

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Voluntary Public

Date: 1/11/2017

GAIN Report Number: E17004

EU-28

Post: Brussels USEU

Exporting Food Supplements to the European Union

Report Categories:

FAIRS Subject Report

Product Brief

Approved By:

Karisha Kuypers

Prepared By:

Food Compliance Int., Hilde Brans, Gerda Vandercammen

Report Highlights:

Marketing food supplements in the European Union (EU) is a complex issue. Food Supplements Directive 2002/46 only contains EU-harmonized rules on labeling and authorized vitamins and minerals. Key aspects in the marketing of food supplements such as minimum and maximum levels for vitamins and minerals and the use of botanical ingredients are subject to the Member States' national rules. Food supplements containing animal origin ingredients must comply with the EU's veterinary inspection and certification rules. This report provides an overview of the main EU legislation applicable to food supplements.

CONTENTS

EXPORTING FOOD SUPPLEMENTS TO THE EU	4
FRAMEWORK LEGISLATION: DIRECTIVE 2002/46	4
DEFINITIONS.....	4
VITAMINS AND MINERALS	4
MAXIMUM AND MINIMUM LEVELS.....	5
PURITY CRITERIA OF THE SOURCES.....	5
OTHER SUBSTANCES	5
BOTANICALS.....	6
NATIONAL LISTS – OTHER SUBSTANCES.....	7
LABELING	7
SPECIFIC MANDATORY LABELING REQUIREMENTS- DIRECTIVE 2002/46.....	7
NOTIFICATION PROCEDURE (ARTICLE 10).....	8
HORIZONTAL RULES APPLICABLE TO FOOD SUPPLEMENTS.....	8
NOVEL FOODS	8
FOOD ADDITIVES	10
GENERAL MANDATORY LABELING REQUIREMENTS (REGULATION 1169/2011).....	10
NUTRITION AND HEALTH CLAIMS	11
BORDERLINE PRODUCTS	13
TRADITIONAL HERBAL MEDICINAL PRODUCTS.....	14
MUTUAL RECOGNITION	15
COMPLIANCE WITH EU FOOD LEGISLATION.....	16
TARIFF RATE QUOTA FOR U.S. ORIGIN PRODUCT	18
VETERINARY INSPECTION AND CERTIFICATION	19
ANNEX I: LIST OF MAIN EU LEGISLATION APPLICABLE TO FOOD SUPPLEMENTS	21
ANNEX II: CONTACT INFO FOR EU FOOD SUPPLEMENT ORGANIZATIONS	23
ANNEX III: AUTHORIZED VITAMINS AND MINERALS IN FOOD SUPPLEMENTS.....	24

ANNEX IV: AUTHORIZED VITAMINS AND MINERAL SUBSTANCES IN FOOD SUPPLEMENTS
..... 25

ANNEX V: NOTIFICATION BASIS FOR BORDER REJECTIONS (RASFF 2014-2016) 31

EXPORTING FOOD SUPPLEMENTS TO THE EU

In the European Union (EU), [Directive 2002/46/EC](#) on “the approximation of the laws of the Member States relating to food supplements” defines food supplements as “food.” This means that all exports of food supplements to the EU must comply with horizontal rules applicable to all foods (including laws on additives, labelling, claims, hygiene, contaminants, GMOs) in addition to the specific rules applying exclusively to food supplements.

Marketing food supplements in the EU is a complex issue which requires careful consideration. Directive 2002/46/EC only contains harmonized rules on labeling and authorized vitamins and minerals and their forms. Key aspects in the marketing of food supplements such as maximum and minimum levels of vitamins and minerals, or the use of other substances such as botanical extracts, essential fatty acids or fiber, remain the competence of the EU Member States. Given their different traditions and approaches, exporters should be aware that having a single product formula which can be used in all 28 EU Member States is rather exceptional, and adjustments for several national markets may be needed.

To complicate things even further, exporters can encounter divergent interpretations of harmonized rules among the authorities of the EU countries. This can be the result of the different understandings of a harmonized rule or of the different implementation of Directive 2002/46 into the national laws of the EU28. Unlike “Regulations,” which are directly applicable in the EU countries, “Directives” need to be implemented into national law, leaving the Member States some margin of discretion. This results in exporters finding, for example, that their product has been classified as a food supplement in one EU Member State but as a regular food in a second Member State, or even as a medicinal product in a third one.

FRAMEWORK LEGISLATION: DIRECTIVE 2002/46

[Directive 2002/46](#) sets out specific labeling and compositional rules for food supplements. Food supplements which do not comply with the Directive are prohibited in the EU.

DEFINITIONS (DIRECTIVE 2002/46 - ARTICLE 2)

“**Food supplements**” means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

“**Nutrients**” means the following substances: (i) vitamins, (ii) minerals.

VITAMINS AND MINERALS (DIRECTIVE 2002/46 - ARTICLE 4)

Only vitamins and minerals listed in Annex I of Directive 2002/46, in the forms listed in Annex II, can be used for the manufacture of food supplements in the EU. The Directive does not lay down rules for the use of other substances with a nutritional and physiological effect such as botanicals, amino acids, essential fatty acids, fiber, etc. Annex III of this Report lists the authorized vitamins and minerals, and Annex IV, their authorized forms.

MAXIMUM AND MINIMUM LEVELS

EU-harmonized minimum and maximum levels of vitamins and minerals have not been adopted yet. In the absence of harmonization, exporters should check whether national rules exist in the countries where they are intending to sell. Some examples include:

UK	Safe Upper Levels for Vitamins and Minerals
FRANCE	Decree of 6 May 2006 on nutrients to be used in the production of food supplements
BELGIUM	Royal Decree of 3 March 1992 on the placing on the market of nutrients and foods with added nutrients
ITALY	Daily levels of vitamins and minerals allowed in food supplements, June 2016

PURITY CRITERIA OF THE SOURCES

There are no EU-harmonized purity criteria for the authorized sources of vitamins and minerals. In their absence, exporters should consult purity criteria which may have been laid down at national level or by EU rules applicable to additives. Finally, generally acceptable purity criteria recommended by international bodies should be consulted if none of the above is available.

OTHER SUBSTANCES

As stated above, food supplements often include substances other than vitamins and minerals which may have a nutritional or physiological effect. Those substances are not regulated by Directive 2002/46. They are sometimes covered by national legislation, and very often, there are no rules clarifying their status.

As an exception to this rule, substances approved for use in the manufacture of foods for particular nutritional uses can also be used in the manufacture of food supplements. For this reason, ingredients such as choline and inositol, several amino acids, carnitine or taurine, which are included in [Regulation 609/2013](#) on foods for special groups, are also permitted in food supplements.

In a [report on the use of substances other than vitamins and minerals in food supplements](#) (published in December 2008), the European Commission concludes that the use of such substances should not be regulated at EU-level. According to the Commission, “mutual recognition” should be sufficient to ensure the free movement of food supplements in the EU. Unfortunately this is not always the case, as explained in the chapter on mutual recognition.

BOTANICALS

Botanical preparations have a wide variety of applications. They can fall under different regulatory regimes depending on their intended use and presentation. As they are not regulated by Directive 2002/46, their use in food supplements may be subject to legislation at national level.

Some EU Member States have adopted lists of prohibited and/or authorized plants and plant parts in their legislation, other Member States have guidelines and unofficial lists. Most Member States do not have specific regulations on the use of botanicals. Some examples of national legislation are provided below:

BELGIUM

Belgium has a long tradition in the use of plants in food supplements. Botanicals in Belgium are regulated since 1997. This means that the safety of more than 1000 plants and their parts have been assessed by the authorities. This is why exporters with food supplements including botanicals tend to notify their products in Belgium first, as obtaining authorization opens the door of other countries via the mutual recognition principle. Botanicals are regulated under [Royal decree of 29 September 1997 relating to the manufacture and trade in foods composed of or containing plants or plant preparations](#). A list with assessments is available on their [website](#). For the inclusion of new plants in the Decree, the authorities have published a [guideline](#).

FRANCE

France has adopted a [Decree on botanicals authorized in food supplements](#) in 2014, establishing a positive list of plants similar to that approved in Belgium.

ITALY

Italy currently has two different positive lists of plants in force, the [Decree of July 9, 2012](#) and the so-called [BELFRIT list](#). Both lists may currently be used, but it is foreseen that the BELFRIT will become the sole applicable list once finalized.

GERMANY

Germany has adopted a [list of plants and plant parts](#), providing guidance on possible medicinal properties, novel status and safety issues. The list has no normative status but serves as a reference guide for authorities and food business operators.

Faced with the fact that the legislation on botanicals is not EU-harmonized, the Belgian, French and Italian authorities decided to develop a common approach for the evaluation of botanicals under the ‘BELFRIT’ project. A first step in this initiative was the compilation of a list of approved plants in food

supplements. This list provides a precise identification of the plants, indicates some key points in the production to be controlled, while also taking information about the traditional use of these botanicals into account.

Although this project has initiated a harmonization between some EU Member States, the differences with other Member States remain substantial.

NATIONAL LISTS – OTHER SUBSTANCES

Other substances may be subject to legislation at national level. Few EU Member States have adopted national legislation. Some examples follow:

BELGIUM	<u>Ministerial Decree of 19 February 2009 on the production and placing on the market of food supplements containing substances other than nutrients and plant or plant preparations</u>	Choline, carnitine, ubiquinone
ITALY	<u>Other nutrients and substances with a nutritional or physiological effect, revision of June 2016</u>	Various substances
FRANCE	<u>Order defining the list of substances authorized in food supplements for nutritional or physiological purposes and the conditions for their use</u> (not adopted yet)	Caffeine, carnitine, creatine, lycopene

LABELING

SPECIFIC MANDATORY LABELING REQUIREMENTS- DIRECTIVE 2002/46

Under Articles 6-9 of Directive 2002/46, food supplement labels must include the following information:

- The names of the categories of nutrients or substances that characterize the product (e.g. vitamins, protein, plant extracts);
- the portion of the product recommended for daily consumption;
- a warning not to exceed the stated recommended daily dose;
- a statement to the effect that food supplements should not be used as a substitute for a varied diet;
- a statement to the effect that the products should be stored out of the reach of young children.

Other important specific labeling rules which exporters need to consider are:

- Labeling or advertising claims suggesting that a balanced and varied diet cannot provide appropriate quantities of nutrients in general are not allowed;

- The amount of the nutrients (vitamins/minerals) or other substances have to be declared per daily dose. The required units and specific names (e.g. niacin instead of vitamin B3) are laid down in the Directive. In addition, the amounts of the vitamins and minerals must also be expressed as a percentage of the Reference Intakes. The Reference Intakes are set out in Annex XIII of the [Food Information to Consumers Regulation 1169/2011](#).

Example of labeling with amount of nutrients per daily dose and reference intakes:

	Amount per daily dose	% Reference Intake
Vitamin C	80 mg	100%
Vitamin D	3 µg	60%
Green tea extract	100 mg	-

- Nutrients and substances with a nutritional or physiological effect may be declared only if they are present in a “significant amount,” capable of producing a nutritional or physiological effect. For vitamins and minerals this means 15 percent of the Reference Intakes. Nutrients present in lower amounts cannot be declared. Their sources should, however, always be included in the list of ingredients.

NOTIFICATION PROCEDURE (ARTICLE 10)

Directive 2002/46 provides that EU Member States may require the manufacturer or the person placing food supplements on the market in their territory to notify the competent authority by forwarding it a model of the label used for the product.

Most Member States (except the U.K., Netherlands, Sweden and Austria) currently have a notification procedure in place for food supplements. The procedure ranges from a mere submission of the label to a factual pre-market authorization. In some EU countries, the procedure includes a stand-still period after the notification before the product may be placed on the market.

HORIZONTAL RULES APPLICABLE TO FOOD SUPPLEMENTS

As food supplements are defined as foods, they are subject to a myriad of horizontal rules in addition to the specific rules set out in Directive 2002/46. A summary of the most relevant provisions follows.

NOVEL FOODS

Foods and food ingredients which have not been consumed to a significant degree by humans in the EU prior to May 15, 1997, are subject to the rules of [Regulation 258/97](#) on novel food and novel food ingredients.

Novel foods can be newly developed, innovative food or food produced using new technologies and production processes as well as food traditionally eaten outside of the EU. Examples of authorized novel foods include agriculture products from non-EU countries (e.g. chia seeds), newly produced nutrients (e.g. synthetic zeaxanthin) or extracts from existing food (e.g. rapeseed protein).

Novel foods require pre-marketing approval. The procedure is long and cumbersome and often takes several years. Exporters should be aware of the novel status of every ingredient they use. If control authorities question the status of an ingredient, they will be required to provide evidence of the non-novel status. This in practice means that exporters should always be prepared to show proof of consumption in the EU before 1997 of their ingredients.

In practice, novel food classification is one of the most common obstacles to the commercialization of food supplements in the EU and should be addressed as early as possible in the phase of adaptation of the U.S. formula to EU regulations.

Determination of novel status

Some guiding steps for establishing novel status are provided below.

1. Assess whether the ingredient is excluded from the scope (food additive, flavoring, extraction solvent or food enzymes are excluded);
2. Assess whether there is any doubt as to the significant history of consumption in the EU before May 15, 1997. Note that the significant consumption should be as foods (regardless the category). Consumption in medicine does not suffice. Pay special attention to the production process, since a novel production process applied to a conventional food may render it novel;
3. Verify on the [website of the European Commission](#) whether the food/food ingredient has been authorized as a novel food;
4. Verify if the ingredient is an authorized source of vitamins/minerals pursuant to Directive 2002/46. If so, it is assumed to have non-novel status;
5. Search in public databases:
 - The [EU Novel Food Catalogue](#) contains the novel status of many ingredients, mainly plants. For food supplements, the status may be either “✓” (not novel in foods) or “FS” (not novel in food supplements). Note that for regular foods, “FS” status does not exclude novel status.
 - The Belgian authorities have published a list of non-novel [plants](#) and [essential oils](#).

- Conduct a search for evidence of a history of use. Evidence may include invoices, import documents, price lists, FAO statistics, literature, labels with date, recipes or cookbooks with a date.
- Finally, EU countries can be consulted on the novel food status of a food/food ingredient. Some EU countries such as Belgium have a special [request form](#).

EU Infringements Database

The EU’s “Rapid Alert System on Food and Feed (RASFF) is an online alert system allowing Member State authorities to report infringements of EU food and feed legislation to the European Commission. The RASFF database provides useful information on the reasons for rejecting imports of food products including food supplements. The most common reason is the presence of unauthorized novel food ingredients or other unauthorized substances (e.g. additives not included in the EU’s positive list). U.S. exporters are strongly advised to check the “novel” status of their products before exporting to the EU as food supplements legally marketed in the United States may not be authorized in the EU. For detailed information on the RASFF, see section “Compliance with EU Food Legislation.”

New rules in the pipeline

Novel Food Regulation 258/97 will be replaced by [Regulation 2015/2283](#) as of January 1, 2018. The most important change for food supplements is a new simplified authorization procedure for traditional foods and food ingredients from third countries. Detailed information is available on the FAS USEU website <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/novel-foods/>.

FOOD ADDITIVES

Only food additives included in the EU’s positive list can be used in the manufacture of food supplements.

[Regulation 1333/2008](#) sets out the rules on the use of food additives. The food additives permitted in food supplements are listed in section 17 of Annex II to regulation 1333/2008. There are different rules for food supplements supplied in solid form (including powders intended for beverage preparation), in liquid form and in syrup or chewable form.

Where maximum levels apply, they apply to the food as marketed, unless otherwise stated. However, for dried and/or concentrated foods which need to be reconstituted (e.g. powders intended for beverage preparations), the maximum levels apply to the food as reconstituted according to the instructions on the label taking into account the minimum dilution factor.

GENERAL MANDATORY LABELING REQUIREMENTS (REGULATION 1169/2011)

As any other food, food supplements are also subject to the EU's general food labelling rules established by [Regulation 1169/2011](#) on the provision of food information to consumers.

Labels should include:

- The name of the food (“food supplement”);
- The list of ingredients;
- Any ingredient or processing aid causing allergies or intolerances;
- The quantity of certain ingredients or categories of ingredients;
- The net quantity of the food;
- The date of minimum durability or the ‘use by’ date;
- Any special storage conditions and/or conditions of use;
- The name or business name and address of the food business operator;
- The country of origin or place of provenance where provided;
- Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions;
- With respect to beverages containing more than 1.2 % by volume of alcohol, the actual alcoholic strength by volume;

A nutrition declaration is not mandatory for food supplements. However, when included on a voluntary basis, the declaration should comply with the provisions of Regulation 1169/2011.

The above list is not exhaustive. Other provisions from Regulation 1169/2011 may apply to food supplements. For more guidance, see the [European Commission Questions and Answers on the application of the Regulation \(EU\) N° 1169/2011 on the provision of food information to consumers](#).

NUTRITION AND HEALTH CLAIMS

Due to their presentation in pills, capsules, and similar forms, food supplements need to distinguish themselves by the beneficial effect they provide. [Regulation 1924/2006](#) lays down harmonized rules on the use of nutrition and health claims on foods, including food supplements.

Legal definitions of “claim,” “nutrition claim” and “health claim” are laid down in Regulation 1924/2006 (Article 2). “Nutrition claim” refers to the nutritional properties of a food while “health claim” refers to the effect of a food on human health. Examples of nutrition claims are “low energy,” “reduced fat,” “no added sugars,” “high fiber,” “source of vitamin C” and “contains glucosamine.” Examples of health claims are “Vitamin C supports the nervous system” “lowers cholesterol,” or the general statements “healthy” or “good for you.”

The rules on health and nutrition claims are very strict and their scope very wide. Wording, slogans, symbols and graphics on the label and in advertising of food supplements should be considered carefully.

For example:

- Product names or brands can be health claims (e.g. “Cardio-care”);

- Implied references are also health claims (e.g. stating that studies have shown a beneficial effect of a food, or that a food has been used throughout history for its beneficial properties);
- Graphic or pictorial representations can be health claims (e.g. a picture of a heart could imply a claim on cardiovascular heart);
- Any reference to weight loss is a health claim;
- The term “*probiotics*” is considered a health claim.

For more information see the European Commission’s [Guidance on the implementation of Regulation 1924/2006](#).

General conditions of use (Regulation 1924/2006 – Article 3)

Nutrition and health claims cannot suggest that a food is intended to prevent or treat a disease, as this may render a product medicinal by virtue of its presentation (see section “Borderline Products”).

Nutrition and health claims cannot be false, ambiguous or misleading, give rise to doubt about the nutritional adequacy of other foods (e.g. “the only effective natural ingredient that lowers cholesterol: plant sterols”), or refer to changes in bodily functions which could exploit fear in the consumer (e.g. “vitamin C deficiency can damage body tissues”). In general, claims should be formulated in positive terms.

Use of specific claims

Both nutrition and health claims may be used only when authorized or pending pursuant to Regulation 1924/2006. The authorized nutrition claims and their conditions of use are laid down in the Annex of Regulation 1924/2006. Authorized general function health claims and their conditions of use are laid down in [Regulation 432/2012](#). Authorized health claims referring to the reduction of disease risk and to children's development and health are laid down in separate authorizing Decisions. The [EU Claims Register](#) allows targeted searching for all authorized health claims on ingredient or health benefit.

Use of general function claims

References to general, non-specific health benefits, such as “energy,” “support,” “antioxidant,” “good for your skin” or “healthy” etc. may be used only in combination with a related specific permitted claim. The more general the claim, the higher the number of specific claims eligible to accompany it. The specific claim should be stated following the general claim, or can be referred to by means of an asterisk (*).

For example:

<p>Good for your skin*</p> <p>* Biotin contributes to the maintenance of normal skin</p>	<p>Healthy*</p> <p>* Vitamin C contributes to normal energy yielding metabolism</p>
--	---

It is permitted to formulate nutrition and health claims differently than the authorized text. However, the wording should always keep the same meaning for the consumer. In particular, the meaning of claims may not be made stronger. [Guidance](#) on this topic has been adopted by the European Commission.

Pending claims (Article 28 – Regulation 1924/2006)

In addition to the list of authorized general function health claims, there is also a list of pending claims on botanicals for which the assessment by the European Food Safety Authority (EFSA) or the approval procedure has not been finalized yet (“on hold claims”). These claims may be used if they can be scientifically substantiated. When using pending claims, it is recommended that exporters compile a supporting dossier with relevant scientific literature in case of an official control. The [list of pending claims](#) is available on the European Commission’s website. [EFSA’s Register of Questions](#) can be searched to look up the status of pending claims.

Mandatory statements (Regulation 1924/2006 – Article 10)

The use of health claims is voluntary. If a health claim is used on the label, the following mandatory statements/warnings must be provided:

- A statement indicating the importance of a varied and balanced diet and a healthy lifestyle in combination with the mandatory warning that food supplements should not be used as a substitute for a varied diet;
- the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
- where appropriate, a statement addressed to persons who should avoid using the food; and
- an appropriate warning for products that are likely to present a health risk if consumed to excess.

Communications to health professionals

The use of nutrition and health claims in communications to health professionals has been a topic of discussion since the adoption of Regulation 1924/2006. It was generally considered that communications to health professionals was not subject to the rules of the Regulation, as long as the information was not actually intended to be forwarded to consumers.

A recent [ruling](#) by the Court of Justice of the EU has established that communications to health professionals fall within the scope of Regulation 1924/2006. Such communications are permitted if they are of a non-commercial nature. Most experts agree that communications containing references to products or brands would not be considered non-commercial.

BORDERLINE PRODUCTS

Some substances, such as botanicals, are used both in food supplements and medicinal products. The EU definitions of medicinal products and food supplements both share a “physiological effect.” Even with harmonized definitions, different EU Member States may still reach different conclusions for the classification of the same products. As a result, there are borderline cases which give rise to situations where a given product is authorized for marketing as a food in some EU Member States but as a

medicinal product in others. These classification problems are addressed in the [Commission Report to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements](#). In case of doubt on the classification it is advisable to contact the authorities of the Member State in which the product will be marketed. A list of competent Member State authorities is available on the European Commission's website https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-supplements-food_supplements_authorities_en.pdf.

Medicinal products by function and by presentation

According to [Directive 2001/83/EC](#) on medicinal products, a product can be considered medicinal either if it is “presented as having properties for treating or preventing disease in human beings” (medicinal product “by presentation”) or if it “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” (medicinal product “by function”).

The definition of medicinal product “by presentation” has been interpreted very broadly by the Court of Justice of the EU. A product recommended or described as preventing, treating or curing a human disease is a medicinal product “by presentation,” even if it is generally regarded as a foodstuff, and even if in the current state of scientific knowledge it has no known therapeutic effects.

On the other hand, the definition of medicinal product “by function” is narrowly interpreted, and covers only those substances which have a genuine medical or therapeutic effect. Food supplements have a physiological effect, and as long they do not significantly affect the metabolism and do not strictly modify the way in which it functions, they will not be classified as medicinal products.

TRADITIONAL HERBAL MEDICINAL PRODUCTS

Botanical preparations can fall under different regulatory regimes depending on their intended use and presentation. [Directive 2004/24/EC](#) on traditional herbal medicinal products lays down a special, simplified registration procedure (“traditional-use registration”) for traditional herbal medicinal products that, despite their long tradition of use, cannot obtain a marketing authorization as medicinal products because of a lack of sufficient scientific literature demonstrating a well-established medicinal use with recognized efficacy and an acceptable level of safety.

The scope of Directive 2004/24 is limited to traditional herbal medicinal products and excludes all other botanical-based products which, as in the case of food supplements, do not fall within the definition of a medicinal product, neither by function nor by presentation.

The simplified procedure allows the registration of herbal medicinal products without requiring particulars and documents on tests and trials on safety and efficacy, provided that there is sufficient evidence of the medicinal use of the product throughout a period of at least 30 years, including at least 15 years in the Community.

MUTUAL RECOGNITION

Exporters intending to market their products in more than one EU Member State may face a large number of different national rules. For example, a botanical extract may be permitted without conditions in one Member State, prohibited in another, while a third one may allow it under certain conditions. In the absence of full EU-harmonization of rules covering food supplements, the mutual recognition principle applies. Mutual recognition guarantees, in theory although not 100% foolproof, that any product lawfully sold in one Member State can be marketed in any other Member State. This means that the botanical extract used in the example above could be lawfully placed on the market in the first Member State and would subsequently have to be accepted by the two other Member States with more restrictive national legislation in place.

Limits to the mutual recognition principle

The mutual recognition principle does not apply if the authorities of a Member State can successfully invoke the protection of health and life of humans, under the following conditions:

- An in-depth risk assessment based on the most reliable scientific data available and the most recent results of international research must show there is a risk to health associated with a product;
- The risk should be sufficiently serious and not purely hypothetical. However, the so-called precautionary principle may be applied, which means that in so far as there are uncertainties as to the existence or extent of the risks, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent;
- The national technical standards should be necessary to achieve the intended effect and they should be proportionate, i.e. not go further than necessary;
- The burden of proof for the above lies with the Member States.

Exporters should be aware that mutual recognition only applies to non-harmonized areas of law (maximum/minimum vitamin and mineral levels, botanicals, other substances). On the other hand, it does not affect the classification of products on the basis of definitions set in harmonized legislation. As explained above, due to differences in the interpretation of the definition of “food supplement” in Directive 2002/46, EU Member States may refuse to accept products exceeding a certain size or energy value as food supplements, even though they are lawfully marketed under that category in another national. Similarly, certain Member States may classify products as medicine although they are marketed as food supplements in other Member States. Such situations cannot be remedied by the mutual recognition principle.

Mutual recognition Regulation

When denying application of the mutual recognition principle, the national authorities need to respect the provisions of [Regulation 764/2008](#) and follow the procedures laid down in that Regulation. Importantly, failure to notify the exporter within the allocated time limit invalidates the applicability of the national rule to the food supplement.

The table below summarizes the areas harmonized and not harmonized relating to food supplements:

FOOD SUPPLEMENTS – SUMMARY OF HARMONIZED AND NON- HARMONIZED AREAS	
PRODUCT CHARACTERISTICS	STATUS
Vitamins and minerals and chemical forms	Harmonized by Directive 2002/46
Purity criteria	Not yet harmonized Regulation 764/2008 applies to supplements lawfully marketed in EU country, unless already specified in other EU legislation (e.g. in the additives legislation)
Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption	Not yet harmonized Regulation 764/2008 applies to supplements lawfully marketed in another EU country
Use of substances authorized for food for special nutritional purposes (e.g. inositol, several amino acids, carnitine, taurine)	Harmonized by Regulation 609/2013
Use of other substances not subject to harmonization, including botanicals (as food supplements)	Not yet harmonized Regulation 764/2008 applies to supplements lawfully marketed in another EU country
Use of botanicals as traditional herbal medicinal products	Harmonized by Directive 2004/24
Use of novel foods	Harmonized by Regulation 258/97
Use of additives	Harmonized by Regulation 1333/2008
Mandatory labeling provisions	Harmonized by Directive 2002/46 and Regulation 1169/2011
Use of nutrition and health claims	Harmonized by Regulation 1924/2006

COMPLIANCE WITH EU FOOD LEGISLATION

Exporters should be aware that it is not unusual for Member State inspectors to check if food supplements comply with EU legislation. The publicly available information on infringements may be very useful to U.S. exporters as it provides real life examples of goods that are not authorized on the EU market, even if they may be legally marketed in the United States.

Member State authorities are responsible for carrying out inspections on a regular basis and in cases where non-compliance is suspected. Products can be checked at import or at all further stages of marketing. Infringements of EU food and feed legislation are reported through the Rapid Alert System on Food and Feeds (RASFF). The rapid alert system is a network of Member State authorities and is managed by the European Commission who maintains a database with information on individual RASFF notifications. Several notification details such as the reason for the non-compliance and the origin of the product are accessible to the public. The public information does not include company information.

For the categories of dietetic foods, food supplements and fortified foods there were 238 notifications for products from the United States in the period 2014-2016 (data through mid-December 2016). The most common reason for non-compliance is the presence of unauthorized substances and novel food ingredients. Often goods are non-compliant for several reasons, e.g. because they contain an unauthorized ingredients as well as an excessive amount of an authorized substance.

Common Reasons for Notifications in the RASFF System for Dietetic Foods, Food Supplements and Fortified Foods originating in the United States in 2014-2016

NOTIFICATION BASIS	NUMBER	NON-EXHAUSTIVE LIST OF EXAMPLES
Unauthorized substances	142	Aegeline, DMAA, synephrine, vanadium, vinpocetine, yohimbine, several plant extracts
Novel food ingredients	115	Agmatine sulphate, betaine, several mushrooms and plant extracts (like Stevia)
High level of substance	43	High content of caffeine, vitamins and minerals
Insufficient labeling	5	Lack of instructions for use in Member State language

For details on notifications from the United States, readers are encouraged to go to the [RASFF portal](#). Under the heading “Products” choose Category “dietetic foods, food supplements, fortified food” and Country “United States.”

Measures in case of non-compliance depend on the stage of marketing and the seriousness of the non-compliance. Non-compliances detected at the border for goods imported from the United States will usually lead to non-admittance of the consignment which gets reported as a “border rejection” in the RASFF system. Other non-compliances are reported as “Information Notifications” will not lead to specific actions, for instance because the product is no longer on the market. “Alerts” on the other hand will require specific actions such as a withdrawal of the product from the market.

U.S. exporting companies and their importers that have a history of non-compliance in the RASFF system are at risk of more frequent controls.

Since the legislation on food supplements is only partially harmonized in the EU (see section “Other substances”) it is especially important to verify:

- the non-exceedance of the maximal levels for nutrients and other substances
- the legal status of botanical and “other substances” in the country where the product will be placed on the market.

For more information see [RASFF reports and publications](#)

TARIFF RATE QUOTA FOR U.S. ORIGIN PRODUCT

The customs classification of a food supplement exported to the EU will depend on its composition. If the proper classification for the goods is CN code 2106 90 98 of the EU Combined Nomenclature, then there is a possibility to ship those goods within the 1,550 MT Tariff Rate Quota for “Other food preparations not elsewhere specified or included.” This quota is specifically for product originating from the United States. It is administered in the EU under quota number 09.0096. The [fill rate](#) can be consulted on the EU Taxation and Customs website.

Access to the quota is conditional upon the presentation by the importer of an official U.S. Certificate of Origin. European importers may ask their exporters to supply such a certificate.

By December 2016, the U.S. Government had empowered 28 Chambers of Commerce to issue Certificates of origin that give access to the 9 percent duty reduction under the tariff rate quota. The list of names of the names of non-governmental U.S. organizations empowered by the U.S. Government to issue certificates of origin for the benefit of the tariff quota applicable can be found [on-line](#).

Exporters are encouraged to work with one of the Chambers of Commerce that is already listed. However, if the exporter is unable to work with these listed approved certifying organizations, the U.S. exporter should initiate the process to have an additional Chamber of Commerce added to the list by doing the following:

1. Contact your local Chamber of Commerce. Confirm that they can authorize certificates of origin or ask them for assistance identifying a local entity which can.
2. Ask the authorizing entity to contact USDA/FAS to receive the relevant paperwork (mail to agexport@fas.usda.gov).
3. Send the completed form to FAS (at the email address provided above) for registration with the EC. Note: Do NOT send completed forms to the EC – they will not be accepted.

Once registration with the EC is complete, the Chambers of Commerce will be added to the above mentioned list. For the latest information, contact the U.S. Mission to the EU (AgUSEU@fas.usda.gov).

VETERINARY INSPECTION AND CERTIFICATION

Supplements may contain products of animal origin (POAO) such as whey ingredients, gelatin, glucosamine, chondroitin and many others. This will likely complicate exports as these products often have to undergo veterinary inspection upon entry in the EU. Exporters are advised to verify with their importers if EU rules on veterinary inspection and certification apply.

In order to have a more harmonized Member State application of EU legislation, [Commission Decision 2007/275/EC](#) publishes a list of animals and animal products that are subject to veterinary checks. This regulation also provides clarification on which “composite products” are subject to veterinary checks. In EU legislation, “composite products” are foodstuffs that contain processed products of animal origin and ingredients of plant origin. This definition covers a wide range of products such as pizzas and cheesecakes but also covers certain food supplements.

All composite products containing a processed meat product are subject to a veterinary check.

Generally speaking, composite products that contain more than 50 percent of animal origin products also require a certificate and there are certification requirements concerning the heat treatment for all dairy products. All of these requirements also apply to food supplements that fall in the category of composite products.

The EU has created a model health certificate for imports of composite products, which was implemented in 2012. A detailed “Product Decision Tree” to clarify the scope of the legislation was made available by the European Commission in 2013. This guidance greatly expanded the number and types of products affected by the legislation. The decision tree is included in [the further guidance](#) (Picture 3 on page 21) that was developed and published in 2015 to address a wide range of implementation questions related to the import and transit of composite products.

Commission Decision 2007/275/EC also lists certain composite products that are not subject to veterinary checks, provided they are shelf stable and properly packaged and labeled. With [Commission Implementing Decision \(EU\) 2016/1196](#), an important update to the list of products that has to undergo veterinary inspection has been published. **This decision restricts the lists of products that are exempt from veterinary inspection, especially affecting the food supplement sector.** As from January 1, 2017, the exemption from veterinary inspection will apply only to food supplements falling under CN codes 2106 10 and 2106 90, packaged for the final consumer, containing small amounts (in total less than 20 percent) of processed animal products (including glucosamine, chondroitin and/or chitosan) other than meat products.

Although Member States have to start applying the new lists as of January 1, 2017, there are still many outstanding questions on the practical implementation of this decision. For more information contact the U.S. Mission to the EU (AgUSEU@fas.usda.gov).

It is not always possible to obtain the necessary certifications from the Food and Drug Administration (FDA), the Agricultural Marketing Service (USDA/AMS) or the Food Safety and Inspection Service (FSIS).

Products of animal origin that require health certification often also need to be sourced from U.S. establishments that have been approved by the European Union following a request by the relevant U.S. Government Competent Authority.

The U.S. Mission has written specific guidance for exporters of whey protein supplements, clarifying the aspects that will be checked by Border Inspectors. These include in particular sourcing from EU approved establishments, proper certification and labeling requirements. See [Certification and Labeling for EU Whey Protein Supplements](#) (GAIN E16057).

For information on certification for dairy (whey) based products, contact:

Carrie Sayasithsena
National Program Coordinator
USDA AMS Dairy Program
1400 Independence Ave SW
Stop 0230 (US Mail)
Room 2750-S (Courier)
Washington, DC 20250
Phone : 202-720-9381
Fax : 844-804-4701
Carrie.Sayasithsena@ams.usda.gov

For information on dairy (whey) approved establishment listing, contact:

Esther Z. Lazar
Consumer Safety Officer
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Safety
Dairy and Egg Branch
Phone : 240-402-1485
Esther.Lazar@fda.hhs.gov

ANNEX I: LIST OF MAIN EU LEGISLATION APPLICABLE TO FOOD SUPPLEMENTS

SPECIFIC LEGISLATION

[Directive 2002/46](#) relating to food supplements

LABELING AND ADVERTISING

[Regulation 1169/2011](#) on the provision of food information to consumers

[Regulation 1924/2006](#) on nutrition and health claims made on foods

COMPOSITION

[Regulation 609/2013](#) on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

GENERAL FOOD LAW

[Regulation 178/2002](#) 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

NOVEL FOODS

[Regulation 258/97](#) on novel food and novel food ingredients ([Regulation 2015/2283](#) applicable from 1 January 2018)

HYGIENE AND QUALITY CONTROL

[Regulation 852/2004](#) on the hygiene of foodstuffs

[Regulation 853/2004](#) laying down specific hygiene rules for food of animal origin

[Commission Regulation 1881/2006](#) setting maximum levels for certain contaminants

[Commission Regulation 2073/2005](#) on microbiological criteria for foodstuffs

CERTIFICATION

[Commission Regulation 28/2012](#) laying down requirements for the certification for imports into and transit through the Union of certain composite products

GMOS

[Regulation 1829/2003](#) on genetically modified food and feed

TARIFF RATE QUOTAS

[Council Regulation 32/2000](#) opening and providing for the administration of Community tariff quotas bound in GATT and certain other Community tariff quotas and establishing detailed rules for adjusting the quotas, and repealing Council Regulation (EC) No 1808/95

VETERINARY CERTIFICATION AND INSPECTION

[Commission Regulation 136/2004](#) laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries

[Commission Decision 2007/275](#) concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC

[Commission Implementing Decision 2016/1196](#) amending the Annexes to Decision 2007/275/EC concerning the lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC

[Regulation 28/2012](#) laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009

ANNEX II: CONTACT INFO FOR EU FOOD SUPPLEMENT ORGANIZATIONS

- Food Supplements Europe www.foodsupplementseurope.org
- European Federation of Associations of Health Product Manufacturers (EHPM) www.ehpm.org
- Association of the European Self-Medication Industry (AESGP) www.aesgp.eu
- FoodDrinkEurope www.fooddrinkeurope.eu

ANNEX III: AUTHORIZED VITAMINS AND MINERALS IN FOOD SUPPLEMENTS

Established by Annex I to Food Supplements Directive 2002/46

VITAMINS

Vitamin A ($\mu\text{g RE}$)
Vitamin D (μg)
Vitamin E (mg a-TE)
Vitamin K (μg)
Vitamin B1 (mg)
Vitamin B2 (mg)
Niacin (mg NE)
Pantothenic acid (mg)
Vitamin B6 (mg)
Folic acid (μg) (⁹)
Vitamin B12 (μg)
Biotin (μg)
Vitamin C (mg)

MINERALS

Calcium (mg)
Magnesium (mg)
Iron (mg)
Copper (μg)
Iodine (μg)
Zinc (mg)
Manganese (mg)
Sodium (mg)
Potassium (mg)
Selenium (μg)
Chromium (μg)
Molybdenum (μg)
Fluoride (mg)
Chloride (mg)
Phosphorus (mg)
Boron (mg)
Silicon (mg)

ANNEX IV: AUTHORIZED VITAMINS AND MINERAL SUBSTANCES IN FOOD SUPPLEMENTS

Established by Annex II to Directive 2002/46

VITAMINS

1. VITAMIN A

- (a) retinol
- (b) retinyl acetate
- (c) retinyl palmitate
- (d) beta-carotene

2. VITAMIN D

- (a) cholecalciferol
- (b) ergocalciferol

3. VITAMIN E

- (a) D-alpha-tocopherol
- (b) DL-alpha-tocopherol
- (c) D-alpha-tocopheryl acetate
- (d) DL-alpha-tocopheryl acetate
- (e) D-alpha-tocopheryl acid succinate
- (f) mixed tocopherols (¹⁰)
- (g) tocotrienol tocopherol (¹¹)

4. VITAMIN K

- (a) phylloquinone (phytomenadione)
- (b) menaquinone (¹²)

5. VITAMIN B1

- (a) thiamin hydrochloride
- (b) thiamin mononitrate
- (c) thiamine monophosphate chloride
- (d) thiamine pyrophosphate chloride

6. VITAMIN B2

- (a) riboflavin
- (b) riboflavin 5'-phosphate, sodium

7. NIACIN

- (a) nicotinic acid
- (b) nicotinamide
- (c) inositol hexanicotinate (inositol hexaniacinate)

8. PANTOTHENIC ACID

- (a) D-pantothenate, calcium
- (b) D-pantothenate, sodium
- (c) dexpantenol
- (d) pantethine

9. VITAMIN B6

- (a) pyridoxine hydrochloride
- (b) pyridoxine 5'-phosphate
- (c) pyridoxal 5'-phosphate

10. FOLATE

- (a) pteroylmonoglutamic acid
- (b) calcium-L-methylfolate
- (c) (6S)-5-methyltetrahydrofolic acid, glucosamine salt

11. VITAMIN B12

- (a) cyanocobalamin
- (b) hydroxocobalamin
- (c) 5'-deoxyadenosylcobalamin
- (d) methylcobalamin

12. BIOTIN

- (a) D-biotin

13. VITAMIN C

- (a) L-ascorbic acid
- (b) sodium-L-ascorbate
- (c) calcium-L-ascorbate (¹³)
- (d) potassium-L-ascorbate
- (e) L-ascorbyl 6-palmitate
- (f) magnesium L-ascorbate
- (g) zinc L-ascorbate

MINERALS

calcium acetate
calcium L-ascorbate
calcium bisglycinate
calcium carbonate
calcium chloride
calcium citrate malate
calcium salts of citric acid
calcium gluconate
calcium glycerophosphate
calcium lactate
calcium pyruvate
calcium salts of orthophosphoric acid
calcium succinate
calcium hydroxide
calcium L-lysinate
calcium malate

calcium oxide
calcium L-pidolate
calcium L-threonate
calcium sulphate
magnesium acetate
magnesium L-ascorbate
magnesium bisglycinate
magnesium carbonate
magnesium chloride
magnesium salts of citric acid
magnesium gluconate
magnesium glycerophosphate
magnesium salts of orthophosphoric acid
magnesium lactate
magnesium L-lysinate
magnesium hydroxide
magnesium malate
magnesium oxide
magnesium L-pidolate
magnesium potassium citrate
magnesium pyruvate
magnesium succinate
magnesium sulphate
magnesium taurate
magnesium acetyl taurate
ferrous carbonate
ferrous citrate
ferric ammonium citrate
ferrous gluconate
ferrous fumarate
ferric sodium diphosphate
ferrous lactate
ferrous sulphate
ferric diphosphate (ferric pyrophosphate)
ferric saccharate
elemental iron (carbonyl + electrolytic + hydrogen reduced)
ferrous bisglycinate
ferrous L-pidolate
ferrous phosphate
ferrous ammonium phosphate
ferric sodium EDTA
iron (II) taurate
cupric carbonate
cupric citrate
cupric gluconate
cupric sulphate
copper L-aspartate
copper bisglycinate
copper lysine complex
copper (II) oxide
sodium iodide

sodium iodate
potassium iodide
potassium iodate
zinc acetate
zinc L-ascorbate
zinc L-aspartate
zinc bisglycinate
zinc chloride
zinc citrate
zinc gluconate
zinc lactate
zinc L-lysinate
zinc malate
zinc mono-L-methionine sulphate
zinc oxide
zinc carbonate
zinc L-pidolate
zinc picolinate
zinc sulphate
manganese ascorbate
manganese L-aspartate
manganese bisglycinate
manganese carbonate
manganese chloride
manganese citrate
manganese gluconate
manganese glycerophosphate
manganese pidolate
manganese sulphate
sodium bicarbonate
sodium carbonate
sodium chloride
sodium citrate
sodium gluconate
sodium lactate
sodium hydroxide
sodium salts of orthophosphoric acid
sodium sulphate
potassium sulphate
potassium bicarbonate
potassium carbonate
potassium chloride
potassium citrate
potassium gluconate
potassium glycerophosphate
potassium lactate
potassium hydroxide
potassium L-pidolate
potassium malate
potassium salts of orthophosphoric acid
L-selenomethionine

selenium enriched yeast (¹⁴)
selenious acid
sodium selenate
sodium hydrogen selenite
sodium selenite
chromium (III) chloride
chromium enriched yeast (¹⁵)
chromium (III) lactate trihydrate
chromium nitrate
chromium picolinate
chromium (III) sulphate
ammonium molybdate (molybdenum (VI))
potassium molybdate (molybdenum (VI))
sodium molybdate (molybdenum (VI))
calcium fluoride
potassium fluoride
sodium fluoride
sodium monofluorophosphate
boric acid
sodium borate
choline-stabilised orthosilicic acid
silicon dioxide
silicic acid (¹⁶)

(¹) OJ C 311 E, 31. 10. 2000, p. 207 and OJ C 180 E, 26. 6. 2001, p. 248.

(²) OJ C 14, 16. 1. 2001, p. 42.

(³) Opinion of the European Parliament of 14 February 2001 (OJ C 276, 1. 10. 2001, p. 126), Council Common Position of 3 December 2001 (OJ C 90 E, 16. 4. 2002, p. 1) and Decision of the European Parliament of 13 March 2002. Council Decision of 30 May 2002.

(⁴) OJ L 109, 6. 5. 2000, p. 29.

(⁵) OJ L 276, 6. 10. 1990, p. 40.

(⁶) OJ L 184, 17. 7. 1999, p. 23.

(⁷) OJ L 311, 28. 11. 2001, p. 67.

(⁸) OJ L 31, 1. 2. 2002, p. 1.

(⁹) Folic acid is the term included in Annex I of Commission Directive 2008/100/EC of 28 October 2008 amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions for nutrition labelling purposes and covers all forms of folates.

(¹⁰) alpha-tocopherol < 20 %, beta-tocopherol < 10 %, gamma-tocopherol 50-70 % and delta-tocopherol 10-30 %

(¹¹) Typical levels of individual tocopherols and tocotrienols:

- 115 mg/g alpha-tocopherol (101 mg/g minimum),
- 5 mg/g beta-tocopherol (< 1 mg/g minimum),
- 45 mg/g gamma-tocopherol (25 mg/g minimum),
- 12 mg/g delta-tocopherol (3 mg/g minimum),
- 67 mg/g alpha-tocotrienol (30 mg/g minimum),
- < 1 mg/g beta-tocotrienol (< 1 mg/g minimum),

- 82 mg/g gamma-tocotrienol (45 mg/g minimum),
- 5 mg/g delta-tocotrienol (< 1 mg/g minimum),
- (¹²) Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.
- (¹³) May contain up to 2 % of threonate.
- (¹⁴) Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2,5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85 % of the total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine shall not exceed 10 % of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1 % of total extracted selenium.
- (¹⁵) Chromium-enriched yeast produced by culture of *Saccharomyces cerevisiae* in the presence of chromium(III) chloride as a source of chromium and containing, in the dried form as marketed, 230-300 mg of chromium/kg. The content of chromium(VI) shall not exceed 0,2 % of total chromium.
- (¹⁶) In the form of gel.

ANNEX V: NOTIFICATION BASIS FOR BORDER REJECTIONS (RASFF 2014-2016)

Notification Basis for Border Rejections for Dietetic Foods, Food Supplements and Fortified Foods originating in the United States notified in the RASFF System (2014-2016):

- Unauthorized novel food ingredient Stevia rebaudiana in food supplements from the United States
- Unauthorized novel food ingredient Siraitia Grosvenorii in herbal food supplement from the United States
- Potassium aspartate unauthorized and unauthorized substance chromium amino acid chelate in food supplement from the United States
- Unauthorized novel food ingredient Siraitia Grosvenorii in protein bar from the United States
- Absence of health certificate(s) for fish oil (cod liver oil, colostrum) from the United States
- Unauthorized substance sibutramine (1690; 1790; 1860 mg/kg - ppm) in slimming coffee from the United States
- Unauthorized substance indole-3-carbinol (in pure form) in food supplement from the United States
- Unauthorized substances synephrine (15040 mg/kg - ppm), octopamine (107500 mg/kg - ppm) and evodiamine in food supplement from the United States
- Unauthorized novel food ingredient clinoptilolite in food supplement from the United States
- Unauthorized placing on the market of food supplement containing Juglans nigra from the United States
- Unauthorized novel food meshima mushroom (Phellinus linteus) to be used in food
- Unauthorized substances tin, cobalt, germanium, vanadium and strontium in food supplement from the United States
- Unauthorized novel food turkey tail mushroom (Coriolus versicolor) to be used in food supplement from the United States

- Unauthorized placing on the market of relax tea containing St. John Wort (*Hypericum perforatum*) from the United States
- Unauthorized substances synephrine (19350; 20120 mg/kg - ppm), 1,3 dimethylamylamine (DMAA) (52950; 55300 mg/kg - ppm) and methylsynephrine (32110; 30030 mg/kg - ppm) in food supplements from the United States
- Unauthorized substance yohimbine (5080 mg/kg - ppm) in food supplements from the United States
- Unauthorized novel food zeolite from the United States
- Unauthorized substance 1,3 dimethylamylamine (DMAA) (8290 mg/kg - ppm) in food supplement from the United States
- Unauthorized substance 1,3 dimethylamylamine (DMAA) (2950 µg/kg - ppb) in food supplement from the United States
- Unauthorized substances yohimbine (1260 mg/kg - ppm), synephrine (21220 mg/kg - ppm), 1,3 dimethylamylamine (DMAA) (13760 mg/kg - ppm) and methylsynephrine (45740 mg/kg - ppm) in food supplements from the United States
- Unauthorized novel food ingredient clinoptilolite in food supplement from the United States
- Unauthorized novel food GTF chromium yeast from the United States
- High content of vitamins in food supplements from the United States
- Unauthorized novel food (*Scutellaria elliptica* & *incana*) food supplement from the United States
- Unauthorized substance sildenafil (24650 mg/kg - ppm) in food supplement from the United States
- Unauthorized novel food ingredient *Coriolus versicolor* in food supplement from the United States
- Absence of health certificate(s) for fish oil Omega 3 from the United States
- Unauthorized substance molybdenum chelate in food supplement from the United States
- Unauthorized novel food ingredient *Hemidesmus indicus*, novel food ingredient *Hydrastis canadensis* and novel food ingredient *Ulmus pumila* and unauthorized substance chromium

polynicotinate in food supplement from the United States

- Unauthorized novel food ingredient tongkat ali (*Eurycoma longifolia*) in food supplement from the United States
- Unauthorized substances vanadium, selenium amino acid chelate and molybdenum chelate in food supplement for pregnant women from the United States
- High content of vitamin B6 (50 mg/item) in food supplement from the United States
- Unauthorized novel food ingredient *Dendrobium nobile* in fruit punch from the United States
- Unauthorized novel food ingredient *Phellinus linteus* in food supplement from the United States
- Unauthorized novel food ingredient *Siraitia Grosvenorii* in food supplement from the United States
- Absence of health certificate(s) for emu oil capsules and liquid emu oil from the United States, via Canada
- Unauthorized placing on the market (*Anacyclus pyrethrum*, contains L-leucine, L-isoleucine and L-valine as BCAAs) of, unauthorized novel food ingredient *Dendrobium nobile*, novel food ingredient *Eurycoma longifolia* and novel food ingredient *Mucuna*
- Unauthorized placing on the market (*Anacyclus pyrethrum*, contains L-leucine, L-isoleucine and L-valine as BCAAs) of, unauthorized novel food ingredient *Dendrobium nobile*, novel food ingredient *Eurycoma longifolia* and novel food ingredient *Mucuna pruriens* and unauthorized substances vanadium and arginine alphaketoglutarate in food supplements from the United States
- Unauthorized novel food ingredient *Epimedium* in food supplement
- Unauthorized novel food ingredient leaves of *Annona muricata* and novel food ingredient raspberry ketone and high content of vitamin D (2500% of NRVs), of vitamin B12 (40000% of NRVs) and of vitamin E (2225% NRVs) in food supplements from the United States
- Unauthorized substance vanadium in food supplement from the United States
- Unauthorized substance dehydroepiandrosterone (DHEA) (20 mg) in food supplement from the United States
- Unauthorized novel food ingredient *Tabebuia impetiginosa* - bark and high content of zinc (50 mg/item), of vitamin B6 (20 mg/item) and of vitamin E (100 IU) in food supplements from the

United States

- Unauthorized substance yohimbine (0.2 mg/item) in food supplements from the United States
- Unauthorized substance sibutramine in food supplement from the United States
- Unauthorized novel food ingredient *Stevia rebaudiana* in food supplements from the United States