Informa Life Sciences’ Inaugural Conference on Food Ingredients Regulations

9-10 September 2014
Crowne Plaza Barcelona - Fira Center, Barcelona, Spain

The latest regulatory guidance and practical compliance strategies for food additives, ingredients, novel foods and food enzymes

Keynote Speakers:

Wim Debeuckelaere, Head of Sector Food Additives, Enzymes and Flavouring, DG SANCO, European Commission, Belgium

Ana Maria Rincon Scientific Officer, EFSA Food Ingredients and Packaging (FIP) Unit, European Food Safety Authority (EFSA), Italy

Klaus Riediger AGES- Austrian Agency for Health and Food Safety, Austria

Direct feedback from EFSA on the re-evaluation procedure for food additives – Plus representatives from ELC, Coca-Cola and FoodDrinkEurope discuss the impact on industry and data collection strategies for robust and reliable assessment

Ensure compliance for the 2015 food enzyme dossier deadline - Gain implementation advice for submissions direct from the European Commission. Plus feedback from submitted dossiers so far and advice on the preparation of joint dossiers by Amfep

Discover how EU Regulatory Authorities, lawyers and industry are evaluating novel and “natural” ingredients and the impact of the revision of the EU novel food regulations

Compare the regulatory landscape for food additives and ingredients across the globe and discuss strategies for global compliance

Industry Experts

- The Federation of European Specialty Food Ingredients Industries (ELC)
- FoodDrinkEurope
- DSM
- Coca-Cola
- Roquette
- The International Food Additives Council (IFAC)
- FEDIMA – The European Union Manufacturers and Suppliers of Ingredients to the Bakery, Patisserie and Confectionery Industries

Media Partners: ChemicalWatch

Associate Sponsor: Field Fisher Waterhouse
Day One: 9 September 2014

08:15 Conference Registration
08:55 Opening Remarks from the Chairperson

Understanding the Procedure for the EFSA Re-Evaluation of Food Additives

09:00 KEYNOTE PRESENTATION: Feedback from EFSA: Status Update on the Re-Evaluation of Food Additives and Future Developments
- The food additive re-evaluation procedure
- Update on the current status of the re-evaluation
- Data sources in the re-evaluation of food additives
- How interested parties can contribute to the re-evaluation of food additives?
- Future developments (2015-2016 timeframe)

Ana Maria Rincon, Scientific Officer, EFSA Food Ingredients and Packaging (FIP) Unit, European Food Safety Authority (EFSA), Italy

09:40 Feedback from Food Additive Manufacturers: Impact of Re-Evaluation of Food Additives
- Impact on EFSA re-evaluation of food additives on industry
- Understanding and interpreting the re-evaluation procedure from EFSA
- Risk management measures on published opinions
- Impact of EFSA re-evaluation on a global scale
- Feedback from food additive manufacturers of experience and meeting EFSA expectations: Meeting criteria changes, data collection, data transparency

Anders Liljegren, ELC, (The Federation of European Specialty Food Ingredients Industries), Belgium

10:20 Morning Coffee & Exhibition Viewing
10:50 Feedback from Food Companies & Additive Users: Re-Evaluation of Food Additives
- Understanding and interpreting the re-evaluation procedure from EFSA
- Practical implications of ongoing requests for submission of data by food business operators and remaining challenges resulting from these requests
- How these challenges trigger uncertainties in later exposure assessments by EFSA
- From EFSA opinions to risk management measure
- Industry suggestions on the way forward

Chris Bruyninckx, Senior SRA Manager Ingredient and Product Safety, Coca-Cola, Belgium

11:30 Data Collection, Assessment and Submission for Exposure Assessment of Food Additives under the EFSA Re-Evaluation Process
- What data collection is required
- Calculating exposure to food additives
- Data reporting strategies for usage figures
- How representative does data need to be?
- Data transparency
- What data is considered enough for confident, reliable and robust assessment?

Angeliki Vlachou, Manager Food Policy, Science and R&D, FoodDrinkEurope, Belgium

12:10 Interactive Panel Discussion: Food Additive Re-Evaluation Programme
Panelists Include:
- Ana Maria Rincon, Scientific Officer, EFSA Food Ingredients and Packaging (FIP) Unit, European Food Safety Authority (EFSA), Italy
- Anders Liljegren, ELC, (The Federation of European Specialty Food Ingredients Industries), Belgium
- Chris Bruyninckx, Senior SRA Manager Ingredient and Product Safety, Coca-Cola, Belgium
- Angeliki Vlachou, Manager Food Policy, Science and R&D, FoodDrinkEurope, Belgium

12:50 Lunch & Exhibition Viewing

Exposure and Toxicology Assessment of Complex Food Ingredients

14:10 KEYNOTE PRESENTATION: Feedback from the European Commission: Update on Food Additives Legislation
- Main principles of the food additives legislation
- Union list of food additives, guidance to assure its correct implementation
- Re-evaluation programme of food additives, state of play, obstacles and follow-up
- Authorisation procedure, main steps, how to apply
- Future initiatives

Wim Debeuckelaere, Head of Sector Food Additives, Enzymes and Flavouring, DG SANCO, European Commission, Belgium

14:50 Practical Advice on Understanding the Authorisation Procedure for New Food Additives and Extension of Uses of Permitted Additives
- Practical advice on the authorisation procedure for new food additives and new uses of old food additives
- Understanding the data requirements for applications – What is essential?
- Exposure assessment
- Labelling of food additives and new uses of food additives
- Feedback to industry on how should applications for new uses of old food additives be carried out

Katia Merten Lentz, Partner, Field Fisher Waterhouse LLP – Brussels & Paris, Belgium

15:30 Afternoon Tea & Exhibition Viewing

Authorisation of New Food Additives and Extension of Uses of Permitted Additives

16:00 Calculating Exposure Assessment for Complex Food Ingredients
- Calculating exposure scenarios and ADI assumptions
- Exposure assessment for food additives, enzymes, novel foods and natural sources
- How representative does data need to be?
- Niche product estimations
- Linking exposure assessment to risk management

If you are interested in presenting on this topic please contact
Martin Cheung, tel:+44(0) 20 7017 4938
e-mail: martin.cheung@informa.com

Feedback from the International Food Additives Council (IFAC)

16:40 Feedback from the International Food Additives Council (IFAC)
For more information on this talk please visit the event website
www.informa-ls.com/foodregs

A Representative from the International Food Additives Council (IFAC)

17:20 End of Day One and Networking Drinks

“Focuses on current EU critical regulatory and industry issues around food additives”

Director, Global Regulatory Affairs, CP Kelco/ J.M. Huber Engineered Materials
## Day Two: 10 September 2014

### 08:55 Chairperson’s Introduction

### 09:00 KEYNOTE PRESENTATION Feedback from the European Commission: Understanding Recent Updates and Forthcoming Changes in Food Enzyme Regulations
- Update on recent and forthcoming changes in food enzyme regulatory framework
- Technical requirements for submitting technical dossiers for the safety evaluation and authorisation of food enzymes
- Procedure and implementation advice for submitting an application for food enzymes in compliance with the 2015 dossier deadline
- Current status of the safety assessment and evaluation of food enzymes by EFSA
- Interplay between food enzyme Regulation and Regulation on GM food and feed

Wim Debeuckelaere, Head of Sector Food Additives, Enzymes and Flavouring, DG SANCO, European Commission, Belgium

### 09:40 The Food Enzyme Regulation and its Implementation. Challenges for the Food Industry
- Advantages and uses of enzymes in the food industry and bakery wares
- Setting up the new Union List of approved enzymes: The role of the food industry
- Work with enzymes suppliers on the introduction of the dossiers
- Relationship with the authorities
- Exploring the articles of the Food Enzymes Regulation regarding labelling

Jean Christophe Kremer, Secretary General, FEDIMA – The European Union Manufacturers and Suppliers of Ingredients to the Bakery, Patisserie and Confectionery Industries, Belgium

### 10:20 The Food Enzyme Regulation and its Implementation.
- Requirements of the dossier (on basis of the EFSA CEF guidelines, the EFSA GMM guidelines as well as the Commission Implementing measures and practical guidance).
- How these are interpreted and handled by food enzyme producers and the challenges they present
- Preparation of joint dossiers by Amfep: Which cases is this justified? How it has been handled?
- Experience with submitted dossiers thus far: Procedures, timing, validation, type of questions from EFSA
- Issues that still have to be clarified

Danielle Praaning, Principal Regulatory Expert Europe, DSM, The Netherlands

### 11:00 Morning Coffee & Exhibition Viewing

### 11:30 Spotlight Presentation
- Spotlight presentations are hosted by leading companies within the food ingredient sector. For more information about hosting a spotlight presentation, please contact Martin Cheung, tel: +44(0) 20 7017 4938 email: martin.cheung@informa.com

### 12:00 Lunch & Exhibition Viewing

### 12:10 COM
- Food Enzymes Regulatory Framework and 2015 Dossier Compliance

### 14:10 Regulatory Feedback: Evaluating Novel Food Ingredients and “Natural” Ingredients
- Definition and borderline issues of novel foods
- Traditional foods (“natural foods”) versus non-traditional food extracts (“compounds”)
- Tools to prove that a food or food ingredient is not a novel food: Safe History of Consumption (“HOC”)
- Member State changes on novel food judgements and penalties
- Insects?
- Risk assessment and special labelling requirements

Klaus Riediger, Expert for Official Food Control in the Field of Novel Foods, Food Supplements and Foods of Plant Origin, AGES-Austrian Agency for Health and Food Safety, Institute for Food Safety Vienna, Austria

### 14:40 Industry Feedback: Preparing for 2015 Food Enzyme Dossier Authorisations
- Requirements of the dossier (on basis of the EFSA CEF guidelines, the EFSA GMM guidelines as well as the Commission Implementing measures and practical guidance).
- How these are interpreted and handled by food enzyme producers and the challenges they present
- Preparation of joint dossiers by Amfep: Which cases is this justified? How it has been handled?
- Experience with submitted dossiers thus far: Procedures, timing, validation, type of questions from EFSA
- Issues that still have to be clarified

### 14:50 Industry Feedback: Evaluating Novel Food Ingredients and “Natural” Ingredients
- Understanding the definition of novel: How to evaluate whether new ingredients are novel or not?
- How to label natural ingredients and the use of the term natural in marketing claims
- Company perspectives on novel foods – Are companies applying for novel food regulations just in case?
- Risk management strategies for novel foods
- Feedback received from authorities on novel food applications

### 15:15 Legal Feedback: Novel Food Ingredients
- Understanding the definition of novel: How to evaluate whether new ingredients are novel or not?
- When should industry apply for the novel food regulations?
- How can proprietary data protection be obtained?
- An example: Evaluating the use of insects as novel foods - Are these classified under the novel food regulation and companies authorised to use them?
- How to label natural ingredients and flavours and the use of natural in marketing claims

Katie Merten Lentz, Partner, Field Fisher Waterhouse LLP – Brussels & Paris, Belgium

### 15:30 Afternoon Tea & Exhibition Viewing

### 16:00 Interactive Panel Discussion: Evaluating Novel Food Ingredients

### 16:20 Understanding Global Regulations for Food Additives and Food Ingredients
- For more information on this talk please visit the event website www.informa-ls.com/foodregs

### 17:00 Summary Panel and Chair’s Closing Remarks

### 17:20 End of Conference

### Partnering Opportunities at CIR 2014
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Attendees from CIR 2013 gave the networking opportunities a rating of 4.3 out of 5!

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t: +44203 377 3287 - Matthew Jowett-Baker or please email matthew.baker@informa.com
Pre-Conference Workshop: 8 September 2014

Global Food Regulations

Registration: 10:00. Start: 10:30. End 16:30. • Lunch, Morning and Afternoon Refreshments will be included.

This full day workshop will focus on providing a complete overview and practical approaches for dealing with and managing food additive and ingredient regulations across the world. Similarities and differences to EU requirements will be discussed as well as approaches for developing methods to deal with regional and country specific requirements.

Some of the topics to be addressed include:

Overview of Key Global Markets and Regulatory Requirements for Food Additives and Food Ingredients
- Comparison of the regulatory landscape and data requirements in: - South America - USA - Asia
- Similarities and differences to EU requirements
- Overview of additives in additives legislation globally
- Update on changes to food additive legislation globally

• Labelling requirements
• Consequences for non-compliance
• Timeframes for product approvals across the globe

Approaches towards Harmonisation of Global Regulatory Procedures for Food Ingredients

Impact of EFSA re-evaluation of Food Additives on a Global Scale

China: Update on the Regulatory Requirements for Food Ingredients in China

USA Food Industry Modernisation Act
- Effect on EU companies of USA Food Industry Modernisation Act
- What does this mean to the rest of the world who supply ingredients to the USA?

Industry Strategies for Overcoming Pitfalls and Considerations for Compliance with Global Food Regulations
- Methods to deal with regional and country specific requirements

Workshop Leaders:

Anne-Claire Le Norcy, Regulatory Affairs Consultant, RNI Conseil, France
Anne-Claire Le Norcy is a regulatory affairs consultant at RNI Conseil. She earned her MSc in food engineering from the Agrocampus Ouest of Rennes (France). Mrs Le Norcy has expertise in European food laws and she offers regulatory guidance and support to RNI Conseil clients including health products, dietary supplements, food and beverage, dietetic and organic food products.

Karine Derouet, Regulatory Affairs Consultant, RNI Conseil, France
Karine Derouet is a regulatory affairs consultant at RNI Conseil. She earned her master's degree in human nutrition – with a major in innovative health products from the Superior Institute of Health and Bioproducts, ISSBA in Angers (France). Mrs Derouet has gained experiences in research and development of functional foods at the University Laval's Food and Agriculture Faculty (Quebec-Canada) and in food and food supplements industries. Mrs Derouet has expertise in European and International food laws and she offers regulatory support to RNI Conseil clients in health products, dietary supplements, food and beverages, dietetic and organic food products. Her areas of expertise include regulatory assessments and assistances, export projects and strategies on getting new products in European and International markets.

Evening Seminar, Discussion and Dinner: 9 September 2014

An Overview of Food Contact Materials and the Legislation that Impacts them in Europe

Registration 18.15 • Start 18:30 • Dinner 20:30

18:30-19:00 High Speed Networking. We will begin our evening seminar with a High Speed Networking session.

Modern living means we purchase more and more packaged food from the supermarket. The packaging materials may vary from plastics to paper to glass and ceramics but the European Commission has long had legislation covering food contact materials. This interactive evening seminar will cover the legislation that applies to each packaging material, what they can be made from and how to test them prove they comply with the legislation.

Some of the topics to be addressed include:
- Update on food contact materials regulations
- Regulatory requirements for the additives used in food contact materials
- Exposure assessment and toxicology testing for the development of new food contact materials
- How to develop new food contact materials in line with regulations
- Food contaminations: Evaluating and testing requirements for possible contaminations from food contact materials

Seminar Leader:
Barry Podd, Independent Consultant, UK

Food Ingredients Regulations 2014: Connecting People

Informa’s Food Ingredients Regulations conference and CIR exhibition is more than just a food regulation conference; it is THE meeting place for industry professionals from manufacturers and users of food ingredients looking to create new business opportunities and hear the most complete and up-to-date coverage of European regulations on food ingredients.

Food Ingredients Regulations brings the food & beverage, food ingredient, additive and enzyme supplier community together working in:
- Regulatory Affairs
- Regulatory Support
- Food Safety
- Toxicology
- Global Regulatory Affairs
- Legal

- Ingredient Regulations
- Registration & Authorisation
- Product Safety
- Nutrition and Health
- Labelling

Join the Conversation

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- 22nd Annual European Chemicals Policy and Risk Management
- 21st Annual Biocidal Products Regulation
- 14th Annual AgChem Forum
- 9th Annual Regulation of Veterinary Medicines
- Inaugural Food Ingredients Regulations

CIR neatly combines all fields which we are active in, in a single venue.

CIR Vital Statistics:

- 500+ Attendees
- 290+ Companies Represented

2013 Attendee Profile:

- Senior Regulatory Affairs Professional: 50%
- Senior Manager/Director: 21%
- Scientific/Technical: 21%
- Commercial: 4%
- CEO/President: 4%
- 75% Senior Management & Above

For more information on the opportunities available please contact

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+44 (0) 20 7017 4938, martin.cheung@informa.com

Chamatkar Sandhu, Business Development Manager,
+44 (0) 20 7017 7278, chamatkar.sandhu@informa.com

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Pre-Conference Workshop X: 8 September 2014

- Global Food Regulations CQ8163CX

Evening Seminar & Dinner Y: 9 September 2014

- An Overview of Food Contact Materials and the Legislation that Impacts them in Europe CQ8163CY

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