

Registration of biocontrol products – bacteria against plant pathogens

Experiences from the EU regulatory process with *Pseudomonas chlororaphis* MA 342

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Bacterial biocontrol products against plant diseases on the market

Bacteria	Products	Target
<i>Agrobacterium radiobacter</i> G-	Galltrol Nogall	Crown gall disease
<i>Bacillus</i> spp. G+	Companion, HiStick, Kodiak, Serenade , EcoGuard, Sublitex, RhizoPlus	Mainly soil-borne diseases
<i>Burkholderia cepacia</i> G-	Deny	Soilborne diseases, nematodes
<i>Pseudomonas</i> spp. G-	Bio-Save, BlightBan, Cedomon , Cerall , (Proradix)	Post-harvest, frost, soil- and seed-borne diseases
<i>Streptomyces</i> spp. G+	Actinovate, Mycostop	Soil-borne Diseases
<i>E. carotovora</i> G-	Biokeeper	Bact. soft rots

Why registration?

- Safety for consumers, users and environment
- Effective products
- Quality guarantee

➔ Safe and reliable business area



Biological seed treatment products against seed-borne fungal diseases

Cedomon[®] – barley, oats

Cerall[®] – wheat, rye, triticale



Regulatory history *P. chlororaphis*

- 1996 Dossier completed and filed
- 1998 Monograph by KemI, Sweden (RMS)
- 1999 Biochemical product DDR discovered by BioAgri, presented to RMS and COM
- 1999-2000 New studies and risk assessment by BioAgri
- 2002 SCP Opinion – no cause for concern
- 2002 Evaluation Table fulfilled or referred to MS level
- 2002-2004 WGE-Expert Meetings-WGL-WGE etc.
- 2004 Annex I inclusion, *P. chlororaphis* MA 342

How to improve the current process?

- Better microbiology and ecology background
 - directive
 - evaluators and regulators
- Specialised lead rapporteurs (as in 4th round)
- Time tables and agendas must be held!
- Regulatory support to BCA companies (IBMA?)
- Study guidelines relevant to microorganisms
- Implementation of uniform principles
- Implementation of mutual recognition
- Three European climatic zones!

Microorganisms with biotechnical use

- Plant protection products: 91/414 (2001/36, 2005/25)
- Biocides: 1998/8
- Feed additives: 1831/2003
- Food additives, probiotics etc: Novel food 258/1997
- Bioremediation: national legislation

Regulatory harmonization for microbes!

QPS – Qualified presumption of safety

“Scientific committees responsible for safety assessments within DG SANCO noted that, for microorganisms deliberately associated with the food chain, there was a: lack of harmonization, proportionality, recognition of familiarity” (Andrew Chesson, EFSA Scient. Colloquium Dec. 2004)

What happened with the BCAs?

How to survive a process of 8 years?

Provisional authorisation on restricted markets:
Sweden -97, Finland -99, Austria -03
Full authorisation Norway -99

MS refused evaluate for provisional authorisation
last 2-3 years

Regulatory expenses for BioAgri

- Direct costs (1,5 empl. + consultant): 1,6 Million Euro
- Indirect costs (sales losses 3 yrs): 2,7 Million Euro
- Patent time lost 1992-2004

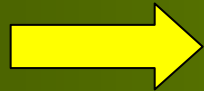
**If this had been known 1996, no investors would
have financed the business**

Future prospects with a reasonable regulatory process

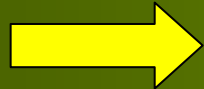
- **Products for new areas/niche crops**
- **Strain flexibility**
- **Products based on microbial mixtures/consortia (PGPR+BCA+VAM+helper bacteria etc)**



better performing products



reduction in agrochemical use



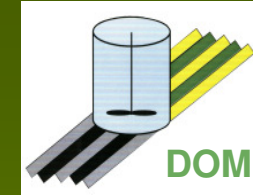
less environmental impact



safe food and feed



Microbial
Activity for a
Sound
Environment



28 – 30 June 2006, UPPSALA, SWEDEN

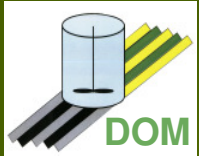
Conference topics will include:

- Microbial solutions to environmental problems in agriculture
- Human and environmental safety
- The regulatory process
- Formulation and production
- Commercialisation of microbial products

30 April 2006 dead-line early registration
www.maselab.se

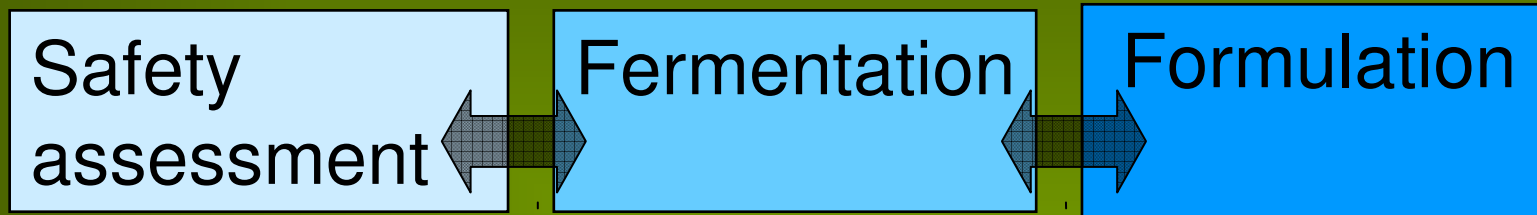
MASE – Microbial Activity for a Sound Environment





DOM

Domestication of Microorganisms



I

Biological control

Pseudomonas spp.

(gram-negative)

II

Bio-preservation

Pichia anomala

(yeast)

Lactobacillus spp

(gram-positive)

III

Bioremediation

Rhodococcus sp.

(gram-positive)