



*What I have seen  
in 10 years in regulation  
of biocontrol*

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# Overview

Introduction - ABIM 2006

- EU PPP Regulation
- OECD
- European projects
- EU Working Group on BioPesticides
- Efsa
- Partnerships & Collaborations
- Sustainable Use Directive and national initiatives
- Looking outside of Europe - Access Benefit Sharing
- IBMA Global - New organisation & tools

Conclusion - ABIM 2015

# Introduction - 1<sup>st</sup> ABIM in 2006

- ~ 100 IBMA members
- ~250 registered delegates

## Plenary session on **New Developments in Regulation** and Policy

- Presentation by Ulf Heilig (IBMA): *Public relations in regulatory affairs for IBMA*
- Same session included...  
Wolfgang Reinert (DG SANCO): *The new regulation on PPP in the EU*

# COM proposal for PPPs

⇒ future Reg. (EC) No 1107/2009

- In coll. with Bernard Blum: **IBMA commenting** on draft text
- **Meetings with MEPs** and their parliamentary assistants
- IBMA tried to introduce option for specific regulation for biocontrol products
  - ☹ dropped out in 3<sup>rd</sup> reading
- IBMA on Low-risk
  - ☺ introduced limitation of “sensitising” criterion to chemicals
  - ☹ failed to exclude microbials from “persistence” criterion in soil

# Reg. (EC) No 1107/2009: Key innovations

## Basic substances

Low-risk concept

Candidates for substitution

Comparative assessment

Zonal system and improved mutual recognition

→ UH presentation at ABIM 2009

# Reg. (EC) No 1107/2009: Key innovations

## Situation today

Basic substances → 7 (+1) substances

Low-risk concept → 5 act. substances

Candidates for substitution → Reg. (EU) No 2015/408

Comparative assessment → applied ???

**Zonal system** and improved **mutual recognition** → System is in place but complex and has many **shortcomings** (recognition of field data & assessments of zRMS)

# Reg. (EC) No 1107/2009 – Zonal System & MR

- *WS on the Implementation of Mutual Recognition in the Authorisation of PPPs* hosted by Germany in Braunschweig, open session on 27<sup>th</sup> Jan. 2010
- *WS on Zonal Evaluation, Mutual Recognition and Re-authorisation of PPPs*, organized by COM, hosted by Irish CA in **Dublin**, 2<sup>nd</sup> - 4<sup>th</sup> June **2015**
- **IBMA** attended both events as a **recognised representative** of Biocontrol Industry: presentations in plenary sessions
- Dublin: **Attendees** identified & acknowledged **shortcomings** ⇔ solutions
- **COM** strongly **committed to improving** Zonal System & M R
- Information on Dublin WS → Regulatory pages in IBMA members-only section

# OECD – Participation of IBMA

- Participation in **WGP** and in **BPSG**
- Chair BPSG (since 2006): Jeroen Meeussen
- Increasing role of and input by IBMA
  - 👍 **Commenting** on draft docs (now by IBMA PG Steering Committees)
  - 👍 **Proposals** for GDs
- Today IBMA also represented in
  - RSG and RRSB
  - EG IPM and EG Pesticides Risk Indicators EG Minor Use

*very important*

# OECD BPSG GD on biocontrol agents

## Important finalised GDs

- **Environmental Safety** Evaluation of Microbial BCAs (2012)
- **Microbial Contaminant Limits** for Microbial PCPs (2012)
- Working Doc on the **Evaluation of Microbials** for Pest Control (2008)

☞ OECD page in Regulatory Pages in IBMA members-only section

## Current subjects include

- Guidance on **storage stability** of Microbial Pest Control Products (Lead **IBMA!**)
- GD on Hazard and Risk Assessment of **Secondary Metabolites** produced by Microbial Pesticides
- Questionnaire on **Test Guidelines** for Microbials: Inadequacy or gaps? Summary - priority - harmonisation
- **Pre-submission** meetings
- Adapting of **EU guidance**

- botanicals
- equivalence microbials
- semiochemicals

*OECD Work on guidance is slow but essential for our industry*

# OECD BPSG Seminars and WS

- Since 2009, **six seminars** on key issues in biological pesticides:
- 2015 - Hazard & Risk Assessment of **Secondary Metabolites** produced by Microbial Pesticides
- 2014 - **Application Techniques for Microbial PCPs and Semiochemicals:** Use Scenarios & Associated Risks
- 2012 - ***Trichoderma* spp.** for the Use in PPPs: Similarities and Differences
- 2011 - Characterisation and Analyses of **Botanicals** for the Use in PPPs
- 2010 - **Fate in the Envi of Microbial BCAs** and their Effects on NTOs
- 2009 - **Identity & Characterisation** of **Micro-organisms**

→ OECD page in Regulatory Pages in IBMA members-only section

# OECD BPSG Seminars and WS

OECD/EPA WS on Regulation of Biopesticides: Registration and Communication Issues  
2008, EPA, Arlington, USA

OECD/KEMI/EU WS on Microbial Pesticides 2013, Saltsjöbaden, Sweden

- Two **key statements**:

*“The **biological properties of living micro-organisms differ from the properties of chemical pesticides.**”*

*“Therefore it was desirable to **reconsider the regulatory requirements for microbial pesticides**”*

- List of action points on issues to be solved
- Report published 

→ Presentation by J. Meeussen at ABIM 2013 

# European project “Rebeca”



EU policy support action\* on *Regulation of BioControl Agents* (2006-2007)

## Microbials - Semiochemicals - Plant Extracts

- Co-ordinator: Prof. Ralf-Udo Ehlers
- Partners: Univ. of Kiel, Birmingham, Helsinki, Innsbruck, DK EPA, FiBL, GAB & CABI
- **European wide forum** for exchanges
  - regulators ↔ evaluators ↔ experts (industry & science)
- **Basis for improved dialogue** between stakeholders and regulators
- Contributed to **better understanding** of needs of biocontrol industry
- Work on **numerous deliverables** on benefits, costs, risks and **comprehensive proposals** for alternative, more adequate regulations for BioControl Agents in the EU



Unfortunately...

the project had no significant impact on the text of Reg (EC) No 1107/2009

Final report 

\*Funded by DG Research

# European project “Rebeca”

EU policy support action on *Regulation of BioControl Agents* (2006-2007)

**Microbials - Semiochemicals - Plant Extracts**

## IBMA involvement ?

- Many IBMA members participated
- Industry BOG chaired by UH → presentation of Industry views in 1<sup>st</sup> conference in Salza
- **Workshop “Rebeca” at ABIM 2006**  
chaired by UH with presentations from Ralf-Udo Ehlers, David Cary

# European project\*



- 2007-2010: 16 partners in 10 countries:  
Research Institutes – Universities – Extension organisations –



IBMA's intent: **pursue dialogue** with EU regulators and evaluators

- Organised internal WG → analyses of regulatory issues
- WS with reps from DG SANCO & DG Agri on situation of Biocontrol substances and products under PPP reg.

IBMA contributed to deliverable DR4.7 incl. regulatory aspects on Biocontrol substances & PPP 

\* European Network for Durable Exploitation of crop protection strategies under EC FP6



# EU WG on BioPesticides

**Creation:** Summer 2014

**Mission:** Contribution to implementation of Reg. (EC) No 1107/2009 art.77

☞ respond to the need to **develop adequate guidance** and

☞ **address technical issues related to biopesticides**

Chair: COM

Participants: 5 MSs, IBMA, Experts (case by case)

Recognised IBMA status based on expertise, scientific arguments & work-sharing

In general: Consensus on conclusions & document

Always: Final decision by regulators and note taking in SC PAFF

# EU WG on BioPesticides

## GDs already issued

- Assessment of the **equivalence** of TGAI for identical **microbial strains** or isolates
- **Semiochemical** as used in PPPs

## Present subjects include

- Template for assessment of MOs/ possibility of read-across at higher taxonomic level
- Non-viable micro-organisms

## Future subjects include

- Issues from OECD-Kemi-EU WS on microbials
- GD for assessment of *Trichoderma spp*

# EU Working Group on Low-risk

Initially: Broad approach favoured by DG SANCO

In the following: **Split between**

- Working group: **Proposals for amended LR criteria**
  - Presentation in this session by Wolfgang Reinert / DG SANTÉ:  
*“The low-risk substances and products – where now”*
- Political level: Stakeholder initiative for **specific LR approval procedure**
  - **European Parliament Luncheon on Low-risk Pesticides**  
Co-organised: IBMA & Copa Cogeca

# Increasing role of Efsa

- Creation in 2002
  - Efsa involvement
    - ✦ Assessment of act. subst. (Peer-review & Conclusion)
    - ✦ MRL setting
- Presentation UH on Efsa and List-4 at ABIM 2012 

Numerous **issues raised by Efsa** in conclusions, “Critical areas of concern”, include for

- **MBCAs:** Extrapolation between strains, exposure models, sec. metabolites
- **SCLPs:** Background exposure
- **Botanicals:** Lacking endpoints for reference values ; background exposure

# IBMA and Efsa

## Pesticide Steering Committee

→ Industry Session on 1<sup>st</sup> December **2010** in Parma

- IBMA delegation and presentation
- Efsa PSC industry hearings in 2012 and 2013

## ECPA – IBMA Joint Workshops with Efsa

- **2012:** IBMA presentation and BOG on biocontrol
- **2014:** Presentation “*IBMA view on the work of EFSA*”  
Specific BOG on Biocontrol: largest number of attendees!
- **Next:** June 2016 ?

**My view:** Exchanges and common work on guidance are improving understanding of biocontrol substances

# Collaborations with PAN and IOBC

## PAN

- 1<sup>st</sup> presentation by UH on Biocontrol in PAN WS in Dec 2009 → Awareness raising
- Participation of speakers at ABIM  
H. Muilerman (2009) & H. Christensen (2012 & 2013)

## IOBC

- 4 ! presentations of IOBC-WPRS council members at ABIM 2013.
- Coll. in ENDURE

## Both

- Coll on various issues & organisation of **joint events** in EESC and EP (with MEPs)  
→ Joint event IBMA IOBC PAN Greenpeace EuroCoop coming on **19<sup>th</sup> Nov. 2015**  
4th Symposium “*Feeding Europe while Reducing Pesticides Dependency*” in EP



# Collaborations with ECPA & COPA-COGECA

## ECPA

- Participation of speaker at ABIM  
J-Ch. Bocquet / DG (2014)  
Stuart Rutherford (attending 2015)
- Co-organisation of **WS with Efsa** in Parma (2012 & 2014)

## COPA COGECA

- Pekka Pesonen speaker at **ABIM 2014**
- Joint **Workshops on IPM**
- Common **Road Map** for coll. (2014/2015)  
→ IBMA website
- **European Parliament Luncheon on Low-risk Pesticides (15<sup>th</sup> July 2015)**  
→ IBMA Summer Newsletter

# Sustainable Use Directive

- Favours **non-chemical** methods
- Compulsory **IPM** programmes
- Compulsory **NAPs for risk reduction**

# Positive events and attitudes at national level

**“Green Deal”** in the NL

ABIM 2015 Key note presentation → Luuk van Duijn (CTgb, NL)

**“Ecophyto”** in France

- ✓ Favours Biocontrol (in keeping with IBMA definition)
- ✓ Creates NODU vert (green pesticide index)

# Looking outside of the EU

## EPA (USA)

→ **Rule** published in Fed. Register Oct. 26, **2007** [40 CFR Part 158]

*“Pesticides; Data Requirements for Biochemical and Microbial Pesticides”* 

## • PMRA (Canada)

→ **Regulatory Directive** DIR2012-01 published on 27 Feb. **2012**

*“Guidelines for the Registration of Non-Conventional Pest Control Products”* 

## • FAO

→ **Work in progress**

*“Guidelines for the registration of micro-organism & botanical pesticides”*

# Nagoya Protocol – Access Benefit Sharing

- Implementation Reg. (EU) No 511/2014  
*Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union*  
Entering into force (NP & Reg.): **12<sup>th</sup> Oct. 2014**

**Scope:** Depending on interpretation, all 4 groups of BCAs could be covered

**Microbials! Botanicals!** Clarity for **Invertebrate BCAs? Semiochemicals?**

- ☹️ Could create considerable **barriers for development and use of Biocontrol** products.
- ☹️ **Impracticability** of current provisions: reference collections!
- ☹️ Implementation Reg. for compliance monitoring **pending**

→ IBMA RegSem 2014 & 2015

→ ABIM plenary 2014 (Johannette Klapwijk)

→ IBMA website: Page on ABS in Reg part (members only)

# IBMA global - New organisation and tools

- Creation of **Steering Committees** in PGs
- Member awareness of importance of reg issues ⇒ **contributions** ↗ ↗
- New communication tools: **IBMA website** with **special section on Reg Affairs**  
Managed by UH



IBMA members are invited to

- 👍 contribute to progressive extension of information
- 👍 suggest Newsflashes

- **Reg Sem** replaced Regulatory WG
  - 👋 2 sessions (90 min, since 2014)



# ABIM 2015 - 10<sup>th</sup> edition

- IBMA members: **226** (Sept. 2015)
- Registered delegates: **> 830**
- **RegSem Attendees: > 100**

**Plenary Session** on Reg Issues (today) includes  
Wolfgang Reinert of **COM's DG SANTÉ**

**Keynote Address** Guest speaker (19<sup>th</sup> Oct.)  
Dr. Luuk van Duijn (CTgb)

## **In recent years**

2014: Jeroen Meeussen / DG SANCO + **OECD BPSG** & Martin Ward / **EPPO**

2013: Michael Flüh / **DG SANCO**, Iman Boot / **DG Agri**, Mark Davis/ **FAO**,  
Jeroen Meeussen/ **BPSG**

# Conclusion

- ✓ Increasing **awareness and understanding** of specificity of biocontrol agents and products **by evaluators and regulators**
- ✓ **Active participation of IBMA in WG of international organisations** with Regulators and Evaluators
  - 😊 **improved** guidance 
  - 😞 still **locked into** existing **legislative framework** for PPPs (EU !)
- ✓ IBMA is **recognised** and respected **as partner** by stakeholder NGOs: industry, farmers, environmentalist ⇒ collaboration and joint action
- ✓ **Meetings and Hearings with Legislators**
  - ⇒ Long way to changes in EU PPP legislation and procedures for biocontrol substances and products but we are on the right track !



# Merci !

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