REPORT

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FOOD SUPPLEMENTS IN EUROPE

Opportunities for consumer health

BLL AK NEM Arbeitskreis Nahrungsergänzungsmittel

food supplements europe

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FOOD SUPPLEMENTS IN EUROPE –
Opportunities for consumer health

On 8 and 9 March 2018, more than 175 high-ranking representatives from the worlds of politics, regulatory authorities, social affairs, science and business throughout Europe met in Berlin to discuss current and future challenges at the European conference on "Food Supplements in Europe – Opportunities for Consumer Health", jointly organised by Food Supplements Europe and its German member association BLL-AK NEM.

Fifteen years after the adoption of the European Food Supplements Directive in 2002 and on the basis of the many achievements that it has brought to the recognition of the products and the sector, the challenges ahead were the main focus of the conference – be it the still to be agreed maximum levels of vitamins and minerals in food supplements, the challenge of controlling internet-trade, the options for a legal framework for the use of botanicals in foods and food supplements, and the important role that food supplements can play for guaranteeing health and wellbeing of consumers.

One of the key conclusions was that in this day and age only European solutions will guarantee adequate frameworks for businesses and protection of consumers who engage in cross-border business and shopping. On the whole, the conference sent the urgent request from all participants to the European Commission to take the initiative to close any legal gaps still existing and propose harmonised legislation, be it specifically for food supplements or beyond when it comes to botanicals or effective control measures.

Dr Klaus Heider,
Federal Ministry of Food
and Agriculture, Germany

OPENING ADDRESS BY THE GERMAN FEDERAL MINISTRY OF FOOD, AGRICULTURE AND CONSUMER PROTECTION

Dr Heider referred to the many regulatory achievements in the area of food supplements in the 15 years since the Food Supplements Directive harmonised the legal framework for these products under food law. He stated that it is the decision of the consumers whether or not to take a supplement to improve their nutritional status. However, the role of food supplement manufacturers is to ensure the safety and quality of the products, and to provide accurate information to consumers. Dr Heider raised issues relating to non-compliant products, particularly from internet sales, and to the need for all products to adhere to general food laws, including the legislation on nutrition and health claims.

Key messages:

- Food supplement manufacturers must ensure safety and quality of products and have to provide accurate information to consumers.
- EU Harmonisation of all aspects concerning food supplements should get highest priority.

Dr Heider underlined that the German Government is keen for the European Commission (EC) to act as soon as possible to complete the harmonisation process, namely in the field of maximum levels of vitamins and minerals, the regulation of "other substances" and health claims on botanicals. He said that an incomplete harmonisation, even against the background of different solutions at national level, has negative impact on everyone – for consumers, authorities, companies and national legislators. Therefore, Dr Heider called on the EC, the scientific community, regulators and industry to identify opportunities, to find solutions and to restart discussions on these topics of interest.

Arūnas Vinčiūnas,
Cabinet of Commissioner Andriukaitis,
European Commission

15 YEARS OF THE FOOD SUPPLEMENTS DIRECTIVE: ACHIEVEMENTS AND CHALLENGES

Mr Vinčiūnas underlined that the existing regulatory framework already provides a high level of consumer protection. Regarding the areas of incomplete harmonisation, he indicated that the Commission intends to address the botanicals issues first, including safety as a key aspect to address. He referred in particular to the ongoing REFIT-evaluation on the Claims Regulation. Mr Vinčiūnas confirmed that the Commission is looking to identify solutions to ensure consumer protection in terms of other substances and health claims – but leaving scope for innovation at the same time.

Key Messages:

- High level of consumer protection already existing due to the EU regulatory framework.
- Harmonisation of botanicals, especially issues concerning safety, has first priority. The decision on potential harmonisation of maximum levels will be up to the next Commission.
- There is a need to tackle the problem of illegal products offered on the internet.

Furthermore, Mr Vinčiūnas pointed out that the decision on potential harmonisation on maximum levels for vitamins and minerals will be for the next Commission. This would comprise at least three phases of evaluation:

- Taking stock of current approaches in the EU
- Update of safety evaluations by EFSA
- Impact assessment on the different policy options

However, referring to the divergent opinions and different approaches being taken by Member States to set maximum levels, he highlighted the need for engagement and dialogue between interested parties.

Finally, Mr Vinčiūnas stressed the need to tackle the problem of illegal products offered over the internet and referred to the EU coordinated control plan on food products offered online. The high number of non-compliant offers is a clear sign that the control of e-commerce today needs to be strengthened.

SESSION 1: THE REGULATORY FRAMEWORK OF FOOD SUPPLEMENTS IN EUROPE

Chair: Dr Renate Sommer,
Member of the European Parliament

15 YEARS OF THE FOOD SUPPLEMENTS DIRECTIVE – ACHIEVEMENTS AND FUTURE CHALLENGES

Dr Sommer indicated that the European Parliament wants the Commission to provide clarification and identification of topics where harmonisation of the regulatory framework of food supplements is incomplete. The key focus is the need to complete the existing regulatory framework, including the setting of maximum levels of vitamins and minerals in food supplements and solving the problems of health claims on botanicals under food law. She observed that the EU Member States are becoming more active themselves, and that she is keen to see EC proposals for action.
Dr Sommer was concerned that different national legislation and uncertainty in the functioning of the internal market was unacceptable, especially for small and medium enterprises (SMEs).

Key Messages:

- The Commission should provide clarification where harmonisation of the regulatory framework is incomplete.
- The focus should be on finalisation of the existing regulation on food supplements to avoid Member States starting their own activities, which might be a threat to the functioning of the internal market.

Dr Márta Horacsek,
National Institute of Pharmacy
and Nutrition, Hungary

15 YEARS OF THE FOOD SUPPLEMENTS DIRECTIVE – ACHIEVEMENTS AND FUTURE CHALLENGES: VIEW OF A MEMBER STATE

Since the introduction of food supplements in Hungary in the 1980s in the form of effervescent tablets, the market is still growing. Initially, the classification and legislation at national level was difficult. However, the harmonisation of regulation and rules at EU level covering food supplements, general food law, labelling, nutrition and health claims, additives and contaminants have provided clear rules for national legislation to regulate this category of products. Nevertheless, in the absence of maximum levels of vitamins and minerals at EU level there have been several national initiatives, decrees and court cases. In addition, Dr Horacsek stated that certain other substances including botanicals and other bioactive substances are only partially harmonised at EU level under Article 8 of Regulation 1925/2006/EC. In the majority of cases, case-by-case evaluations are needed to determine the minimum and/or maximum amounts of these substances.

Key Messages:

- Harmonisation at EU level has already provided a certain number of clear rules for the category.
- Main remaining challenges are maximum levels, use of other substances and the different notification systems of Member States.
- Pragmatic approaches and the willingness for compromise are needed to find appropriate solutions at European level

Dr Horacsek summarised the main challenges for the future as follows:

- Maximum and minimum amounts of vitamins/minerals in food supplements
- Harmonisation of the use of other substances (other than botanicals) including minimum and maximum amounts at EU level
- Harmonisation of the use of botanicals (safety, claims) at EU level (REFIT)
- Harmonised systems regarding notification of food supplements at EU level

Dr Horascek concluded that while the safety of the products has the highest priority, pragmatic approaches and the willingness for compromise are needed to find appropriate solutions at European level.

Monique Goyens,
BEUC The European Consumer Organisation

15 YEARS OF THE FOOD SUPPLEMENTS DIRECTIVE – ACHIEVEMENTS AND FUTURE CHALLENGES: VIEW OF THE CONSUMER

Ms Goyens noted that consumer intake of food supplements varies across Europe and is on the rise, at least in Eastern Europe. Several national food safety agencies have warned about possible health risks and questioned their usefulness. She referred to the lack of harmonisation in the areas of maximum amounts of vitamins and minerals, the different rules on classification of plant-based products and the possibility to ban or restrict substances under Article 8 of Regulation 1925/2006. Ms Goyens was concerned about the uneven level of consumer protection and consumer confusion.

Key Messages:

- Consumer associations are concerned about the incomplete harmonisation and uneven level of consumer protection across the EU.
- Potential of interaction with medicines, adverse effects and contraindications are important elements to consider
- There should not be a special treatment for the assessment of health claims on botanicals, nor for traditional herbal medicinal products.

She discussed the current regulatory requirements for labelling, presentation and advertising and identified what is still missing, namely that the quantity of active ingredients is not always declared and the potential for interaction with medicines, adverse effects or contraindications is not known. She also stressed the need for restrictions on marketing to children, particularly for food supplements presented in the form of sweets or candies. Ms Goyens' prime concerns are that safety is ensured, label declarations are accurate, and enforcement and compliance are strengthened in all Member States, particularly for products offered for sales online.

She concluded that regulatory gaps must be closed and rules on food supplements harmonised across the EU. She wants robust proof of efficacy and no special treatment for the assessment of health claims on botanicals. In addition, she stated that consumers should be educated to ensure cautious use of food supplements when needed, and to make them aware of potential risks.

Simone König,
Bayer Consumer Care AG

15 YEARS OF THE FOOD SUPPLEMENTS DIRECTIVE – ACHIEVEMENTS AND FUTURE CHALLENGES: VIEW OF INDUSTRY

Ms König stated that the Food Supplements Directive has facilitated the development of a well-established market in Europe, built under a strong food safety framework and with strong representation of the sector through Food Supplements Europe (FSE). In an FSE survey among its members in 2017, it was recognised that the Food Supplements Directive had had a positive contribution to the establishment of a definition at EU level, the recognition and enhanced credibility of the category, the reduction of trade barriers and the reduction of bad practices such as illegal and fraudulent products, although there is still insufficient control over internet sales.

She highlighted that despite the effective safety framework, it is still not possible to market the same product in all Member States, and that resources are wasted on making products conform to national laws rather than being invested in research and development and product innovation. The priority areas for industry regarding the further development of the Food Supplements Directive in the next five years include the harmonisation of the use of botanicals and other substances and the harmonisation of maximum levels for vitamins and minerals.

Key Messages:

- The Food Supplements Directive has strengthened the sector and its recognition and credibility.
- There are still problems to market an identical product in all EU Member States due to lack of harmonisation of certain areas.
- Industry expects help from the EC to close those gaps based on science-based principles.

Ms König concluded that the industry and FSE expect help from the EC to establish a harmonised legal framework and to build on science-based principles and best practice in the Member States. In addition, she emphasised that research is accumulating about the beneficial role of food supplements and good nutrition for public health and she highlighted a number of studies undertaken by FSE illustrating the potential of supplementation for healthcare cost savings.

Dr Georg Schreiber,
European Commission

OFFICIAL CONTROLS OF FOOD SUPPLEMENTS OFFERED IN THE INTERNET

Dr Schreiber stated that the increasing internet offers of food, in particular food supplements, pose specific challenges to competent authorities. To address these challenges and to protect consumers in the European Union from unsafe food or misleading practices, official controls of internet offers need to be strengthened. He described the various elements introduced by the Official Control Regulation (EU) 2017/625, including goods offered for sale by means of distance communication, actions to be taken by competent authorities where non-compliance is established, and official controls on food fraud.

Dr Schreiber presented the EU actions on e-commerce control. In particular, he highlighted the results of the first coordinated control plan on eFood. The coordinated control plan includes the checking of websites for non-compliance, identification of the location of traders and closer cooperation of the Member States on cross-border offers of products which are non-compliant with national or EU food legislation. Nearly all Member States participated in this EU-coordinated control plan for food products offered online and a high number of non-compliant online offers (mainly unauthorised novel foods or food supplements with medicinal claims) were found.

Key Messages:

- Internet offers of food supplements pose specific challenges to competent authorities, which are addressed in the Official Control Regulation.
- An EU action plan is implemented on eCommerce control which includes the checking of websites, identification of location of traders and closer cooperation between Member States to tackle non-compliant products.

Dr Schreiber summarised that the development of e-commerce control is a new task, and the EC is helping to support the competent authorities in the EU Member States and also at international level. The first coordinated control plan on eFood has shown that the competent authorities are capable to perform eCommerce control.

SESSION 1: DISCUSSION

In the discussion, there was general agreement that the Food Supplements Directive has been a milestone in the history of European harmonisation in the food area. Nevertheless, there is the need to further harmonise the legal requirements to provide a European wide equal level of consumer protection, to remove legal uncertainties and to establish equal marketing conditions and fair competition.

The participants called on the EC to take the initiative, in particular to resume discussions on European maximum levels for vitamins and minerals. At the same time, it was underlined that complete harmonisation can only succeed if all parties work together in a spirit of dialogue and compromise to resolve divergent views and to find European solutions.

Dr Valeriu Curtui,
European Food Safety Authority (EFSA)

EFSA'S ROLE AND ACTIVITIES IN THE FIELD OF FOOD SUPPLEMENTS

Dr Curtui underlined the key role of EFSA to provide independent scientific advice for EU risk managers and policy makers on food and food safety and risk communication. EFSA's work in the field of food supplements focuses on safety and nutritional assessments of nutrient sources. EFSA also assesses novel foods and health claims and provides opinions on tolerable upper intake levels (UL) and botanicals.

One main task is the assessment of safety and bioavailability of new nutrient sources which are proposed for addition to the list of permitted substances (vitamins and minerals) for food supplements. Furthermore, Dr Curtui pointed out the centralised safety assessment by EFSA in the context of applications for authorisation of a novel food and the scientific benefit assessments undertaken by EFSA under Regulation (EC) No 1924/2006 for nutrition and health claims. Regarding other substances he highlighted EFSA's role in the so-called article 8 procedure of Regulation (EC) No 1925/2006. Furthermore, he referred to the EFSA guidance for assessing botanicals and the compendium of botanicals, which is available as a web-based database.

Key Messages:

- The key role of EFSA is providing independent scientific advice for EU risk managers and policy makers on food safety.
- Its focus in the field of food supplements is on safety and bioavailability of new nutrient sources, novel foods, claims, tolerable upper intake levels and botanicals.

Referring to the discussion on maximum levels for vitamins and minerals, Dr Curtui described the work EFSA has already done, in particular the establishment of ULs for all vitamins and minerals. It is the aim of EFSA to support the EC and Member States in establishing maximum levels of nutrients authorised in food supplements and fortified foods. However, as Dr Curtui noted, pragmatism is required in addition to science for setting maximum levels, as Member States have very different views.

SESSION 2: BOTANICALS IN FOOD SUPPLEMENTS – ARE SOLUTIONS POSSIBLE?

Chair: Dr Márta Horacsek,
National Institute of Pharmacy
and Nutrition, Hungary

Alexandra Nikolakopoulou,
European Commission

REFIT – THE RESULTS OF THE FITNESS CHECK (CLAIMS)

Ms Nikolakopoulou explained that the REFIT-evaluation of Regulation (EC) No 1924/2006 is focused on nutrient profiles and on health claims on botanicals in food. A key issue is that similar ingredients are used in food supplements and in Traditional Herbal Medicinal Products (THMPs), but evidence of "traditional use" is accepted only for therapeutic indications on THMPs but not for claims on foods.

The first results of the REFIT evaluation indicate that the current legislative framework for botanicals is sufficient in terms of safety. The challenge, however, is to assess the non-implementation of the legislation on health claims on botanicals and whether the rules on health claims are "fit for purpose". Without a doubt, the current situation results in legal uncertainty and barriers for innovations both for food and pharmacy sector. In addition, the national approaches result in barriers to trade between the Member States. Ms Nikolakopoulou acknowledged that the mutual recognition does not work in practice and therefore a more harmonised approach would be good.

Key Messages:

- The first results of the REFIT-evaluation indicate that the current framework for botanicals is sufficient in terms of safety, but the current situation results in legal uncertainty and barriers for innovations both for the food and pharmacy sectors.
- Today, it is too early for the Commission to present conclusions, but the consultant's report on REFIT is expected to be finalised shortly.

The Commission expects to receive the finalised report of the consultant with the results of the REFIT evaluation shortly. Therefore, as Ms Nikolakopoulou stated, it is too early to present the conclusion from the Commission's point of view. Nevertheless, an approach which covers health claims as well as safety aspects could be a solution, e.g. in form of a positive list of botanicals for use in foods together with a list of permitted health claims for botanicals at EU level, based on traditional use.

Andreea Pantazi,
European Commission

REFIT – THE RESULTS OF THE FITNESS CHECK (MUTUAL RECOGNITION)

Ms Pantazi presented a proposal for a new regulation on the mutual recognition of goods, which is aimed at bringing added value in relation to the free movement of goods and refining and clarifying the procedures put in place by Regulation 764/2008. Currently, the principle of mutual recognition does not function well. The lack of legal certainty and lack of trust between Member States and stakeholders has made it challenging to ensure easy and reliable use of mutual recognition in the internal market.

The action plan, therefore, includes measures to raise awareness among national competent authorities, to exchange officials, to develop a "train the trainer" package with a "mutual recognition rule book", to build trust and mutual understanding of different regulatory approaches and concerns, and to focus on particular problematic sectors. The action plan will endeavour to make the national technical rules more comprehensive in terms of the use of clear and unambiguous legal clauses. Good examples are a clear definition of the term "lawfully marketed" and a mutual recognition declaration with the use of a standardised template, both actions of which could reduce unnecessary burdens, delays and additional costs. The declaration would facilitate the way economic operators provide accurate information to competent authorities on the goods they are marketing on their territory.

Key Messages:

- The current mutual recognition regulation does not work well due to lack of legal certainty and lack of trust and cooperation between Member States.
- A proposal for a new regulation and an action plan is being developed to improve mutual recognition and to reduce unnecessary burdens, delays and additional costs.

The proposal will also aim to provide a problem-solving mechanism by means of which economic operators could challenge national decisions that deny market access via the SOLVIT Centers, and improve communication channels through Product Contact Points (PCPs). The role of the PCPs is to offer more reliable administrative, technical and logistical support between economic operators and the competent national authorities.

Dr Helmut Tschiersky,
Federal Office of Consumer
Protection and Food Safety, Germany

HARMONISATION IN THE CASE OF BOTANICALS – BEST WAY FORWARD? THE VIEW OF GERMANY

Dr Tschiersky discussed the fact that, on an EU level, there are no substance-specific rules that apply to botanicals in foods or food supplements. There are no harmonised negative or positive lists, no minimum or maximum levels yet set, and no pre-market approval or authorisation procedures. Although general, non-specific law applies, the safety assessment and classification of other substances and botanicals is time consuming and is done on a case-by-case basis.

Key Message:

- For botanicals, there are no substance-specific rules for food supplements, which results in safety assessment and classification beingdone on a case-by case basis. This is a time-consuming process.
- Germany has developed a systematic approach for classification of products and for differentiation between medicines, novel foods, unsafe and safe foods, which could be a basis for harmonisation.

He advocated that the classification of these substances must be based on scientific evidence, and that a systematic approach is necessary. Such a systematic approach should employ the use of an effective and consistent exclusion principle under existing laws to remove medicinal products, novel foods without approval and unsafe food. It should be based on a decision tree, taking into account case law and the legal framework to classify the substance, and a list of substances established by means of a common approach. An expert commission to publish substance-specific recommendations would complete the approach.

Dr Tschiersky explained how Germany has already implemented such a systematic approach at national level. He referred to classification for medicinal product and the crucial interpretation of the wording of pharmaceutical, immunological or metabolic properties. He highlighted the German Joint Expert Commission to classify borderline-substances and the German "List of Substances" – a tool for competent authorities and companies to classify plants and parts thereof as food (ingredients). Nevertheless, harmonised positive and negative lists for botanicals would be preferable from Germany's point of view.

Dr Bruno Scarpa,
Ministry of Health, Italy

HARMONISATION IN THE CASE OF BOTANICALS – BEST WAY FORWARD? THE VIEW OF ITALY

Dr Scarpa began by referring to Directive 2002/46/EC on food supplements and Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, which both make provision for the use of various plants and herbal extracts that have nutritional or functional physiological effects. He stated why these substances are eligible as ingredients in food supplements as long as they are safe and not novel foods.

Key Messages:

- In Italy, products containing safe plants without therapeutic effects have been classified as botanical food supplements based on their traditional use.
- To help mutual recognition, a project was undertaken with Belgium and France to compile a common list (BELFRIT)
- The goal is to achieve EU harmonisation and the BELFRIT project could be a useful model, based on current practice.

After the Food Supplements Directive was implemented in Italy, products containing plants without therapeutic effects have been classified and marketed as botanical food supplements. Italy has implemented a positive list of safe plants and their parts that can be used in food supplements because of their traditional use. This list was last updated based on the so-called BELFRIT-list, which was a result of the initiative between BELgium, FRance and ITaly.

Dr Scarpa illustrated the complexities of the classification of botanicals as well as the imbalance between the acceptance of evidence for efficacy based on traditional use for Traditional Herbal Medicinal Products (THMP) but not for food. He concluded that an EU harmonisation process for botanical use in food supplements is the goal to achieve. He promulgated the BELFRIT project as a useful model, that has shown its usefulness in practice. He recommended that acceptance of traditional use for the beneficial effects of botanicals in food supplements should be considered not only to assess safety and efficacy but also to remove the existing discrepancy with the regulatory framework for THMP.

Patrick Coppens,
Food Supplements Europe

THE KEY ELEMENTS FOR ESTABLISHING A LEGAL FRAMEWORK FOR PLANT-BASED FOOD SUPPLEMENTS

Mr Coppens began by describing the economic importance of the (plant) food supplements sector in terms of market size, market growth and employment. He illustrated how this dynamic and innovative market had progressed over several decades.

Mr Coppens underlined that the assessment of claims on botanicals with the same scientific approach as other claims would have had considerable negative economic impact on the sector and would have resulted in less product choice for consumers. He described how traditional knowledge and history of use could be used for the assessments of safety and health effects for botanicals. He provided examples of proposed methodologies and solutions to describe the plant, safety and quality criteria as well as the health relationship and conditions of use.

Key Messages:

- The EU market for botanical FS is an important economic sector.
- A harmonised legal framework for botanicals could be based on a positive list considering harmonised quality and manufacturing requirements, complemented by harmonised notification requirements and a nutrivigilance system.

In his conclusions, Mr Coppens clearly set out the requirements for a harmonised legal framework for botanicals. Such a legal framework would build on a common list of plants that are accepted for use in food supplements with health benefits based on traditional use, with common conditions of use and, where necessary, any restrictions or warnings. Such a common list should be based on work already undertaken at national level, e.g. within the BELFRIT project. Together with specific quality and manufacturing requirements, where necessary, this would result in harmonised requirements across the EU. Quality, safety and lawful marketing could be complemented by harmonised requirements for notification and the creation of a "nutrivigilance" system to facilitate monitoring. He also stressed the importance of effective control and enforcement.

SESSION 2: PANEL DISCUSSION

In summary, there was agreement that further harmonisation of the use of botanicals in food supplements in regard to safety, claims and quality was necessary.

The report of the Commission with the results of the fitness check on the claims regulation in terms of botanicals will be the starting point for the discussion including the requirements for the assessment of claims. During the conference, the majority of participants favoured a more comprehensive European solution and underlined the willingness to support the establishment of a new legal framework for botanicals that covers all aspects.

In the short-term a joint positive list that considers traditional use and best practices would help to facilitate mutual recognition and provide common approaches for the effective control of safety and quality, market control and enforcement.

SESSION 3: MAXIMUM LEVELS OF VITAMINS AND MINERALS – ARE WE READY?

Chair: Dr Gert Krabichler,
Merck Consumer Health

Alexandra Nikolakopoulou,
European Commission

THE VIEW OF THE EUROPEAN LEGISLATOR

Ms Nikolakopoulou set out the general objectives of the Food Supplements Directive to provide a high level of protection of human health and ensure the free movement of goods in the EU internal market. Safety is the basis for setting maximum amounts of vitamins and minerals, and the criteria for food supplements are the same as for setting their maximum amounts in fortified foods in Regulation (EC) No 1925/2006.

Key Messages:

- Very diverse views between Member States and initiatives of some very vocal groups, mainly in the UK, were the reasons for putting harmonisation on hold.
- While Member States have started their own approaches, the EC is looking at the feasibility of relaunching the work.
- It is for the next Commission to decide whether to include this topic in its work programme.

Ms Nikolakopoulou underlined that in the past, the majority of Member States and interested parties already supported the setting of maximum amounts of vitamins and minerals, although their positions were often different and some preferred a more restrictive approach. However, negative reactions were very vocal and political, particularly from some representatives of high-dose food supplements in the UK. Thus, the initiative to set maximum levels was put on hold by the EC in 2009.

Subsequently, a number of Member States developed their own approaches towards maximum levels, some of which were restrictive and had raised questions about their validity and safety. The EC is looking at the feasibility of relaunching the work on setting maximum levels, as this work corresponds to a legal obligation to set implementing rules. Ms Nikolakopoulou explained that the resumption of this work will require an updated Impact Assessment Report, an update of the scientific background by EFSA, technical discussions with Member States, and liaison with relevant industry groups. The next Commission will have to decide whether to include this topic in its working programme.

Jean Savigny,
Avocat

THE LEGAL FRAMEWORK ESTABLISHED BY THE EUROPEAN COURT OF JUSTICE

Mr Savigny explained the background goals of EU law to establish an internal market and the means to achieve the free movement of goods. This movement of goods is reliant on harmonisation of national laws and/or mutual recognition when harmonisation is impossible or unnecessary for the free movement of safe goods throughout the EU.

He set out the principle of mutual recognition developed by the European Court of Justice and confirmed by Regulation EC No 764/2008 together with key decisions taken in case law, whereby a product that is lawfully marketed in one Member State must be accepted in other Member States provided that all mandatory requirements are fulfilled, e.g. protection of public health and consumer interests. Any restrictive measures, however, must be justified by the Member State, based on a case-by-case risk assessment, precise identification of the alleged risk and the identification of the probability of its occurrence and assessment of the severity of consequences. A Member State must prove the reality of the risk and any restrictive measures must be proportionate.

Key Messages:

- The principle of mutual recognition as developed by the ECJ and confirmed by Reg 764/2008 is the basis that a product lawfully marketed in one Member State must be accepted in other Member States.
- The principle of mutual recognition applies for the non-harmonised areas of food supplements. The burden of proof for any restrictive measure is with the Member State.

For food supplements, Mr Savigny listed the areas that are not harmonised, namely the maximum and minimum levels for vitamins and minerals, a positive list of other substances including botanicals and maximum and minimum levels for those substances. Therefore, as Mr Savigny concluded, in these areas the principle of mutual recognition applies and the legal framework established by the European Court of Justice has to be considered.

Professor David Richardson,
DR Nutrition

THE EUROPEAN RISK MANAGEMENT MODEL FOR FOOD SUPPLEMENTS

The proposed risk management model, as Professor Richardson highlighted, applies both quantitative and qualitative assessments, taking into account information from recognised authoritative scientific assessors and in particular EFSA. Due account is also taken of the EU regulatory criteria for setting maximum amounts of vitamins and minerals in food supplements and fortified foods.

Professor Richardson explained that the risk management model developed a process by which the nutrients could be allocated into three categories of risk. When authoritative risk assessments show no adverse effects, there are no safety concerns about a nutrient, and when a tolerable upper intake level (UL) cannot be established, the risk management model placed these nutrients in Group 1 and no further risk management measures are required for the normal healthy population and no maximum levels are set. In the case that the chance of exceeding the UL is extremely low, the maximum levels are calculated based on model equations (Group 2). If there is a potential risk of exceeding the UL (those nutrients in Group 3) a case-by-case assessment is required.

Key Messages:

- The proposed risk management model for setting maximum supplement levels for vitamins and minerals applies both quantitative and qualitative assessments, taking into account information from recognised authoritative scientific assessors.
- The model allocates nutrients according to their potential risks into three categories of risk.
- The proposed model for food supplements also considers the intake of nutrients from all other sources and incorporates substantial precautionary measures.

Furthermore, he pointed out that the proposed model incorporates substantial precautionary measures for potential future changes in nutrient intakes, as well as the P97.5 intake data including fortified food from food surveys. For nutrients with and without established ULs, the case-by-case methodology used is consistent with international standards for nutritional risk analysis that utilise both quantitative and qualitative risk assessments and risk management data.

Dr Karen Ildico Hirsch-Ernst,
German Federal Institute for
Risk Assessment

PROPOSED MAXIMUM LEVELS FOR VITAMINS AND MINERALS IN FOOD SUPPLEMENTS IN GERMANY

Dr Hirsch-Ernst began by explaining the risk assessment of nutrients, the concept of a safe intake range, the definition of the Tolerable Upper Intake Level (UL) together with a comparison of the ULs derived by EFSA/SCF for vitamins and minerals with their Recommended Daily Amounts (RDA) determined by D-A-CH (Germany, Austria and Switzerland). The presentation continued with the dietary intakes (P95) of adolescents aged 15 years and adults compared with the ULs and RDA values.

Dr Hirsch-Ernst presented the new proposals published by German Federal Institute for Risk Assessment for maximum levels for vitamins and minerals in food supplements that apply to persons aged 15 years and over. She explained the methodology underlying the derivation of the proposals. The German Federal Institute for Risk Assessment methodology derives the maximum levels of a nutrient by subtracting the P95 intake from the UL and then dividing the residual amount by a factor of 2 to account for a 50:50 split for a nutrient between food supplements and fortified foods. A further factor of 2 is also used to allow for possible multiple intake of different food supplements containing the same nutrient. For nutrients with no UL and/or no adequate intake data, the maximum levels were determined on a case-by-case basis.

Key Messages:

- The maximum levels proposed by the German Federal Institute for Risk Assessment consider not only the risk for adults, but also the risk for adolescents aged 15 years and older.
- The German Federal Institute for Risk Assessment model splits the amounts available for fortification and supplementation with a 50:50-ratio. A second factor of 2 takes into consideration the potential for multi-exposure to the same nutrient consumed through supplements.

Finally, Dr Hisch-Ernst pointed out that the goal of the proposals is to serve as protection against excessive nutrient intake for the large proportion of the German population. The proposals of the German Federal Institute for Risk Assessment should be a decision-making aid for the risk management by the national legislator for setting maximum levels at national level in Germany.

Katrien De Pauw,
Federal Public Service Health,
Food Chain Safety and Environment,
Belgium

SETTING MAXIMUM LEVELS – A NATIONAL APPROACH

Ms De Pauw introduced the system that has been put in place to regulate food supplements in Belgium, with maximum levels for vitamins and minerals and composition requirements for other substances, including botanicals.

She explained that since 1992, maximum levels of vitamins and minerals were set in a Royal Decree. A process to update these amounts was initiated in 2014, and this resulted in the publication of national legislation on 31st October 2017.

Key Messages:

- The maximum levels for vitamins and minerals set in the Belgium Royal Decree from 1992 were updated in October 2017, based on the risk assessment by the Belgium Superior Health Council (BSHC).
- To ensure safety, additional mandatory warning statements for certain nutrients exceeding a certain amount are required for certain population groups.

Ms De Pauw explained that the risk assessments have been carried out by the Belgium Superior Health Council (BSHC), and the re-evaluation resulted in no maximum being established for vitamins B1, B2, B5 and B8 and selenium, chloride and silicon. To ensure safety, additional mandatory warning statements for certain nutrients exceeding a certain amount were required for certain population groups.

Ms De Pauw illustrated her presentation with tabulations showing the old and new maximum values. For the majority of nutrients, the maximum levels remain unchanged from the 1992 values. She also outlined the notification requirements for food supplements and fortified foods.

SESSION 3: PANEL DISCUSSION

All panel speakers agreed without doubt that a harmonised European approach is the best solution for consumers as well as for companies. Safety should be the first priority. Therefore, setting maximum levels has to be science based and proportionate, as well as being in line with the legal framework established by the European Court of Justice.

In particular, an agreement at European level on the appropriate risk management approach is key. It was concluded that it is clear that the divergent opinions and approaches in the EU will require open dialogue, exchange of information and appropriate involvement of all interested parties to develop harmonised maximum levels across the EU. The participants called on the risk managers and policy makers at national and EU level to restart such an open-minded discussion in the spirit of willingness to compromise.

SESSION 4: THE ROLE OF FOOD SUPPLEMENTS FOR HEALTH AND WELLBEING – WHAT DO WE KNOW?

Chair:
Professor Manfred Eggersdorfer,
DSM Nutritional Products

Professor Philip Calder,
University of Southampton

MICRONUTRIENT INTAKE IN EUROPE – NEED FOR ACTION?

Professor Calder highlighted the fact that healthy nutrition for all is one of the most pressing topics in the 21st century. Non-communicable diseases (NCDs) dominate the global pattern of morbidity and mortality. The World Health Organisation (WHO) projects a global increase of 17 % in some NCDs over the next decade, leading to decreased productivity, impaired quality of life and a huge healthcare cost burden. According to WHO and the United Nations more than 40 % of nutrition-related diseases take place before the age of 70 years, and that about one third of cancers and up to 80 % of deaths from heart disease, stroke, diabetes and type 2 diabetes are preventable.

Key Messages:

- Micronutrients are essential to health and wellbeing, but in several cases it is difficult to achieve recommended or sufficient intakes from foods.
- Increased intake of essential micronutrients would improve the nutritional status, enhance physiological functions, improve health and wellbeing and lower risk of disease.

Having set the scene, Professor Calder indicated that micronutrients are essential to health, wellbeing and life because of their involvement in all biochemical reactions and cellular functions. He illustrated the health consequences of deficiency and insufficiency of several essential micronutrients including vitamins C, D and E, folate and iodine and the omega-3 long chain fatty acids. For example, Professor Calder emphasised the clear relationship between vitamin D intake, nutritional status and benefits of using vitamin D food supplements to benefit the individual and society as a whole.

Professor Calder concluded that increased intake of the essential micronutrients would improve nutritional status, enhance physiological functions, improve health and wellbeing and lower disease risk. He added that there would be huge economic benefits from improved micronutrient intake, and stated that, in many cases, it was difficult to achieve recommended or sufficient intakes from foods.

Dr Bernd Haber,
BASF SE

THE IMPORTANCE OF FOOD SUPPLEMENTS FOR PUBLIC HEALTH AND WELLBEING

Dr Haber began by referring to the EU health newsletter 2015 on how to keep EU citizens healthy. The Commission has called for a complete rethink on its understanding about health in policymaking, pointing out that only around 3 % of health budgets are being spent on prevention, yet NCDs, which are often preventable, account for up to 80 % of healthcare costs. Proactive investment in promoting health lifestyles and tackling major risk factors could reduce the burden of NCDs, saving lives and also money.

Key Messages:

- Sufficient micronutrient intake plays a major role in the prevention of NCDs and its consequences. Given the example of vitamin D, even people working for one of the largest vitamin manufacturers in the world have insufficient vitamin D status.
- Recent studies by Frost & Sullivan demonstrated that sufficient nutrients intake could save billions of euros of healthcare costs in Europe.

A good illustration is the high prevalence of low vitamin D status in all European countries, especially in the elderly population. Dr Haber referred to a study of BASF employees and their vitamin D status after the winter season. Approximately 70 % of BASF employees had deficient or insufficient vitamin D status, and only 10 % met the recommendations for reduced risk of osteoporosis.

Dr Haber stated that although people are living longer, they are not necessarily healthier than before. Nearly a quarter (23 %) of the overall global burden of death and illness is in people aged over 60 years, and healthcare costs are expected to increase dramatically over the next few years. In this context he referred to the Food Supplements Europe's research by Frost and Sullivan showing that regular consumption of calcium (1000 mg) and vitamin D (15 micrograms) could reduce the risk of osteoporosis-attributed fractures and provide nearly 20 billion euros of cost savings to the healthcare systems over five years, as well as significant reductions of hospital events.

Dr Manfred Ruthsatz,
Nestlé Health Science

INNOVATIONS IN THE FIELD OF FOOD SUPPLEMENTS – A FUTURE OUTLOOK

Dr Ruthsatz referred to the rapid changes that are occurring throughout the world. Consumer expectations are changing substantially, the competitive landscape is reshaping, particularly with respect to the impact of digital technology on the way of shopping, on what products are bought and what services are expected. He observed that consumers are managing their health more proactively and increasingly understand the important role food plays in health and wellbeing. He referred to the EU Horizon 2020 Initiative, which focuses on changing lifestyles, unhealthy diet and physical inactivity as major risk factors, innovations in the food sector at all stages of the food chain, and advances in scientific and technological knowledge, including the recognition of the benefits of personalised nutrition and health services. He noted that policies and regulatory frameworks are having a big impact on future developments related to food production, diet and health.

Key Messages:

- Consumer behaviour and lifestyles are changing rapidly, and consumers are managing their health more proactively.
- Innovations in food, and advances in scientific and technological knowledge, lead to strong recognition of the benefits of personalised nutrition and health services.
- Science plays a crucial role in effective law and policy making - and to enable nutrition solutions for sustained health benefits in the interest of society.

Dr Ruthsatz spoke of the general trends in food preferences and consumer needs for different population groups, especially for active and healthy ageing and customised nutrition. He extolled the benefits of personalised nutrition and the opportunities for adapting the power of nutrition to specific needs. Dr Ruthsatz emphasised the crucial role of science to underpin the development of effective law and policy making and to enable nutrition solutions for sustained health benefits in the interest of society.

He concluded by underlining the need for continued constructive, multi-stakeholder dialogue to enhance the role of nutrition, the need to stimulate innovation and to use the nutrition potential of food supplements as part of the solutions in health and disease management.

SESSION 4: DISCUSSION

In particular and in the light of the existing suboptimal nutrient intake of the European population, food supplements can help to close nutritional gaps.

The speakers agreed that the use of supplements not only can contribute to maintaining the health of individuals, but can also generate societal and public health benefits. The information and data presented showed the value of food supplements for the people's wellbeing as a part of a varied and balanced diet to improve people's nutritional status, support healthy ageing and save healthcare costs.

Evolving consumer habits and needs will create challenges for society and legislation. Therefore, the speakers emphasised the importance of a legal framework that guarantees safe products and a high degree of consumer protection, while at the same time supporting research and new technologies as well as promoting rapid innovation.