

Public relations in regulatory affairs for IBMA

Presentation by Ulf HEILIG

International Relations in Regulatory Affairs

Professional background

Experience in **industry** :

10 years in Product Development, Technical advice and Regulatory Affairs

Experience in **CRO** for Safety, Toxicity & Residue Studies
3 years Business Development

Independent **consultant** since 1998

Personal experience with Biocontrol Products

- Organisation of field trials with CROs, technical institutes & authorities
- Preparation of biological dossiers

Semiochemicals

Pheromones for mating disruption in orchards

Microbials

Bt kurstaki in orchards & vegetable gardens

Bt israelensis for mosquito control

Granulose virus in orchards

Botanicals

Pyrethrum for stored product protection

Macro-organisms

The Mission

Through regular contacts, visits and meetings
with officials, regulators & politicians ...

- Keep up-to-date with organisations and staff working on biocontrol & IPM within EU and European based international organisations
- Collect information relative to PP policies, regulations etc.
- Bring IBMA positions / comments to the attention of the appropriate authorities within the EU
(Jointly with Heads of International Affairs and PGs)

The Mission (2)

but also...

- Identify projects & programmes relative to biological control & IPM of interest and inform IBMA members
- Assist applicants with submissions and follow-up of proposals
(limited and case by case)

Position in IBMA

as a consultant ...

- Co-ordination with / reporting to
Vice Pdt, Head of IBMA International Relations WG
- Collaboration with
Head of International Relations
Professional Group heads concerned by subjects
- Reports to
Executive Committee
Annual General Meeting

Overview over activity since May 2005

Representative examples

Activity related to European Regulations

Short and mid-term

- Preparation of IBMA position paper on **SANCO Draft Regulation** for PPP
- Contribution to IBMA position on **Impact Study** conducted by CIVIC Consulting on behalf of **DG SANCO**
- Meetings with officials of DG SANCO and DG Environment in Brussels
- Perspective : initiative to discuss Com proposal for new regulation with European MPs

Activity related to European Regulations

Long term

- Participation in OECD WGP meetings
June 2005 & February 2006 in Paris
Next : 14th & 15th Nov 2006 in Bonn
- Participation in OECD BPSG meetings
June 2005 in Brussels & June 2006 in Paris

Meetings allow ...

- ⇒ Contacts with officials from COM and CAs of EU MS
- ⇒ Information and discussion about international harmonisation of regulations, guidance documents & methods
mutual recognition, templates & work sharing
etc.

Activity related to European Regulations

Long term

- Participation in European Project Rebeca (voluntary)

Facilitator of Industry Stakeholder Meeting in Sept 2006 in Salzau

... introduced ideas of IBMA White Paper into discussion
and presented industry views in plenary session

Activity in support of IBMA National Sections, PGs & TFs

- Participation in IBMA UK section meeting on 19th Jan 2006 in Whittlesford
- Presentation at PG MBCA meeting on 3rd Aug 2006 in Stansted
Among key issues : status of MBCAs of EU revision list 4
Detailed notes on IBMA web site
- Assistance to IBMA Italy section
Approached ECPA to confirm agreement of mutual respect

Activity in support of IBMA National Sections, PGs & TFs

- Support to IBMA TF on SCLPs (PPP)
organisation of informal meeting with Senior official of Austrian CA (AGES)
- Defence of IBMA position on SCLPs re-evaluation by RMS Austria (BPD)
In coll with IBMA President & PG Semiochemicals leader:
letters to DG Environment
- Support to *Trichoderma harzianum* TF
Contribution to letter to DG SANCO

International Collaborations and Relations

... *in coll with Vice-President International Relations*

- BioPesticide Industry Alliance
Joint letter BPIA – IBMA to stress common position on EPA Proposed Rule
- German GTZ
Organisation of RV with OECD BPSG chair in NL
Support of GTZ project of Commercialisation of BCPs in S E A
- Relationship with ECPA and CEFIC

Activity in France

... *Voluntary as associated member, not as part of IBMA mission*

➤ Participation in meetings of IBMA France section and its WG

➤ Participation in national conferences and meetings

Lille Conference on Non-chemical C.P. in March 2006

AFSSA on new organisation and procedures for PPP approval

➤ Participation in AFPP WGs on

Macro-organisms

Natural products

Micro-organisms

Limits

- More feedback from PG leaders and members desired
 - ... possible remedy: creation of a Regulatory Steering Group
- REBECA not covered by mission
- Some current practical restrictions to be discussed

Challenges

General acceptance of specificity & specific status of Biocontrol Products

Gain public support: subsidies
projects

Obtain for BCAs: reduced fees,
appropriate alleviated requirements
specific procedures

Thank you

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