



DIE AKADEMIE  
FRESENIUS

*Where experts meet!*

International Fresenius Conference

# FOOD SUPPLEMENTS

25 and 26 June 2014  
in Mainz/Germany

## HIGHLIGHTS:

- Health claims for Food Supplements
- Labelling of Food Supplements
- Food Supplements and Codex Alimentarius
- Safety and efficacy assessment of Food Supplements in the European Union
- "Stofflisten des Bundes und der Länder"  
– A guidance of German authorities
- Marketing of Food Supplements in several EU markets
- Food Supplements for specific consumer groups
- Legal framework for beauty claims
- Botanicals in Food Supplements – harmonizing the evaluation in the European Union
- Case study: Fruitflow® the first food ingredient supported by a proprietary EU Health Claim

▣ **Share industry experience and get the latest news on regulatory issues, from science and authorisation!**



## THE EXPERTS:

**Christian Ballke** Meisterernst Rechtsanwälte | **Joris Geelen** Belgian Federal Public Service Health, Food Chain Safety and Environment | **Jiří Hrádek** schoenherr attorneys at law | **Dorothee Klöpf** Diapharm | **Joanna Krakowiak** Wardyński & Partners | **Peter Loosen** German Federation for Food Law and Food Science (BLL) | **Bernd Mussler** DSM Nutritional Products | **Laure Normand** Inneov | **Lea Pollak** Croatian National Institute of Public Health | **Florian Riedel** German Federal Office of Consumer Protection and Food Safety (BVL) | **Sebastián Romero Melchor** K&L Gates | **Giorgio Rusconi** Mondini Rusconi | **Irene Scholten-Verheijen** Legaltree | **Vittorio Silano** II University of Rome, European Food Safety Authority | **Robert Verkerk** Alliance for Natural Health International

## SCIENTIFIC ADVISOR:

**Andreas Meisterernst** Meisterernst Rechtsanwälte

# THE PROGRAMME

Get-Together on Tuesday, 24 June 2014



Will you arrive on Tuesday? Come into the hotel bar at 8 p.m. and meet other participants and speakers in a relaxed atmosphere.

## Wednesday, 25 June 2014

8.30 Registration & coffee

9.00 **Welcome address and introduction by the organisers and the Chair**

**Andreas Meisterernst**, Meisterernst Rechtsanwälte, Germany

### Regulatory frame

9.05 **Health claims for Food Supplements – actual issues**

- Regulation (EU) No.432/2012 and the application for authorization
- Regulation (EC) No 1924/2006 and definition of health claims
- Specific cases regarding Food Supplements

**Giorgio Rusconi**, Mondini Rusconi, Italy

9.30 **How to deal with beauty claims?**

- EU legal framework
- Food Supplements EU Guidelines on beauty claims
- Way to work for food operators

**Laure Normand**, Inneov, France

10.00 **Food Supplements for specific consumer groups**

- Legal frame for consumer-specific products
- Communication to target groups
- Taylor-made health claims
- Utilization of general health claims

**Christian Ballke**, Meisterernst Rechtsanwälte, Germany

10.30 Panel discussion

11.00 Coffee break

11.30 **Labelling of Food Supplements**

- FIC Regulation
- Food Supplements Directive
- QUID

**Irene Scholten-Verheijen**, Legaltree, The Netherlands

12.00 **FSMP or FS – The categorization of products with respect to Reg. 609/2013 (EBD)**

- Introduction to the European regulation and its categorization
- Overview of current Czech legislation on Food for Special Medical Purposes (FSMP) and Food Supplements (FS)

- Categorization of FSMP and FS
- Role of European regulation and changes in Czech law

**Jiří Hrádek**, schoenherr attorneys at law, Czech Republic

12.30 **Marketing Food Supplements in several EU markets: is mutual recognition really enough?**

- Legal framework: From Cassis de Dijon to the Solgar case
- Role of regulation 764/2008 (the “Mutual Recognition Regulation”)
- Practical application to maximum limits of vitamins and minerals, botanicals and other substances

**Sebastián Romero Melchor**, K&L Gates GP, Belgium

13.00 Panel discussion

13.30 Lunch

### Botanicals and other ingredients

15.00 **Safety and efficacy assessment of Food Supplements in the European Union**

- Using the example of botanicals
- Harmonization of botanical products
- Regulation on marketing of Food Supplements in member states

**Vittorio Silano**, II University of Rome, Chair of CONTAM Panel, European Food Safety Authority, Parma, Italy

15.30 **„Stofflisten des Bundes und der Länder“ – a guidance of German authorities relating to the use of plants as food or food ingredients**

- Background
- Development of the list
- Ongoing work on national and European level

**Florian Riedel**, Federal Office of Consumer Protection and Food Safety (BVL), Germany

16.00 Panel discussion

16.30 Coffee break

17.00 **Botanicals in Food Supplements – harmonizing the evaluation in the European Union**

- The regulatory system in Belgium
- The BELFRIT-project

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

17.30 **Functional ingredients and health claims – implications of the Commission proposal for a „new“ novel foods regulation**

- The novel definition of novel foods: All new ingredients will be novel!?
- Retroactive effect vs. legal certainty and compatibility with regulation (EC) No. 1935/2006
- Procedures and data protection: Lessons to be learned from the claims regulation

**Peter Loosen**, Federation for Food Law and Food Science (BLL), Germany/Belgium

18.00 Panel discussion

18.20 End of the first conference day

19.00 Departure time for the evening event



After the first conference day, Akademie Fresenius would like to invite you to a leisurely evening at the vineyard "Klostermühle". During a wine-tasting and a joint dinner you get the great opportunity to deepen the contacts you made during the day.

Thursday, 26 June 2014

## Present and future of the market

**Chair: Irene Scholten-Verheijen**

### 9.00 Positive impact of Food Supplements for a better nutrition

- Global trends
- Why do so many consumers choose Food Supplements?
- Connection between active ingredients, health claims and impact on health
- Monitoring of bioactive compounds in Food Supplements on the Croatian market

**Lea Pollak**, National Institute of Public Health, Croatia

### 9.30 National Report: Regulatory framework applicable to marketing of Food Supplements in Poland

- Peculiarities of the notification proceedings in Poland
- Mutual recognition versus current administrative practices
- Prospects for the future

**Joanna Krakowiak**, Wardyński & Partners, Poland

### 10.00 Food Supplements and Codex Alimentarius

- Overview of international Codex guidelines and their impact on EU regulation
- Codex influence on US regulation and FDA rules and how this impacts global markets
- Risk assessment developments in the EU
- Future prospects for sustainable growth of the food supplements sector

**Robert Verkerk**, Alliance for Natural Health International, UK

10.30 Panel discussion

11.00 Coffee break

### 11.30 Commercialization of Fruitflow<sup>®</sup>, the first food ingredient supported by a proprietary EU health claim – challenges and opportunities in the market place

- Does the proprietary § 13.5 health claim enable improved marketability of innovative ingredients?
- Increased consumer understanding and consumer acceptance due to approved proprietary EU health claim?
- Are there any specific and novel marketing requirements arising for an ingredients producer?

**Bernd Mussler**, DSM Nutritional Products, Switzerland

### 12.00 Plant health products – innovation, tradition or stagnation?

- A market observation
- The regulatory landscape of plant health products
- Possible scenarios for the future

**Dorothee Klöpf**, Diapharm, Germany

### 12.30 Forecast – Food Supplements 2020

- The legal frame will change the market
- Transatlantic Trade and Investment Partnership (TTIP) – following wind for FS?
- Is there a future for personalised products?

**Andreas Meisterernst**

13.00 Panel discussion

13.30 Lunch buffet and end of the conference

## THE EXPERTS

**Christian Ballke** is a registered lawyer and partner of Meisterernst law firm in Munich, Germany. He is specialized in all food law matters, in particular marketability and advertising of products. Another focus is intellectual property law, especially trademark and unfair competition law.



**Joris Geelen** is Regulatory Expert for Botanicals in the service food, feed and other consumption products of the DG Animals, Plants and Food of the Federal Public Service Health, Food Chain Safety and Environment in Belgium. Furthermore he is responsible for the dossiers with botanicals and for the coordination of the Advisory Commission on botanicals. He is the chairman of Policy Advisory Board of the PlantLIBRA project.



**Jiří Hrádek** is an attorney at the Prague branch of the law offices of schoenherr and a researcher at the Center for Comparative Law at the Faculty of Law of Charles University in Prague. He specializes in dispute resolution and intellectual property law including life sciences.



**Dorothee Klöpf** is working at the service provider Diapharm as Head of the OTC team, which mainly focuses on food supplements, cosmetics and borderline issues. Before she joined Diapharm she worked in regulatory affairs for GlaxoSmithKline Consumer Healthcare.



# THE EXPERTS

## THE EXPERTS

**Joanna Krakowiak** is Legal



Adviser and member of the Life Science and Regulatory Law Practice Wardyński & Partners in Warsaw. She handles

pharmaceutical law, food law and regulations concerning food supplements, cosmetics and medical devices. She serves as an expert of the National Council of Food Supplements and Nutritional Foods.

**Peter Loosen** has been Managing



Director of the BLL since 2007. He became Head of the Brussels Office in 2003. Besides counselling members

he focuses on the representation of members' interests to the European institutions. Moreover, he is visiting lecturer for food law at the University of Bonn.

**Andreas Meisterernst** is Lawyer at



Meisterernst Rechtsanwälte (law firm) in Munich, Germany. He is visiting lecturer at the Technical University of Munich

as well as author and editor of a large number of publications.

**Bernd Mussler** works as Global



Innovation Project Director for DSM. He is responsible for global scouting and licensing of new food ingredients for the

DSM portfolio and is furthermore leading an open innovation projects to develop new functional ingredients.

**Laure Normand** has been working



as Pharmacist in the health sector for 20 years. Currently she is Director of regulatory affairs and safety at INNEOV, a joint venture of Nestlé and L'Oréal.

**Lea Pollak** is Head of the Food



Supplements and Dietetic Products (PARNUTS) Unit at the Croatian National Institute of Public Health. She is actively

involved in the analyses, evaluation and legislation of food supplements, food for special nutritional uses and fortified food.

**Florian Riedel** works as Pharma-



cist at the Federal Office of Consumer Protection and Food Safety (BVL) on "Food Supplements" and "Novel Food". With a group of colleagues he generated the "Stoffliste des Bundes und der Länder".

**Sebastián Romero Melchor** is a



partner of the Brussels-based firm K&L Gates GP. He has practiced as a Lawyer in top-tier law firms and in the European Commission.

**Giorgio Rusconi** is a Lawyer at the



Italian law firm Mondini Rusconi and has acquired experience in the field of food and drug law. He is one of the

founders and permanent member of the Board of FLN - Food Lawyers' Network Worldwide.

**Irene Scholten-Verheijen** works as



an attorney at law and is a partner at the Dutch law firm Legaltree. She specializes in regulated markets in

which the interaction between government and corporations is a center piece. Within this framework, her focus is pharma and food industries.

**Vittorio Silano** is contract



Professor of "Food Safety Legislation" at the Medical School of the II University of Rome, Italy. He has chaired the Scientific

Committee since the inception of the EFSA as well as various Scientific Committee working groups including animal cloning and botanicals. He moreover is editor-in-chief of the EFSA Journal and chairs the editorial board.

**Robert Verkerk** is a Scientist and



regulatory specialist in the field of sustainability, specifically in the areas agriculture and healthcare. In 2002, he founded Alliance for

Natural Health International as an independent NGO to help promote natural and sustainable approaches to healthcare worldwide.



## WHOM DO YOU MEET?

### Sectors that should take part

- Food Industry: manufacturers of food products, functional foods, dietetic food, nutraceuticals, food ingredients, food supplements, food additives
- Food Retailers
- Pharmaceutical Industry
- Medicinal Industry
- Regulatory Authorities
- Research Institutes

### Groups that should take part

- Managing Directors, Boards of Directors, Members of Supervisory Boards, Managers and Scientists in the fields of:
- Food Law
  - Legal and Regulatory Affairs
  - Regulatory Support
  - Registration / Authorisation
  - Business Development
  - Product Management
  - Marketing and Sales



## THE ORGANISERS

AKADEMIE FRESENIUS is a joint venture of SGS Institut Fresenius and COGNOS, one of the leading private educational institutes in Germany. Akademie Fresenius organises national and international conferences and congresses on current topics from the economic and scientific sectors for both specialists and the industry. You can find details on upcoming and new events at [www.akademie-fresenius.com](http://www.akademie-fresenius.com).

Consumer protection is becoming increasingly important and food producers and food retailers integrate extended quality assurance measures into their operating processes. In addition to the experience of SGS INSTITUT FRESENIUS in the field of analytics, customers also benefit from many years of experience in the assessment of legal issues concerning food, nutritional supplements and organic products. [www.institut-fresenius.de](http://www.institut-fresenius.de)

## TRADE EXHIBITION

Our conference provides you with the opportunity of presenting your company in a trade display. Present your products and services and reach out to your specific target groups. We would be happy to provide you with information on all the various options available – from displaying product information to an exhibition stand – with no further obligation on your part.

Use the attached fax reply sheet to request our information material. Or simply call us. We would be more than pleased to assist you personally.

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If you have any **questions regarding the programme:**  
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## REGISTRATION

### By web

www.akademie-fresenius.com/2059

### By mail

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DIE AKADEMIE  
**FRESENIUS**

## PARTICIPATION

- Yes!** I would like to take part in the International Fresenius Conference „**Food Supplements**“, **25 to 26 June 2014** in Mainz/Germany. Fee: € 1,695.00 plus VAT.
- Yes!** I am a representative of an authority or a public university and therefore eligible for a reduced fee of € 795.00 plus VAT per person (please provide evidence). The reduced fee cannot be combined with other rebates.

I would like to take part in the **evening event** on 25 June 2014 (included in the above prices).

Yes  No

## CONFERENCE DOCUMENTATION

- No!** Unfortunately, I am unable to attend. Please send me the complete conference documentation for € 295.00 plus VAT (hard copy and electronic version).

## TRADE EXHIBITION

- Yes!** Please send me information on exhibition possibilities during the event.

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## TERMS OF PARTICIPATION AND PURCHASE

The registration fee includes the **conference participation, complete conference documentation, lunch, coffee breaks, conference beverages** as well as the **evening event** on 25 June 2014.

You will receive written confirmation of your registration. Upon receiving our invoice, please transfer the amount due without further deductions before the conference begins.

The price of the conference documentation includes a hard copy of the documentation as well as an access code to the secure Akademie Fresenius download area where you can download the complete conference documentation, including any subsequent updates, in electronic form – subject to the approval of the respective speakers. Both the documents and the secure access code will be dispatched around two weeks after the event and as soon as advance payment has been received.

## GROUP REDUCTIONS

For joint bookings received from one company we grant a **15 % discount** from the third participant onwards.

## TERMS OF CANCELLATION

**Written cancellations or transfers will be accepted free of charge** up to four weeks prior to the start of the event. After this date and up to a week prior to the start of the event we will reimburse 50 % of the registration fee. We cannot, unfortunately, provide refunds for later cancellations. **Please note that you can name a substitute free of charge at any time.**

## GENERAL TERMS AND CONDITIONS

By registering, you agree to our General Terms and Conditions as well as to our Privacy Policy. You can find our General Terms and Conditions on the internet ([www.akademie-fresenius.com/general-terms](http://www.akademie-fresenius.com/general-terms)) or receive them on request.

## PERSONAL DATA

The Akademie Fresenius will keep your personal data for the purpose of organising this event. We will under no circumstances use your data for commercial trade purposes. In signing this form you consent to our occasionally contacting you by **mail, email, fax or phone (please strike through if unwanted)** in order to provide you with further information from our company. You can, of course, withdraw your consent whenever you wish. Further information can be found at: [www.akademie-fresenius.com/dataprotection](http://www.akademie-fresenius.com/dataprotection).

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## VENUE/CONFERENCE HOTEL

Atrium Hotel Mainz  
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We have reserved a **limited number of rooms** for our participants **at reduced rates** at the hotel. These rooms can be booked up to four weeks prior to the start of the event. Please book early and directly through the hotel quoting **“Fresenius”** as reference.