Berlin 2005
A Regulatory Forum

Food Supplements in Europe: Challenges for the Future

BLL, EHPM, ERNA, IADSA Conference • 20 - 21 September 2005

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ENTER REPORT

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Welcome Address

- Prof. Dr Matthias Horst, Director General, German Federation of Food Law and Food Science (BLL)

Welcoming Conference delegates to Berlin, BLL Director General, Professor Dr Matthias Horst, recalled the Conference organised by IADSA and the European associations in Prague in May 2004, an important event attended by key decision-makers from the scientific, regulatory and industry arenas. BLL were particularly pleased to have become one of the organisers of this international event in Berlin, an equally prestigious occasion.

Professor Horst said there had been many achievements in food harmonisation in the last two decades, particularly in the area of safety, but there was still much to do in respect of enforcement and filling the remaining gaps in food legislation.

He emphasised the need for food legislation to be based on science, and stressed the importance of maintaining the central role of EFSA as an EU authority with an unblemished reputation, so as to retain consumer confidence.

- Prof Dr Matthias Horst, Director General of BLL

Welcome Address

- Bernhard Kühnle, Director General, Federal Ministry of Consumer Protection, Food and Agriculture (BMVEL), Germany

Thanking the Conference organisers for inviting him, Mr Kühnle said he also brought best wishes for a successful event from Renate Künast, the German Minister for Consumer Protection Food and Agriculture.

Mr Kühnle said he saw many challenges in the food supplements sector. On the one hand there was a large and diverse product range available, and an increasing demand for products to slow the ageing process and to promote health. On the other, while in his view supplementation was appropriate for certain vulnerable groups – for instance the elderly – there were concerns from some nutritional experts that supplements were being taken to replace a normal diet.

Stressing the importance of the consumer being able to rely on true, scientifically sound claims, Mr Kühnle said that he was concerned that the expectations of consumers were often too high and supplements could not fulfil them. In his view the Health Claims regulation was an appropriate legal framework to deal with this issue.

In conclusion Mr Kühnle said that setting maximum levels for vitamin and mineral supplements and the regulation of other substances used in food supplements were outstanding challenges for scientists, regulators and industry, and called on the Commission to act on these challenges without delay.

Welcome Address

- Dr Gert Krabichler, Chairman, European Responsible Nutrition Alliance (ERNA)

Dr Krabichler welcomed the high level of interest from scientists, regulators and industry in the forthcoming Conference, and, reiterating the theme of his closing remarks at the 2004 Prague Conference, said that in the interests of harmonisation the need was for more 'European' and less 'national' thinking. The aim for the next two days should be for regulators, scientists and industry to work together to achieve a harmonised European Union (EU) regulatory framework that was:

- Appropriate
- Understandable
- Easy to implement

Session 1 - The Challenges for Regulating Food Supplements

- Chaired by Prof. Dr Matthias Horst, Director General, BLL

The Emerging Regulatory Environment for Food Supplements in the EU

- Basil Mathioudakis, Acting Head of Unit, DG SANCO, European Commission, Brussels.

Introducing a comprehensive presentation which covered:

- ECJ Judgement and consequence
- Modification of Annexes
- Update on state of affairs as regards Article 4.6
- Maximum/minimum levels
- Claims
- Labelling issues (Reference Values, tolerances)
- Ingredients other than vitamins and minerals

Mr Mathioudakis said that the Conference was particularly timely in view of the recent judgement of the European Court of Justice (ECJ) on the actions brought by some UK trade and retailer associations to contest the validity of the Food Supplements Directive. There had been some uncertainty about the future of the Directive as a result of the interim opinion of the Advocate General. However the ECJ's decision that the Directive was indeed valid meant that it fully applied as of August 2005.

Mr Mathioudakis said that the target of the ECJ actions had been the Annexes to the Food Supplements Directive and the procedures for adding substances to those Annexes. He announced that, after a positive opinion by the European Food Safety Authority (EFSA), a draft directive is shortly to be submitted to the Standing Committee for the addition of several substances to the Annexes of the Directive, demonstrating that the procedure outlined in the Food Supplements Directive worked.

Mr Mathioudakis gave an overview of the derogation dossiers: 710 dossiers had been submitted to the European Commission, the majority just prior to the closing date for seeking derogation. 45 dossiers were not retained as either the substances they concerned were already in the Annexes, or were not vitamins or minerals or they concerned finished products. Multiple submissions for the same substance further reduced the total number of dossiers which had now been sent to EFSA to about 410. Of the 460 dossiers that had been received from the UK, only 160 were 'full' dossiers, the others being of poor quality with respect to relevant EFSA Guidelines. He emphasised that the ECJ judgement did not mean that there was any shift in the burden of proof for submission of data for dossiers - it remained the responsibility of the submitter, not of EFSA.

Mr Mathioudakis further highlighted a number of key issues during his presentation:

Better Regulation: Acknowledging industry demands for a reduction in the regulatory burden, Mr Mathioudakis pointed out that better regulation is not the same as no regulation. He commented that although one minor food law proposal on food labelling would be abandoned, the proposed claims Regulation remained firmly on the table.

Maximum Levels: The Commission has made little progress as yet on setting maximum levels for food supplements and fortified foods, but intends to devote time to the issue soon. Upper levels have not been established for all vitamins and minerals by EFSA, and for some nutrients it may be questioned whether there is a need to set maximum levels. Mr Mathioudakis emphasised that the Food Supplements Directive supports safety as the prime criterion for establishing maximum levels and that no undue constraint should be put on the marketing of safe products. There were concerns about the availability of reliable intake data, which must be taken into consideration.

The Health Claims Regulation: Mr Mathioudakis said he saw the proposed Regulation, which could finally be adopted in mid-2006, as working to the long-term advantage of the reputation of the food industry as a whole. In his view the compliance costs for the food supplement industry were likely to be less than claimed because few dossiers would be submitted for disease risk reduction claims. He did not think that a post-marketing notification process would be received favorably by Member States and noted that the Council had reached a unanimous political agreement which included pre-marketing authorisation, and that therefore industry's emphasis should be on the development of the proposed central list of nutrient function claims.

Labelling Issues: Progress was long overdue, but work would start soon, with decisions on the revision of the Directive on nutrition labelling being taken by the year end. Particular issues include:

- Tolerance levels for the declaration of nutrients
- Update of Recommended Daily Allowances values

Other Ingredients/Botanicals: The Commission has not yet started work on its report on the advisability of establishing rules for the use of nutrients or substances other than vitamins and minerals, due in July 2007. However, EFSA has given itself a mandate on botanicals – specifically to:

- Analyse relevant information submitted by 26 EU Member States
- Prepare a guidance document on safety assessment
- Establish a list of the main categories for assessment

EFSA's report is due by May 2006.

The legal Framework established by the European Courts

- Jean Savigny, Senior Partner,
Keller & Heckman LLP, Brussels

Mr Savigny's presentation centred on the contribution by the European Court of Justice (ECJ) towards a harmonised Europe for the marketing of food supplements, concentrating in particular on:

- The principle of mutual recognition
- The legal validity of Directive 2002/46/EC
- Guidelines for national courts to resolve borderline classification issues

Taking the principle of mutual recognition to mean the free movement of goods to non-harmonised situations, Mr Savigny outlined both the scope of the application of the principle, and the exception which permits Member States, on grounds of public health protection, to prohibit the import of specific products.

Commenting on the recent ECJ ruling on the validity of the Food Supplements Directive, Mr Savigny noted that the Court had been critical of some aspects of the drafting of the Directive, particularly those dealing with transparency and the timescale for EFSA's work on dossier assessment. However, he also indicated that there were some aspects of the Court judgement which could create future problems for the industry, such as the clear endorsement of positive lists over negative lists. Overall, he considered the case had been a negative step for the industry.

Member States have the right to decide the status of a particular product (and a recent ECJ ruling has confirmed that the same product may be differently classified in individual Member States). However the exercise of this right means that the central pillar of European Union regulation, mutual recognition, cannot apply and the question then is whether the Member State's classification decision is correct.

Questions and Answers

Negative Lists: Further to the recent ECJ ruling on the Food Supplements Directive and its comments on positive and negative lists, EHPM Chairman Peter van Doorn asked why, unlike the Fortified Foods Regulation, there could not be a negative list for food supplement nutrient sources. In response, Mr Mathioudakis said that the correct description for the Fortified Foods list was a 'restricted' list, and it was not a negative list in the sense referred to by the Court.

The borderline between food supplements and medicines: It was asked whether the revised definition of a medicinal product (which now includes reference to 'physiological' effect), would mean that supplements would be classified as medicines, Mr Savigny said that this was not necessarily the case, and that at present the same product might be classified differently by individual Member States. Echoing this response, Mr Mathioudakis said that the revised definition of a medicine had not really clarified borderline issues, and it remained difficult to achieve legal certainty in this area.

Nutrition Intake Data: Dr Christine Brombach of the Federal Research Center for Nutrition and Food in Germany informed the audience that a new survey on national consumption levels, commissioned by the German Ministry of Consumer Protection, was to be carried out in Karlsruhe with a target for completion of February 2007.

National Rules: It was asked whether individual Member States could implement 'national rules' for maximum levels for food supplements in addition to the European levels. In response Mr Mathioudakis said that the Commission's Legal Services had been asked the same question in relation to the positive list of the Food Supplements Directive and their response had been unfavorable. He also pointed out to paragraph 106-107 of the ECJ's judgement that national rules would perpetuate distortion of competition and create obstacles to trade.

Maximum Levels and RDAs: In response to a question about the validity of some Member States setting national maximum levels based on multiples of the RDA, Mr Mathioudakis replied that the Commission has reacted when some Member States notified maximum levels based on RDAs. Once the Commission had set maximum levels, then the way towards harmonisation would be clear.

Session 2 - Establishing Maximum Levels for Vitamins and Minerals

Chair: Prof. Dr Åke Bruce, National Food Administration, Sweden

EFSA Risk Assessment of Vitamins and Minerals

- **Prof. Dr Hildegard Przyrembel, Member of the EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) and Director and Professor at the Federal Institute for Risk Assessment (BfR), Germany**

Professor Przyrembel said that following her presentation on establishing Upper Levels, given at the Prague Conference in 2004, she would now concentrate on EFSA's approach to the assessment of risk of vitamins and minerals, a project that is now complete with upper levels (ULs) set for 16 nutrients.

Following an explanation of the steps in risk assessment: hazard identification and characterisation, exposure assessment and risk characterisation - and the strengths and weakness of the NOAEL/LOAEL model developed by the US Council for Responsible Nutrition, Professor Przyrembel noted the uncertainties caused by different experts arriving at different ULs.

In conclusion Professor Przyrembel said that:

- ULs are derived from a risk assessment based on, in most cases, insufficient and not systematically gathered data
- They are based on the best possible judgement at the time
- They should not be considered and used as isolated figures but as part of the complete risk characterisation

Adding that she considered the most important aspect of risk assessment to be risk characterisation (which seeks to determine what fraction of the population, if any, incurs intakes greater than the upper level, and to what extent these intakes exceed the UL), Professor Przyrembel said that she considered that risk assessment should be an on-going process as new data become available, and she hoped that the FAO/WHO Nutrient Risk Assessment project would give some general guidelines.

European Food Intake Data European Food Consumption Validation (EFCOVAL)

- Dr Evelien de Boer, Coordinator of EFCOVAL, TNO, Zeist, The Netherlands

Dr de Boer's presentation explained the aims of EFCOVAL, an EU proposal on European Food Consumption Validation, following the EFCOSUM project of 2000-2002. The overall aim of the project is to arrive at comparable EU-wide food data, via the development of:

> 'a validated food consumption instrument to assess dietary intakes necessary for studying associations with (public) health and food safety issues in future pan-European studies and for policy makers'.

To date 11 Member States have agreed to take part, with more being sought, and formal negotiations on the project, which will also be discussed with EFSA, FAO and WHO, will begin in October 2005.

European Food Information Resource Network (EuroFIR) – a challenge to know what is in your food

- Ms Claudia Krines, Member of EuroFIR Network of Excellence, ttz Bremerhaven, Germany

Ms Krines' presentation outlined the aim and strategic objectives of EuroFIR – the establishment of a unified, reliable and accessible food composition information resource on EU level.

Stressing the importance of data quality, Ms Krines said that current joint research projects include:

- Developing food composition data bank systems
- Updating and including additional critically assessed data on bioactive compounds with putative health benefits.

Further collaboration with the food supplement industry was sought.

In response to a question from the Chairman, Prof. Bruce, as to whether data collection for dietary supplements could be included, Ms Krines said that it could be a sub-project, but that at present there was no budget for it.

Risk Management Models for Vitamin and Mineral Supplements and Fortified Foods

- Prof. Albert Flynn, Member of the EFSA NDA Panel, University College Cork, Ireland

Prof. Flynn's presentation covered the key principles for science based models for setting maximum safe levels of vitamins and minerals in supplements and foods via a nutrient by nutrient approach, and the determination of nutritionally significant amounts of micronutrients that can be added safely to food supplements and foods.

Prof. Flynn presented the ILSI model which concentrates on setting maximum levels for addition of nutrients to foods but does not take into consideration intake through food supplements. He also focused on the model presented in the ERNA/EHPM 2004 publication 'Risk Management for Supplements' which sets out a three-stage model for setting maximum levels:

- Those with no evidence of risk within ranges currently consumed and where maximum levels cannot be set on the basis of science
- Those with a low risk of exceeding the UL, where maximum levels should take into account intake from food and potential intake from fortified food
- Those with potential risk of exceeding the UL where a nutrient by nutrient approach is required taking into account intakes from foods, risk of deficient and excessive intake, and labelling options.

For the future Prof. Flynn's view was that more work on model development was needed, including:

- How models apply to other groups, for instance, children
- Validation of data on intakes from supplements and fortified foods
- Integration of models for foods and supplements.

- Prof. Dr. Dr. h.c Arpard Somogyi, Ministry of Agriculture and Rural Development, Hungary and Prof. Albert Flynn, University College Cork, Ireland, member of EFSA NDA panel

Panel Discussion

- **Prof. Dr Hildegard Przyrembel, Member of the EFSA NDA Panel, Director and Professor at BfR, Germany**
- **Dr Gert Krabichler, Chairman, ERNA**
- **Dr John Hathcock, Vice President, Scientific and International Affairs, Council for Responsible Nutrition, (CRN), USA**
- **Basil Mathioudakis, Acting Head of Unit, DG SANCO, European Commission, Brussels**
- **Prof. Albert Flynn, Member of the EFSA NDA Panel, University College Cork, Ireland**
- **Alicja Walkiewicz, National Food and Nutrition Institute, Poland**

As introduction to the Panel's discussion, Alicja Walkiewicz, of the National Food and Nutrition Institute, Poland gave a presentation on 'Applying national food intake data to a risk management model'

Against a background of concern about health problems in the Polish population connected with poor nutrition and inadequate food quality, Ms Walkiewicz first presented a study carried out in 2000, 'Household Food Consumption and Anthropometric Survey'. The study covered 4134 individual from 1362 families, with 24 hour recalls being used to collect food intake data. Energy and nutrient intakes were then compared with Polish Recommended Daily Allowances, which differ according to group and sex.

At present, Poland has not set any maximum levels for food supplements and Ms Walkiewicz's presentation then considered risk management models for setting levels focussing on the application of the ERNA/EHPM Risk Management Model for Poland. The overall conclusion was that while current intake of many nutrients were over the Polish RDA, those for calcium, iron, zinc, copper and niacin for many age groups and for vitamin B1 and B2 for women, were lower - and that if diet could not cover consumers' nutrition requirements, then food supplementation was an appropriate method of complementing it.

EU Harmonisation: Opening the Panel Discussion, Dr Krabichler said that he must again reiterate the importance of harmonisation now that the Food Supplements Directive had been ruled to be valid. European wide maximum levels were needed to ensure free trade, binding on and accepted by all Member States. A harmonised approach to risk management was also needed to bring food supplements and fortified foods into a harmonised model. In respect of any lack of data on which to base decisions on upper levels, he expected the authorities to take a pragmatic approach where there was no risk based on scientific evidence.

RDAs, NOAELs, OSLs and Maximum Levels: Referring to the Polish data presented by Ms Walkiewicz, Dr Hathcock said that the RDA was not the ideal to supply an adequate intake, and was often too low. In the selection of human data, he recommended high confidence in the NOAEL approach, to which an uncertainty factor could be added if considered necessary. In the absence of a UL Dr Hathcock said that the US CRN has recommended to the FAO/WHO Committee working on risk assessment that they should use an Observed Safety Level (OSL) for nutrients for which there is no known toxicity, the OSL being the highest level where data exists to show that the nutrient is safe.

Prof. Przyrembel said that RDAs covered more than minimum levels, and with regard to determining maximum levels she was not happy with using toxicological data alone – there were also nutritional considerations. Additionally she has advised the FAO/WHO committee working on risk assessment that there should be guidelines for nutrients where no UL has been found.

Mr Mathioudakis said that this discussion was taking place in advance of the Commission's work on setting levels, which would need to be pragmatic, reasonable, and take into account both ECJ judgements and science.

Continuing the theme of a pragmatic approach to setting maximum levels based on existing evidence and looking at different options, Prof. Flynn used the example of iron, where no upper level has been set, but there is evidence of minor adverse responses to non-haem iron supplements. This evidence could then be used to set maximum levels for iron supplements, but would not apply to iron in foods.

Saying that food composition/micro nutrient data was becoming ever more important, Patrick Coppens of ERNA asked if such data could be made available earlier than in four years' time and whether the EU had a role in gathering input data. Mr Mathioudakis said that this was a task for EFSA, and Prof. Flynn said that EFSA had a mandate for intake data, and that the focus was likely to be on exposure to food chemicals/ contaminants.

Risk Assessment:
Referring to the consistencies between the ERNA and ILSI models for risk assessment, particularly in relation to risk banding, Professor Richardson commended the categorisation of no risk / low risk / potential risk as a principle to be carried forward for further consideration. In response, Prof. Flynn said that it was his personal view that this could be an appropriate pragmatic approach, but that it required a nutrient specific approach, and Mr Mathioudakis said that in relation to the concept of better regulation, it was potentially a valid principle.

Session 3- Nutrition and Health Claims

Chair: Dagmar Roth-Behrendt, Vice President, Member of the European Parliament, Brussels

Dr Gert Krabichler, Chairman of ERNA, introduced Dagmar Roth-Behrendt, Chair for the second day of the Conference.

Dagmar Roth-Behrendt said that she was delighted to be in Berlin, the constituency which had re-elected her to the European Parliament 3 times since 1989, and said that as an MEP her main 'hobby horses' were pharmaceutical and food legislation.

Potential Impact of the Nutrition and Health Claims Regulation

- Patrick Coppens, Secretary General, ERNA

Mr Coppens' presentation covered the history and content of the proposed Regulation and its impact on food supplements, and raised a number of specific points of concern and areas where the Regulation needs clarification and further improvements:

- In respect of the generic list of claims, what type of claims will be accepted and on what basis?
- Will claim wording be fixed or flexible?
- What will the transition period be and how will it work?
- What will the timings for EFSA's authorisation procedures be?
- Why is there no possibility to defend or explain a dossier to EFSA or the Standing Committee?
- What is the definition of 'Generally accepted scientific data'?

Suggesting that notification as opposed to authorisation could be a more proportionate way of dealing with claims, Mr Coppens pointed out that, based on current experience with authorisation procedures, the EFSA's proposed procedure could last up to two-three years and as much as a further 2.5 years could be added on product design and scientific research at the beginning of the process and label design and media campaign at the end – making placing new products to the market an extremely onerous and lengthy process.

- Patrick Coppens, Secretary General, ERNA

In addition, the lack of protection for commercial confidentiality meant further negative effects on innovation, and, even for existing claims, there would be a lengthy period of uncertainty caused by the three year time gap between the submission and approval of claims for the Article 12 'positive' list of claims.

Mr Coppens' conclusion was that, given the need to inform the consumer as to the purpose of the product, as presently drafted the Nutrition and Health Claims Regulation had a serious impact on an industry where claims were essential in order to be able to provide the consumer with the necessary information about the product – and there remained too many uncertainties as to how the procedures of the Regulation would operate.

Scientific Substantiation and Consumer Understanding of Health Claims

- **Prof. David Richardson, Scientific Adviser, European Federation of Associations of Health Product Manufacturers (EHPM)**

Continuing the theme of 'better regulation' Prof. Richardson's comprehensive presentation began by setting out what regulatory developments in the area of food should aim to achieve:

- A high level of consumer protection
- Benefit for consumers by providing information on healthy eating patterns
- A reference point and a measure of confidence for consumers and healthcare professionals that label claims are supported by sound scientific data
- A return for the claimant on their research investments and a measure of 'due diligence' in dealings with regulatory authorities
- The stimulation of new research to fill in knowledge gaps.

The different types of health claim and the Regulation's proposals for their scientific substantiation were then discussed, noting in particular two points where further clarification is urgently needed:

- Article 12 – what is meant by the phrase 'generally accepted scientific data'? How will this science be assessed, and how much is needed?
- What is the 'relevant scientific justification' that Member States must reference to their list of claims?

Prof. Richardson then covered proposals for the assessment of scientific support for health claims, based on the EC Concerted Action project on 'Process for the Assessment of Scientific Support for Claims on Foods', (PASSCLAIM), and cited the following as the key issues:

- The development of validated biomarkers to reflect the true endpoint of a claimed benefit
- The interpretation of the totality of the available data and the weighing of that evidence.

A critical key issue is the weight of scientific evidence sufficient to permit a health claim and here Prof. Richardson proposes a concept already accepted by the WHO and the FDA, that health claims can be graded as 'Convincing', 'Probable' or 'Possible', according to the amount of evidence available in support of the claim. He sees the particular virtue of such a system is that while it makes the status of the science behind the claim clear to the consumer, it also encourages market diversity and innovation by allowing for the use of 'emerging science'.

In conclusion, with respect to the Regulation's requirements for consumer understanding of health claims, Professor Richardson commended the ILSI model which aims to measure consumer understanding by a series of step by step 'tool-box' procedures.

Netherlands Proposal for a Generic List of Health Claims

- **Theo van Rooij, Member of the Dutch Working Group on Health Claims**

After explaining the Netherlands self-regulatory systems for foods and food supplements, Mr van Rooij's presentation set out the details of a proposal for a systematic approach to a generic list of health claims which has been prepared by a Covenant made up of representatives from government, consumers, the self-regulatory systems and industry.

In preparing the proposal, all known official nutrient/substance health effects were compiled from existing claims lists - mainly from EU countries - and a recommendation was then made to classify them according to the PASSCLAIM criteria, as 'Possible', 'Probable' or 'Convincing', depending on the strength of the scientific data available.

The proposal, which covers claims for vitamins and minerals, was published in 2004 and shows the majority of claims as being 'probable' and 'convincing' – future work will cover other categories of substances, diets, and botanicals, an important product category for the Dutch industry.

In conclusion, Mr van Rooij said that he hoped that other EU Member States would devote themselves to similar projects because a good generic claims list was essential for the future of the food supplement industry.

Panel Discussion

- **Introduction by the Chair, Dagmar Roth-Behrendt**
- **Patrick Coppens, Secretary General, ERNA**
- **Prof. David Richardson, Scientific Adviser, EHPM**
- **Theo van Rooij, Member of the Dutch Working Group on Health Claims**
- **Basil Mathioudakis, Acting head of Unit, DG SANCO, European Commission, Brussels**
- **Bernhard Kühnle, Director General, BMVEL, Germany**

Opening the discussion, Dagmar Roth-Behrendt said that, although she did see the need for legislation, the claims regulation was a bad proposal and she questioned whether it would be effective. In her view, it was badly written and should be withdrawn.

Making the parallel with the European Medicines Evaluation Agency, which she described as 'a kind of servant to industry', Dagmar Roth-Behrendt said that what was needed was clear, transparent, foreseeable legislation so that industry understood what it must accept. Her question to industry, however, was whether it had made its arguments to the European Parliament sufficiently convincing?

- Basil Mathioudakis, Acting Head of Unit, DG SANCO, European Commission and Dagmar Roth-Behrendt, Vice President, Member of the European Parliament

In response, Mr Mathioudakis said that although no Community legislation was perfect, the proposal was not badly written: it had been worked through and substantially improved. Commenting on the previous session, he said that he found Mr Coppens' presentation to be negative and defensive, lacking proposals for improvement – and he also disputed some of the examples of health claim he gave, considering them to be statements of fact rather than claims.

In response to Mr Mathioudakis' comments, Mr Coppens said that his presentation was meant to illustrate that the proposal lacks clarity on a number of issues, that the uncertainties are difficult for industry to deal with, and that a number of questions remained outstanding and answers to those questions might remove industry's fears.

Mr Mathioudakis said that he appreciated that 'one liner' claims were a problem, and said that there was movement away from such a prescriptive view, particularly in view of the number of Community languages. As regards the authorisation procedure, in his view few claims would need to make use of it.

Welcoming both the Netherlands' list of claims and the concept of grades of evidence, Mr Mathioudakis said that he had appreciated the presentations of Prof. Richardson and Mr van Rooij because they contained concrete proposals.

Mr Kühnle said that the proposed regulation covers not just food supplements, but all foods. The difference between risk reduction and generic health claims meant that, for the protection of the consumer, the data must be better. In his view it was time to stop 'fighting the battles of yesterday', (to stop the regulation), and instead to get industry together to talk to Parliamentarians.

Mr Coppens stated that:

- The support of the European Commission was needed to achieve textual improvements
- There was a need to know clear timings and procedures
- It would be necessary to know the status of dossiers during the EFSA review process
- Industry is working on the scientific substantiation of claims and on a 'claims' list but needs to know if this approach will be acceptable.

Professor Richardson said the main issues he wanted to emphasise from his presentation were:

- How much data will be needed to substantiate a claim?
- Industry needs to know the accepted process for claims substantiation
- The scientific community needs to develop mechanisms for the weighing of evidence and for its grading so as to allow for the communication of 'convincing', 'probable' and 'possible' health claims.

In response to a question, Ms Roth-Behrendt indicated that industry could not expect to have both national and European systems. She also disagreed with Mr Kühnle that the proposed regulation was of benefit to the food industry overall, because it will suit only the large European food companies. She said the costs of compliance with the Regulation were very difficult for small companies to meet. Consumer safety was paramount and the aim should be to inform consumers but leave them free choice.

Mr Kühnle stated that the Regulation had different purposes: the level of consumer protection was very important and they should not be misled. He saw the central 'positive' list, which was a list of nutrients and related health effects on which health claims could be based, as an advantage for SMEs as they would be able to use it without complicated authorisation procedures.

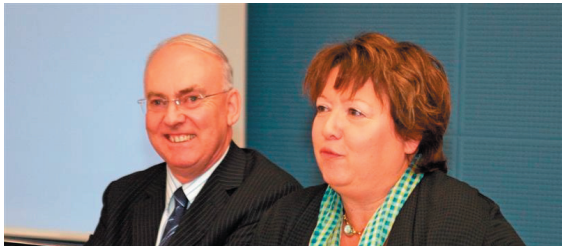
In response to Prof. Richardson's presentation, Prof. Flynn said that as Chair of the EFSA NDA panel, he welcomed the opening of discussion on the scientific substantiation of claims, as it was an area on which EFSA would have to work. In response, Prof. Richardson agreed that there was a need for a form of 'PASSCLAIM 2' to work on the totality, weighing and grading of scientific evidence in support of health claims and their communication, via flexible wording, to the consumer – with the overall goal of an internationally approved system.

Prof. Richardson made the point that several European countries were working on claims lists, but that there was no central process as yet. He considered that authorisation should be applicable only to disease risk claims, with a notification procedure (which also required companies to have detail of the scientific substantiation of the claim available on request) for other types of claims.

Ms Roth-Behrendt responded that she strongly disagreed with the authorisation procedure. However, Mr Kühnle disagreed equally strongly, saying that while authorisation procedures were usually for goods that posed a potential consumer risk, what was being discussed was a procedure for health claims, which could also be dangerous, and he wanted to see a high level of protection. In response Mr van Doorn said that there was already enough European legislation to protect the consumer against irresponsible claims.

Mr Mathioudakis said that in his view the current proposal for a Regulation is a good basis for proceeding, but that there were possibilities to bring change at its second reading in the European Parliament and he was ready to discuss well constructed proposals.

Concluding Session 3, ERNA Chairman Gert Krabichler thanked the speakers and panel for an exciting morning, and called on all stakeholders to work together to move things forward.



- Prof. David Richardson, Scientific Adviser, EHPM and Dagmar Roth-Behrendt, Vice President, Member of the European Parliament

Session 4 - Other Substances and Botanicals in Food Supplements

- Chair: Prof. Dr. Dr. h.c. Arpad Somogyi, Pre-Accession Adviser, EU Twinning Project Food Safety Office, Ministry of Agriculture and Rural Development, Hungary

Introducing the afternoon session, the Chair, Prof. Somogyi, highlighted both the complicated issues and the challenging nature of looking at regulation for substances other than vitamins and minerals.

Benefits and Safety of Other Substances

- Dr Derek Shrimpton, Scientific Adviser, EHPM

The presentation highlighted the importance and role of 'other substances' in promoting optimum health, their validity as food supplement ingredients and their categorisation.

Dr Shrimpton's presentation then offered a proposal for establishing the safety of these ingredients via a system, developed by Dr John Hathcock which modifies the No Observed Adverse Effect Level (NOAEL)/Lowest Observed Adverse Effect Level (LOAEL) methodology for determining the upper safe levels of vitamins and minerals into a model which allows an Observed Safety Level (OSL) to be set.

For 'other ingredients', the OSL method has the advantage that:

- It provides an objective basis when neither a NOAEL or a LOAEL can be identified
- Ensures that the absence of a UL is not taken to mean high risk
- Offers an objective basis for the assessment of the safety of specific intakes, even in the absence of toxicity data.

Dr Shrimpton concluded his presentation by presenting examples of the OSL method in action by applying it to a selection of other 'ingredients', including leucine, lysine, glucosamine and chondroitin.

Benefits and Safety of Botanicals

- Prof. Dr Robert Anton, Member of the ad hoc Working Group on Food Supplements, Council of Europe, Strasbourg

Prof. Anton began his presentation by discussing the diversity of botanical substances, their position at the interface of nutrition and therapeutics, and the regulatory system for herbal medicines in Europe.

Moving to Herbal Food Supplements, where there is no agreed EU-wide framework, Prof. Anton noted the diversity and differences of the current regulatory systems for herbal supplements in individual Member States – and the consequent potential safety hazards for consumers caused by differences in or lack of agreed standards. Pointing to the need to establish clear rules to ensure safe consumption levels, Prof. Anton explained the work of the French food agency AFSSA and the Council of Europe in developing Guidelines for the evaluation of the safety and benefits of plant-based foodstuffs.

Prof. Anton noted the recent mandate to EFSA's Scientific Committee to review the work already carried out by other bodies on Botanicals and their usage in order to prepare, by May 2006, a guidance document on the assessment of their safety.

In answer to a question about the difference between the physiological and the pharmacological effect of a botanical, Prof. Anton replied that it was a question of the dose, but that both effects could be present in the same plant.

Responding to a question from Prof. Somogyi about the Commission's intention with the regulation of this 'difficult area', Mr Mathioudakis said that the Commission would need to evaluate the work of the Council of Europe and of EFSA to see if it is sufficient for the report they are required to make on the regulation of other categories of substance under the Food Supplements Directive.

Panel Discussion: Regulatory Options

- **Dr Derek Shrimpton, Scientific Adviser, EHPM**
- **Dr Márta Horácsek, Head of Department of Notified Foods, National Institute of Food Hygiene and Nutrition, Hungary**
- **Solange Vynckier, Member of the Belgian Plant Commission, Belgium**
- **Pascale de Gryse, Ministry of Health, Belgium**
- **Peter van Doorn, Chairman, EHPM**

Ms Vynckier explained the Belgian legislation which has determined a list of plants for use in medicines and food supplements, and, in 2004, carried out further work to determine the dosage level which would differentiate physiological from pharmacological effect.

Dr Horácsek said that in Hungary the definition of food supplements was based on nutritional effect, and botanicals would need novel food evaluation as they are normally used as medicines.

Mr Mathioudakis pointed out that substances must fit their regulatory definition – General Food Law, Novel Foods Regulation etc. He put up for question whether the use to which some botanical ingredients are put in the EU is a usage usually attributed to a food. In response, Jonathan Griffith from the Irish trade association, IHTA, said that herbals in food supplements are usually there for their physiological effect, and that he saw a clear distinction between medicinal and supplementary use, which offered a positive physiological effect.

Ms de Gryse said that it was consumers who make the decisions to buy food supplements – it is the job of Government to ensure they are safe.

Mr van Doorn made the point that herbs are neither food nor medicine per se – their classification depended on a number of issues. He also informed participants of the creation of the Botanical Forum, a forum dedicated to the discussion of a regulatory framework for botanical food supplements in the EU.

In conclusion, Prof. Somogyi thanked the speakers and panel for their contribution to two stimulating days which had dealt with real-life, practical issues affecting both regulators and producers.

Conclusion

- Dr Martina Hagen, Chair, BLL Supplement Group

Summing up, Dr Hagen thanked the Conference organisers, speakers and participants, saying that the purpose of the event had been to present critical issues for future regulation. The key driver for the legal framework was harmonisation and to achieve this there was a need to relax national views in favour of a European outlook.

Speaking of future challenges for the regulation of food supplement, Dr Hagen said that the EJC verdict meant that the legal framework was now established, and the next stage was the determination of maximum levels for food supplements and fortified foods – a process where the lack of intake data had been noted. She welcomed the fact that intake data surveys were planned, but said that the work needed to start soon and has to work with intake data that is currently available. Dr Hagen also noted that while EFSA had established upper levels for 16 nutrients, it had not done so for many others. Here risk characterisation could be an aid to the risk managers. While different measures would apply to different nutrients, it offered a pragmatic approach.

With regard to the discussions earlier in the day on the substantiation of health claims, Dr Hagen highlighted the importance of grading claims according to the evidence and to ensuring that wording for each claim is flexible.

On the question of possible models for upper levels of other ingredients and the safety of herbals in future European regulation, Dr Hagen said that it was important that this work be progressed.

In conclusion, Dr Hagen again thanked everyone who for a stimulating and progressive Conference, and said that in the interests of harmonisation, discussions between regulators, scientists and industry on future regulation must continue.