Nutraveris Post

Nutrition & Health Breaking News by NUTRAVERIS, the leading Regulatory & Scientific European Experts

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Regulatory Categories:

the best options for your products

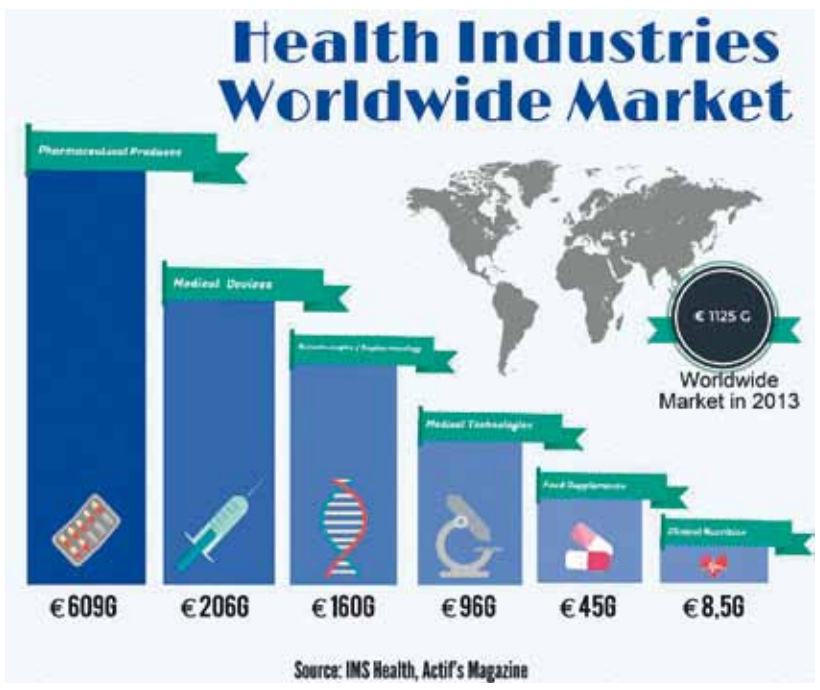
Numerous new European regulatory developments (health claims, novel foods, information to consumers, food for specific groups) that may impact the nutrition and health market are awaited in 2015. Nutraveris gives you an overview of the current dossiers depending on each category of products: food supplements, sport nutrition, foods intended for infants and young children, foods for special medical purposes, foods for weight control, health ingredients.

As examples:

Scientific advices from EFSA will be basis of future European regulatory decisions concerning on hold claims related to caffeine and concerning delegated acts on foods for specific groups.

Additional clarifications regarding the application of FIC Regulation have to be available by the European Commission as the definition of engineered nanomaterial.

Member States continue to work on the specificities of botanicals, while generic health claims referring to botanicals remain on hold.



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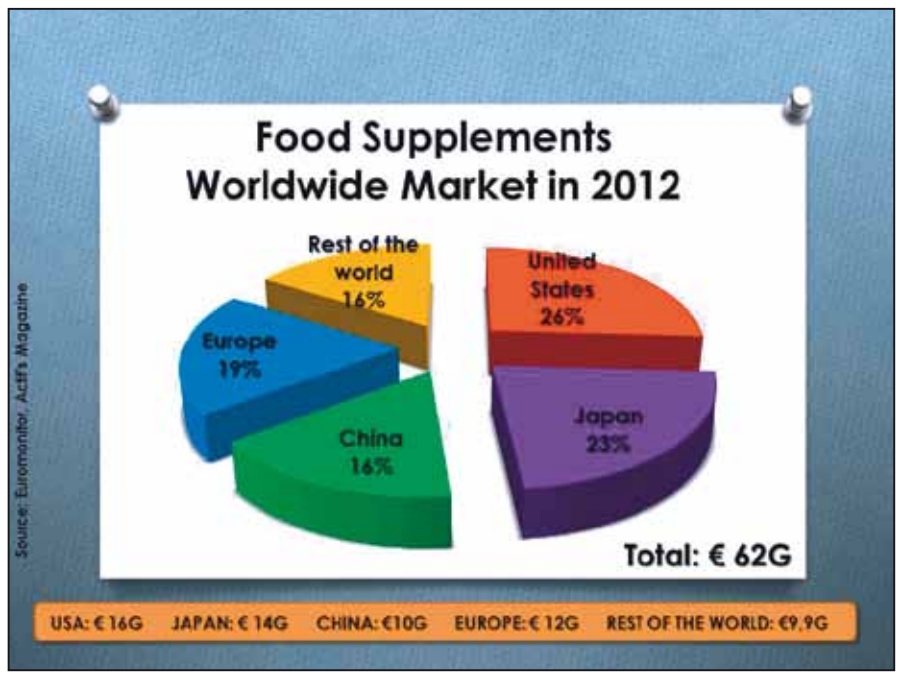
EXPERTISE

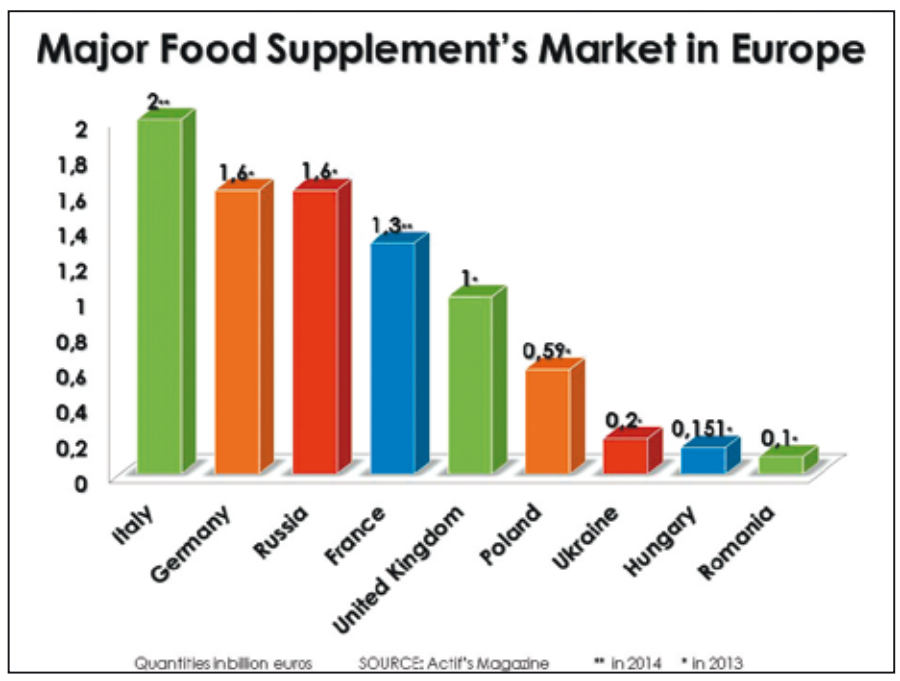
FOOD

- The purpose of food supplements which are foodstuffs is to supplement the normal diet. They are concentrated sources of nutrients or other substances with a nutritional or physiological effect. They are marketed in dose form designed to be taken in measured small unit quantities.
- Directive 2002/46/EC establishes the specific provisions on the labelling of food supplements and lists vitamins and minerals (and their forms) authorized in food supplements. However, maximum amounts of those vitamins and minerals as well as the use of substances with a nutritional or physicological effect including botanicals are not harmonized at European level. For formulation of a food supplement, the national specific legislations as amended on authorized ingredients and possible maximal daily doses have to be checked.
- General food law (food safety, information to consumers, novel foods, nutrition and health claims,...) also applies to food supplements.
- For placing a food supplement on the market, each of the 28 Member States has established its own notification or registration procedure.

MARKET

Worldwide and European Market





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EXPERTISE

SUPPLEMENTS

NEWS

Main provisional conclusions of EFSA on the safety of caffeine

EFSA has launched a public consultation regarding its draft scientific opinion on the safety of caffeine.

EFSA reached the following main provisional conclusions on caffeine intakes which do not raise safety concerns for specific groups of the general population:

Adults:

- Single doses of up to 200 mg (3 mg/kg body weight) from all sources do not raise safety concerns, even if consumed less than two hours prior to intense physical exercise under normal environmental conditions.
- Caffeine intakes from all sources **up to 400 mg per day** (about 5.7 mg/kg body weight) do not raise safety concerns for adults in the general population, except pregnant women.
- Other common **constituents of "energy drinks"** (i.e. taurine, D-glucurono-γ-lactone) **and alcohol are unlikely to interact adversely with caffeine.**
- The short and long-term effects of co-consumption of **caffeine and synephrine** on the cardiovascular system **have not been adequately investigated** in humans.

Pregnant women:

Caffeine intakes from all sources **up to 200 mg per day** by pregnant women in the general population do not raise safety concerns for the foetus.

Lactating women:

Single doses of caffeine up to 200 mg and caffeine intakes of 400 mg per day (about 5.7 mg/kg per day) consumed by lactating women in the general population do not raise safety concerns for the breastfed infant.

Children and adolescents:

Owing to the limited information available for this population subgroup, caffeine intakes are not derived for acute consumption in adults **(3 mg/kg body weight per day)** may serve as a basis to derive daily caffeine intakes of no concern for children and adolescents.

Interested parties are invited to submit their written comments about this draft opinion **by 15 March 2015.** EFSA will also organize a ***scientific meeting on 5 March 2015*** in Brussels in order to exchange scientific views on this draft opinion with other stakeholders.

This scientific opinion was asked by the European Commission during the discussions concerning **on hold health claims related to caffeine** (on endurance, alertness and concentration). Indeed Member States expressed concerns about relation to the safety of caffeine intake within different target groups of the population. So when the EFSA's scientific opinion will be finalized and published, European Commission and Member States should take a decision concerning on hold health claims related to caffeine.

This European scientific opinion could also be a basis of a possible positive harmonization **for food and food supplements with caffeine in the current complex regulatory context:**

- Regulation (EU) N° 1169/2011 on information to consumers established **additional mandatory mentions for foods supplements and foods other than the beverages in which caffeine is added with a physiological purpose:** "Not recommended for children or pregnant women (X mg caffeine / per portion or per 100 g/ml)" in the same field of vision as the name of the food.
- Currently some Member States have **low maximal daily dosages for caffeine** (for example for food supplements 80 mg/day in Belgium and 100 mg/day in France).
- Some Member states have also **forbidden products containing Citrus aurantium containing synephrine combined with caffeine.**

RI or NRV for labelling of food supplements?

According to Regulation (EU) N° 1169/2011, applicable since 13 December 2014, the terms **Reference Intakes (RIs) and/or Nutrient Reference Values (NRVs) replace Recommended Daily Allowances (RDAs**) for vitamins and minerals set out in previous Directive 90/496/EEC. The new wording does not include changes in terms of value.

For food supplements, current indications from European discussions are that you should use the generic term "Reference Intakes" (RI) in interests of consistency with other foodstuffs. The term "nutrient reference values" (NRVs) could also be used with RI.

For food supplements, it is also needed to apply the European Guidance on tolerances for labelled nutrient values for tolerance values and round numbers for vitamins and minerals.

Do you know?

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Nutraveris ACHIEVEMENTS

More than 1000 food supplements and sport foods audited and notified in the different European Member States

National Authorization of exceeding maximum permitted limit dosages granted (e.g: Chromium, Vitamin D) for France, Belgium…

Preparation of several Appendixes 2 (Quality) and 3 (Safety) meeting the new French law requirements on botanicals.

Formulation and development of liquid food supplements without preservatives for skin, heart and joints.

Formulation of a brand new range of food supplements for women health (menopause, pregnancy, nausea, libido…)

Training of different big players in the industry on the EU regulation on Food Supplements and Food Supplements, Sports Foods and strategic solutions.

EXPERTISE

DIETETIC FOODS

Dietetic Foods for Weight Control

- Dietetic foods for weight control are regulated by specific provisions on **composition** and **labelling** according to **Directive 96/8/EC** on foods intended for use in energy-restricted diets for weight reduction. It covers both the total diet replacements for weight control and meal replacements for weight control. National **notification procedures** or criteria for some other products (very low calorie diet, hypo-caloric snacks) may exist in some Member States.
- General food law (food safety, information to consumers, novel foods, nutrition and health claims…) also applies to dietetic foods for weight control.
- From July 2016 : According to **Regulation (EU) N° 609/2013** regarding the revision of PARNUTS legislation, total diet replacements for weight control will still have a specific legislation, whereas meal replacements for weight control will become ordinary foods or fortified foods with possible **nutrition and health claims**.

Sport Foods

- According to the **Directive 2009/39/EC Foods for sportspeople** are currently Foodstuffs for particular nutritional uses (PARNUTS) and have to comply with specific provisions on the **labelling of dietetic foods**. There is no harmonized legislation with **composition** criteria at European level for this category. However, some Member States may have specific rules. Indeed some countries have established a **notification procedure** for those products.

General food law (food safety, information to consumers, novel foods, nutrition and health claims,…) also applies to sport foods.

From July 2016 : According to **Regulation (EU) N° 609/2013** concerning the revision of PARNUTS legislation, all foods for sportspeople should become ordinary foods, fortified foods or food supplements, with possible nutrition and health claims.

However Regulation (EU) No 609/2013 requires the European Commission, after consulting EFSA, to present both the European Parliament and to the Council a report on the necessity, if any, of provisions for food intended for sportspeople. The Commission is currently working on the preparation of this report, taking into account the implementation of the rules on health claims for sportspeople.

Foods for Infants and Young Children

- Intended for children under three years old who have specific nutrition requirements, infant formulae, follow-on formulae and other foods intended for infants and young children (meals, desserts, processed cereal-based foods,…) are specifically regulated at European level concerning **composition**, **labelling** and communication by **Directives 2006/141/EC and 2006/125/EC.** Infant formulae must be notified at national level.
- General food law (food safety, information to consumers, novel foods, nutrition and health claims,…) also applies to foods for infants and young children without prejudice to their specific provisions.
- **Regulation (EU) N° 609/2013** concerning the revision of PARNUTS legislation provides that current directives on food for infants and young children will be replaced by new specific texts expected to be published in 2015.

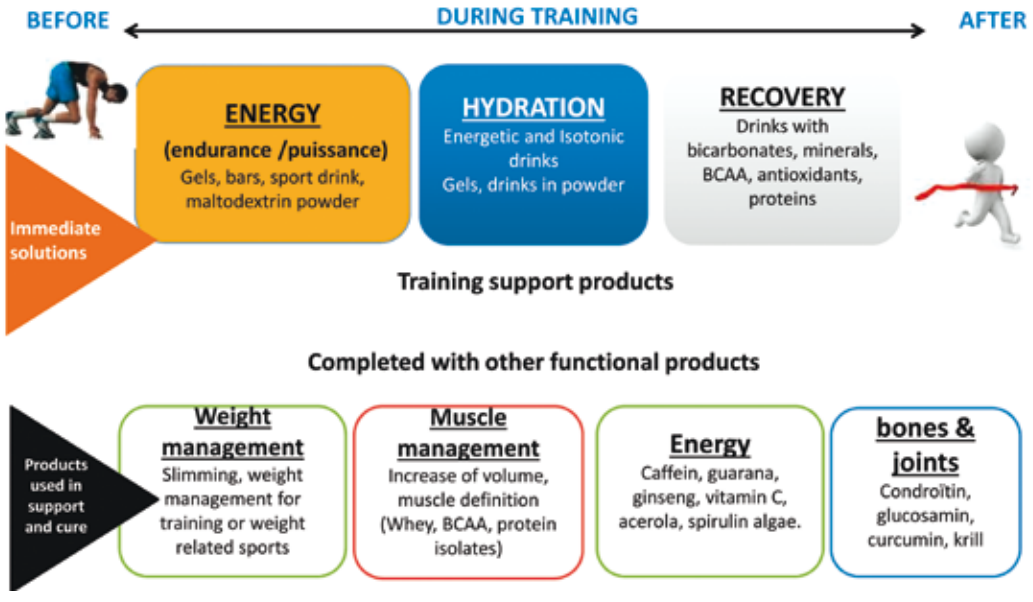
Foods for Special Medical Purposes

- **Dietary foods for special medical purposes (FSMPs)** are intended for the dietary management of patients and can be used only under medical supervision. They are regulated by **Directive 1999/21/EC** for **composition and labelling.** Those products have to be **notified** at national level and competent Authorities may request a bibliographic dossier justifying that the product meets the specific requirements of the target population.
- Dietary General food law (food safety, **information to consumers, novel foods, nutrition and health claims,…**) also applies to FSMPs.
- **Regulation (EU) N° 609/2013** concerning the revision of PARNUTS legislation provides that current directive on FSMPs will be replaced by a new specific text expected to be published in 2015.

MARKET

Focus on sports Nutrition

Market Segments and Products



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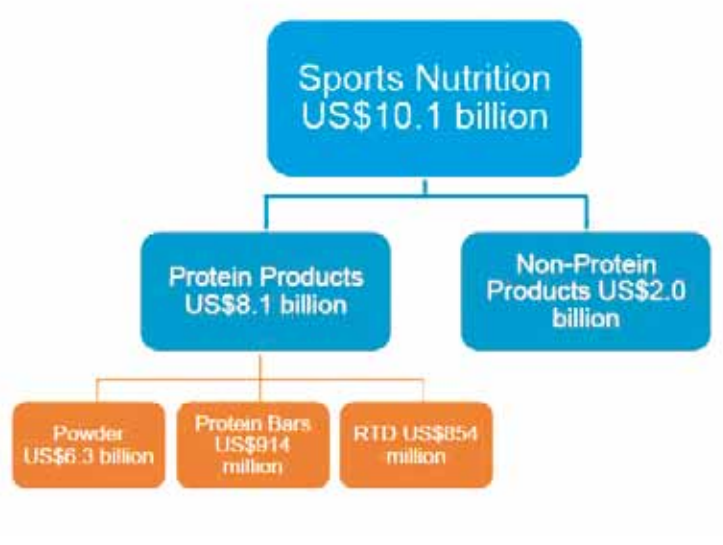
Sports Nutrition Global Sales in 2014



SOURCE: Euromonitor

EXPERTISE

NEWS

A new authorized health claim on carbohydrates and recovery of normal muscle fonction

Until the end of 2014, the authorized health claims that can be linked to sport concerned some micronutrients (e.g vitamin C), proteins (for muscle mass), creatine (physical performance) and carbohydrate-electrolyte solutions (for absorption of water during physical exercise and maintenance of endurance performance).

Regulation (EU) 2015/7 of 6 January 2015 has recently authorized a health claim concerning carbohydrates clearly intended for sportspeople:

"Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive and/or long-lasting physical exercise leading to both muscle fatigue and the depletion of glycogen stores in skeletal muscle".

With the following conditions of use:

- The claim may be used only for food providing carbohydrates which are metabolised by humans (excluding polyols).
- Information shall be given to the consumer that the beneficial effect is obtained with the consumption of carbohydrates, from all sources, at a total intake of 4 g per kg body weight, at doses, within the first 4 hours and no later than 6 hours, following highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.
- The claim may be used only for foods intended for adults who have performed highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.

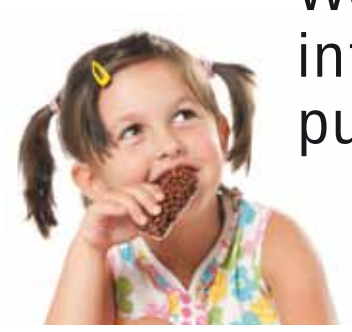
However, in the meantime five health claims on glucose which received positive opinions from EFSA in 2012 have been rejected in Regulation (EU) 2015/8 of 6 January 2015:

- Glucose is metabolised within body's normal energy metabolism
- Glucose supports normal physical activity
- Glucose contributes to normal energy-yielding metabolism
- Glucose contributes to normal energy-yielding metabolism during exercise
- Glucose contributes to normal muscle function

The European Commission considers that those health claims are inconsistent with the most accepted nutrition health principles and they would encourage consumption of sugars for which national and international authorities inform the consumer that their intake should be reduced and concludes that such a health claim does not comply with point (a) of the second paragraph of Article 3 of Regulation (EC) No 1924/2006 which foresees that the use of claims should not be ambiguous or misleading.

It seems that as a consensus on nutrient profiles has not been reached, European Commission and Member States are using other conditions set in Regulation (EC) N° 1924/2006 to avoid that foods high in sugars could bear health claims…

Work on future delegated acts on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control.



Regulation (EU) N° 609/2013 on the revision of dietetic legislation foresees that delegated acts on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control should be adopted by 20 July 2015 in order to replace the current specific directives.

European Commission and Member States are working on those delegated acts, taking into account the new rules on nutrition declaration in Regulation (EU) N° 1169/2011 and scientific opinions of EFSA on essential composition of the concerned food categories.

EFSA has published in July 2014 an updated scientific opinion on the essential composition of infant and follow-on formulae with recommended intake levels of energy, macronutrients and micronutrients in infant and follow-on formulae. The proposed amounts for fat and carbohydrate do not differ significantly from those in the current regulations. However, the Panel proposes that the maximum for protein should be towered to 3 g/100 kcal in infant formula and 3.5 g/100 kcal in follow-on formula to 2.5 g/100 kcal in formulae (infant and follow-on) based on milk protein, and to 2.8 g/100 kcal in formulae (infant and follow-on) containing isolated soy protein or hydrolyzed protein. The proposed minimum contents of numerous micronutrients are updated (in comparison with the current minimums of the Directive 2006/141/EC). EFSA concluded that there is no need to add arachidonic acid, eicosapentaenoic acid, non-digestible oligosaccharides, "probiotics" or "synbiotics", chromium, fluoride, taurine and nucleotides to infant and follow-on formulae. EFSA did not consider it necessary to propose specific compositional criteria for formulae consumed after one year of age, as formulae consumed during the first year of life can continue to be used by young children.

In January 2015 EFSA has also published a scientific opinion on the essential composition of total diet replacements for weight control with recommended intake levels of energy (600 kcal/day), macronutrients and micronutrients for total diet replacements for weight control which are to be used by healthy overweight or obese adults with the intention to lose weight. The opinion also advises on potential conditions and restrictions of use for these products. The compositional advice given by EFSA is based on the assumption that total diet replacements for weight control are used for a single short period of time and the nutrient content may not necessarily be appropriate when these products are consumed for prolonged or repeated short periods of time. EFSA also noted the importance of an adequate fluid intake during energy restriction in line with the Adequate Intakes for adult men and women, i.e. 2.5 L and 2.0 L/day, respectively.

Moreover European Commission has requested to EFSA to elaborate a scientific and technical guidance for the assessment of products notified as Food for Special Medical Purposes (FSMP). EFSA will deliver a scientific opinion by 31 October 2015, following a period of public consultation. Today the application of the current legislative framework for FSMP may differ from one Member State to another. From 20 July 2016, Article 3 of Regulation (EU) N° 609/2013 empowers the Commission to decide by means of implementing acts whether a given food falls within the scope of the Regulation and / or to which specific category of food covered by the Regulation a given food belongs. Commission will have the possibility to consult EFSA on those matters. This guidance could also be a tool in the future to assist national competent Authorities in their enforcement tasks for FSMP.

Information to consumers on the absence or reduced presence of gluten in food

Regulation (EU) No 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food has been published in the European Official Journal and **will apply from 20 July 2016.**

Currently Regulation (EC) No 41/2009 sets out harmonised rules on the information provided to consumers on the absence ('gluten-free') or reduced presence of gluten ('very low gluten') in food.

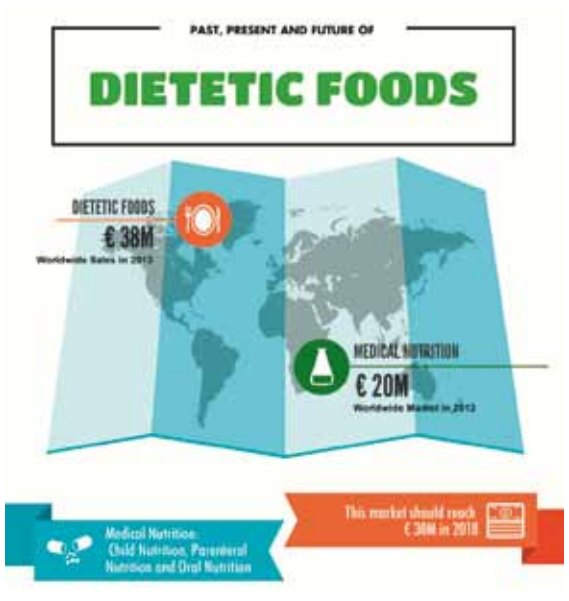
In the context of the revision of the legislation on foodstuffs intended for particular nutritional uses, Regulation (EU) No 609/2013 repeals Regulation (EC) No 41/2009 from 20 July 2016 and indicates that the current specific rules from Regulation (EC) N° 41/2009 have to be transferred in Regulation (EU) N° 1169/2011 on food information to consumers.

The main provisions of Regulation (EU) No 828/2014 are nearly the same as those from Regulation (EC) No 41/2009.

The definitions and thresholds to indicate **«gluten-free» and «very low gluten»** are maintained.

Some **other optional statements** and their conditions of use are also clarified, such as:

- "suitable for people intolerant to gluten" or "suitable for coeliacs"
- "specifically formulated for people intolerant to gluten" or "specifically formulated for coeliacs".



SOURCE: Euromonitor, Actif's Magazine - www.editionsbgm.fr

Nutraveris ACHIEVEMENTS

Formula & Labeling analysis and Registration of more than 500 Sport foods into the different EU Member States

EU Authorization of new forms of minerals

Formulation and development of Foods for Special Medical Purposes

Training of different big players in the industry on the EU Food Supplements regulation, Sports Foods and strategic solutions.

EXPERTISE

FOOD INGREDIENTS

Numerous legislations concerning food ingredients have to be taken into account for product formulation, particularly:

- **Regulation (EC) N° 1333/2008** on food additives
- **Regulation (EC) N° 1334/2008** on food flavourings
- **Regulation (EC) N° 1332/2008** on food enzymes
- Positive lists of vitamins and minerals issued **from the Directive 2002/46/EC, Regulation (EC) N° 953/2009 and Regulation (EC) N° 1925/2006**
- **Regulation (EC) N° 258/97 on novel foods and novel food ingredients** which have not been used for human consumption to a significant degree within Europe prior to 15 May 1997, for which an authorization is needed before launching the product on the market (full authorization procedure or substantial equivalence).

Some **specific national rules** may exist for **substances with a nutritional or physiological effect as for botanicals**.

Our **Nutraveris Online database** lists the legislative status in countries for more than 2100 ingredients with nutritional or physiological effect for use **in food supplements**. The communication on those ingredients is regulated by **Regulation (EC) N° 1924/2006** on **nutrition and health claims.**

Botanicals

The use of botanicals in foods is currently not harmonized at European level. Each European Member State may have its own positive and/or negative lists of botanicals, with possible specific conditions of use (parts of plants, warnings, maximal doses…). Our Nutraveris Online database lists the legislative status in countries for more than 2100 ingredients with nutritional or physiological effect, including botanicals, for use in foods supplements.

In the framework of Regulation (EC) N° 1924/2006, the process of evaluation for health claims on botanicals is still under consideration by the European Commission.

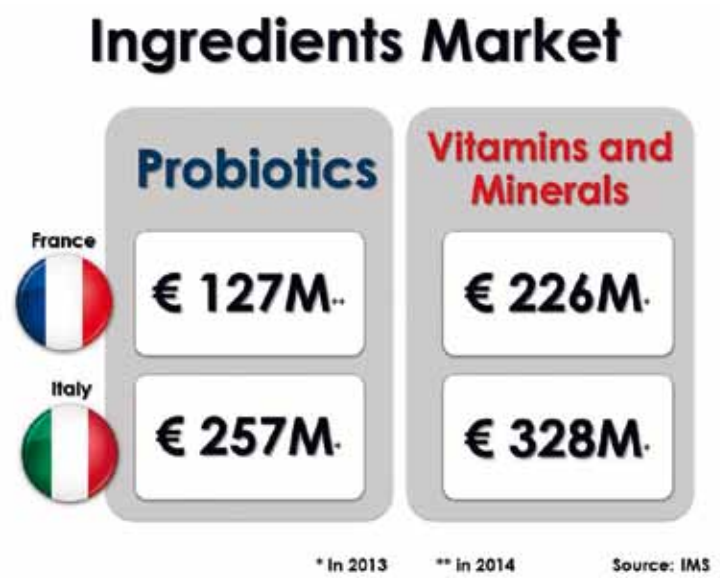
MARKET

Health claims on gut and immune function: small concessions from EFSA without no clear standpoint

Following a public consultation, EFSA has just published an update of the guidance on the scientific requirements for health claims related to gut and immune function and the outcome of this public consultation. This updated was long-awaited by manufacturers since gut and immunity are two health applications with very low success rates. Health claims on immune function are notably arduous, with authorization only for vitamins and minerals. The reason of this particular context is due to the specific evaluation of claims on essential nutrients (vitamins and minerals). It is interesting to note that, for the first time, EFSA recognized in these documents that claims for well-established functions of essential nutrients are treated in a different way other than claims. The requirements for the definition of the claimed effect, for the scientific substantiation of the claim and for establishing conditions of use, differ between essential nutrients and other foods/ingredients. This position explains the difference between health claims submitted pursuant to Article 13(5) of Regulation (EC) N°1924/2006, which are almost all rejected, and health claim on vitamin and minerals which have been accepted with unjustified conditions of use (15% of RDA), based on the health function affected by deficiency and not by the demonstration of the efficacy of a supplementation. Even if this was already known, EFSA indicates firmly for the first time in this document that health claim evaluations are not equivalent, a point of view that may be in contradiction with Regulation (EC) N°1924/2006.

In the outcome of the public consultation, EFSA refuses to give any opinion on several wordings, new populations or on markers that may be pertinent for the substantiation of a claimed effect, arguing that a specific application is required to obtain the EFSA position on these specific parameters. However, the NDA panel has broaden the possibilities of health claims, notably regarding health claim on immunity which were so far very limited. For instance, health claim related to defense against pathogens may be now substantiated by studies conducted in new populations, including notably travelers to high risk countries, subjects under heavy physical exercise, elderly individuals in nursing homes, etc. Another example of the evolution of EFSA position on health claim on immune system is the acceptance of a "beneficial change in response to allergen" as a beneficial physiological effect. Such claims can be substantiated by human studies showing a decrease incidence, severity and/or duration of allergic manifestations in subjects at risk of allergic reactions. This updated guidance does not revolutionize the system, but provides new possibilities for health claims on immune function.

However, even if EFSA has made few concessions, this update will not change significantly the situation. EFSA still refuses any pre-submission meeting or to give its opinion on specific points (accepted population, health relationship, outcomes, etc) without any specific application, two points that are frequently requested by applicants. The NDA panel also frequently reminds the applicants about the evaluation of evidences on a case-by-case basis. Gut and immunity remain consequently difficult applications in the context of health claims, with several parameters which still have to be validated by EFSA. Health claims on these applications require a real expertise that Nutraveris has acquired thanks to its perfect knowledge of health claim applications, EFSA requirements and design of pertinent clinical trials. Do not hesitate to contact our experts for more information on health claim applications in Europe.



Euromonitor, Actif's Magazine - www.editionsbgm.fr.

EXPERTISE

NEWS

Novel foods revision

European Commission has published in December 2013 a new legislative proposal on the revision of the Novel Food regulation.

Compared with the current Regulation (EC) N° 258/97, this proposal for a regulation on novel foods:

- **Clarifies the Novel food definition:**

- The main criteria for the Novel Food definition remain unchanged (foods and food ingredients which were not consumed in the EU to a significant degree before 15 May 1997).
- Current categories of Novel foods have disappeared though.
- Engineered nanomaterials are clearly included in this definition.
- Foods from animal clones are not within the scope, they are addressed in a separate legislative proposal.

- **Improves the authorization procedure:**

- One centralized procedure at European level for the assessment (by EFSA) and authorization (Commission and SCFCAH) of novel foods, it would last 18 months instead of 3 years in average currently.
- Current system of individual authorizations replaced by generic authorizations. However, for really innovative novel foods, authorization with data protection will be granted to the applicant for a 5 year period.
- A simplified procedure for the placing on the market of the traditional foods from third countries which have not been marketed in the EU but which have a history of safe use in non-EU countries.

Following numerous discussions, the European Parliament's Environment, Public Health, and Food Safety (ENVI) Committee has published in December 2014 its final Report on the Commission's proposal for the revision of Regulation on novel foods.

The main amendments introduced by ENVI Committee are the following:

- **Clarification of the scope and definitions:**

- Re-introduction of categories of novel foods as in Regulation 258/97 in an updated form, and adoption of a guidance document – following consultation with stakeholders – on the categories of novel foods to assist the applicants and the Member States in understanding whether a food falls within the scope of the Regulation.

- Definition of "nano"-foods amended in line with EFSA recommendations (10% of nano-particles threshold for a food ingredient to qualify as "nano" instead of 50% as proposed by the Commission).
- Re-inclusion of food from cloned animals and their descendants into the proposal, until they have specific legislation.

- **Simplification of the authorization procedures** with clearly stated or reduced deadlines for the different stages of the procedure.

- **Data protection:** extended from 5 to 7 years.

This ENVI report will serve as **a basis for the Parliament's first reading position** to be voted on by the plenary session expected in April 2015. Following the Parliament's vote, the proposal will be formally transferred to the Council. Then, both institutions will have to agree on the proposed text and appropriate amendments in order to adopt the text in first reading.

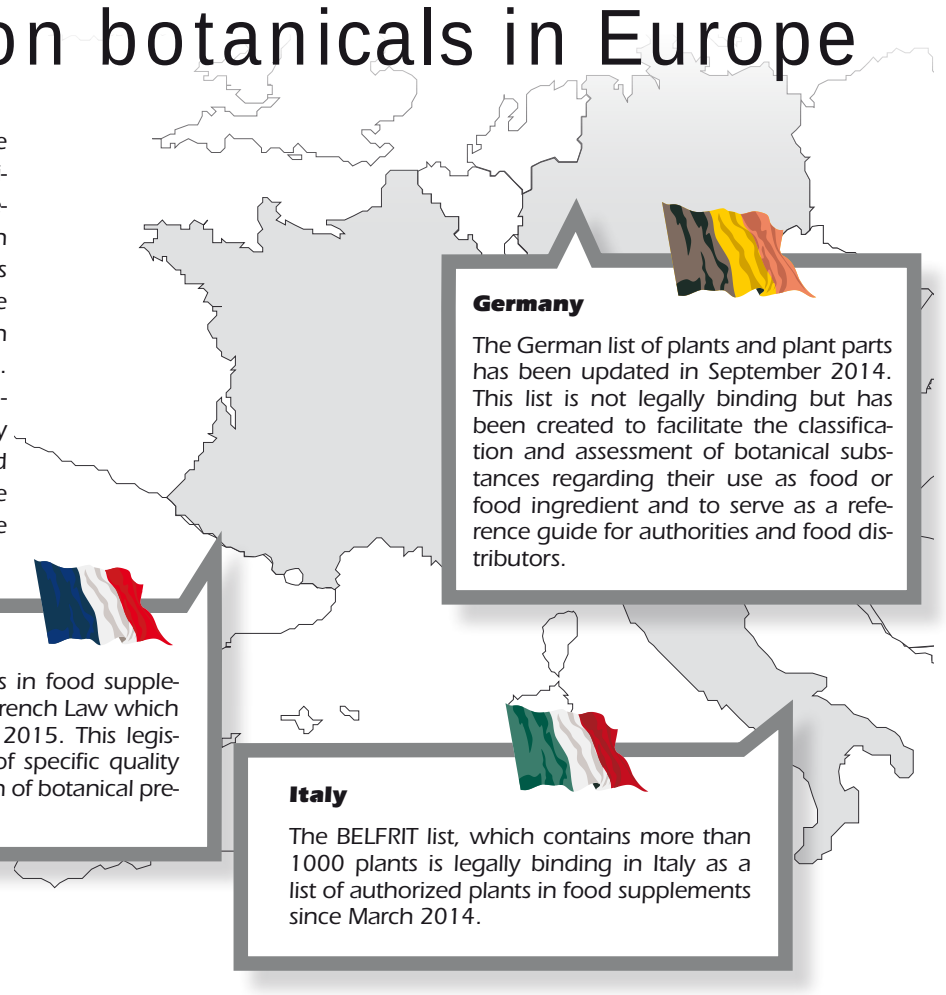
Definition of engineered nanomaterial

According to Regulation (EU) N° 1169/2011 on information to consumers, all food ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients with [nano].

A delegated act to update the definition of engineered nanomaterial is currently under discussion at European level. In 2013, the European Parliament has vetoed a first Commission proposal because Parliament was opposed to the exemption of food additives. The current draft delegated act proposed by Commission includes food additives but keep the principle of 50% of nano-particles threshold to qualify a food ingredient as "nano", because currently it is the technically detectable level. It is not clear if this draft will be accepted by the Parliament in the coming months, but the amendment replacing the 50% threshold by 10% that has been adopted by ENVI Committee under the novel foods revision is not a positive sign. Legally two different definitions could exist depending on the purpose (labelling or novel food) but it is not wished by the European Commission and not practical for food business operators.

Activities on botanicals in Europe

European Member States can continue working on the specificities of botanicals used in food and food supplements, even if all the generic health claims referring to botanicals ("Claims on botanical substances for which the finalization is pending") remain on hold and may continue to be used. Indeed, as long as they are not regulated by Commission, proving they comply with the claims Regulation and existing national provisions applicable to them and the conditions for use under assessment are fulfilled.



Germany

The German list of plants and plant parts has been updated in September 2014. This list is not legally binding but has been created to facilitate the classification and assessment of botanical substances regarding their use as food or food ingredient and to serve as a reference guide for authorities and food distributors.

France

A list of 540 authorized botanicals in food supplements has been published in the French Law which is enforced since the 1rst January 2015. This legislation requires the establishment of specific quality dossier concerning characterization of botanical preparations.

Italy

The BELFRIT list, which contains more than 1000 plants is legally binding in Italy as a list of authorized plants in food supplements since March 2014.

Nutraveris ACHIEVEMENTS

EU Authorization of new forms of minerals

Health Claim applications under review and successful outcome for article 13.5

Training of different big players in the industry on the EU Food Supplements regulation, Sports Foods and strategic solutions.

Novel food Substantial equivalence and Extension of use. Notification with success in several European member states

Preparation of several Appendixes 2 (Quality) and 3 (Safety) meeting the new French law requirements on botanicals.

Nutraveris Online

NEW VERSION

Food Supplements
Sport Foods
Dietetic Foods
Fortified Foods
Ingredients
Plants

The European reference database to develop innovative and compliant health products

Over 2100 ingredients classified in 132 health applications:

- Legislative status in 28 EU Member States
- Approved EFSA health claims, with conditions of use
- Scientific studies: EFFICACY and SAFETY

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