REPORT

8–9 December

BERLIN 2011

THE REGULATION OF FOOD SUPPLEMENTS IN EUROPE

How much harmonisation is needed?

BLL ERNA ehpm european botanicalforum IADSA

INDEX

SUMMARY

WELCOME & OPENING

SESSION 1: THE REGULATION OF FOOD SUPPLEMENTS IN THE EU – EXPERIENCES AND FUTURE PROSPECTS

Chaired by Peter Loosen, German Federation for Food Law and Food Science

SESSION 2: MAXIMUM LEVELS FOR VITAMINS AND MINERALS

Chaired by Dr. Gert Krabichler, German Federation for Food Law and Food Science

SESSION 3: HEALTH CLAIMS

Chaired by Peter van Doorn, European Federation of Associations of Health Product Manufacturers

SESSION 4: BOTANICALS AND OTHER SUBSTANCES IN FOOD SUPPLEMENTS

Chaired by Professor Vittorio Silano, the Scientific Committee, European Food Safety Authority

CONCLUSION

THE REGULATION OF FOOD SUPPLEMENTS IN EUROPE

How much harmonisation is needed?

The International Food Supplements Conference was held in Berlin from 8 to 9 December 2011. More than 200 delegates from all over the world came to Berlin to discuss existing and future challenges for marketing food supplements in the European Union (EU).

The joint conference, hosted by the German association BLL and coorganised by the European associations ERNA, EBF, EHPM and the global food supplement association IADSA, was attended by representatives from the European Food Safety Authority (EFSA), the European Commission and the European Parliament, as well as various national regulatory authorities, academics and industry representatives. For two days the experts intensively discussed the issues of key relevance for the sector, namely the setting of maximum levels for vitamins and minerals, the Nutrition and Health Claims Regulation and the use of other substances, specifically botanicals, and health claims thereon.

The conference highlighted the need for further harmonisation in Europe based on sound science. Even though the issues are highly complex, in many aspects controversial and bound to become political, the participants in the conference agreed upon continuing the initiated dialogue between scientists, regulators and industry representatives, with the aim of achieving further harmonisation.

WELCOME & OPENING

Professor Matthias Horst, General Director, German Federation of Food Law and Food Science

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Professor Matthias Horst welcomed the participants and expressed his hope that the exchange of opinions and experiences would fuel discussions and introduce new ideas. He appreciated the major achievements which had already been made, but pointed out that much more has to be done before the European Union regulatory framework on food supplements will be fully harmonised. Professor Horst underlined that safety and quality of food supplements must have top priority and regulatory decisions must be based on scientific evidence, eventually paving the way for European solutions on all the issues yet unsolved.

Bernhard Kühnle, Director General, German Federal Ministry of Food, Agriculture and Consumer Protection


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Bernhard Kühnle agreed that, even though the ideal varied and balanced diet may not be widespread, the role of food supplements was uncertain because of scientists questioning benefits and highlighting risks. He highlighted that, due to the lack of harmonisation, there are different levels of consumer protection in the Member States leading to disruption of the market and uncertainty among consumers. He therefore called for the urgent setting of maximum levels and nutrient profiles and for the application of a common procedure for safety assessment for other substances.

SESSION 1: THE REGULATION OF FOOD SUPPLEMENTS IN THE EU – EXPERIENCE AND FUTURE PROSPECTS

Chaired by Peter Loosen, Managing Director and Head of Brussels Office, German Federation for Food Law and Food Science

Basil Mathioudakis, Head of unit, DG Sanco, European Commission

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Basil Mathioudakis gave an overview of what has been achieved in the field of harmonisation and highlighted that further harmonisation has become both controversial and highly political.

He indicated that the views on maximum levels are very diverse but now that the article 13 list has been adopted, work could be reinitiated. He underlined that, for the European Commission, it is very important that the basic principle of safety continued to apply as a basis for setting maximum levels.

In relation to other substances, the intention of the European Commission on further harmonisation has not changed - there is neither a need nor is it feasible. On the other hand, member states have expressed their concern with regard to the safety and quality of botanicals in food. While member states insist that the procedure under article 8 of Regulation 1925/2006 should be used more intensely, it is the opinion of the European Commission that the intention of that legislation is not to establish negative lists.

Mr. Mathioudakis reported that on botanicals a fundamental reflection is ongoing. Harmonisation will be linked to solving the problem of claims. He reiterated that it is important to minimize disruption of the markets when solving this problem. He also highlighted that the revision of the dietetic food framework is intended to remove the possibility to avoid the claims Regulation by marketing food supplements as dietetic foods and thereby reduce unfair competition.

Dagmar Roth-Behrendt, Vice President of the European Parliament

Dagmar Roth-Behrendt, European Parliament

Dagmar Roth-Behrendt underlined that foods have a nutritional purpose and all other purposes must be covered by pharmaceutical law. She clearly stated that it is not acceptable to establish claims for food supplements on the basis of monographs for traditional herbal medicinal products (THMP). These monographs have a different approach and are therefore not suitable for food supplements. Furthermore, she expressed her concern at having plant food supplements on the market without control of safety and quality. Food supplements have no safety or quality requirements whereas for medicinal products, this is covered by the Traditional Herbal Medicinal law. She warned against any new legislation with regard to botanicals as the outcome would not be predictable. If botanicals are used under food law, there should not be any health claim.

Dr. Markus Rudolph, Vice President R&D and Operations at Merck Consumer Health Care

Dr. Markus Rudolph, Merck Consumer Health Care

Dr. Markus Rudolph said that for the competitive strength of the EU industry, a business friendly environment is necessary. This should be based on further harmonisation and strengthening mutual recognition. He called for harmonisation but warned that new rules must be workable. This would apply to all fields, be it claims, maximum levels, novel foods, or botanicals. On claims, he highlighted the need for a gold standard in evidence based nutrition, not in medicine. He warned that nutritional research is more expensive than pharmaceutical research and that a judgment should take into account the current knowledge on food and should grade the evidence. He also reiterated that botanicals are, and must continue to be, used in both medicinal and food products – on the understanding that the products are safe, of good quality and not misleading.

SESSION 2: MAXIMUM LEVELS FOR VITAMINS AND MINERALS

Chaired by Dr. Gert Krabichler, Vice Chair of the Food Supplement Working Group within the German Federation for Food Law and Food Science

Professor David Richardson, Scientific Advisor of CRN UK and Professor Peter Aggett, School of Health and Medicine, Lancaster University

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Professor Peter Aggett, Lancaster University

Both Professor David Richardson and Professor Peter Aggett stressed the need for a science-based approach for setting maximum levels.

Professor Richardson explained the ERNA/EHPM risk management model and its underlying scientific basis. He also demonstrated a risk management approach to the setting of maximum levels for children aged 4–10, following the same methodology as the ERNA/EHPM model for the setting of maximum levels for adults.

Professor Aggett widened the perspective to international risk assessment approaches and underlined the fact that the establishment of tolerable upper levels of intake (ULs) should be science based.

Professor Alfonso Lampen, Head of Department of Food Safety, Federal Institute of Risk Assessment

Professor Alfonso Lampen, Federal Institute of Risk Assessment

Professor Alfonso Lampen raised serious doubts about the safety of high dosed food supplements. His conclusion was that, in recent years, the benefit of food supplements has been questioned and multiple risks highlighted. He illustrated this with examples of data on folate, vitamin E, beta-carotene and calcium. Professor Lampen also highlighted the use of ULs as the benchmark for setting maximum amounts for adding nutrients to supplements and foods. Consumers should be able to consume all kinds of foodstuff in combination, without venturing into intake ranges beyond the ULs. Therefore, maximum levels for food supplements and fortified foods have to be considered concertedly.

Guillaume Cousyn, Unit Nutrition and FIC, Ministry of Economy, Finance and Industry

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Guillaume Cousyn presented the work of the French authorities on setting maximum levels and the relevant judgment of the Court of Justice of the European Union. The main conclusion is that, in the absence of harmonized EU levels, the national authorities remain competent to adopt legislation on maximum levels, but they have to abide by the same criteria as specified in the Food Supplements Directive. Levels must be safety based and in the absence of safety concerns, no maximum level should be set. It is possible to set the level to zero provided the intake of a nutrient cannot be calculated precisely and there is a genuine risk that the upper safe level of intake may be exceeded.

Discussion

During the discussion it was again reiterated that both the ERNA/EHPM model for food supplements and the Gubbio model for fortification of food are suitable for setting maximum levels. It was also stressed that there is too much focus on potential high intake, while demonstrated insufficient intake of many nutrients is largely ignored. Despite different positions on how to settle maximum levels in detail, the experts at the conference agreed on the need for harmonized maximum levels, and called on all involved parties to work together to find a joint solution.

SESSION 3: HEALTH CLAIMS

Chaired by Peter van Doorn, Chairman, European Federation of Associations of Health Product Manufacturers

Catherine Geslain-Lanéelle, Executive Director, European Food Safety Authority

Catherine Geslain-Lanéelle, European Food Safety Authority

Catherine Geslain-Lanéelle presented the broader spectrum of the EFSA's work in the field of public health (intake data and dietary surveys, dietary reference values, food-based dietary guidelines). She also explained, in detail, the reasoning behind the EFSA approach and highlighted the resultant changes in the EFSA infrastructure in order to be able to communicate better with applicants (e.g. creation of a new application unit).

Basil Mathioudakis, Head of unit, DG Sanco, European Commission

Basil Mathioudakis, DG Sanco, European Commission

Basil Mathioudakis presented the latest developments with regard to the Nutrition and Health Claims Regulation. In particular, he highlighted the adoption of the first article 13.1 list of accepted claims by the Standing Committee on Monday 5 December 2011. Furthermore, he explained the deeper meaning of this together with the other measures taken to implement the Claims Regulation. He repeatedly said that the Nutrition and Health Claims Regulation was there to clean the market and that the vast majority of the parties, including the 'serious' industry, support this.

Professor Hans Biesalski, Deparment of Biological Chemistry and Nutrition, University of Hohenheim

Professor Hans Biesalski, University of Hohenheim

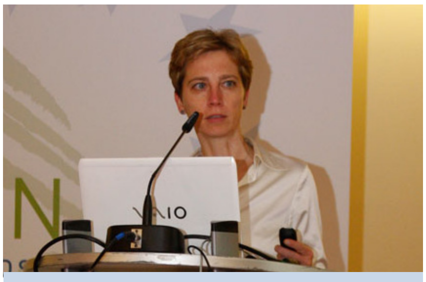
Professor Hans Biesalski gave a presentation on the reasons why the pharmaceutical approach has serious limitations for nutritional research, citing ample examples. He also presented the outcome of the 26th Hohenheim consensus conference on evidence based nutrition, that reached the same conclusions. He finally stated that external scientists and claim applicants should discuss the conflicting aspects of different approaches to establish, at least, an evidence based nutrition framework.

Marian Harkin, Member of the European Parliament

Marian Harkin, European Parliament

Marian Harkin, who could not attend, sent a statement to the conference. She clarified that Article 13.1 of the claims Regulation was adopted to protect consumers from misleading claims, but also to help SMEs by preventing them from having to go through an extensive and costly authorisation process for the generic health claims.

Martina Simova, Medical Director, Walmark



Martina Simova, Walmark

Martina Simova highlighted the consequences, both practical and economic, of the claims outcome. She particularly illustrated this with the example of joint health products which currently contribute 20% to the company's sales and therefore are the key segment for Walmark, a Czech based food supplement manufacturer. Most of all, she asked for a longer transition period because changing the packing and marketing materials in only six months is unrealistic or will at least cause major financial loss.

Discussion

The round table discussion was centered on the appropriateness of the scientific approach and the call to EFSA to sit together with experts to develop an appropriate framework. It was agreed that the scientific community is still in the phase of finding out the basics and that more investigation in nutrition research is needed. Nevertheless, the knowledge available today should have a higher impact on the weighing of the evidence.

Mrs. Geslain-Lanéelle reiterated that EFSA has applied the highest scientific standard, as requested by the Regulation, and that the article 13 process had serious shortcomings leading to many negative opinions. – for example, every rejected claim has a second chance via an application for authorization. However, EFSA is open to having an academic discussion with experts to find a more appropriate approach for a mid-time and longer perspective.

SESSION 4: BOTANICALS AND OTHER SUBSTANCES IN FOOD SUPPLEMENTS

Chaired by Professor Vittorio Silano, Chair of the Scientific Committee, European Food Safety Authority

Professor Mauro Serafini, Department of Plant Biology, University of Rome

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Professor Mauro Serafini focused on the question of how to assess health claims for botanicals and, in particular, on the value of traditional use. He explained the need to define each claim exactly with regard to the scientific name, the used part and the preparation of the plant. However, the enforcement of the evidence based medicine approach on botanicals is very difficult; mainly because of the complex composition of plants. He therefore recommended the preservation of traditional knowledge, whilst at the same time investing in better strategies for the coming years.

Dr. Helmut Tschiersky-Schöneburg, President, Federal Office of Consumer Protection and Food Safety

Dr. Helmut Tschiersky-Schöneburg, Federal Office of Consumer Protection and Food Safety

Dr. Helmut Tschiersky-Schöneburg explained the approach of German authorities towards botanicals and the 'Stoffliste', which was developed as a tool to help industry and enforcement authorities to address the legal status and the safety concerns of botanicals. This German list was developed because there is no EU-list existing. It considers the work which had already been done by European institutions, in particular the EFSA compendium of botanicals. He strongly advocated the harmonisation of the use of botanicals in food considering food and medical law.

Joris Geelen, Expert plants, Federal Public Service for Health, Food Chain Safety and Environment

Joris Geelen, Federal Public Service for Health, Food Chain Safety and Environment

Joris Geelen presented the Belgian legal system based on lists for plants. He explained the national notification system and the role of the Advisory Commission on Plant Preparations. The Advisory Commission is responsible for the scientific safety evaluation and for the setting of maximum levels, as well as for the definition of mandatory warnings if needed. He also highlighted the current problems with a restrictive interpretation of the novel food legislation.

Professor Patrizia Restani, Department of Pharmacological Sciences, University of Milan

Professor Patrizia Restani, University of Milan

Professor Patrizia Restani presented the current status of the EU funded plant LIBRA project, which will contribute to the understanding and availability of data on botanical food supplements. The target of the project is, firstly, to collect information about the level of intake and on consumption patterns across Europe. Secondly, scientific data about benefits and risks of such ingredients and products are analysed. A database will provide a uniquely comprehensive overview of plant food supplements for experts and all companies.

Professor Robert Anton, Faculty of Pharmacy, University of Strasbourg

Professor Robert Anton, University of Strasbourg

Professor Robert Anton shortly demonstrated other national and international concepts for the safety evaluation of plants for human diet. He recommended working on existing plant lists to find a consensus for a future European harmonisation.

Discussion

The experts agreed in the discussion that the assessment of quality, safety and benefit of botanicals in food should be science based and that the risk assessment must be carefully carried out. There was a strong call for further harmonisation and the need to have a joint European group of botanical experts to deal with borderline issues.

CONCLUSION

Dr. Gert Krabichler, Vice Chair of the Food Supplement Working Group within the German Federation for Food Law and Food Science

Dr. Gert Krabichler, Food Supplement Working Group within the German Federation for Food Law and Food Science

Dr. Gert Krabichler thanked the Conference organisers, speakers and participants, saying that the purpose of the event had been to present critical issues for future regulation and to jointly search for solutions. Summing up, in his view, the contributions and discussions of the conference clearly showed the need for more harmonisation.

In regard to maximum levels of vitamins and minerals, it has become quite clear that most parties strongly support the need to find a uniform way of determining maximum levels within Europe. The experts agreed that the setting of maximum levels must be based on considerations of safety, namely upper safe levels (ULs) considering the intake from all sources. Dr. Krabichler highlighted that the discussion on the basis of scientific models was far developed and expressed his hope that the conference debate was the trigger for the resumption of a constructive debate for a European solution.

The Nutrition and Health Claims Regulation and its implications, Dr. Krabichler continued, remains the hottest issue. He pointed out that it is probably the most challenging process so far. The discussions during the conference focused on whether EFSA's approach to the scientific assessment of claims for foods was appropriate. Experts agreed that nutrition science has to do its homework, but there were different views as to the proper scientific approach for assessing health claims on foods. Dr. Krabichler appreciated EFSA's willingness to engage in a constructive dialogue on the assessment of claims.

The discussion on botanicals and their use in food and food supplements are at a very early stage in comparison with the developments on vitamins and minerals, Dr. Krabichler continued. Considering the controversial views that have been discussed during the conference, he called for practical solutions to give botanicals their rightful place under food law. The conference presented interesting options on how to deal with botanicals in food supplements which should become the basis of future discussions.

Dr. Krabichler thanked all participants for the stimulating and constructive debate that clearly showed the need and room for further harmonisation on the basis of open exchange between regulators, scientists and industry.