THE USE OF SUBSTANCES WITH NUTRITIONAL OR PHYSIOLOGICAL EFFECT OTHER THAN VITAMINS AND MINERALS IN FOOD SUPPLEMENTS

STUDY UNDERTAKEN FOR DG SANCO, EUROPEAN COMMISSION

Service contract nr SANCO/2006/E4/018

European Advisory Services (EAS)

28 March 2007

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EAS, March 2007

INTRODUCTION

This study has been carried out for DG SANCO of the European Commission by European Advisory Services (EAS) following the submission of a tender which was issued in 17 July 2006 (number Nr SANCO/2006/E4/018). The study focuses on the use of substances with a nutritional or physiological effect other than vitamins and minerals in food supplements. Work has been divided into five main areas:

Other substances used in food supplements in the EU: includes the categorisation and characterisation of substances with an overview of the EU food supplement market. Regulatory and non-regulatory approaches on the use of botanicals and other bioactive substances are illustrated and compared.

Borderline issues and European Court Judgements: reviews the approach of Member States towards mutual recognition and highlights the issues raised. Barriers to trade of food supplements are discussed.

Relevant developments of other organisations and institutions: provides an overview of the activities of the Council of Europe, the European Food Safety Authority (EFSA), the European Agency for the Evaluation of Medicinal Products (EMEA), and the International Life Sciences Institute (ILSI).

Regulatory models outside the EU: outlines the variety of models for food supplement products existing in Australia, Canada, China, Japan and the United States.

Interaction with other EU legislative frameworks: examines the impact of other legislative frameworks and provisions applicable to food supplements.

EAS would like to thank the European Commission, Member State administrations and other experts who have provided information and advice facilitating the development of this study.

EAS is a specialist advisory company in European and international regulation on food and nutritional products

EXECUTIVE SUMMARY

With the implementation of Directive 2002/46/EC, food supplements have been harmonised at the EU level with common rules concerning certain aspects of vitamins and minerals. In view of further harmonisation, article 4.8 of this Directive foresees that the European Commission presents a report to the European Parliament and to the Council on the advisability of establishing specific rules for the use of substances with a nutritional or physiological effect other than vitamins and minerals in food supplements.

In order to better understand the potential need for harmonisation of other substances in food supplements, it was considered necessary to analyse the market for such products, the national regulatory and non-regulatory approaches, and the interaction between these other substances and existing EU legislation. By way of comparison, the regulatory and non-regulatory approaches in countries outside Europe were also reviewed.

OTHER SUBSTANCES USED IN FOOD SUPPLEMENTS IN THE EU

This study takes as a starting point the categorisation and characterisation of substances other than vitamins and minerals. Six categories were identified and 31 substances were chosen in order to review other substances with a nutritional or physiological effect in food supplements on the EU market. The different categories are:

- *amino acids*
- *enzymes*
- *pre- and probiotics*
- *essential fatty acids*
- *botanicals and botanical extracts*
- *miscellaneous bioactive substances*

The substances in each category were chosen based on their significance in the EU food supplement market and/or the extent to which they could illustrate effectively the different regulatory approaches taken by the Member States.

Market data from the data collection and analysis company Euromonitor International is used to illustrate the total size of the EU food supplement market and its segments: 50% for vitamin and mineral products, 43% for supplements containing other substances, and 7% for tonics and bottled nutritive drinks. Growth projections to 2010 provide an indication of the extent to which previous rapid growth cannot be taken as an indicator of future rapid growth with a significant slowdown expected in a number of countries, but the new Member States continuing to record the fastest growth rates. A breakdown of the EU market analyses the most commercially important other substances and variations across the EU region.

The regulatory and non-regulatory approaches for botanicals and other bioactive substances in 27 EU Member States are presented based on a questionnaire sent to the Member States, and EAS analysis and experience in reviewing substances and products across the EU. Country overviews include information on positive/negative lists of botanicals and other bioactive substances. Based on the questionnaire completed by the authorities in 26 of the 27 Member States, a review of the regulatory status of a representative sample of substances is provided. This shows that the majority of substances fall within the categories 1-4 below and a minority

require either authorisation or are regarded as medicinal substances, falling under categories 5-6 below:

1. *Permitted for use in food supplements either under national law or internal guidelines.*
2. *Permitted for use in food supplements - maximum level established.*
3. *Permitted for use in food supplements under specific conditions.*
4. *Permission may be given on a case by case basis following evaluation.*
5. *Not currently permitted. May be permitted following authorisation.*
6. *Not permitted for use in food supplements, or regarded as medicinal.*

The review of the regulatory status on the use of certain other substances in food supplements and a comparison of the national approaches illustrate the substantial differences across the Member States.

BORDERLINE ISSUES AND EUROPEAN COURT JUDGEMENTS

Despite the overall positive approach of Member States towards mutual recognition, application of this principle appears to be problematic in a number of countries in respect of other substances sold in supplements. Mutual recognition applies to those aspects of food supplements that are not yet harmonised and prohibits quantitative restrictions between Member States. Relevant ECJ cases to mutual recognition issues are highlighted.

Of importance to food supplements is the interpretation of the medicines definition which has very often been the subject of ECJ cases. Several borderline issues have been reported and are seen differently across the Member States.

RELEVANT DEVELOPMENTS OF OTHER ORGANISATIONS AND INSTITUTIONS

The requirements for further legislative work in the field of other substances are considered through reference to the activities of EMEA (European Agency for the Evaluation of Medicinal Products), HMPC (Herbal Medicinal Product Committee), EFSA's (European Food Safety Authority) work on the safety of botanicals, the Council of Europe's Ad Hoc Group on Food Supplements and ILSI's (International Life Sciences Institute) report on the guidance for the safety assessment of botanicals. Additionally, the revision of the novel foods legislation may have an important effect on food supplements, especially when it concerns botanical extracts and isolates.

REGULATORY MODELS OUTSIDE THE EU

Work has also been carried out on the regulatory models that exist outside the EU, and this indicates the existence of approaches as diverse as those present in the EU.

Models were reviewed for Australia, Canada, China, Japan and the United States.

In Australia, all food supplements fall within the category of '*complementary medicines'* which are evaluated according to their level of risk, and include vitamin, mineral, herbal, aromatherapy and homeopathic products. A positive list of substances that may be used in supplements has been established.

Food supplements in Canada are regarded as "Natural Healh Products" and may contain a wide range of substances. All products must be registered. A list of

acceptable non-medicinal substances that are generally considered to be of minimal toxicological concern is included in the Canadian Natural Health Products Regulations.

The State Food and Drug Administration in China regulates supplements as *'health foods'* and maintains positive and negative lists of substances that may be used in health foods/food supplements.

In Japan, food supplements containing a broad range of substances are widely sold. Lists clarify which substances are not restricted to medicinal use and can therefore be used in food supplements.

In the United States, a wide range of substances is encompassed by the definition of a dietary supplement in the Dietary Supplement Health Education Act.

INTERACTION WITH OTHER EU LEGISLATIVE FRAMEWORKS

The interaction with other EU legislative frameworks is examined and legal provisions applicable to food supplements are reviewed. Current EU food legislation applies to all food supplement products. Examples of applicable legislation include the general food law requiring safety substantiation and defining traceability rules, and the future list of health claims in the Regulation on nutrition and health claims other than those referring to the reduction of disease risk, and to children's development. Some of these measures can already be seen as providing a level of indirect harmonisation on the use of other substances in food supplements.

Provisions set by other legislative frameworks should also be taken into consideration to avoid overlaps and contradictions, for example when it concerns novel foods, or substances already approved for food additive use.

I. HARMONISATION OF THE FOOD SUPPLEMENTS LEGISLATION – DIRECTIVE 2002/46/EC

Since July 12, 2002 food supplements[1] have been harmonised at the EU level under food law. At this stage, only the use of vitamins and minerals has been harmonised. Nevertheless, the definition of food supplements incorporates all substances with a nutritional or physiological effect, establishing their status as a specific category of foodstuffs.

For those aspects where harmonised rules have not yet been established, national rules remain applicable without prejudice to the Treaty[2], in particular articles 28 and 30 thereof (article 11.2). The Directive requires the European Commission to submit prior to July 12, 2007 a report to the European Parliament and the Council on the advisability of establishing specific rules, including, where appropriate, positive lists, on categories of nutrients or substances with a nutritional or physiological effect accompanied by any proposals for amendment to the Directive.

This first harmonisation exercise has two main consequences. Firstly it makes the EU food legal framework applicable to food supplements. And secondly it stresses the application of the principle of mutual recognition for those aspects that are still not harmonised.

[1] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L183/51. 12/07/2002
[2] Consolidated Version of the Treaty establishing the European Community. OJ C325/33. 24/12/2002

II. OTHER SUBSTANCES USED IN FOOD SUPPLEMENTS IN THE EU

In this part of the report research was focused on the categorisation of substances currently existing on the EU market, market data and the presentation of regulatory and non-regulatory models in 27 EU Member States.

1. THE CATEGORISATION AND CHARACTERISATION OF SUBSTANCES

It is estimated that there may be in excess of 400 other substances with nutritional or physiological effect on the EU market in food supplements. This report uses the following terminology:

other substances:	substances other than vitamins and minerals, ie botanicals and other bioactive substances;
botanicals:	includes herbs, plants, fungi, algae and extracts thereof;
other bioactive substances:	any substance with a nutritional or physiological effect, other than vitamins, minerals and botanicals.

For the purposes of this study it was necessary to categorise and review a number of substances that would reflect the key elements of both the market and the regulation across the EU. Six categories were identified and 31 substances were chosen for evaluation. The categories and substances are below:

Amino acids

- L-arginine
- Other essential amino acids
- Non-essential amino acids

Enzymes

- Lactase
- Papaine

Pre- and Probiotics

- Inulin
- *Lactobacillus acidophilus*
- *Bifidobacterium* species
- Yeast species

Essential fatty acids

- Gamma-linoleic acid
- EPA/DHA
- Evening Primrose oil (*Oenothera biennis* (L.))
- Borage oil (*Borago officinalis*)
- Flax seed oil (*Linum usitatissimum* (L.))

Botanicals & botanical extracts

- Aloe (*Aloe vera* (L.))
- Ginkgo (*Ginkgo biloba*)
- Ginseng (*Panax ginseng*)

- Garlic (*Allium sativum* (L.))
- Green tea extract (*Camellia sinensis*)
- Garcinia extract (*Garcinia cambogia*)
- Guarana extract (*Paullinia cupana*)

Miscellaneous bioactive substances[3]

- Lycopene
- Lutein
- Coenzyme Q10
- Taurine
- Carnitine
- Inositol
- Glucosamine
- Chitosan
- Spirulina
- Soy isoflavone

Since there is no legal categorisation of other substances currently used in food supplement products in the EU, the above categorisation was made based on defined biochemical classes of molecules (eg amino acids, enzymes and fatty acids), or on their nature and origin (eg botanicals, extracts, oils etc). In addition, commonly used terms such as pro- and prebiotics characterising specific ingredient categories were taken into consideration. There is always potential overlap between the categories. For example, although borage is a botanical, borage oil falls within the fatty acids category. It is important to highlight that herbal oils classified under the "essential fatty acids" category do not refer to essential oils but only to commonly extracted oils.

The substances in each category were chosen based on their significance in the EU food supplement market and/or the extent to which they could illustrate effectively the different regulatory approaches taken by the Member States.

2. OVERVIEW OF MARKET DATA

The EU market for other substances used in food supplements was reviewed in order to establish:

- The proportion of other substances in the total food supplement market.
- Which other substances are of greatest significance.
- The variations across the EU region.
- The growth patterns and projections.

A number of data sources were considered for potential reference in the study. The criteria for choosing the data source were identified as follows:

- Provision of a broad data set from across the EU.
- Comparable data from country to country.
- Provision of adequate detail on the substances in question.

[3] There are some substance categories that could be broken down into further sub-categories, eg Coenzyme Q10 could be classified under a general "coenzymes" category.

- Focus on products which are marketed as food supplements under food law and trying to eliminate data entries on products which have been registered and marketed as medicines.

Based on these criteria, the most recent statistics from the specialist company Euromonitor International (hereafter Euromonitor) were chosen as the main source of data used. While the data provided gives good indications of the total size of the market and relative importance of a range of other substances within the market, a number of factors need to be considered when looking at this data:

- Collecting complete data on the food supplement market is notoriously difficult. Due to the diversity of retail channels (pharmacies, parapharmacies, supermarkets, drug stores, herb stores, health stores etc) and other sales channels (eg direct sales, mail order), it can be that significant sales in certain substances are not included.

- It is difficult to distinguish in the market between those products that are sold as food supplements under food law and those that are sold under medicines law. For example, free-sale medicines may be alongside food supplement products in drug stores and supermarkets in Germany. Moreover, food supplements may be alongside registered products in pharmacies, sometimes containing similar ingredients. This has presented some challenges for this study. For example, ginkgo is included within the market data for Germany even though it is required to be registered as a medicine in that market. Rather than modifying the data to delete products which could potentially be registered, it was considered appropriate to present the data as it is and comment on those areas where this might be the case.

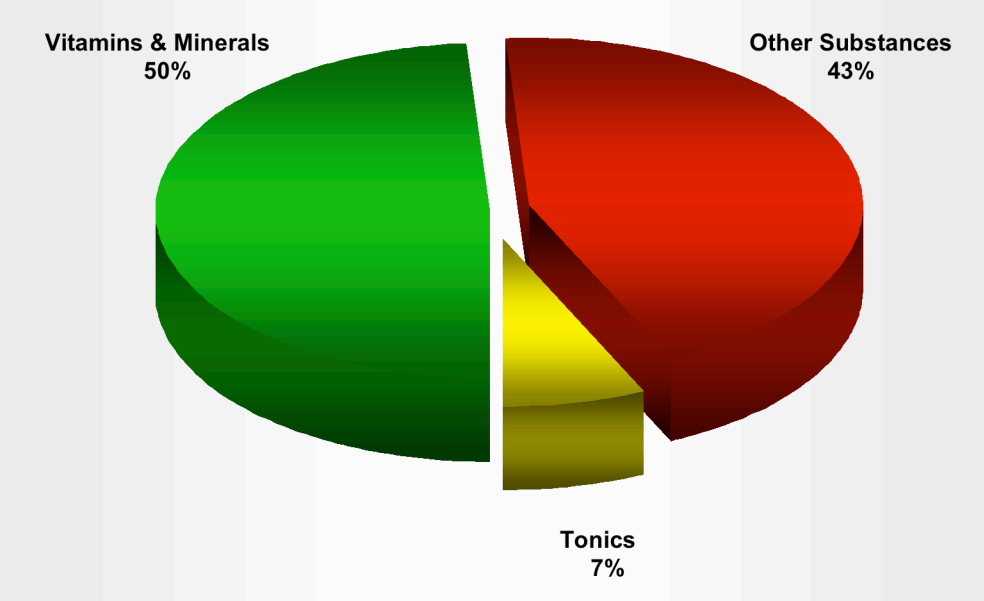
2.1 Total size of the EU food supplement market

The total size of the EU food supplement market was estimated by Euromonitor to be around 5 bn Euro (Retail Selling Prices) in 2005 (see Graph 1). This is divided between vitamin and mineral products which take the largest share at 50%, and food supplements containing other substances at 43%. The remaining 7% of the market is composed of tonics and bottled nutritive drinks[4].

The Euromonitor data for tonics does not distinguish between tonics containing vitamins and minerals, and tonics containing other substances.

[4] *Tonics and bottled nutritive drinks:* includes liquid versions of dietary supplements, typically a combination of ingredients (such as vitamins, minerals and botanicals). Tonics and bottled nutritive drinks classified as OTC products, or marketed as functional foods are not included in Euromonitor's data (Euromonitor, 2005).

Graph 1: Relative market share of the food supplement segments in the EU

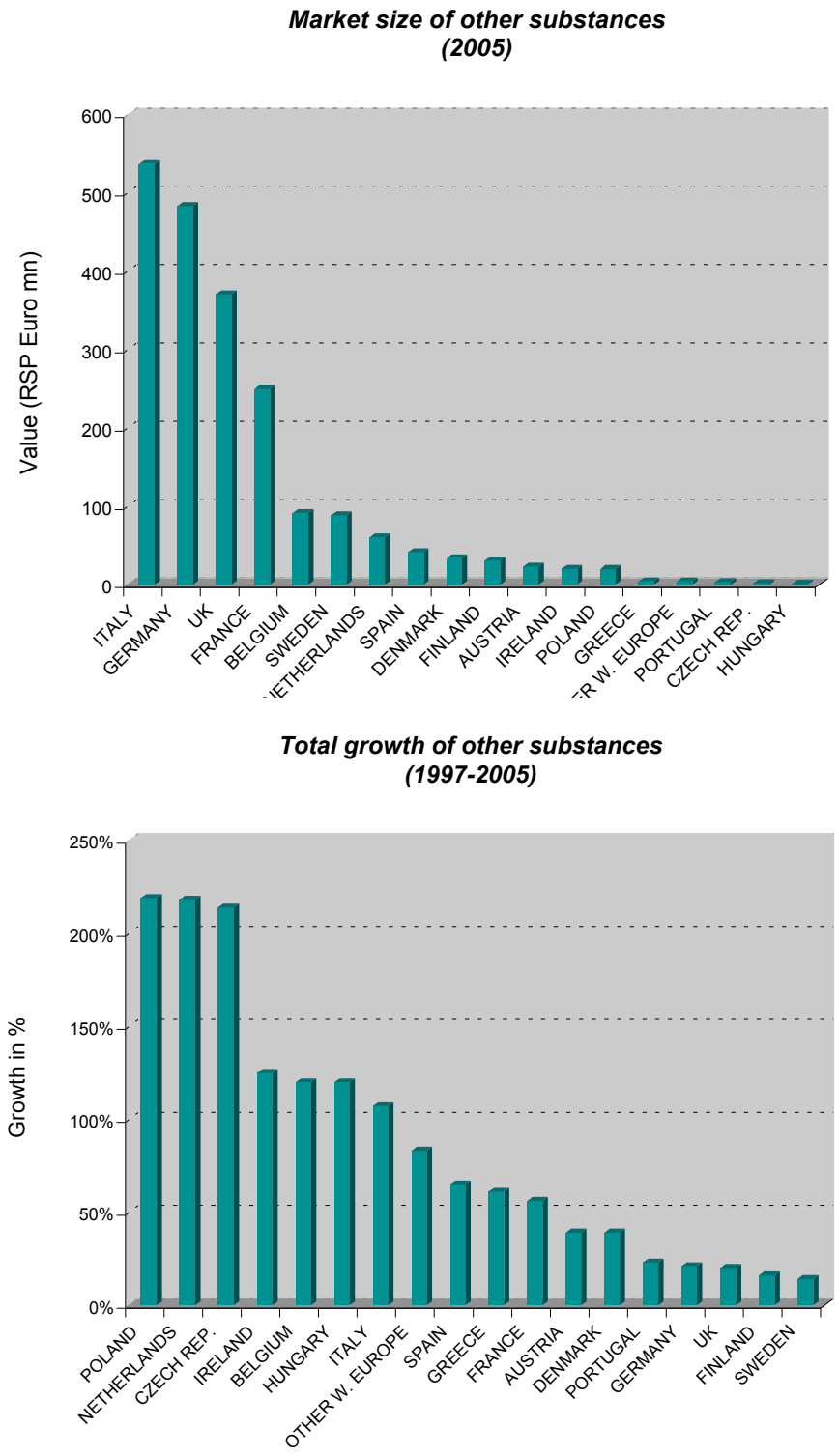


Source: Euromonitor, 2005

2.2 EU Member States: Market size and growth of other substances segment

As would be expected, the four largest EU Member States have the largest markets in terms of sales (Retail Sales Prices: RSP), led by Italy which is closely followed by Germany, UK and France (see Graph 2). However, from that point there is no consistent link between size of population and size of market. Growth rates across the countries also vary widely with the growth rate of 219% in Poland between 1997-2005 being the highest level recorded in the countries surveyed by Euromonitor and 20% in the UK being one of the lowest in the same period.

Graph 2: Current market size and total growth of other substances in the EU *(in RSP Euro mn)*

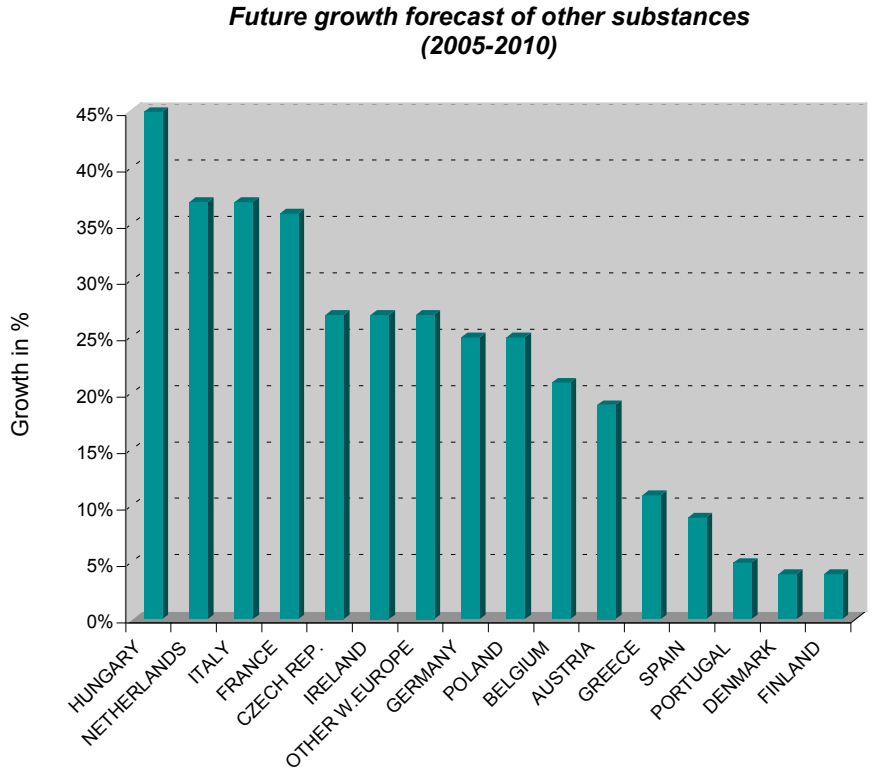


Source: Euromonitor, 2005

The reasons for the varying growth rates are considerable and depend of course on economic factors, the pre-existing state of the market, price competition and the level to which the market is already approaching saturation. However, one relevant driver of growth is regulatory change and particularly reductions in restrictions. While it can only be considered one reason, it is notable that the Belgian and Dutch authorities introduced laws on botanicals in 1997 and 2001 respectively, which provided a more solid basis for marketing products. In addition, the three countries of Czech Republic, Hungary and Poland - after adapting to the free market environment - have gone through the process of implementing EU legislation, including the Food Supplement Directive, in this time frame.

Growth projections to 2010 provide an indication of the extent to which previous rapid growth cannot be taken as an indicator of future rapid growth. For example, having achieved 39% growth from 1997-2005, Denmark is only expected to show a 4% rise between 2005-2010 (see Graph 3). Overall, market growth is not expected to reach the levels achieved in the previous decade. The reasons for the market growth decrease might be due to changes of some important economic factors, for example market saturation. Other factors having strong impact on the growth of the market of food supplements containing other substances might be the notification/authorisation national requirements, restrictions on distribution channels and the extent to which the national authorities apply the mutual recognition.

Graph 3: Future Projected Growth (2005 –2010)

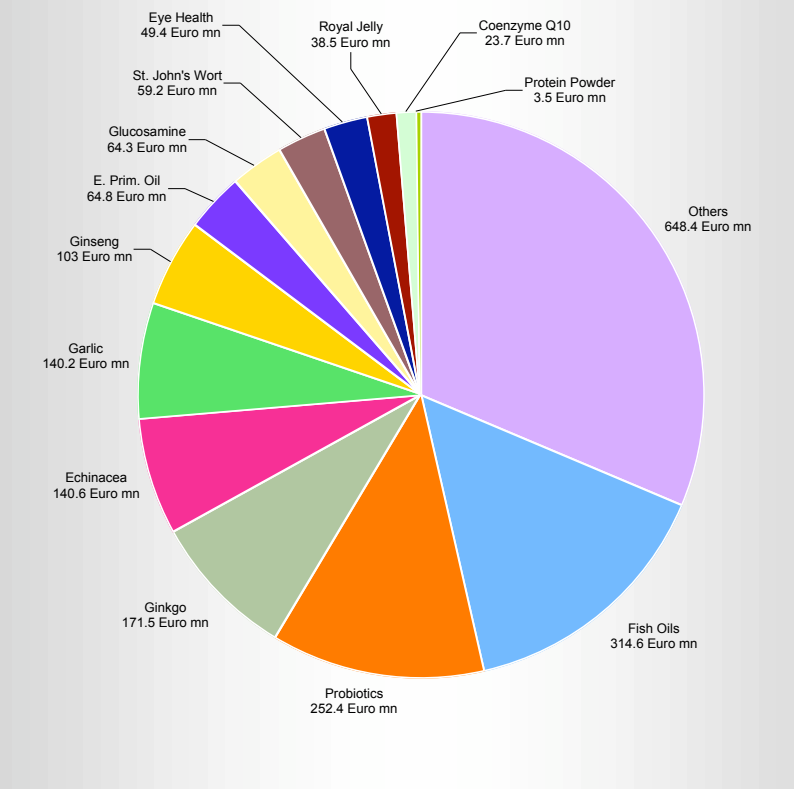


Source: Euromonitor, 2005

2.3 Breakdown of the EU market in other substances in food supplements

When the combined markets of seventeen EU Member States were surveyed, the most commercially important other substances were identified by Euromonitor as being fish oils, probiotics[5] and certain herbal ingredients (see Graph 4). It is important to point out here that a significant proportion of the market in some of the botanicals (particularly echinacea and gingko) is composed of products registered as medicines.

Graph 4: Market size of other substances across 17 EU Countries



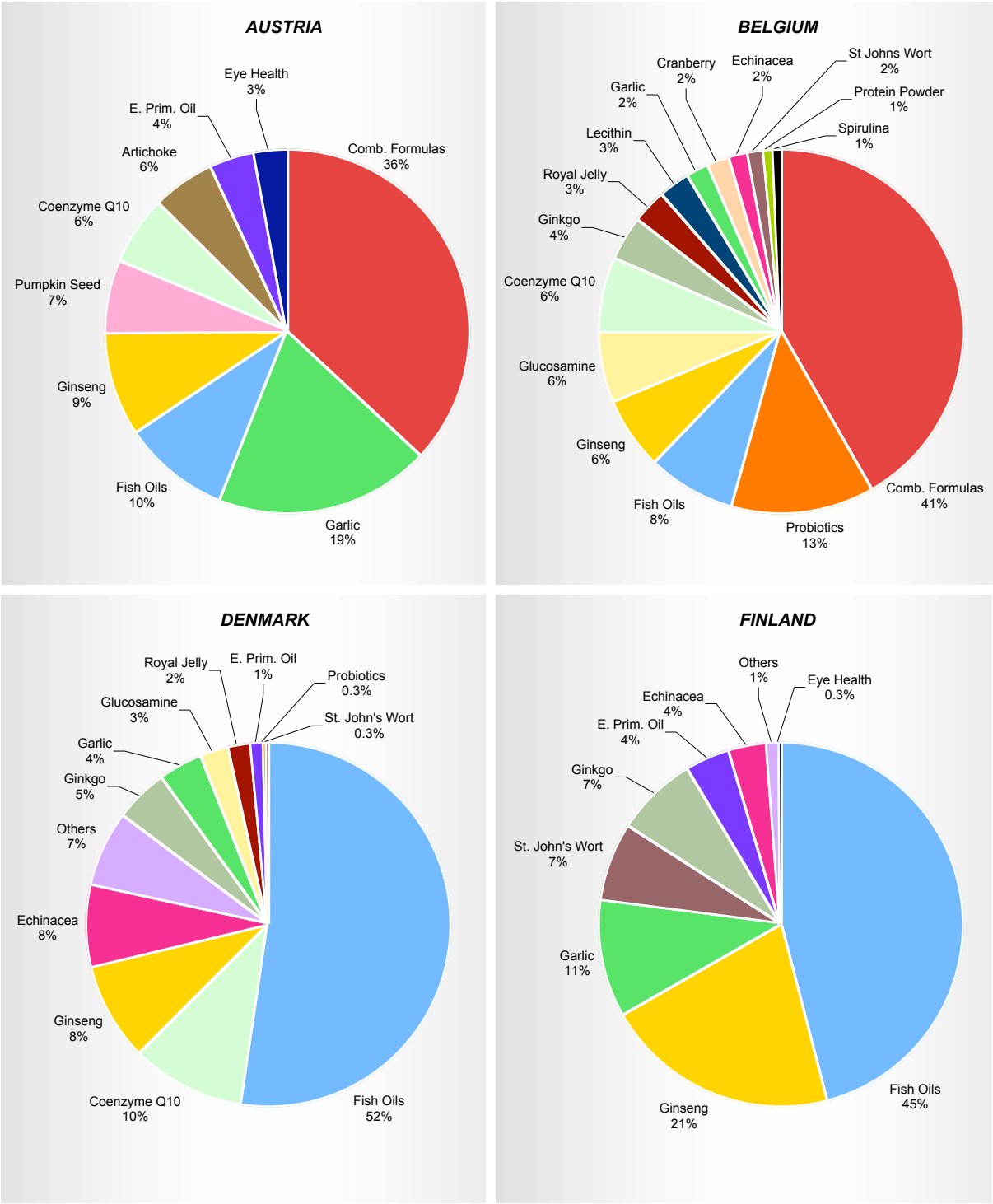
Source: Euromonitor, 2005

However, significant national variations were often apparent (see Graph 5). These variations can be seen clearly in Graph 6 for fish oils, glucosamine, 'eye health[6]' (eg lutein), coenzyme Q10, echinacea and ginkgo. For the purpose of this study, we have introduced 'others' to be understood as a wide variety of substances sold as single form product or as combination formulas, excluding vitamins and minerals.

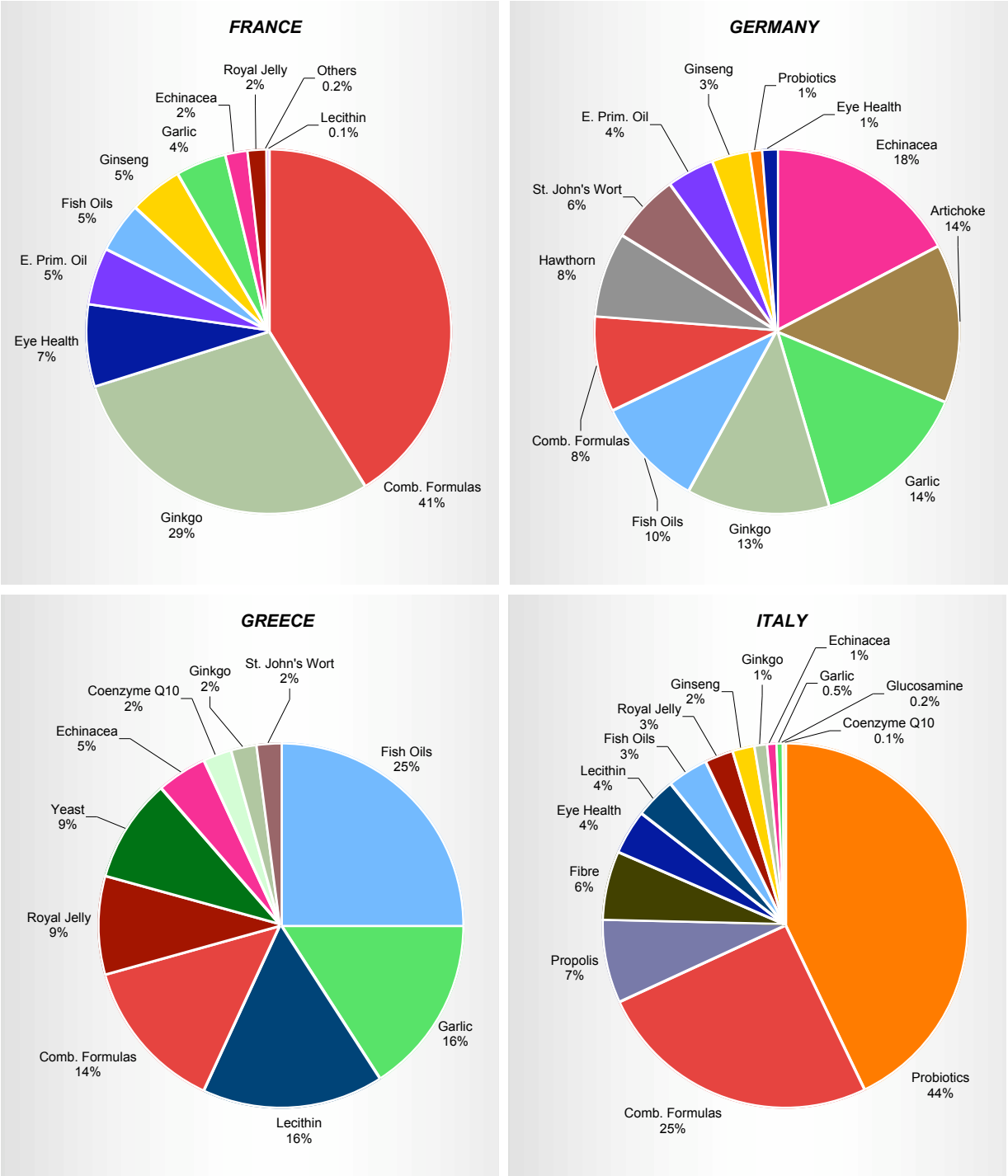
[5] *Probiotic supplements:* Beneficial bacteria, such as *Lactobacillus acidophilus* and *Bifidobacterium bifidum*, are called probiotics. Supplement forms only, excludes probiotic yoghurts and bio drinking yoghurt (Euromonitor, 2005).

[6] *"Eye health" supplements:* Includes all formulas to promote eye health or to prevent macular degeneration, eg "ocular defence" formulas. Lutein is key ingredient, bilbery also, usually combined with others. Includes only those positioned for eye health, excludes products for general ageing/all-round health (Euromonitor, 2005).

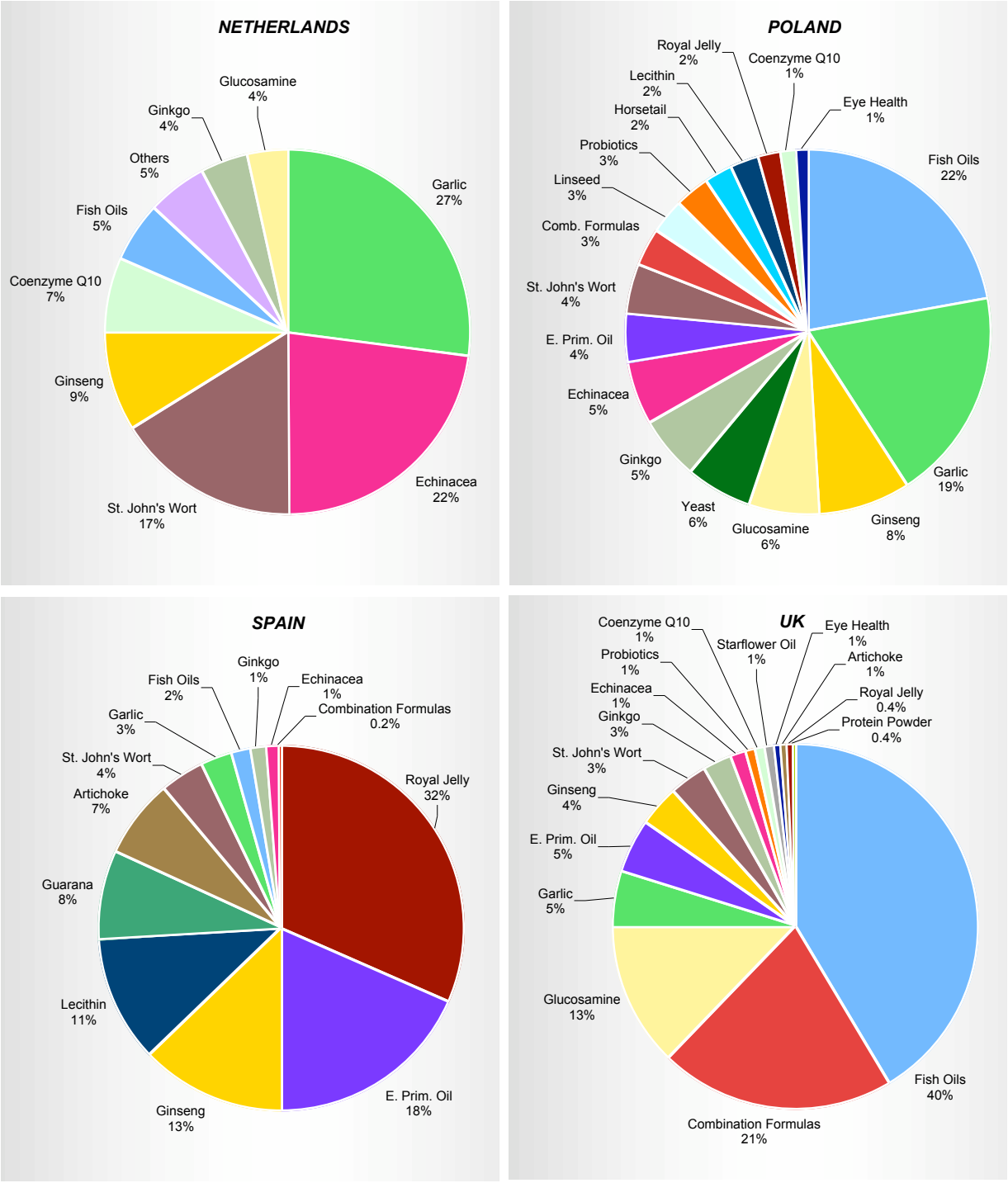
Graph 5: National preferences: Market size of other substances



Source: Euromonitor 2005

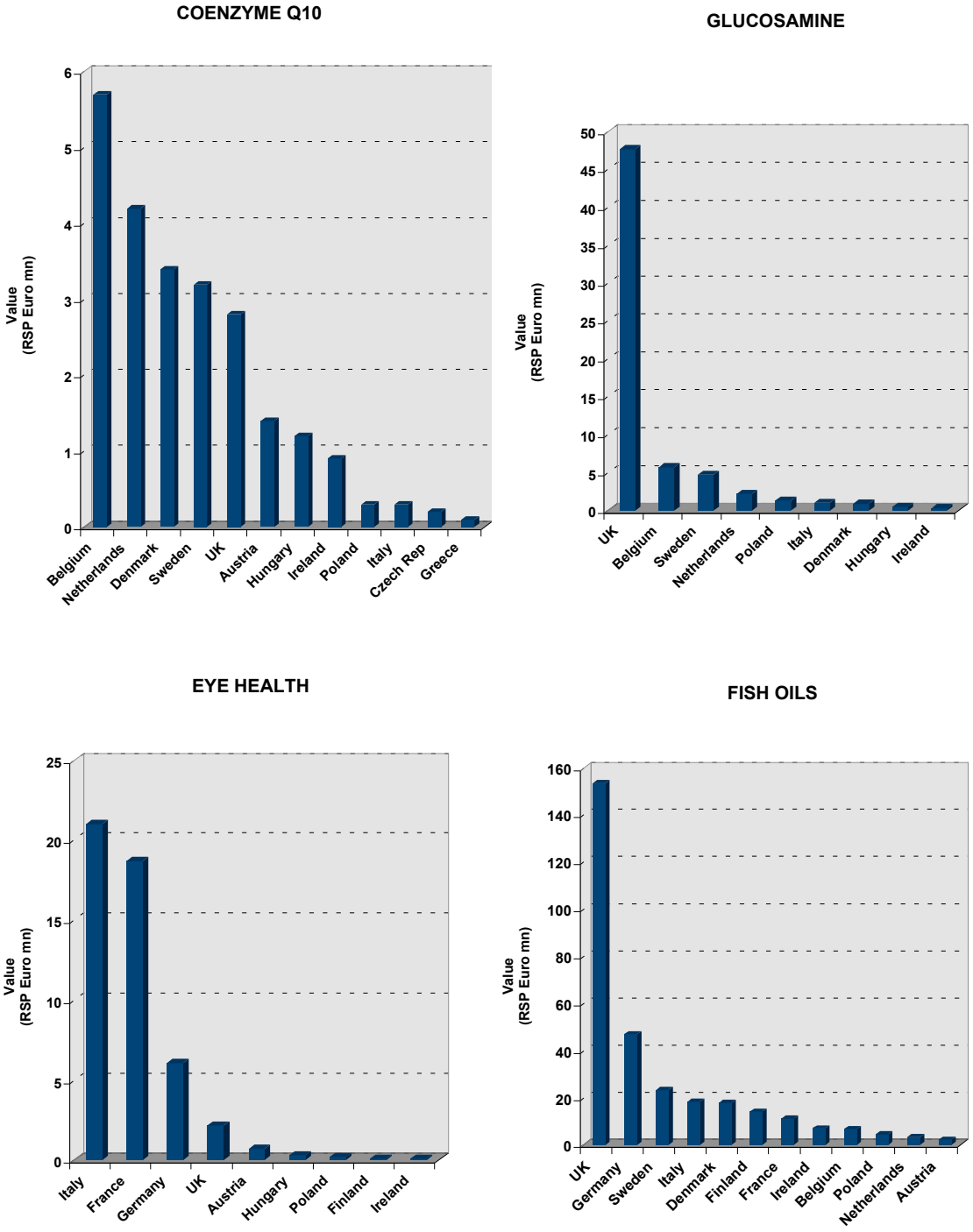


Source: Euromonitor 2005



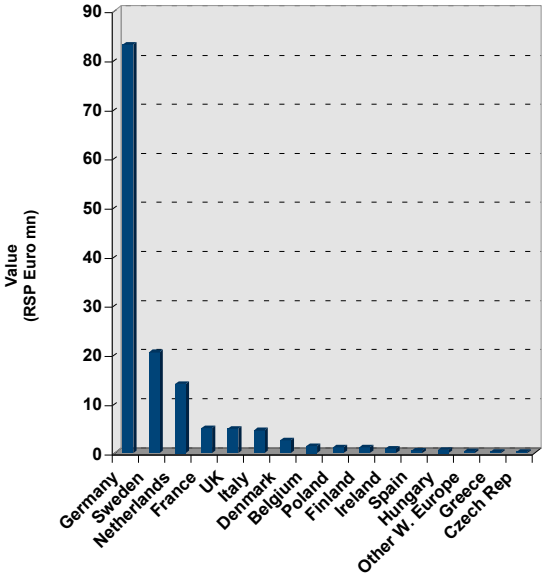
Source: Euromonitor, 2005

Graph 6: Market size variation of other substances across the EU

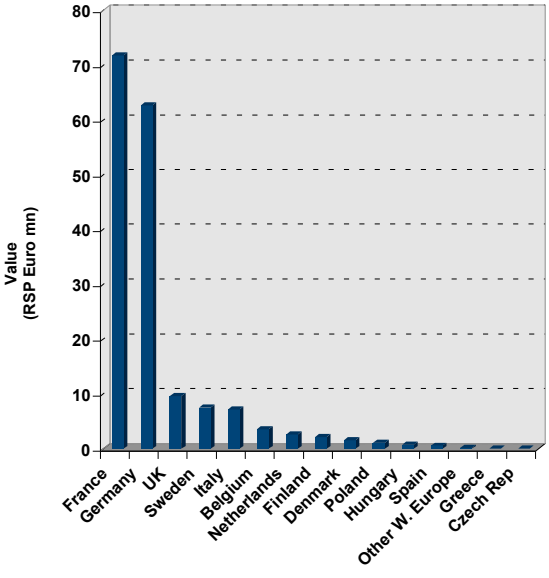


Source: Euromonitor, 2005

ECHINACEA



GINKGO



Source: Euromonitor, 2005

For illustrating market size variation, data on other substances has been included for countries where data was available.

The wide variations in the size of national markets have, in some cases, regulatory origins. For example, the market for glucosamine in the UK is relatively high and there is no figure for Germany. The reason for this is that glucosamine is considered by the German authorities to be a medicine. Glucosamine is however also sold as a non-registered product in Germany, in addition to products classified as medicines. It would appear however that this has not been picked up in the market data.

Price is also a significant factor in such data development. While the total packages sold may not differ significantly between some markets, the fact that the major product is a registered pharmaceutical, selling often at a higher price than the unregistered product, can have significant implications.

Based on the market data assessment the following could be observed:

- The EU food supplement market is highly diverse resulting in enormous difficulties in gathering accurate market data. It is likely that due to the wide range of sales channels used for supplements, the figures presented above are underestimates of the total market size.

- The market share of vitamins and minerals, and other substances is currently considered by Euromonitor to be almost evenly split. While some of the products containing other substances have clearly been registered as pharmaceuticals, this is also expected to be the case for some vitamin and

mineral products incorporated in the Euromonitor data for that segment of the market.

- The fastest projections for growth are in those markets where there is change or where they are coming from a low base. In this context, the new Member States are experiencing higher growth rates than the average of the EU-10.

- There are strong traditions surrounding the use of certain substances in certain markets. The clearest case is in the area of fish oils which have particular consumer support in the UK and the Nordic countries.

The market data presented in this report illustrates a general picture of the European market; they are however based on best selling ingredients and of course do not cover the full range of the 400 plus substances which are currently used in food supplements on the EU market. A number of ingredients - which may be important for some ingredient or finished product companies, such as green tea extract and grape seed extract - do therefore not appear in these charts.

3. OVERVIEW OF REGULATORY AND NON-REGULATORY APPROACHES

The review for all 27 Member States of the EU covers the following areas:

- Regulatory and non-regulatory approaches on botanicals and other bioactive substances.

- Overview of existing national lists of botanicals and other bioactive substances (chart 1).

- Regulatory status of a representative sample of other substances in food supplements across all 27 Member States *(response from Bulgaria pending)* (chart 2).

- Comparison of national approaches on the use of botanicals and other bioactive substances in food supplements (chart 3).

During the research, it was recognised that there is a substantial 'grey zone' in the regulatory status of many ingredients. While EAS maintains a good understanding of what is legal and what is not generally accepted in individual Member States, the views of different officials, even in some Ministries, may vary. In order to provide a level of consistency from each country, it was considered necessary to issue a questionnaire to each Member State. The questionnaire is attached in Annex 1.

Member States were requested in this questionnaire to point out their regulatory and non-regulatory approaches towards the use of other substances (ie botanicals and other bioactive substances) in food supplements. Regulatory approach in this report should be understood as national law, while non-regulatory approach refers to internal guidelines, databases, agreements, recommendations and other administrative practices clearly outlining the approach.

In addition, the regulatory status of a representative sample of other substances in food supplements was examined, and information on control mechanisms, procedures on law enforcement, and application of mutual recognition was requested.

Responses to this questionnaire were received from 26 out of the 27 Member States. An overview of the regulatory and non-regulatory approaches towards the use of other substances in food supplements was elaborated, and chart 1 presents a summary of existing national lists of botanicals and other bioactive substances. This chart shows the extent to which lists on other substances have been developed at the national level. It appears that substantial work has been undertaken for botanicals, while lists on other bioactive substances are limited and mainly refer to substances such as amino acids.

The national approaches towards the acceptability of the particular substances in food supplements are summarised in chart 2. Since it was difficult to illustrate in one chart the various approaches, six of the most common responses were identified taking into consideration certain assumptions:

- **Permitted for use in food supplements either under national law or internal guidelines**[7], with the assumption that the substance is not novel and its safety can be substantiated.

- **Permitted for use in food supplements - maximum level established.** The level at which a substance is used is in most cases a decisive factor for product classification. These levels are mainly mentioned in internal guidelines or used as common administrative practice. However, higher levels may in certain cases be permitted should scientific data substantiating the safety be submitted to the authorities, or where mutual recognition applies.

  Levels may exist in more Member States but were not explicitly mentioned in the responses of the respective national authorities to the questionnaire.

- **Permitted for use in food supplements under specific conditions** (eg type of extract, ingredients combination in the final product, etc). These conditions of use are mostly stated in national laws (especially in the case of botanicals) and also in guidelines established by certain Member States.

  Conditions of use may exist in more Member States but were not explicitly mentioned in the responses of the respective national authorities to the questionnaire.

- **Permission may be given on a case by case basis following evaluation**, considering issues such as the ingredient function. This approach is mainly followed by certain Member States where a case by case assessment is required, mostly to confirm safety and product suitability as a food supplement (eg product function, purpose and level). In these cases the applicant will need to receive a response from the national authorities about the acceptance of its product prior to marketing.

- **Not currently permitted. May be permitted following authorisation.** This applies to Member States that have an established pre-marketing authorisation procedure, such as France and Denmark where a scientific dossier substantiating the safety and the nutritional or physiological function of the substance has to be submitted.

- **Not permitted for use in food supplements, or regarded as medicinal.** This is the case where the substance is regarded as medicinal or as having no nutritional/physiological function.

Based on the national approaches and taking into consideration the responses on the regulatory status of certain substances of the Member States, a comparison presented in chart 3, shows that the approaches may vary from safety to a pre-marketing authorisation. In case of a safety approach (eg Ireland, Netherlands and UK), the full responsibility for the product lies with the food operator (manufacturer/distributor/importer). In countries where a pre-marketing authorisation procedure is established (eg Denmark, France and Germany), national food authorities are involved in the decision process.

[7] Internal guidelines might be any administrative document that has no legal power but is commonly used by the national authorities as a guidance for ingredients' acceptance and/or final product evaluation/classification.

Regulatory and non-regulatory approaches on botanicals and other bioactive substances

AUSTRIA

REGULATORY APPROACH	NON-REGULATORY APPROACH
The 2006 Austrian Law on Food Safety and Consumer Protection (Lebensmittelsicherheits- und Verbraucherschutzgesetz – LMSVG) foresees the use of simple or multiple concentrates of nutrients or other substances with nutritional or physiological effect in food supplements. The Austrian Ordinance 88/2004 implements the EU Food Supplement Directive including all compositional and labelling provisions. There are currently no legal positive or negative lists of botanicals and other bioactive substances.	In July 2005, the Federal Ministry of Health and Women issued under the framework of the Austrian Codex Alimentarius the *"Recommendation for food supplements concerning content of vitamins and minerals, overages and use of plant parts"* which, among others, includes: - a list of herbs prohibited for use in food supplements, - a short list of herbs and parts thereof for which there are generally no safety concerns and which can be used in food supplements. Herbs not covered in the Recommendations and other bioactive substances are evaluated on a case by case basis.

Mutual Recognition
The Austrian authorities indicated that they apply mutual recognition to products lawfully marketed in other EU Member States.

BELGIUM

REGULATORY APPROACH	NON-REGULATORY APPROACH
The transposition of the EU Food Supplement Directive in Belgium resulted in the Royal Decrees of 15 May 2003 amending: - the Royal Decree of 29 August 1997 on the production and marketing of foods composed of plants or containing plant preparations, and - the Royal Decree of 3 March 1992 on the marketing of nutrients and foods with added nutrients. In the food supplements' definition, reference is made to nutrients (ie certain vitamins, minerals, amino acids and fatty acids), plants, plant preparations or other substances with a nutritional or physiological effect. The Royal Decree of 29 August 1997 includes a list of prohibited plants, a list of permitted mushrooms and a list of plants permitted in food supplements specifying, in some cases, their conditions of use. The Royal Decree of 3 March 1992 includes a number of permitted amino acids and fatty acids. A specific list indicating the permission or prohibition of other bioactive substances in food supplements is currently under development.	There is no internal list or guidelines for the use of botanicals and other bioactive substances in food supplements. Other bioactive substances with a nutritional or physiological effect are permitted for use in food supplements provided that they are safe and the final product does not make medicinal claims.

Mutual Recognition
The Belgian authorities indicated that they take into consideration the opinions from other EU Member States for the application of mutual recognition.

BULGARIA

REGULATORY APPROACH	NON-REGULATORY APPROACH
Ordinance No 47 (December 2004) on requirements related to food supplements transposes the EU Food Supplement Directive into national law. This legislation covers the use of substances other than vitamins and minerals in food supplements. Annex 4 of the Bulgarian Ordinance includes a list of botanicals which are prohibited for use in food supplements. The Ordinance specifies that “other nutritional matters or substances with nutritional or physiological effect” are provitamins, proteins, amino acids, peptides, essential fatty acids, fish and vegetable oils, carbohydrates, nutritional fibres, metabolites, probiotics and prebiotics, apiarian products, nutritional concentrates, enzymes, parts and extracts of plants, organic or inorganic bioactive substances, in an individual or a combined form.	There is no internal list or guidelines for the use of botanicals and other bioactive substances in food supplements.

Mutual Recognition
The Bulgarian authorities indicated that they would accept food supplement products lawfully sold in other EU Member States based on the principle of mutual recognition.

CYPRUS

REGULATORY APPROACH	NON-REGULATORY APPROACH
The 2004 Regulation on Food Supplements transposes the EU Food Supplement Directive. The definition of food supplements mentioned in the Cypriot law covers the use of botanicals and other bioactive substances. There are however no positive or negative lists of botanicals and other bioactive substances. The use of substances other than vitamins and minerals in food supplements is evaluated by a scientific committee following one of the two established procedures: - mutual recognition if the food supplement product is lawfully sold in another EU Member State, or - an authorisation procedure by submission of a detailed dossier to gain a license prior to marketing.	There is no internal list or guidelines for the use of botanicals and other bioactive substances in food supplements. Permission to market botanicals and other bioactive substances is evaluated on a case by case basis. Risk assessment evaluations of food supplement products containing substances other than vitamins and minerals are undertaken by the National Committee on Food Supplements.

Mutual Recognition
The Cypriot food supplements law establishes a procedure of product evaluation based on mutual recognition. The authorities take into consideration the option to mutually recognise food supplement products produced in other EU Member States.

CZECH REPUBLIC

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Czech General Food Law 316/2004 includes the definition of food supplements which permits the use of substances with nutritional or physiological effect in food supplements. Ordinance No 446/2004 stipulates requirements on food supplements and on fortification of food with nutrients. It transposes the EU Food Supplement Directive and provides rules on botanicals and some other bioactive substances with their maximum permitted daily levels. Annex 4 of the Ordinance No 446/2004 includes a negative list of herbs for use in food supplements. List a) of Annex 4 of the Ordinance 343/2003 on herbs used for pharmaceutical and therapeutical purposes includes herbs containing very strong substances. Herbs included in this list are prohibited for use in food supplements. Annex 3 of the Ordinance No 446/2004 includes a list of certain other food substances specifying their maximum permitted daily levels.	Agreements between the State Institute of Drug Control and State Institute of Public Health on borderline products are used during product evaluations.

Mutual Recognition
According to the Czech authorities a product recognised as food supplement and placed on the market in other EU Member States can be launched in the Czech Republic provided that it meets the requirements of the national Food Law and related Czech food supplement legislation.

DENMARK

REGULATORY APPROACH	NON-REGULATORY APPROACH
The 2003 Danish law on food supplements (BEK no 683) permits the use of vitamins, minerals, botanicals and other bioactive substances in food supplements. In particular, the use of substances with a nutritional or physiological effect other than vitamins and minerals is regulated according to § 21 of the 2005 Danish Order on food additives no. 22. All approved substances with a nutritional and/or physiological effect are listed in the “Positivliste” according to § 8 of the 2005 Food Law no. 526 and which is also referred to in § 10 of the “Danish Order on food additives”. "Positivliste" is a non-exhaustive list and is updated following an ingredient authorisation based on an established procedure. Nutrients not listed in the "Positivliste" have to be approved before they can be used in food supplements as nutrients. Extracts of vegetable, animal, fungal or mineral origin which are not concentrated up to a degree, and are not regarded as food additives but as ingredients, can be used in food supplements, provided that the ingredients are effective and safe as required according to § 2 of the 2003 Danish Order no. 683 on food supplements and article 14 of the EU Regulation no. 178/2002 respectively.	There is no internal list or guidelines for the use of botanicals and other bioactive substances in food supplements. The "Drogeliste" includes botanicals and fungi that have been evaluated in the past and are regarded as medicines. Although this list is not legislatively grounded, it is used by the authorities as a guideline for whether a substance is considered safe. The list is neither definite nor exhaustive, and can at all times be challenged by new documentation.

Mutual Recognition
The Danish Veterinary and Food Administration indicated that it takes into consideration the use of food supplement substances legally sold in other EU Member States, during the evaluation/authorisation procedure.

ESTONIA

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Food Act of 1999, as amended, and Regulation 165/2004 regulate food supplements in Estonia. Regulation 59/2005 covers the requirements for classifying products as medicinal, and includes a list of botanicals indicating whether these can be sold outside pharmacies or these are regarded as medicinal and cannot be used in food supplements. There is currently no legal list specifying the permission or prohibition of other bioactive substances in food supplements.	There is no internal list or guidelines for the use of botanicals or other bioactive substances in food supplements.

Mutual Recognition
The Estonian authorities indicated that in principle apply mutual recognition to food supplement products that have been lawfully sold in other EU Member States. However, there may be cases where mutual recognition is not applied, for example if a product contains botanicals that may only be used in medicinal products in Estonia.

FINLAND

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Finnish Regulation of the Ministry of Trade and Industry on Food Supplements 571/2003 permits the use of botanicals and other substances with nutritional or physiological effect. There are currently no legal lists specifying the permission or prohibition of botanicals or other bioactive substances in food supplements. The permission of botanicals and other bioactive substances is evaluated on a case by case basis.	There are no national lists of permitted and/or prohibited botanicals or other bioactive substances for use in food supplements. The economic operator should ensure that substances used are safe and not injurious to health or otherwise unfit for human consumption. The National Agency for Medicines has published a guidance list of medicinal substances and herbs. However, their use in food supplements is not prohibited provided they fulfill the general requirements set for foodstuffs and no medicinal claims are made for the final product. The Finish Food Safety Authority (EVIRA) recommends contacting the National Agency of Medicines for clarity on the classification.

Mutual Recognition
The Finnish authorities indicated that they would take into account mutual recognition for products lawfully marketed in other EU Member States.

FRANCE

REGULATORY APPROACH	NON-REGULATORY APPROACH
The provisions of the EU Food Supplement Directive are transposed by the 2006 Food Supplements Decree No 2006-352 which permits the use of botanicals and other bioactive substances. Botanicals are permitted for use in food supplements as long as: - these are known for their traditional use as foodstuffs, exempting their non-traditional preparations in foodstuffs, or - these are authorised by the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF) following a positive opinion from the Agence Française de Sécurité Sanitaire des Aliments (AFSSA), or - these are lawfully sold in another EU or EEA (European Economic Area) Member State and have obtained a positive opinion from the DGCCRF via the mutual recognition procedure. The French Decree regarding medicinal plants or parts of plants entered in the Pharmacopoeia, which may be sold to the public by persons other than pharmacists, includes a list of 34 plants. A draft Order amending this Decree includes a list of 147 plants with their conditions of use. Other medicinal plants or parts of medicinal plants entered in the French Pharmacopoeia may only be used in food supplements following a pre-marketing approval and provided that these are not included in the toxic list. As regards substances with a nutritional or physiological purpose, the Food Supplements Decree addresses the substances: - authorised for use in foods for particular nutritional uses, - authorised by the DGCCRF following a positive AFSSA opinion, - lawfully sold in another EU or EEA (European Economic Area) Member State and authorised via the mutual recognition route (without having received a refusal).	For authorising the use of certain botanicals and other bioactive substances in food supplements the DGCCRF may require a pre-marketing approval via the established AFSSA authorisation procedure. The AFSSA opinions are used as a guidance by the DGCCRF for product evaluations.

Mutual Recognition
The French Food Supplements Decree foresees a mutual recognition procedure for products that have been lawfully sold in other EU/EEA Member States.

GERMANY

REGULATORY APPROACH	NON-REGULATORY APPROACH
The 2004 German Regulation on Food Supplements permits the use of substances with a nutritional and/or physiological effect in food supplements. The 2005 German Law on Food and Feed (Lebensmittel- und Futtermittelgesetzbuch – LFGB, 6.9.2005) stipulates the legal position of non-regulated substances (such as amino acids and enzymes) used in foods for purposes other than technological, and classifies them as equal to food additives. In accordance with §2 (3) of LFGB the only general exemption is granted for substances of natural origin or substances chemically identical to the natural ones which are predominantly used for their nutritional/calorific, olfactory or taste value. There is currently no legal list specifying the permission or prohibition of botanicals or other bioactive substances in food supplements.	Food supplements containing herbal ingredients are evaluated on a case by case basis and are generally not prohibited as foods if their use is considered to have a primarily nutritional purpose. The working group of food chemistry experts of Lands of the Federal Republic and of the Federal Institute for Consumer Protection and Food Safety (BVL) in co-operation with experts of the Drug Control authorities has developed an inventory list of herbs (Inventarliste). The inventory list is based on a list of the Trade Association of Herbal and Fruit Teas (WKF) and includes herbs and parts thereof considered to be foodstuffs or medicines depending on the common trade practice. This inventory list is not exhaustive and is open for additions resulting from new developments. The German supervising authorities use this list as a guideline during the evaluation process of food supplements. There is no internal list or guidelines for the use of other bioactive substances in food supplements.

Mutual Recognition
§54 of the 2005 German Law on Food and Feed (LFGB) establishes a specific mutual recognition procedure, the so called Allgemeinverfügung, for food supplement products containing ingredients not compliant with the German legislation and which have been lawfully sold in other EU/EEA Member States.

GREECE

REGULATORY APPROACH	NON-REGULATORY APPROACH
The 2004 Food Supplement Ministerial Decision (AR. U1/ GP. 127962/03) implements the EU Food Supplement Directive. The Ministerial Decision permits the use of substances with physiological or nutritional effect in food supplement products. There is no legal positive or negative list of botanicals. The new food supplements' definition refers to plant extracts which can be used in a single or combined form. The decisive factor for the classification of a herbal product as food or medicine is its purpose of use. A short list of substances with nutritional or physiological effect is included in the food supplements' definition of the Greek law. Among vitamins and minerals, the following are listed: - edible plant extracts and other, - amino acids, - proteins, and - antioxidants. No specific list of other bioactive substances has been or is envisaged to be established by the Greek authorities.	The permission to market botanicals or other bioactive substances in food supplements is evaluated by the Greek Organisation of Medicines (EOF) on a case by case basis following an established authorisation procedure. The authorities might use as a guidance their internal database of already notified food supplement products.

Mutual recognition
According to the Greek authorities, there is no special provision on the application of mutual recognition for food supplement products that have been lawfully sold in other EU Member States.

HUNGARY

REGULATORY APPROACH	NON-REGULATORY APPROACH
The 2004 Hungarian Regulation on Food Supplements permits the use of substances with physiological or nutritional effect in food supplement products. The Hungarian food authorities are in the process of drafting a list of botanicals prohibited for use in food supplements. The Annex of the 2004 Regulation permits the use of amino acid chelates, yeast-metal complexes, humic acid and fulvic acid chelates until the end of December 2009. The Hungarian Food Authorities are in the process of drafting a list of permitted bioactive substances for use in food supplements.	There is an internal list from the National Institute of Food, Hygiene, and Nutrition of herbs and other bioactive substances for use in food supplements and their recommended maximum daily levels.

Mutual Recognition
The Hungarian authorities indicated that they apply mutual recognition to products that have been lawfully sold in other EU Member States, unless there is concern over the ingredient safety or product status (eg novel food).

IRELAND

REGULATORY APPROACH	NON-REGULATORY APPROACH
The 2003 Food Supplements Regulations (S.I. No 539) permit the use of substances with physiological or nutritional effect in food supplements. The Irish law on food supplements does not include any negative and/or positive lists of botanicals and other bioactive substances.	Botanicals and other bioactive substances with or claiming to have medicinal properties are prohibited. Assessment of such products is carried out on a case by case basis. The Irish Food Safety Authority (FSAI) maintains a record of all products notified to the Authority, which may be used as a guidance during product notification.

Mutual Recognition
The Irish authorities indicated that they apply the principle of mutual recognition to food supplement products lawfully sold in other EU Member States.

ITALY

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Italian Decree on food supplements permits the use of botanicals and other bioactive substances in food supplements. The Italian Ministry of Health has issued a positive and negative list of plants and their derivatives that have been evaluated by the Commission on Dietetic Foods and Nutrition (CUDN). This list is not exhaustive and is subject to modification. The Ministry of Health has issued guidelines on food supplements, fortified and functional foods, which were last updated in July 2006. These guidelines include positive lists of other bioactive substances (also mentioning maximum levels for some substances), which have been officially approved for food supplement use by the Ministry. Moreover, they cover specific conditions of use for the food supplement use of amino acids and amino acid derivatives, fatty acids, proteins, probiotics, fibres and some plants	In addition to the Ministerial lists on plants, the positive/negative lists of botanicals drafted by the Italian Parliament in the past may be used as background reference by the authorities.

Mutual recognition
The Italian authorities indicated that they would apply the principle of mutual recognition to food supplement products in case a proof of its legal sales in other EU Member States can be provided.

LATVIA

REGULATORY APPROACH	NON-REGULATORY APPROACH
Food supplements are covered by the Latvian Regulations 154/2001 and 725/2005. As regards botanicals, Regulation 154/2001 indicates that food supplements may contain one or several plants, parts thereof, extracts, or products of metabolism or processing. Annex 2 of the Latvian Regulation 154/2001 includes a list with prohibited plants or parts thereof, and a list with plants or parts thereof for limited use in food supplements. As regards other bioactive substances, Regulation 154/2001 indicates that food supplements may contain one or several micro-organisms, products of metabolism or processing, or products of animal metabolism or processing origin. The Latvian Regulation does not include a specific negative and/or positive list of other bioactive substances.	A database of food supplements distributed in Latvia is maintained and may be used as guidance by the authorities for product permission. There is no internal list or guidelines for the use of botanicals and other bioactive substances in food supplements.

Mutual Recognition
The Latvian authorities indicated that they take mutual recognition into consideration for the permission to market food supplements.

LITHUANIA

REGULATORY APPROACH	NON-REGULATORY APPROACH
The 2003 Lithuanian Decree on Food Supplements HN 17/2003 permits the use of botanicals and other bioactive substances. The law on food supplements does not include any negative and/or positive lists of botanicals. Work on positive and negative lists of botanicals and other bioactive substances is currently under discussion.	There is no internal list or guidelines for the use of botanicals and other bioactive substances in food supplements.

Mutual Recognition
The Lithuanian authorities indicated that they apply the principle of mutual recognition to food supplement products lawfully sold in other EU Member States.

LUXEMBOURG

REGULATORY APPROACH	NON-REGULATORY APPROACH
The definition of food supplements as defined in the 2003 Food Supplement Regulation covers only vitamins and minerals. The Food Supplement Regulation does not include any negative and/or positive lists of botanicals and other bioactive substances.	The authorities evaluate the use of botanicals and other bioactive substances in food supplements on a case by case basis.

Mutual Recognition
The Luxembourg authorities indicated that they apply the principle of mutual recognition to food supplements.

MALTA

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Food Safety Act (ACT NO. XIV OF 2002) on Food Supplements Regulations 2003 (L.N. 239 of 2003) permits the use of botanicals and other bioactive substances in food supplements. It does not include any negative and/or positive list of botanicals and other bioactive substances.	The Maltese authorities evaluate the permission to market botanicals and other bioactive substances in food supplements on a case by case basis following a risk assessment by the Malta Standards Authority.

Mutual Recognition
Mutual recognition may apply but the authorities indicated that they mainly rely on the risk assessment of individual products in order to permit their sale as food supplements in Malta.

NETHERLANDS

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Decree of 15 March 2003 on Food Supplements implements the EU Food Supplement Directive and permits the use of substances with nutritional or physiological effect. The Commodities Act Decree of January 2001 on herbal preparations provides rules on the use of botanicals in foodstuffs, including food supplements, and prohibits the use of herbal preparations containing high amounts of pyrrolizidine alkaloids or aristolochic acid. It further includes a negative list of plants/fungi regarded as having medicinal properties. There are no other specific lists of permitted and/or prohibited bioactive substances.	Botanicals not mentioned in the Commodities Act Decree and other bioactive substances can generally be used in food supplements as long as they are safe. In 1999, the Dutch Health Council published its opinion on the safe use of a number of amino acids with their recommended quantities for supplementation. Consequentially, the authorities tolerate the use of certain amino acids in food supplements.

Mutual Recognition
A product lawfully sold as a food supplement in other EU Member States is mostly, if not always, recognised as a food supplement by the Dutch authorities, based on the principle of mutual recognition.

POLAND

REGULATORY APPROACH	NON-REGULATORY APPROACH
The provisions of the EU Food Supplement Directive are laid down in the 2002 Polish Decree on Food Supplements and the 2006 Polish Act on Food Safety. The definition of food supplements mentioned in the Polish laws permits the use of botanicals and other bioactive substances in food supplements. However, it does not include any negative and/or positive lists of botanicals and other bioactive substances.	Scientific institutes are involved in the assessment of non-regulated ingredients for food supplements. The National Food and Nutrition Institute is developing a database of food supplements placed on the Polish market.

Mutual Recognition
According to the 2006 Polish Act on Food Safety, in order to apply the principle of mutual recognition, the economic operator should inform the Chief Sanitary Inspector about the competent authority of the EU Member State which was notified, by forwarding a copy of the notification documents.

PORTUGAL

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Portuguese Decree No 136/2003 on food supplements permits the use of botanicals and other bioactive substances in food supplements. The Portuguese Decree does not include any negative and/or positive lists of botanicals and other bioactive substances.	The permission to market botanicals and other bioactive substances in food supplements is evaluated on a case by case basis. The Portuguese authorities use as an internal guideline the Botanicals negative list by APARD (Associação Portuguesa de Alimentação Racional e Dietética) the Portuguese food supplements producers' association. In addition, ASAE (Autoridade de Segurança Alimentar e Económica) uses as guidance their internal database of food supplement notifications.

Mutual Recognition
According to the Portuguese authorities the principle of mutual recognition would apply to food supplement products lawfully sold in other EU Member States.

ROMANIA

REGULATORY APPROACH	NON-REGULATORY APPROACH
The 2003 Order No 1214 on food supplements permits the use of botanicals and other bioactive substances in food supplements. The Romanian Order includes a list of other substances regarded as having a nutritional or physiological effect, such as proteins, amino acids, essential polyunsaturated fatty acids etc. The 2005 Common Order of Ministry of Health and Ministry of Agriculture, Forests and Rural Development no. 401/244 regulates the use of botanicals in food supplements and includes a positive and negative list of herbs and plants, and a positive list of cultivated and wild mushrooms. Moreover, the Order 1228/2005 specifies rules on the approval of food supplements containing animal or herbal products (extracts), or in combination with vitamins and minerals.	There is no internal list or guidelines for the use of botanicals and other bioactive substances in food supplements.

Mutual Recognition
The Romanian authorities indicated that they apply the principle of mutual recognition to food supplement products lawfully sold in other EU Member States.

SLOVAKIA

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Decree 608/2/2004 - 100 (Chapter 7) of the Slovak Food Codex provides the food supplement definition which permits the use of substances with nutritional or physiological effect. There is no negative and/or positive list of botanicals or other substances.	There are lists of permitted and prohibited botanicals which are not legally binding. The lists are for internal use of the Slovak Public Health Authority only and were prepared in cooperation with the State Institute for Drug Control. There is no internal list or guideline for the use of other bioactive substances in food supplements.

Mutual Recognition
If a food supplement was produced and placed on the market in another EU Member State and there are no health concerns, this product may be placed on the market in Slovakia following a product notification.

SLOVENIA

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Regulation 82/2003 on Food Supplements permits the use of botanicals and other bioactive substances in food supplements. The use of herbs and their parts is regulated under Decree 1/99 on the classification of medicinal plants, and includes four categories of plants: - plants permitted for use in foods, including food supplements, provided that no medicinal claims are made, - plants permitted for use in OTC medicines, - plants permitted for use in prescription only medicines, - plants prohibited from use in all types of food and medicinal products. The Regulation 82/2003 on Food Supplements indicates in the definition of food supplements that these could also contain other bioactive substances such as amino acids, fatty acids, fibres, microorganisms and other substances with nutritional or physiological effect. Annex III of this Regulation includes chemical forms of the following substances permitted for use in food supplements: amino acids, carnitine and taurine, nucleotides, choline and inositol.	There is no internal list or guidelines for the use of botanicals or other bioactive substances in food supplements.

Mutual Recognition
The authorities indiacted that the principle of mutual recognition applies, unless the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia considers a food supplement to be medicinal (eg glucosamine and Ginkgo biloba are classified as medicines).

SPAIN

REGULATORY APPROACH	NON-REGULATORY APPROACH
The use of botanicals in foodstuffs, including food supplements, in Spain is regulated by: - Real Decreto 3176/1983, regarding the formulation, circulation and marketing of vegetable species of infusions for food use (B.O.E. 28.12.83), - Real Decreto 2242/1984, regarding the formulation, circulation and marketing of substances and spices (B.O.E. 22.12.84), - Orden SCO/190/2004, establishing a negative list of plants which are prohibited or have a restricted use due to their toxicity.	The authorities tolerate the use of other bioactive substances in food supplements only if they are combined with vitamins and minerals. Products containing bioactive substances are permitted to be sold as food supplements on a case by case basis. Proof of the legal sales of the product in other EU Member States facilitates product acceptance based on the principle of mutual recognition.

Mutual Recognition
The Spanish law on food supplements (Real Decreto 1275/2003) foresees the application of the principle of mutual recognition, provided that the food operator can supply an official document on the status of the product in another EU Member State and that the ingredient/product has not been classified as a medicine.

SWEDEN

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Food Supplement Ordinance (LIVSFS 2003:9) permits the use of botanicals and other bioactive substances in food supplements. The authorities tolerate the use of other bioactive substances in food supplements as long as they are not classified as medicines or natural remedies by the Medicinal Products Agency. There is no official list of other bioactive substances in Sweden.	The authorities use as a guideline the negative list of plants and plant parts unsuitable for use in food (VOLM). This list is non-exhaustive and subject to modification. In borderline cases, the advice of the Medicinal Products Agency (MPA) may be required for the final product classification.

Mutual Recognition
The Swedish authorities apply the principle of mutual recognition to food supplements that have been lawfully sold in other EU Member States, unless the substance or product is concidered to be medicinal product by the Medicinal Products Agency (MPA).

UK

REGULATORY APPROACH	NON-REGULATORY APPROACH
The Food Supplement (England) Regulations 2003 (S.I. 2003 No.1387) permit the use of substances with nutritional or physiological effect in food supplements. The Regulation does not include positive and/or negative lists of botanicals or other bioactive substances.	To assist companies in determining the likely status of their product, a list of herbal ingredients has been compiled by regulatory bodies and industry in the UK. This non-exhaustive list, which has no legal status, includes plants specifying their recorded uses in the UK (ie food, medicines, cosmetics and aromatherapy). There is also a list of herbal ingredients prohibited or restricted in medicines, which are the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA). Both lists might be used by the authorities as a guidance for product classifications. Other bioactive substances can be used provided that their safety can be proven and there has been no negative opinion from the Food Standards Agency (FSA) or MHRA.

Mutual Recognition
The UK authorities do not necessarily apply mutual recognition where food supplements are viewed to be medicinal. In such instances the UK upholds the 1989 European Court of Justice ruling (ECJ C112/89 Upjohn vs Farzoo) which states that it is for the national courts to determine the classification of each product.

Chart 1: Overview of existing national lists of botanicals and other bioactive substances

		REGULATORY	NON-REGULATORY
Only Positive List	**Botanicals**	Denmark	Czech Republic
	Other bioactive substances	Belgium* *(draft law)* Bulgaria* Czech Republic Denmark France Greece* Hungary Italy Netherlands Romania* Slovenia	Czech Republic Hungary *(working document)* Netherlands
Only Negative List	**Botanicals**	Bulgaria Czech Republic Finland Netherlands	Denmark Portugal Sweden
	Other bioactive substances	Finland	
Positive & Negative List	**Botanicals**	Belgium Estonia France Italy Latvia Romania Slovenia Spain	Austria Germany Hungary *(working document)* Italy Slovakia UK
	Other bioactive substances	-	-

** Short list of substance categories mentioned in the definition of food supplements*

Chart 2: Regulatory status of a representative sample of other substances in food supplements across all 27 Member States

Symbols	
✓	Permitted for use in food supplements either under national law or internal guidelines.
L	Permitted for use in food supplements - maximum **level** established.
C	Permitted for use in food supplements under specific **conditions** (eg type of extract, ingredients combination in the final product, etc)
E	Permission may be given on a case by case basis following **evaluation**, considering issues such as ingredient function.
A	Not currently pemitted. May be permitted following a pre-marketing **authorisation**.
✖	Not permitted for use in food supplements, or regarded as medicinal.

		AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH REPUBLIC	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM
Amino acids	L-arginine	E	✓	✓	E	C	E	✓	✓	L	A	✓	E	C	C	✓	✓	✓	✓	L	✓	✓	✓	✓	✓	L	✓	✓
	Other essential amino acids	E	C	✓	E	C	E	✓	✓	L	A	✓	E	C	C	✓	✓	✓	✓	L/C	✓	✓	✓	✓	✓	✓	C	L/C
	Non-essential amino acids	E	✓	✓	E	C	E	✓	✓	A	A	✓	E	C	C	✓	✓	✓	✓	L	✓	✓	✓	✓	✓	✖	✓	✓
Enzymes	Lactase	✖	✓	✓	E	C	✖	✓	✓	A	✖	✓	✖	✓	✖	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓
	Papaine	E	✓	E	E	C	✖	✓	✓	A	✖	✖	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓

Symbols	
✓	Permitted for use in food supplements either under national law or internal guidelines.
L	Permitted for use in food supplements - maximum **level** established.
C	Permitted for use in food supplements under specific **conditions** (eg type of extract, ingredients combination in the final product, etc)
E	Permission may be given on a case by case basis following **evaluation**, considering issues such as ingredient function.
A	Not currently pemitted. May be permitted following a pre-marketing **authorisation**.
✖	Not permitted for use in food supplements, or regarded as medicinal.

		AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH REPUBLIC	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM
Pre- and Probiotics	Inulin	✓	✓	✓	E	C	✓	✓	✓	A	✓	✓	✓	✓	C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Lactobacillus acidophilus	E	✓	✓	E	✓	A	✓	✓	✓	✖	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✖	✓
	Bifidobacterium species	E	✓	✓	E	✓	A	✓	✓	✓	✖	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✖	✓
	Yeast species	✖	✓	✓	E	✓	A	✓	✓	✓	A	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Essential fatty acids	Gamma-linolenic acid	E	✓	✓	E	C	A	✓	✓	A	C	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	✓	✓
	EPA/DHA	E	✓	✓	E	C	A	✓	✓	A	C	C	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	L/C	✓
	Evening Primrose oil (*Oenothera biennis* (L.))	E	✓	E	E	C	L	✓	✓	A	A	✖	L	C	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓
	Borage oil (*Borago officinalis*)	E	C	E	E	C	L	✓	C	A	A	✖	C	C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓
	Flax seed oil (*Linum usitatissimum* (L.))	E	✓	E	E	C	✓	✓	✓	A	✓	✖	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓

Symbols		
	✓	Permitted for use in food supplements either under national law or internal guidelines.
	L	Permitted for use in food supplements - maximum **level** established.
	C	Permitted for use in food supplements under specific **conditions** (eg type of extract, ingredients combination in the final product, etc)
	E	Permission may be given on a case by case basis following **evaluation**, considering issues such as ingredient function.
	A	Not currently pemitted. May be permitted following a pre-marketing **authorisation**.
	✖	Not permitted for use in food supplements, or regarded as medicinal.

Botanicals & botanical extracts	AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH REPUBLIC	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM
Aloe (*Aloe vera* (L.))	E	✓	E	E	C	L	✓	C	A	C	✖	C	✓	✓	✓	E	✓	✓	✓	✓	✓	✓	C	L/C	✓	✓	C
Ginkgo (*Ginkgo biloba*)	E	L	E	E	L	✓	✖	C	A	✖	✖	L	✖	C	L	E	✓	✓	✓	✓	✓	✓	L	✖	✖	✖	C
Ginseng (*Panax ginseng*)	E	✓	E	E	L	L	✓	C	A	✖	L	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	L	✓	✓	C
Garlic (*Allium sativum* (L.))	✓	✓	E	E	C	✓	✓	✓	A	C	✓	L	C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	✖	✖	C
Green tea extract (*Camellia sinensis*)	E	L/C	E	E	C	E	✓	✓	A	C/A	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	C
Garcinia extract (*Garcinia cambogia*)	E	✓	E	E	L	✖	C	✓	A	✖	✖	L	✖	✓	✓	E	✓	✓	✓	✓	✓	✓	✓	C	✖	E	✖
Guarana extract (*Paullinia cupana*)	C	✓	E	E	C	L	✓	✓	A	C/A	✖	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓

Symbols	
✓	Permitted for use in food supplements either under national law or internal guidelines.
L	Permitted for use in food supplements - maximum **level** established.
C	Permitted for use in food supplements under specific **conditions** (eg type of extract, ingredients combination in the final product, etc)
E	Permission may be given on a case by case basis following **evaluation**, considering issues such as ingredient function.
A	Not currently pemitted. May be permitted following a pre-marketing **authorisation**.
✖	Not permitted for use in food supplements, or regarded as medicinal.

		AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH REPUBLIC	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM
Miscellaneous bioactive substances	Lycopene	E	✓	E	E	L	A	✓	C	A	A	✖	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	C
	Lutein	E	✓	E	E	L	A	✓	✓	A	A	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	✖	✓	✓
	Coenzyme Q10	E	✓	E	E	L	E	L	✓	A	L	L	L	C	L	✓	✓	✓	✓	✓	✓	✓	✓	L	L	✖	✓	✓
	Taurine	E	✓	E	L	L	E	✓	✓	L	A	✓	L	C	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓
	Carnitine	E	✓	E	E	L	E	✓	✓	L	C	L	L	C	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	✖	✓	✓
	Inositol	E	✓	E	E	✓	E	✓	✓	L	A	✓	L	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓
	Glucosamine	E	✓	E	E	C	✖	L	C	A	✖	✖	L	L	L	✓	E	✓	✓	✓	✓	✓	✓	✓	✖	✖	✖	C
	Chitosan	E	✓	E	E	C	A	✓	✓	A	✖	✖	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓
	Spirulina	E	✓	E	E	✓	L	✓	✓	A	✓	✖	L	C	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✖	✓	✓
	Soy isoflavones	E	L	E	E	C	A	✓	✓	A	A	✓	L	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	✓	✓	✓

Chart 3a: Comparison of national approaches on the use of botanicals in food supplements

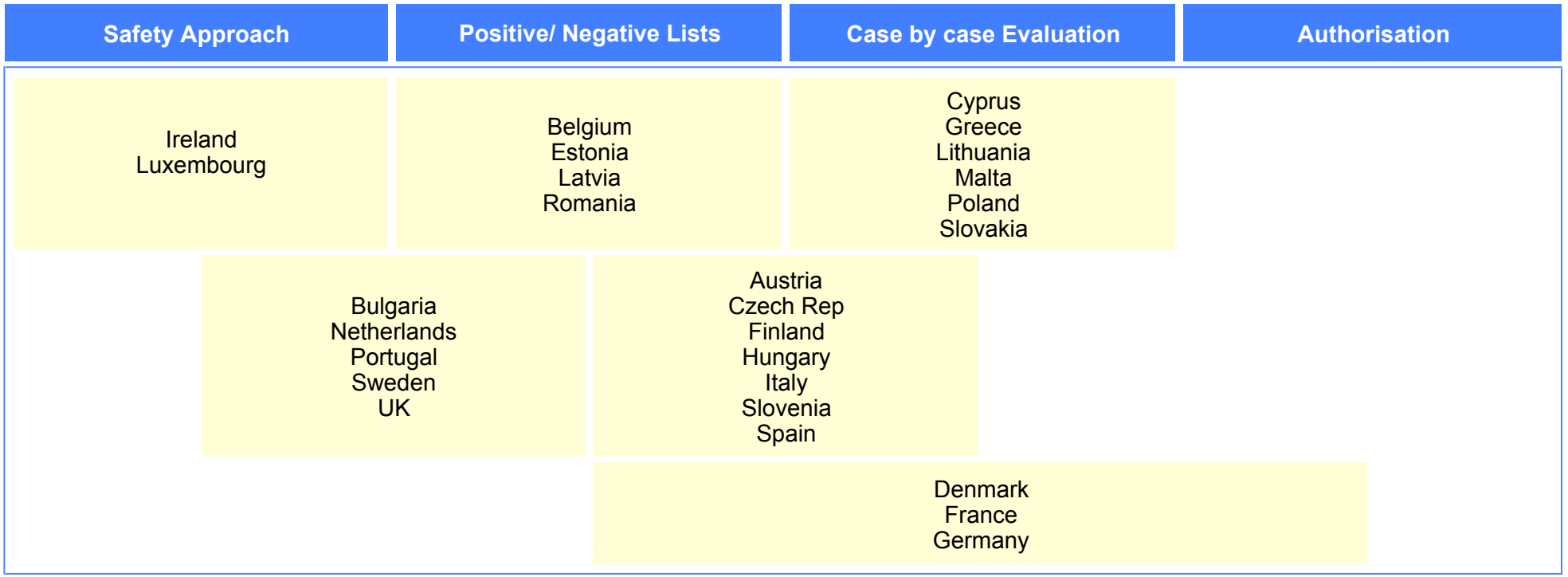
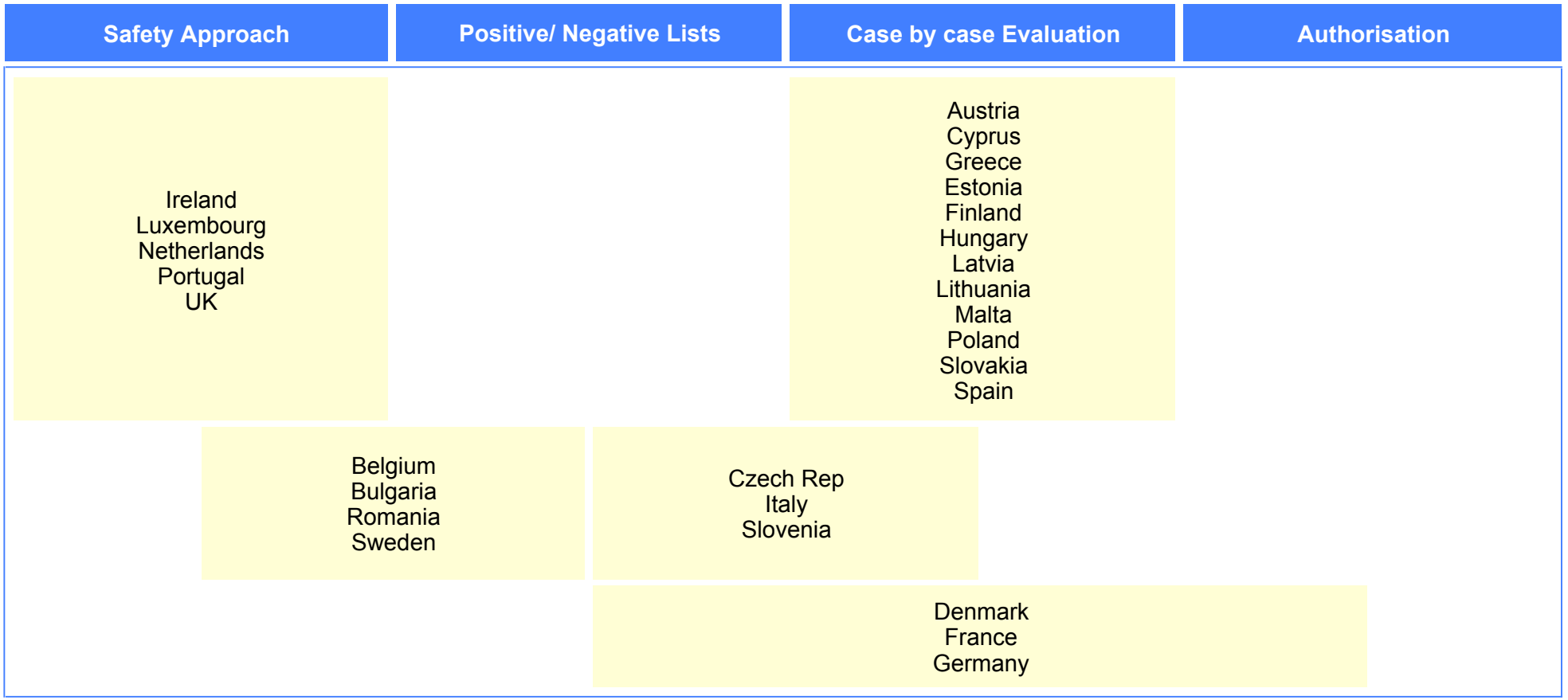


Chart 3b: Comparison of national approaches on the use of other bioactive substances in food supplements



III. BORDERLINE ISSUES AND EUROPEAN COURT JUDGEMENTS

Relevant ECJ Cases will be elaborated and presented to show the issues raised in borderline cases with medicinal products, and the issue of mutual recognition.

1. MUTUAL RECOGNITION

The 'principle of mutual recognition' as laid down in article 28 of the Treaty relating to the prohibition of quantitative restrictions between Member States, applies to those aspects of food supplements that are not yet harmonised. In principle it means that Member States are not allowed to prohibit or restrict, or make subject to administrative procedures having an equivalent effect, the import of products from another Member State if such a product is lawfully manufactured or marketed in the exporting Member State. Thus, they cannot prohibit the sale of such products on their territory, not even when those products are produced to technical or qualitative specifications that differ from those required in the importing Member State. The only reasons that are considered sufficient basis for import restrictions are those specified in article 30 of the Treaty: public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; and the protection of industrial and commercial property.

The principle of mutual recognition originated in the 'Cassis de Dijon' Judgement[8] and the European Court of Justice (ECJ) has established through numerous case law further criteria for the application of restrictive measures. Most important in this respect is that any measures taken must be compatible with the principles of necessity and proportionality, and the burden of proof to demonstrate the valid ground for one of the conditions spelled out in article 30 (including safety concerns) is on the Member State.

In practice, it can be difficult for food business operators to challenge enforcing authorities in this respect as they are dependent on them for many other aspects (licences, approvals, controls, etc). In practice therefore, industry generally conforms to national rules and adapts products and labels rather than going for a lengthy procedure to challenge the barriers to trade. The European Commission has however on several occasions taken administrative measures against certain Member States and finally taken Member States to court. In each of these cases, the ECJ ruled that the actions taken by the Member States were not in line with article 28 of the Treaty[9,10,11,12,13] and that Members States had therefore not fulfilled their obligations under the Treaty. Furthermore, the ECJ also ruled that articles 28 EC and 30 EC must be interpreted as meaning that they do not preclude a Member State from prohibiting the marketing without prior authorisation of foodstuffs lawfully manufactured and marketed in another Member State provided that certain conditions are satisfied. Firstly, the prior authorisation procedure must be readily

[8] Case 120/78, Rewe-Zentral AG v. Bundes-monopolverwaltung für Branntwein European Court Reports p. 649, 20/02/1979
[9] Case 387/99: 29/04/2004. Commission of the European Communities v. Federal Republic of Germany. OJ C118/2; 30/04/2004
[10] Case 24/00: 05/02/2004. Commission of the European Communities v. French Republic. OJ C85/2; 03/04/2004
[11] Case 150/00: 29/04/2004. Commission of the European Communities v. Republic of Austria. OJ C118/3; 30/04/2004
[12] Case 192/01: Commission of the European Communities v. Kingdom of Denmark. OJ C275/12. 15/11/2003
[13] Case 41/02: 02/12/2004. Commission of the European Communities v. Kingdom of The Netherlands. OJ C19:1; 22/01/2005

accessible and capable of being completed within a reasonable time. If it leads to a refusal, the decision must be open to challenge before the courts. Secondly, refusal to authorise marketing must be based on a detailed assessment of the risk to public health, based on the most reliable scientific data available and the most recent results of international research.[14]

Table 1 lists the relevant ECJ cases with respect to mutual recognition.

Table 1: Court Cases on free movement of goods in relation to food supplements (and fortified foods)

Case 387/99: Commission of the European Communities v. Federal Republic of Germany, April 2004.
Case 24/00: Commission of the European Communities v. French Republic, February 2004.
Case 150/00: Commission of the European Communities v. Republic of Austria, April 2004.
Case 95/01: Criminal proceedings against John Greenham and Léonard Abel, February 2004.
Case 192/01: Commission of the European Communities v. Kingdom of Denmark, September 2003.
Case 41/02: Commission of the European Communities v. Kingdom of The Netherlands, December 2004.

2. BORDERLINE ISSUES

One element of particular relevance to food supplements is the borderline with medicinal products. This borderline exists in the context of varying national traditions and practices in relation to interpretation, market, regulations, control and enforcement. However, there are a number of important factors in existing law that clarify the nature of this borderline.

First, recital 7 of the medicinal product Directive[15] states: “Where a product comes clearly under the definition of other product categories, in particular food, food supplements, medical devices, biocides or cosmetics, this Directive should not apply”. This is coherent with the view, expressed on several occasions by the EC, that it was not the intention of medicinal law to expand the registration procedure into the field of foodstuffs, but to change the definition to allow inclusion of novel medicinal therapies, such as gene therapy, cell therapies, xenogenic somatic therapy, radiopharmaceutical products and certain medicinal products for topical use. Also Recital 12 of the Traditional Herbal Medicinal Product Directive (THMPD)[16] clearly states that this Directive allows non-medicinal herbal products, fulfilling the criteria of food legislation, to be regulated under food legislation in the Community.

[14] Case 95/01: 05/02/2004. Criminal proceedings against John Greenham and Léonard Abel. OJ C 85/4; 03/04/2004

[15] Art 2 (2) of Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. OJ L 136/34, 30/04/2004

[16] Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use. OJ L 183/51, 30/04/2004

Secondly, the definition of medicinal product itself reads: “Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis”.

This definition therefore contains two distinct elements: a definition by virtue of its presentation, and a definition by virtue of function.

It is clear that if a product is presented as having properties for treating or preventing disease in human beings, it must conform to medicinal product legislation. This not only warrants that products promoted for their curative or preventive effects are assessed for their safety and efficacy, but also that products lacking such efficacy can effectively be removed from the market. It is however important to note that the therapeutic or preventive effect should relate to a disease. This inherently also means that claimed effects on bodily functions (eg lowers cholesterol) that do not refer to a disease should not be judged under this part of the definition.

This is also coherent with food law. For many years and in many legislative texts, including labelling, foods for particular nutritional uses[17] and food supplements, it has been clearly indicated that the labelling, presentation and advertising must not attribute to the said foodstuffs the property of preventing, treating or curing a human disease, nor refer to such properties. Furthermore, the recently adopted Nutrition and Health Claims Regulation (NHCR) defines health claims as all claims that state, suggest or imply a relationship exists between food or one of its constituents and health, including claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body. Based on the increasing knowledge of the relationship between food components and their influence on risk factors for specific diseases, the NHCR has also introduced the category of reduction of disease risk claims. This category was not generally allowed in the past but will be allowed in future when approved via an approval procedure. Therefore, although a potential overlap is possible with claims that relate to the preventive or curative properties, since their approval requires a decision, the chances of overlap and confusion will in practice be considerably reduced.

The inclusion of the ”function criterion” in the definition of a medical product refers to every product that may be used in or administered to human beings, which will obviously include all foodstuffs. But it specifies that in order to be able to fall under medicinal law, this use or administration should aim to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action. In theory at least, this offers the possibility to consider as medicinal products many functional substances present in foodstuffs that have an effect on physiological functions. However, this was clearly not the intention of the legislator, as already stated. This part of the definition is there to cover medicinal products that do not act on a specific disease but may nevertheless have a profound, be it a dangerous effect on the human physiology by blocking or suppressing physiological pathways (eg contraceptives, anaesthetics, etc), by correcting physiological functions that have been disturbed (eg oral antidiabetic drugs, hormones, etc) or by modifying the way in which the body functions (muscle relaxants, sedatives, etc). In that respect this is not

[17] Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses. Official Journal of the European Union L186/27. 30/06/1989

contradictory to the use of functional ingredients in foods for health promoting purposes.

It is no wonder that in the past a number of disputes have been settled before the ECJ[18,19,20,21,22,23,24]. In these cases, the ECJ has always ruled in the same way: It is the responsibility of the national authorities to determine, subject to review by the courts, whether or not each product constitutes a medicinal product within the meaning of the definition, having regard to all of its characteristics. These include its composition, its pharmacological properties as they may be ascertained in the current state of scientific knowledge, the way in which it is used, the extent to which it is sold, its familiarity to the consumer and the risks which its use might entail.

This means that it is possible in the current state of European law for a national authority to judge a specific product as a medicinal product on its territory, even when such a product is lawfully marketed as a food supplement in another Member State. But it cannot do so solely based on the definition and in a general way. It needs to perform a case by case assessment of each individual product and consider all relevant aspects.

This was confirmed by medicinal law through the recent amendment of article 2.2, states that in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply (Directive 2004/27 art 1.2). The scope of this provision is firmly limited to "cases of doubt" and is restricted to individual products. It thereby confirms the case by case assessment approach as established by case law.

The ECJ is of the opinion that the scope of the terms "restoring, correcting or modifying physiological functions" is broader than only "treating or preventing disease". In order to protect consumers by prohibiting the marketing of such products, it was judged to cover all products capable of having an effect on the actual functioning of the body - not only products which have a real effect on physiological functions but also those which do not have the advertised effect. An essential requirement for the interpretation of this functional requirement is therefore the presence of a medicinal purpose or therapeutic activity. Medicinal law therefore, cannot cover products which have an effect on the human body but do not significantly affect the metabolism and thus do not modify the way in which it functions. This is important because otherwise products such as soaps and vitamin supplements could be considered medicinal products on the basis of their antiseptic, hydratating, physiological, etc effects.

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[18] Case 227/82. 30/11/1983. Criminal proceedings against Leendert van Bennekom. European Court Reports 1983 page 3883

[19] Case C-369/88. Criminal proceedings against Jean-Marie Delattre. European Court Reports 1991 page I-1487

[20] Case C-60/89. Criminal proceedings against Jean Monteil and Daniel Samanni. European Court Reports 1991 page I-1547

[21] Case C-112/89. Upjohn Company and Upjohn NV v Farzoo Inc. and J. Kortmann. European Court Reports 1991 page I-1703

[22] Case C-290/90. Commission of the European Communities v Federal Republic of Germany. European Court Reports 1992 page I-3317

[23] Case C-219/91. Judgment of the Court (Fifth Chamber) of 28 October 1992. Criminal proceedings against Johannes Stephanus Wilhelmus Ter Voort. European Court Reports 1992 page I-5485

[24] Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03. Judgment of the Court (First Chamber) of 9 June 2005. References for a preliminary ruling from the Oberverwaltungsgericht für das Land Nordrhein-Westfalen: HLH Warenvertriebs GmbH, Orthica BC v Federal Republic of Germany, European Court Reports 2005 page I-5141

Table 2 lists the relevant ECJ cases with respect to borderline cases.

Table 2: Court cases in relation to borderline issues
Case 227/82: Criminal proceedings against Leendert van Bennekom. European Court Reports 1983.
Case C-369/88: Criminal proceedings against Jean-Marie Delattre. European Court Reports 1991.
Case C-60/89: Criminal proceedings against Jean Monteil and Daniel Samanni, March 1991.
Case C-112/89: Upjohn Company and Upjohn NV v Farzoo Inc. and J. Kortmann, April 1991.
Case C-290/90: Commission of the European Communities v Federal Republic of Germany, May 1992.
Case C-219/91: Criminal proceedings against Johannes Stephanus Wilhelmus Ter Voort, October 1992.
Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03: References for a preliminary ruling from the Oberverwaltungsgericht für das Land Nordrhein-Westfalen: HLH Warenvertriebs GmbH, Orthica BC v Federal Republic of Germany, June 2005.
Notice for the OJ: Action brought on 19 August 2005 by the Commission of the European Communities against the Federal Republic of Germany (Case C-319/05)

IV. RELEVANT DEVELOPMENTS OF OTHER ORGANISATIONS AND INSTITUTIONS

It is a fact that marketing products under medicinal law or under food law may have competitive advantages for individual companies in specific markets. This is mainly caused by the way in which markets and distribution channels have been traditionally structured between Member States. In some markets substances are mainly used in medicinal products and sold through pharmacies. In other Member States, they are mainly sold as food supplements and sold through retail, health shops, direct sales, etc.

This, and the fact that mutual recognition is frequently not applied, should be considered as factors that may complicate the harmonisation process. Furthermore, as harmonisation efforts progress both in the field of medicinal law and food law, care will need to be taken to arrive at a coherent approach which avoids confusion and borderline cases as much as possible.

On 28/10/2004 the EC organised a workshop on the "borderline with pharmaceuticals". From the discussions it became clear that there are currently not many borderline issues between food and medicinal products. The EC argued that further activities would only need to be considered once the food legal framework, including harmonisation of claims, fortification, setting of maximum levels for vitamins and minerals and the extension of the Food Supplements Directive to other substances would be completed[25]. These aspects are currently either accomplished (claims and fortification) or being considered by the EC (maximum levels, other substances).

Work in progress under medicinal law may also affect the marketing of food supplements containing other substances. As part of the application of the Traditional Herbal Medicines Directive (THMPD), the Herbal Medicinal Product Committee (HMPC) within the EMEA is currently developing monographs for medicinal products and establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. It is noted that these monographs concern many botanicals that are also currently widely used as ingredients in foods and food supplements (eg garlic, valeriana, senna, etc).

There is another development that may have an impact on future harmonisation of other substances used in food and food supplements. Companies may introduce applications for medicinal product licence of products containing certain substances (eg as in the case of glucosamine), which are marketed as food supplements in other Member States. Medicinal Law requires a case by case assessment of all the products' characteristics before a decision as to the applicable legal framework can be taken. But such a medicinal licence may be granted also at the EU level and therefore set a precedent for the use of the substance in foodstuffs, including food supplements, in all EU Member States.

Finally a number of activities by Member States and other European organisations in this field may influence legal activities. Apart from the activities of the EMEA HMPC on botanicals, these include the activities of EFSA on botanical products[26], the activities of the Council of Europe's ad hoc group on Food Supplements and the

[25] Workshop on 'Borderline Products with Pharmaceutical', 28/10/2004. Summary of discussions.
[26] Mandate for the Scientific Committee on botanicals and botanical preparations, Brussels, Ref. HK/sm (2005) 1094. 11/08/2005

activities of the sectors concerned[27]. Also the announced revision of the novel foods legislation may have an important impact on food supplements, especially botanical extracts and isolates.

[27] Use of Botanicals in Food Supplements. Regulatory Scope, Scientific Risk Assessment and Claim Substantiation. Coppens P. et al. Annals of Nutrition & Metabolism 2006:50:538-554. DOI: 10.1159/000098146.

V. REGULATORY MODELS OUTSIDE THE EU

The diversity of regulatory approaches seen in the European Union is equally prevalent outside the EU. Five regulatory models were reviewed. Two of these, China and the US, base their food supplement rules within the framework of food law; in Japan, a specific category for food supplements has not been established; Australia and Canada place it within the framework of medicines law.

Australia

Food supplements are regulated in Australia as complementary medicines by the Therapeutic Goods Administration (TGA). 'Complementary medicines' include vitamin, mineral, herbal, aromatherapy and homeopathic products.

All complementary medicines are evaluated according to their level of risk. Products assessed as having a higher level of risk are assessed for their quality, safety and efficacy. Products assessed as having a lower risk, such as food supplements, are assessed for quality and safety only.

Low-risk products, including food supplements, may only be composed of approved substances. All substances that are permitted for use in such food supplements are placed on the positive list by the TGA, including technological additives, colours etc. Any substance that is not on the positive list and has not already been reviewed is evaluated by the Complementary Medicines Evaluation Committee following the submission of an evaluation application form by a company. Currently, several hundred substances such as botanicals and amino acids are included on the Australian positive list.

The Australian and New Zealand authorities have been working to establish a Trans Tasman regulatory system in this area for some years which would create one single framework for complementary medicines. This work has been held up due to fears that the costs of conforming to the Australian requirements will put many small and medium-sized New Zealand companies out of business, since they have previously been trading within the very different New Zealand regulatory framework for supplements which is based within food law.

Canada

Food supplements are covered by the Natural Health Product Regulations of 2003. Natural Health Products (NHPs) may contain a wide range of substances from plants and plant extracts to amino acids, vitamins and probiotics. All NHPs must be registered with the Natural Health Products Directorate (NHPD) and must carry a Product License number.

The NHP Regulations contain a list of "acceptable non-medicinal substances" that are generally regarded to be of minimal toxicological concern, including vitamins, herbs and many other bioactive substances. This list also contains requirements for the use of the ingredients in some cases, including, for example, the plant part or the maximum level.

Where a company decides to use ingredients from this list of acceptable non-medicinal substances and they are within the specified conditions for the use of these ingredients, no further assessment of the substances is carried out by the NHPD.

China

China regulates food supplements within the category of Health Foods. Health food products may only be manufactured, marketed or imported if they obtain an approved code number issued by the State Food and Drug Administration (SFDA). The SFDA maintains positive and negative lists of substances that may be used in health foods/food supplements, including lists of botanicals, fungi and probiotics.

These lists include:

- 87 substances that may be used in health foods and which are also used widely in Chinese medicines, including many botanicals.

- 114 substances that cannot be used in general food, but can be used in health foods, including ginseng, aloe and abalone.

- 11 fungi that can be used in health foods.

- Probiotic bacteria that can be used in health foods.

- 59 substances that may not be used in health foods, mainly including botanicals and substances from certain wild animals.

Modifications to the lists are evaluated by the SFDA, in some cases on the basis of submissions from companies marketing in the region.

Japan

There is currently no legal definition or classification of food supplements in Japan.

Much of the clarification on which non-vitamin and mineral substances can be used is provided in the Pharmaceutical Affairs Law. This seeks to provide a degree of clarification on what substances are not restricted to medicines use and can therefore be used in food supplements.

The Pharmaceutical Affairs Law therefore provides a long list of substances that are permitted to be used in foods. Since 2001 reviews have been carried out by the Ministry of Health Labour and Welfare which have resulted in moving substances away from pharmaceutical-only status so that they can be used in food supplements. For example:

- 1st Review, March 2001: coenzyme Q10 was given approval to be used in foods/food supplements.

- 2nd Review, November 2002: carnitine changed status.

- 3rd Review, March 2004: alpha-lipoic acid changed status.

The most recent change was published in December 2006 when a further 55 ingredients (mainly herbs) were added to the list of substances that can also be used in foods/food supplements.

Where appropriate, the part of the plant that is permitted for food use is established in the list. Guidelines for maximum levels only exist for vitamins and minerals.

United States

Food supplements are regulated under the 1994 Dietary Supplement Health Education Act (DSHEA). A wide range of substances are encompassed by the definition of a dietary supplement in DSHEA, including botanicals, amino acids and other substances for use to supplement the diet.

Under DSHEA, food supplements do not need to be approved by the Food and Drug Administration prior to marketing but manufacturers must ensure that the products that are placed on the market are safe and contain the ingredients listed on the label.

There is no formal list of other substances that may be used. However, DSHEA does require any manufacturer or distributor of any ingredient that was not on the market before DSHEA was adopted in 1994 to submit a New Dietary Ingredient (NDI) notification to the FDA at least 75 days before placing the product on the market. The FDA must then review the data during the course of the 75 days and may request further data if necessary. If the FDA has provided no comment within the 75-day period, the company is free to market the ingredient.

In order to ensure maximum clarity of what was on the market prior to 1994, the US trade associations developed a number of ‘grandfather lists’ of substances. While these have no specific legal value, they are still used as a reference point by companies in deciding whether an NDI notification is necessary or not.

The FDA is currently in the process of reviewing and further clarifying the NDI process.

Based on information provided by government and industry experts, the following chart illustrates the regulatory status of a number of other substances for use in ‘food supplements’, as defined in the countries covered in this section.

VI. INTERACTION WITH OTHER EU LEGISLATIVE FRAMEWORKS

1. EU FOOD LAW PROVISIONS APPLICABLE TO FOOD SUPPLEMENTS

The legal framework for foodstuffs is applicable to food supplements that are marketed in the European Community. Some of the regulations applicable to foodstuffs or their application have specific consequences for food supplements containing other substances. A short overview and potential interactions with other EU food legislative frameworks with other substances is described below:

1.1 General Food Law Regulation[28]

This Regulation specifies an EU-wide definition of a foodstuff and lays down amongst others the responsibilities of food business operators in relation to food safety. These responsibilities include the obligation that foods put on the market are safe, to ensure traceability of products on the market, to be able to immediately initiate procedures to withdraw foods that are not or suspected not to be in compliance with the food safety requirements and to inform the competent authorities thereof.

It also lays down the missions and tasks of the European Food Safety Authority (EFSA), which is now involved in a number of activities that are directly relevant to food supplements (eg the establishment of tolerable upper levels of vitamins and minerals; guidance on the scientific evaluation of health claims and subsequent assessments; involvement in risk assessment under chapter three of the Addition of Nutrients legislation; assessment of nutritional substances submitted in conformity with article 4.6 of the Food Supplements Directive, the self-tasking mandate on botanicals and botanical ingredients, etc). It is generally considered that the establishment of the General Food Law Regulation creates a legal counterpart of medicinal law, effectively regulating the safety aspects of foodstuffs, including food supplements.

1.2 Novel Foods Regulation[29]

This Regulation specifies the requirements for putting on the market novel food ingredients, ie ingredients corresponding to the definition of novel foods that were not marketed in the EU to a significant degree prior to May 1997. This legislation has important consequences for the marketing of certain specific substances used in food supplements because of the unclear interpretations and application of the law. This is illustrated by the following examples:

- The point at which a new ingredient becomes a novel food can be interpreted in different ways. Substances for use in food and food supplements can be produced to several degrees of purity from raw materials. It may be the unchanged raw material, be refined, be isolated, extracted and purified. When using traditional raw materials and conventional processing methods, such ingredients would normally not fall under the scope of the novel foods legislation. This is

[28] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L31/1. 01/02/2002

[29] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L43/1. 14/02/1997

however, not the view of all and some argue that as soon as a substance is extracted or isolated or undergoes a purification step, novel foods legislation applies. And it appears that the current EC opinion is that a novel extract that differs significantly from an established extract might require authorisation as novel food. It is quite difficult to assess what would be significantly different in this respect. This is aggravated by the fact that some novel food dossiers are introduced and accepted for conventional substances which then can act as a precedent for other substances that have already been on the market for years (eg the application for lycopene oleoresin from tomatoes). A conservative interpretation that all new extracts or isolates would have to undergo a novel foods approval would cover many more products than currently is the case, and affect many of the food supplement producing companies.

- The notion of an ingredient/food being on the market "to a significant degree" is difficult to define and has resulted in considerable interpretation difficulties. This culminated in the agreement of the Standing Committee of the Food Chain and Animal Health during their session of 14/02/2005 that an ingredient used in a food supplement that was on the market prior to 15 May 1997 would not require a novel food authorisation, whereas such authorisation would be required for other, non-food supplement use (the lycopene application was such a case). Moreover, there is also a novel food Working Group where issues concerning the novelty or the consumption to a significant degree are discussed,

- It is not always feasible to seek clarification as to the status of an ingredient. Enquiries with national authorities can give divergent replies and the classification of only a few substances are discussed by the Working Group. The Member States informally discussed the status of many ingredients used and included the results of this reflection in an unofficial internal document, the so-called "EU novel food catalogue". This catalogue is said to contain many substances used in foods and food supplements and their status. However, since the document is not public, manufacturers are not aware of the informal opinion on the status of their ingredients until confronted with the opinion of a Member State as to the status of their ingredient.

- A negative decision on a dossier by one applicant may affect the marketing of the same substance in the Member States. This was the case with betaine. The EC decision to a particular applicant on 25/07/05 mentioned that betaine must not be placed on the market as a food or food ingredient. It is important to highlight that the initial request was for the use of betaine in beverages, cereal products, confectionery and dairy products and the EC decision was based on EFSA's opinion. This opinion explicitly indicated that the safety evaluation of betaine was only undertaken for the intended use as proposed by the applicant. A number of Member States however wrongly interpreted this decision as applying to all forms of betaine, and tended to prohibit its use in all food applications including food supplements.

These are some examples of the consequences the Novel Food Regulation currently has on certain ingredients used in food supplements. A revision of

this legislation is expected. This revision could have an important impact on the market of other substances used in the manufacture of food supplements for the reasons illustrated above.

1.3 Legislative framework on additives[30] (including the sub-directives on sweeteners[31], colourings[32] and others[33])

Food supplements have been specifically included in these Directives (mostly referred to as food or dietary supplement). All additives allowed to be used in food supplements are specified, including in many cases their purity criteria.

Another aspect is that some substances that are approved for additive uses may also be used as an ingredient in food supplements for their health effects. This is the case with a number of nutrients (eg vitamin C (E 300), Vitamin E (E 307), many nutritional substances (eg calcium carbonate (E 170), magnesium chloride (E 511)…) and a number of other substances (eg lecithin (E 322), …).

1.4 Directive on permitted extraction solvents[34]

This Directive specifies the extraction solvents that are allowed for use in the production of foodstuffs. This is important in relation to the production of many herbal extracts.

1.5 Legislative framework on residues of contaminants[35]

Maximum levels of certain contaminants[36] have been established for many foodstuffs but not yet for food supplements. Discussions on levels for food supplements are currently being undertaken.

1.6 Hygiene rules[37]

The hygiene legislation imposes an obligation upon food supplements manufacturers at all stages of production, processing and distribution to put in place, implement and maintain a permanent procedure based on the principles of HACCP. These include also specific rules on foods from animal origin[38] and the organisation of official controls[39]. In particular, the obligation

[30] Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption. OJ L40/27. 11/02/1989

[31] European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs. OJ L237/3. 10/09/1994

[32] European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs. OJ L237/13. 10/09/1994

[33] European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. OJ L61/1. 18/03/1995

[34] Council Directive of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. OJ L157/28. 24/06/1988

[35] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food. OJ L37/1. 13/02/1993

[36] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs OJ L364/5. 20/12/2006

[37] Corrigendum to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. OJ L226/3. 25/06/2004

[38] Corrigendum to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. Official Journal of the European Union L226/22. 25/06/2004

to establish documents and records to demonstrate the effective application of the HACCP measures is important for controlling authorities as a tool to assess compliance with these rules.

1.7 General food labelling legislation[40]

This Directive is applicable to food supplements, without prejudice to specific rules specified in the Food Supplements Directive.

1.8 Foods for Particular Nutritional Uses (PARNUTs – dietetic foods)

Parnuts legislation[41] may have an influence on food supplement legislation in two ways:

All product characteristics should be taken into account to correctly classify it as a food supplement or a Parnuts product, which is not always easy. However, it is important to highlight that only one legislation applies to each product category; food supplements are subject to the EU Directive 2002/46 and Parnuts subject to EU Directive 89/398.

There is already a positive list of a number of substances that may be added to Parnut foods. This list mainly contains forms of vitamins and minerals and is currently virtually identical to the lists included in the food supplements and addition of nutrients legislation. But it also contains amino-acids, carnitine, taurine, nucleotides, choline and inositol. This Directive[42] specifies that for the categories listed only the chemical substances mentioned under each category may be used. No restrictions are imposed to substances that do not belong to one of the categories listed. This has as particular consequence that the creation of a new category for including a substance has as consequence that all other substances of this category would become illegal (eg was the case with creatine (creatine monohydrate) that was ultimately not added). One of the options could be that for the extension of the food supplement Directive to other substances the Parnut lists are used.

1.9 Regulation on nutrition and health claims[43]

This Regulation will have a significant effect on the harmonisation of other ingredients in food supplements. It is fully applicable to food supplements, lays down the definition of health and reduction of disease risk claims and the modalities for their approval. This legislation covers communication to the consumer on the product's health effects.

The list provided for under article 13 will be established as a positive list of health claims. This list will contain the nutrient or other substance, the health

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[39] Corrigendum to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Official Journal of the European Union L226/83. 25/06/2004

[40] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. OJ L109/29. 06/05/2000

[41] Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses. OJ L186/27. 30/06/1989

[42] Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses. OJ L52/19. 10/02/2004

[43] Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L12/3. 18/01/2007

claim and any conditions of use. It is clear that for the majority of substances in use today a claim will be submitted. Furthermore, an application for a health claim may include conditions of use, such as minimum levels.

The list is intended to harmonise the use of health claims for all other substances used in food supplements. It may thereby also indirectly harmonise the use of these substances and their conditions of use in foods and food supplements.

Finally, the choice of the scientific criteria that EFSA will use to evaluate claims will have an impact on the number of claims approved.

1.10 Regulation on the addition of nutrients and other substances to foods[44]

Chapter three of this legislation is also applicable to other substances that are used in food supplements. It provides for a system whereby substances can be subjected to EFSA risk assessment when they are added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of these substances greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers. The commission itself, or following a request from MS may initiate the procedure in order to list a certain substance on a list in order to prohibit or restrict its use. The application date of the Regulation is 1 July 2007 and therefore the lists are currently empty. It is feasible that the system will be used to include specific substances that were already found in one of the earlier versions of the proposal (eg guarana, taurine, glucuronolactone, kava kava, etc)[45].

In summary, the harmonised legal framework covering food supplements is quite extensive and deals with most aspects relevant for consumer protection. It covers food operator responsibilities, processing modalities, consumer information and procedures to deal with safety concerns. In itself it is already a significant basis for intra-community trade.

[44] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L404/26. 30/12/2006

[45] Commission of the European Community. Preliminary draft proposal for a Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods. SANCO/329/03. 17/01/2003

VII. CONCLUSIONS

This report indicates that the EU food supplement market is economically important and continues to grow as a whole, with non vitamin and mineral ingredients providing almost half of the total market at this point, and potentially a greater share in the future.

There is currently a wide variation of regulatory and non-regulatory approaches across the EU which have their origin in different traditions, markers and regulatory frameworks. Of many the ingredients surveyed, there was significant acceptance by the Member State authorities that they could be used in food supplements, albeit in some countries with varying conditions of use. Botanicals, however, remain the most complex area, with some countries maintaining a wide list of botanical ingredients that may be used and others permitting only a very limited list. For example, there was general acceptance of ginseng in more than 20 countries, while this dropped to 15 for ginkgo. This demonstrates not just the complexity of the category but variation within it.

There are currently a number of regulatory initiatives within food law that may have a direct or indirect impact on the 'other ingredients'. These include the revision of novel foods Regulation and the entry into force of the Regulation on the addition of vitamins, minerals and other substances to food. Notably, the most significant implications could come from the entry into force of the Regulation on nutrition and health claims and in particular the development of the positive list of claims under article 13 of the Regulation.

This report highlights many of the issues that would need to be considered before any decision is taken to harmonise further ingredient categories for use in food supplements across the Community. While the divergence of regulations remains considerable, the market in such products continues to grow in those countries where such products may be legally sold. It is therefore clear that ensuring that regulatory actions are in tune with the market evolution is one area that will need to be considered carefully in any future decisions in this area.

ANNEX

THE USE OF SUBSTANCES WITH A NUTRITIONAL OR PHYSIOLOGICAL EFFECT OTHER THAN VITAMINS AND MINERALS FOOD SUPPLEMENTS

- QUESTIONNAIRE -

Please enter the full name of the responsible authority department and contact details. This information is purely to facilitate the co-ordination of responses and to follow up on any missing information.

Authority_____

Key contact person _____

Contact tel. no. _____

Contact e-mail _____

To select YES / NO, please double click on the grey boxes and select "checked" in the window that appears.

PART A

NATIONAL REGULATIONS ON THE USE OF OTHER SUBSTANCES IN FOOD SUPPLEMENTS

Q.A1. How is the use of substances other than vitamins and minerals (ie botanicals and other bioactive substances) in food supplements regulated in your country?

a. **Regulatory Approach (specific legislation)**

NO ☐
YES ☐

If yes, please enclose a copy or reference:

_____
_____

b. **National list(s) of botanicals**

List of permitted botanicals		**List of prohibited botanicals**	
NO	☐	NO	☐
YES	☐	YES	☐

If yes, please enclose a copy or reference:

_____
_____

c. **National list(s) of bioactive substances**

List of permitted bioactive substances		**List of prohibited bioactive substances**	
NO	☐	NO	☐
YES	☐	YES	☐

If yes, please enclose a copy or reference:

_____
_____

d. Non-Regulatory/Administrative approaches (guidance notes, database, agreements…)

NO ☐
YES ☐

If yes, please specify and enclose a copy, if possible:

_____

_____

_____

e. Notification or authorisation procedure in place

NO ☐
YES ☐

If yes, please specify and enclose a copy where possible.

_____

_____

_____

Q.A2. If national list(s) of botanicals and other bioactive substances exist:

a. How have these been established? Please select and specify, if possible:

Options	Please check	Please comment/specify
Based on risk assessment from existing safety models	☐	
Upon advise of responsible scientific national body	☐	
By risk management decision	☐	
After consultation of involved sectors	☐	
Others	☐	

b. What is the scope of such list(s)?

i. These lists apply to the following food categories:

- food supplements ☐
- common foodstuffs ☐
- Others (please specify): ☐

_____

_____

_____

ii. Substances covered by these lists:

- Other bioactive substances (e.g. non-nutrient, non-botanical substances) ☐
- Botanicals (e.g. whole herbs, mushrooms, ...) ☐
- Botanical preparations (e.g. extracts, isolates, ...) ☐
- Pre- and probiotics ☐

- Others (please specify): … ☐

_____

_____

_____

c. Is there any work foreseen on the currently existing positive or negative list(s) of substances other than vitamins and minerals?

Other bioactive substances	NO	☐
	YES	☐
Botanicals and botanical preparations	NO	☐
	YES	☐

Q.A3. If no national list(s) exist(s), is work on positive or negative lists of substances other than vitamins and minerals currently being undertaken or under discussion?

Other bioactive substances	NO	☐
	YES	☐
Botanicals and botanical preparations	NO	☐
	YES	☐

PART B

REGULATORY STATUS OF TYPICAL SUBSTANCES USED IN FOOD SUPPLEMENTS

Q.B1. Is the use of the following substances allowed in food supplements (F.S.)?

Product Group: Amino acids	**F.S.**	**Conditions of use** (in legislation, guidelines, administrative practice…)
L-arginine	NO ☐	
	YES ☐	
Other essential amino acids	NO ☐	
	YES ☐	
Non-essential amino acids	NO ☐	
	YES ☐	

Product Group: Enzymes	**F.S.**	**Conditions of use** (in legislation, guidelines, administrative practice…)
Lactase	NO ☐	
	YES ☐	
Papaine	NO ☐	
	YES ☐	

Product Group: Pre- and Probiotics	**F.S.**	**Conditions of use** (in legislation, guidelines, administrative practice…)
Inulin	NO ☐	
	YES ☐	
Lactobacillus acidophilus	NO ☐	
	YES ☐	

Bifidobacterium species	NO ☐	
	YES ☐	
Yeast species	NO ☐	
	YES ☐	

Product Group: Essential fatty acids	**F.S.**	**Conditions of use** (in legislation, guidelines, administrative practice…)
Gamma-linolenic acid	NO ☐	
	YES ☐	
EPA/DHA	NO ☐	
	YES ☐	

Evening Primrose oil *(Oenothera biennis* (L.))	NO ☐	
	YES ☐	
Borage oil *(Borago officinalis)*	NO ☐	
	YES ☐	
Flax seed oil *(Linum usitatissimum* (L.))	NO ☐	
	YES ☐	

Product Group: **Botanicals and botanical extracts**	**F.S.**	**Conditions of use** (in legislation, guidelines, administrative practice…)
Aloe (*Aloe vera* (L.))	NO ☐	
	YES ☐	
Ginkgo *(Ginkgo biloba)*	NO ☐	
	YES ☐	
Ginseng *(Panax ginseng)*	NO ☐	
	YES ☐	
Garlic *(Allium sativum* (L.))	NO ☐	
	YES ☐	
Green tea extract *(Camellia sinensis)*	NO ☐	
	YES ☐	
Garcinia extract *(Garcinia cambogia)*	NO ☐	
	YES ☐	
Guarana extract *(Paullinia cupana)*	NO ☐	
	YES ☐	

Product Group: Miscellaneous bioactive substances	**F.S.**	**Conditions of use** (in legislation, guidelines, administrative practice…)
Lycopene	NO ☐	
	YES ☐	
Lutein	NO ☐	
	YES ☐	
Coenzyme Q10	NO ☐	
	YES ☐	
Taurine	NO ☐	
	YES ☐	
Carnitine	NO ☐	
	YES ☐	
Inositol	NO ☐	
	YES ☐	
Glucosamine	NO ☐	
	YES ☐	
Chitosan	NO ☐	
	YES ☐	
Spirulina	NO ☐	
	YES ☐	
Soy isoflavones	NO ☐	
	YES ☐	

PART C

CONTROL AND ENFORCEMENT

Q.C1. How are regulations on the use of substances in food supplements enforced and controlled? Please specify, where possible:

Options	Please check	Please comment/specify
By national enforcement authorities	☐	
Product composition control	☐	
Product label control	☐	
Notification	☐	
Inspections at company premises	☐	
Store checks	☐	
Others	☐	

Q.C2. Who is responsible for dealing with disputes on the legal status and modalities of use of substances in food supplements? Please specify the responsible control / enforcement authority in your country:

_____
_____
_____
_____
_____

Q.C3. What procedure is in place or applied if a dispute arises in relation to the legal status or modalities of use of substances in food supplements? Please specify:

_____
_____
_____
_____
_____

Q.C4. Is mutual recognition applied in relation to products lawfully produced in other EU Member States?

_____
_____
_____
_____
_____

We thank you for taking the time to complete this questionnaire.