SMEs. Possible increased bureaucratic burden.
Consumers	3.0	2.8	AT (3): sportspeople generally voluntarily consume such	3.8	DK (4): easier to carry out product controls.	3.3	DE (2): no deterioration of consumer protection, but in the case of

Area	Average all	Other horizontal rules of food law		Specific national rules		Unclear (political decision required)	
		Average	Comments	Average	Comments	Average	Comments
			<p>products.</p> <p>BE (3): no change expected as legal framework same.</p> <p>IE (1): no legal framework to regulate compositional criteria. Possible misuse of FISP high in sugar, resulting in obesity issues.</p> <p>LU (1): consumers ignore that products placed on the market may not be suitable for them; resulting in negative health impacts.</p> <p>SE (5): scientific substantiation of claims on FISP will ensure maximum consumer protection.</p>				different national regulations, the number of products on the EU market will fall.

HOW TO OBTAIN EU PUBLICATIONS

Free publications:

- one copy:
via EU Bookshop (<http://bookshop.europa.eu>);
- more than one copy or posters/maps:
from the European Union's representations (http://ec.europa.eu/represent_en.htm);
from the delegations in non-EU countries
(http://eeas.europa.eu/delegations/index_en.htm);
by contacting the Europe Direct service (http://europa.eu/europedirect/index_en.htm)
or calling 00 800 6 7 8 9 10 11 (freephone number from anywhere in the EU) (*).

(*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Priced publications:

- via EU Bookshop (<http://bookshop.europa.eu>).

Priced subscriptions:

- via one of the sales agents of the Publications Office of the European Union
(http://publications.europa.eu/others/agents/index_en.htm).

