First experiences of 1107: Critical feedback on zonal submissions post June 14th 2011

Life Sciences' 19th International Conference on:

REGISTRATION OF AGROCHEMICALS IN EUROPE

17-18 April 2012, Hotel Le Plaza Brussels, Brussels, Belgium

Essential feedback from the EU Commission:

Francesca Arena, *Head of Pesticides Sector,* **European Commission, DG SANCO,** Belgium

Jeroen Meeussen, EU Commission, DG SANCO, Belgium

Latest scientific opinion from EFSA:

Herman Fontier, *Head, Pesticides Unit,* **EFSA,** Italy

Hear from 8 Member States:

Darren Flynn, *Health and Safety Executive,* **CRD,** UK

Maarten Trybou, *Head of Service Pesticides and Fertilizers,* **Federal Public Service for Public Health, Food Chain Security and Environment,** Belgium

Gordon Rennick, *Scientific Coordinator,* **Department of Agriculture, Food and the Marine,** Ireland

Léa Riffaut, *Scientific Officer, Phytopharmaceutical Product Coordination Unit,* **ANSES,** France

Gunilla Ericson, *Head of Unit Plant Protection Products,* **Swedish Chemicals Agency,** Sweden

Christian Prohaska, *Head of Department for Residue Behaviour,* **Austrian Agency for Health and Food Safety (AGES),** Austria

Philip Marx-Stoelting, *Toxicologist,* **Federal Institute for Risk Assessment (BfR),** Germany

Pavel Minářfi, *Head of Plant Protection Products Section,* **State Phytosanitary Administration,** Czech Republic

Industry experts include:

Dow, Bayer, ECPA, DuPont Crop Protection, Syngenta and BASF

Programme highlights

- **The EU Commission and EFSA provide** critical feedback on the implementation of 1107/2009: What can be learnt from experiences so far? What is the outlook for the future?
- **Assess the progress of AIR 2 and AIR 3 projects** with the EU Commission and Bayer. Learn the timelines for re-registration, who the rapporteurs are and how the new data requirements will influence AIR 3.
- **Examine the zonal authorisation procedure and post approval issues** with Member States from each zone, the CRD and ECPA. Take advantage of our panel discussion and have all your questions answered.
- **Identify the candidates for substitution and conduct a successful comparative assessment** whilst minimising workload: Guidance from industry experts and the Swedish Chemicals Agency.
- **Review the definition of endocrine disruptor criteria** and hear consequences of the commissioned report. Understand how endocrine disruptors are built into the regulation and assess the impact of different sets of criteria on active substances.

PRE-CONFERENCE SYMPOSIUM: MONDAY 16 APRIL 2012

Including implementation of 1107

Registration of Agrochemicals in Europe

Please see inside for expert speaker panel

EVENING SEMINAR, DISCUSSION AND DINNER: TUESDAY 17 APRIL 2012

New for 2012

A Practical Approach to Zonal Submissions

Led by: **Lucy Croucher,** *Managing Director,* **JSC International Limited,** UK
Lesley Halford, *Regulatory Affairs,* **JSC International Limited,** UK

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PRE-CONFERENCE SYMPOSIUM: MONDAY 16 APRIL 2012

Updated for 2012

Registration of Agrochemicals in Europe

08:00 Registration

09:00 Introduction from the Chair

09:10 **The New Plant Protection Products Regulation 1107/2009**
- Key Elements of 1107/2009
  - Cut-off criteria
  - Comparative assessment and substitution
  - Data protection and data sharing
  - Zonal authorisations
  - MRLs
  - Efficacy
- Transitional arrangements
  - Relationship with 91/414/EEC
  - Current position
- Sustainable Use Directive 2009/128/EC

Terry Tooby, *Regulatory Consultant,* **Terry Tooby Consulting, UK**

09:50 **Interaction between elements of the SUD and the PPP risk assessment in Regulation 1107**
- Discordance within 1107
- Discordance within SUD
- 1107 versus SUD, conflict or not?
- Is there conflict between the level of regulation and Europe's agricultural competitiveness?

Gordon Rennick, *Scientific Coordinator,* **Department of Agriculture, Food and the Marine, Ireland**

10:30 Morning Coffee and Networking

11:00 **Setting MRLs in the EU**
- Main points in the Regulation
- Procedure to be followed
- Data requirements
- Guidance documents - calculation of MRLs
- Trends and developments

Sabine Henning, *Regulatory Consultant,* **Gowan Comércio Internacional e Servicos, Belgium**

11:40 **New efficacy data requirements for dossier generation**
Speaker to be confirmed, please visit www.informa-ls.com/agrochemicals

12:20 Lunch

13:40 **Dietary risk and hazard assessment**
- Risk assessment
- Reference doses and maximum residue levels (MRLs)
- NOAELs and safety factors
- Animal and plant metabolites
- The draft assessment report
- Change under Regulation 1107/2009

Timothy C Marrs, Edentox Associates, UK

14:20 **Ecotoxicology and 1107/2009**
- Data requirements, base-set and higher tiers
- Analysing protection goals
- Examining risk assessment and risk refinement

Mick Hamer, *Environmental Safety,* **Syngenta, UK**

15:00 Afternoon Tea and Networking

15:30 **Environmental exposure assessment**
- Exposure: Scope of assessment
- FOCUS modelling
- Groundwater, surface water, soil, air
- Higher tier options
- EU vs. Member State

Adrian Terry, Cambridge Environmental Assessments, UK

16:10 Closing Remark from the Chairman

16:20 End of Symposium

EVENING SEMINAR, DISCUSSION AND DINNER: TUESDAY 17 APRIL 2012

Registration 18:15 * Start 18:30 * Networking Dinner 20:30

A Practical Approach to Zonal Submissions

This evening seminar offers a highly practical and interactive approach and is designed to complement Day 1 and feedback from the Member States.

With the introduction of the zonal approach to national submissions there has been a significant change in the procedure, format and submission requirements for national registration applications.

Topics to be covered include:
- An introduction to zonal submission
- Overview of the guidance on dRR preparation
- Practical aspects of zonal application preparation
  - o Notification
  - o Risk envelope
  - o draft Registration Report

Key reasons for delegates to attend:
- To gain an understanding of the basics of zonal applications
- To learn about the most recent guidance on dRR preparation
- To benefit from the experience gained at JSC on zonal applications

Led by: **Lucy Croucher,** *Managing Director,* **JSC International Limited, UK**
Lesley Halford, *Regulatory Affairs,* **JSC International Limited, UK**

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Crop Protection: Off Patent Products and Generics
November 2012, Brussels, Belgium (dates TBC)

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DAY ONE: TUESDAY 17 APRIL 2012

08:00 Conference Registration

09:00 Introduction from the Chair
Terry Tooby, *Regulatory Consultant*, **Terry Tooby Consulting, UK**

ESSENTIAL FEEDBACK FROM EFSA AND THE EU COMMISSION

09:10 **EFSA: Feedback, progress and future initiatives**
- Feedback on the implementation of 1107/2009
- Progress on the peer review programme for new active substances
- Update on the stage 4 green track substances
- Future initiatives at EFSA

Herman Fontier, *Head, Pesticides Unit,* **EFSA, Italy**

09:50 **EU Commission feedback on the implementation of Regulation (EC) No 1107/2009**
- Assessment of the implementation of 1107/2009
- What can be learnt from experiences so far?
- Future outlook

Francesca Arena, *Head of Pesticides Sector*, **European Commission, DG SANCO, Belgium**

10:30 Morning Coffee and Networking

AIR 2 AND AIR 3 PROJECTS

11:10 **EU Commission feedback on AIR 2 and AIR 3**
- AIR 2 update – what is the current situation?
- Renewal of active substances: What are the timelines for re-registration?
- AIR 3 progress – what does the work programme look like? Who are the rapporteurs?
- How will the new data requirements influence AIR 3?

Jeroen Meeussen, European Commission, DG SANCO, Belgium

11:40 **Industry experience with AIR 2 and AIR 3**
- Summary of AIR 1
- Update on AIR 2
- Proposals for the AIR 3 programmes
- Timelines for re-authorisation of products after substance approval
- Confirmatory data
- Future programmes

Martyn Griffiths, *European Regulatory Strategy Manager,* **Bayer, France**

12:10 **Panel Discussion Session: AIR 2 and AIR 3**

12:30 **Lunch**

"Very interesting presentations and Q&A sessions"

Bayer, 2011 Delegate

FIRST EXPERIENCES OF 1107 POST JUNE 14TH 2011: THE ZONAL AUTHORISATION PROCEDURE AND POST APPROVAL ISSUES

13:50 **Feedback from the Post Approval Issues group**
- Experiences post June 14th 2011
- Dealing with confirmatory data
- Overcoming common hurdles in the authorisation process
- Harmonisation across Member States

Darren Flynn, *Health and Safety Executive,* **CRD, UK**

Examining the zonal authorisation process
In this session representatives from The North, South and Central Zones will each present a paper addressing the points outlined below. Presentations will be followed by a panel discussion during which delegates will be able to pose any outstanding questions to the Member States.
- Feedback from applications post June 14th 2011
- Assessment of confirmatory data
- Development of guidance docs
- Use of the dRR - is it working? Is it strong enough?
- What are the agreed timeframes and are they working?
- Harmonisation between zones
- Examining risk envelopes
- Model A and Model B and the zonal approach
- How are Member States handling the backlog of work?

14:20 **Feedback from The Northern Zone**
Gunilla Ericson, *Head of Unit Plant Protection Products,* **Swedish Chemicals Agency, Sweden**

14:40 **Feedback from The Central Zone**
Pavel Minář, *Head of Plant Protection Products Section*, **State Phytosanitary Administration, Czech Republic**

15:00 **Feedback from The Central Zone**
Christian Prohaska, *Head of Department for Residue Behaviour,* **Austrian Agency for Health and Food Safety (AGES), Austria**

15:20 **Feedback from The Southern Zone**
Léa Riffaut, *Scientific Officer, Phytopharmaceutical Product Coordination Unit,* **ANSES, France**

15:40 Afternoon Tea

16:10 **National requirements and other blockers to the zonal system**
- What have we learned about the zonal system?
- Is mutual recognition working throughout Europe or only in some Member States?
- Are national requirements a real hurdle to the zonal process?
- What other major blockers exist?
- What can be done by industry and authorities to remove these blockers?

Euros Jones, *Director, Regulatory Affairs,* **ECPA, Belgium**

16:40 **Panel Discussion Session: The Zonal Approach**
Euros Jones, *Director, Regulatory Affairs,* **ECPA, Belgium**
Léa Riffaut, *Scientific Officer, Phytopharmaceutical Product Coordination Unit,* **ANSES, France**
Christian Prohaska, *Head of Department for Residue Behaviour,* **Austrian Agency for Health and Food Safety (AGES), Austria**
Gunilla Ericson, *Head of Unit Plant Protection Products,* **Swedish Chemicals Agency, Sweden**
Pavel Minář, *Head of Plant Protection Products Section*, **State Phytosanitary Administration, Czech Republic**

17:10 Closing remarks from the Chair

17:20 End of Day 1 and Networking drinks

DAY TWO:WEDNESDAY 18 APRIL 2012

09:00 Introduction from the Chair
Terry Tooby, *Regulatory Consultant*, **Terry Tooby Consulting, UK**

COMPARATIVE ASSESSMENT

09:10 **Comparative assessment from a Member State perspective**
- When will this enter into force?
- When will the guidance document be issued?
- What is the regulatory framework?
- How should industry implement this?

A representative from the Swedish Chemicals Agency

09:40 **Candidates for substitution: Comparative assessment and substitution – Industry's views and recommendations**
- Identifying candidates for substitution
- Managing their publication
- Possible consequences of a CfS status
- Avoiding unwarranted substitutions - Managing consequences

Jean-Pierre Busnardo, *European Regulatory Affairs Manager,* **DuPont Crop Protection, Belgium**

10:10 **Conducting comparative assessment – Industry's recommendations**
- Industry guidance on conducting a comparative risk assessment
- How to minimise workload
- Maintaining sufficient PPP for EU farmers

Carolyn Thomas, *Regulatory Manager,* **Syngenta, Switzerland**

10:40 **Panel Discussion Session: Comparative Assessment**

11:00 Morning Coffee

ENDOCRINE DISRUPTORS AND THE REGULATORY FRAMEWORK

11:40 **Member State feedback on developing endocrine disruptor criteria**
- Feedback and consequences of the commissioned report
- Where are we in the process of formalising the definition?
- How are EDs built into the regulation?
- Impact of different sets of criteria on active substances

Philip Marx-Stoelting, *Toxicologist,* **Federal Institute for Risk Assessment (BfR), Germany (TBC)**

12:10 **Industry view on the definition of endocrine disruption criteria**
- State of the art report
- Ongoing activities
- Industry position and proposed ways forward

Coralie Van Breukelen Groeneveld, *Global Regulatory Affairs Manager,* **BayerCrop Science, Germany**

12:40 Lunch

NEW DATA REQUIREMENTS AND THE UNIFORM PRINCIPLES

14:00 **Examining the new data requirements and uniform principles under 1107**
- The input of new data requirements on the scientific knowledge we have on pesticide products
- Updating dossiers for national submissions, the renewal process and the new AS developments
- Future initiatives: The proposed way forward

Anne Alix, *European Risk Management Leader,* **Dow, UK**

DATA SHARING, CONFIDENTIALITY AND CONFIRMATORY DATA

14:30 **Access to data and confidentiality**
- The difference between data protection and confidentiality
- Access to documents and confidentiality provisions under 1107/2009
- To what extent do the Aarhus provisions apply in the crop protection area?
- Recent/ongoing court cases
- Protection of Confidential Business Information under 1107/2009: The way forward

Gérardine Garçon, *Attorney at Law, Central Legal Department,* **BASF SE, Germany**

15:00 **Data sharing under 1107/2009: Transitional measures, renewal data and confirmatory data**
- Renewal and confirmatory data; what should this be? How much is it protected? Timelines for submission
- Examining vertebrate data sharing
- Legal framework under 1107 and transitional rules
- Commercial negotiations and letters of access: The way forward
- Comparison with US system under FIFRA

Claudio Mereu, *Partner,* **Field Fisher Waterhouse LLP, Belgium**

15:30 Afternoon Tea

CLP: INTERACTION WITH 1107

16:00 **Classification and labelling and the relationship with 1107 from a member state perspective**
- How is C&L of active substances dealt with by the Member States?
- How does C&L of active substances affect C&L of PPPs?
- Examing the apparent conflict between the CLP regulation and 1107/2009
- What are the implications of self-classification?
- Possible solutions

Maarten Trybou, *Head of Service Pesticides and Fertilizers,* **Federal Public Service for Public Health, Food Chain Security and Environment, Belgium**

16:30 **The relationship between classification and labelling and 1107: An industry perspective**
- Current implementation status of the CLP regulation
- The harmonized classification process for substances
- Relationship between the harmonized classification process for substances and the 1107 authorisation process for active ingredients
- Classification of plant protection products: Who is responsible?

Phil Todd, *Global Distribution Safety Manager,* **Syngenta, Switzerland**

17:00 Closing remarks from the Chair

17:10 End of Conference

Dear Colleague

On reviewing the conference programme I hope that you will agree that we have an exceptional line up of speakers for 2012. Registration of Agrochemicals 2012 will provide a forum to hear first experiences of 1107/2009 and ensure successful implementation for your company.

Unrivalled networking opportunities, with over 190 senior level attendees in 2011, makes this a must attend event for 2012.

The agenda is composed of the following sessions and is specifically designed to ensure you achieve success under the new regulation 1107/2009:

- **Essential feedback from EFSA and The EU Commission**
- **AIR 2 and AIR 3 projects**
- **First experiences of 1107 post June 14th 2011: The zonal authorisation procedure and post approval issues**
- **Comparative assessment**
- **Endocrine disruptors and the regulatory framework**
- **New data requirements and the uniform principles**
- **Data sharing, confidentiality and confirmatory data**
- **CLP: Interaction with 1107**

Hear from 28 speakers throughout the conference including:
2x EU Commission, EFSA, ECPA, 8x Member States, Dow, Bayer, ECPA, DuPont Crop Protection, Syngenta and BASF

Make the most of your time out of the office and take advantage of our interactive seminars. Both offer a highly practical and interactive approach designed to complement the main programme.

I hope that you are able to join us at this exciting event and I look forward to welcoming you to Brussels in April.

Best wishes

GMBurns

Gemma Burns
Conference Director, Informa Life Sciences

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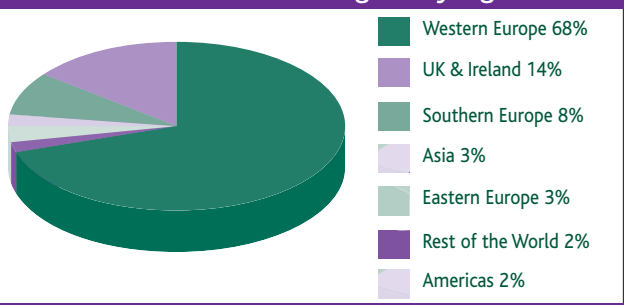
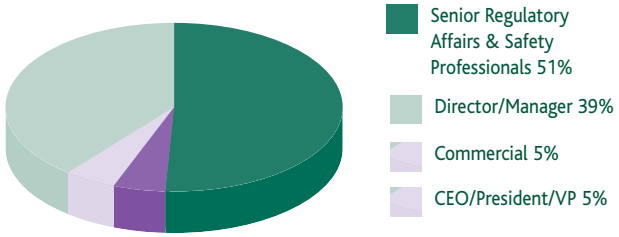


Breakdown of 2011 delegates by job function



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2 Day Conference + Evening Seminar	CQ8119CS	17-18 April 2012	☐ £1798 + 21% VAT = £2175.58	£200	☐ £1898 + 21% VAT = £2296.58	£100	☐ £1998 + 21% VAT = £2417.58	
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3 Day Conference + Pre-Conf Workshop + Evening Seminar	CQ8119CWS	16-18 April 2012	☐ £2297 + 21% VAT = £2779.37	£300	☐ £2397 + 21% VAT = £2900.37	£200	☐ £2497 + 21% VAT = £3021.37	£100

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