Minor Uses a Place for Biocontrol Solutions

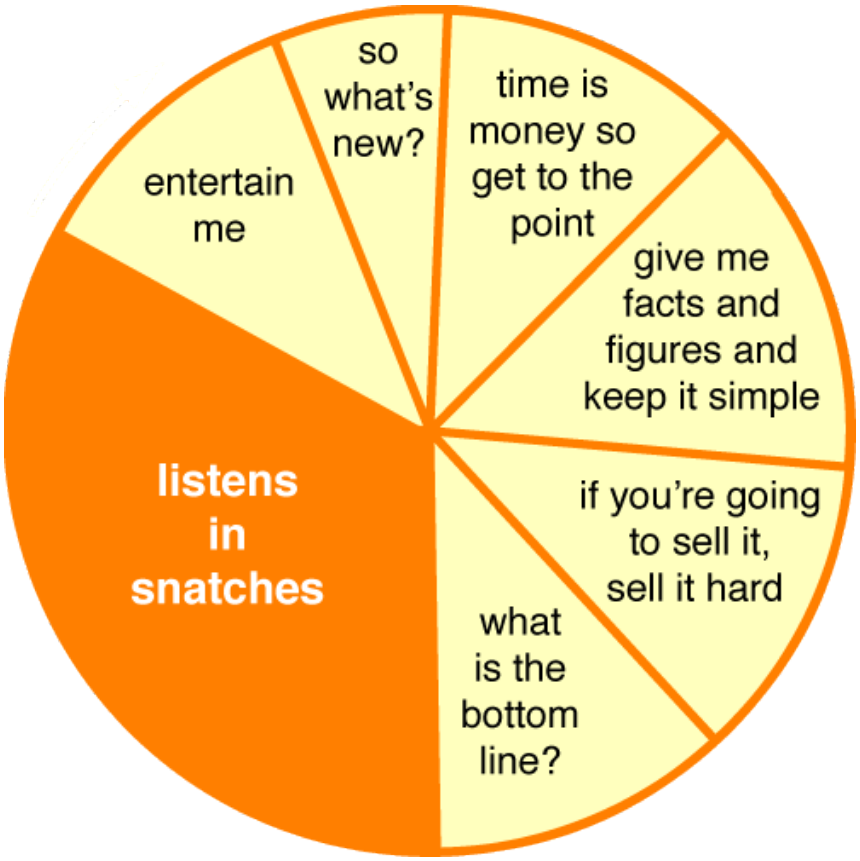
Jeroen Meeussen

EU Minor Uses Coordination Facility

BPIA Meeting, 2 March 2016, Monterey CA

MinorUses
EU Minor Uses Coordination Facility

Listening Habits - USA



Minor Uses
a Place for Biocontrol Solutions

Content

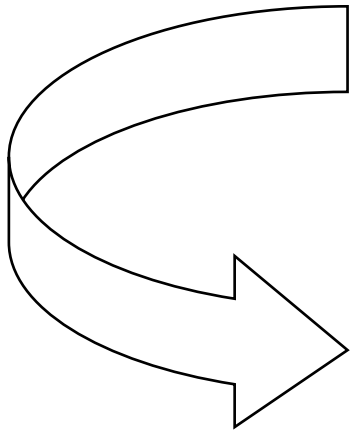
- Minor Uses
- The EU Minor Uses Coordination Facility
- Sustainable Agriculture
- OECD-Biopesticides Steering Group
- Biocontrol Solutions

MinorUses
EU Minor Uses Coordination Facility

Regulation (EC) No 1107/2009

Approval

SUBSTANCE A



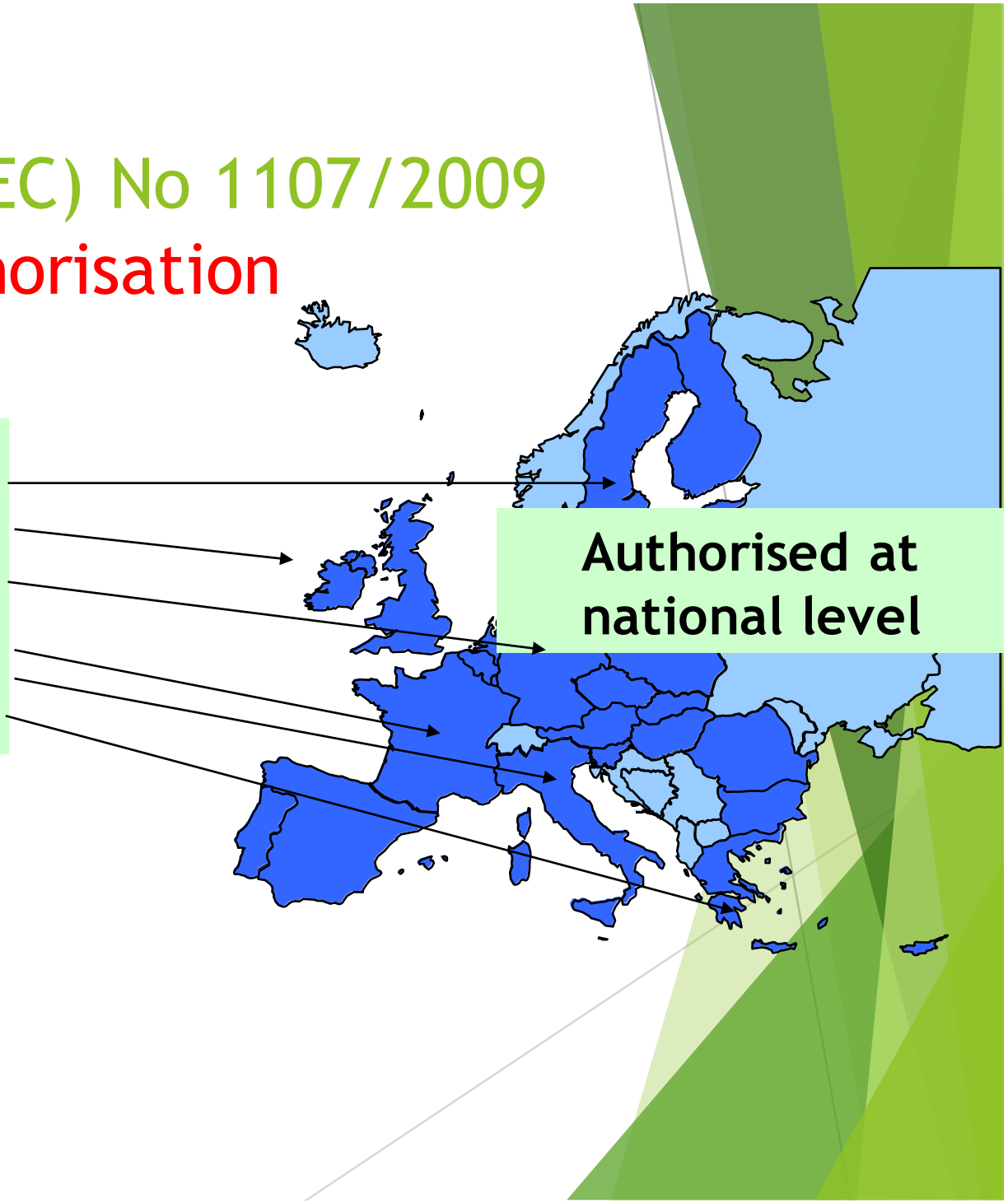
Approved at Community level

One decision applying to all 28 Member States

Regulation (EC) No 1107/2009

Authorisation

Plant protection products (formulations) containing the substance A



Authorised at national level

Minor Uses – EU definition

Regulation (EC) No 1107/2009 – Article 3(26):

Use of a plant protection product in a particular Member State on plants or plant products which are:

(a) not widely grown in that Member State,

or

(b) widely grown to meet an exceptional plant protection need

Minor Uses - Importance

Only 3% of the cultivated area, but representing 22% of the value of the entire EU plant production value.

Across the EU these minor crops represent a value of more than 70 billion Euros per year.

Minor Crop – US definition

- Minor crop: any crop grown on 300,000 acres or less. This includes most vegetables, fruit, nuts, herbs, spices, nursery and landscape plants and flowers.
- Major crops: large acreage crops like corn, soybean, wheat, peanuts, rice and cotton.
- Minor crops account for over 67 billion dollars in annual sales, which is about 40 percent of the total agricultural sales for the US.

The IR-4 Project

Minor Uses – EU definition

Is this a workable definition?

- Leaves it up to individual EU Member States to define what is considered a ‘minor use/crop’.
- Hinders the zonal procedure and mutual recognition in the EU.
- Different definition of ‘major crop’ for MRL-setting.
- A fixed acreage (at least per zone) is favoured by most EU growers associations.

Content

- Minor Uses
- The EU Minor Uses Coordination Facility
- Sustainable Agriculture
- OECD-Biopesticides Steering Group
- Biocontrol Solutions

MinorUses
EU Minor Uses Coordination Facility

Coordination Facility

- Report from Commission resulted in the creation of the EU Minor Uses Coordination Facility.

- Hosted by EPPO (in Paris) and jointly funded by the EU and by the governments of France, Germany and the Netherlands. Initially for a period of 3 years.

- Grant contract was signed on 15 April 2015.

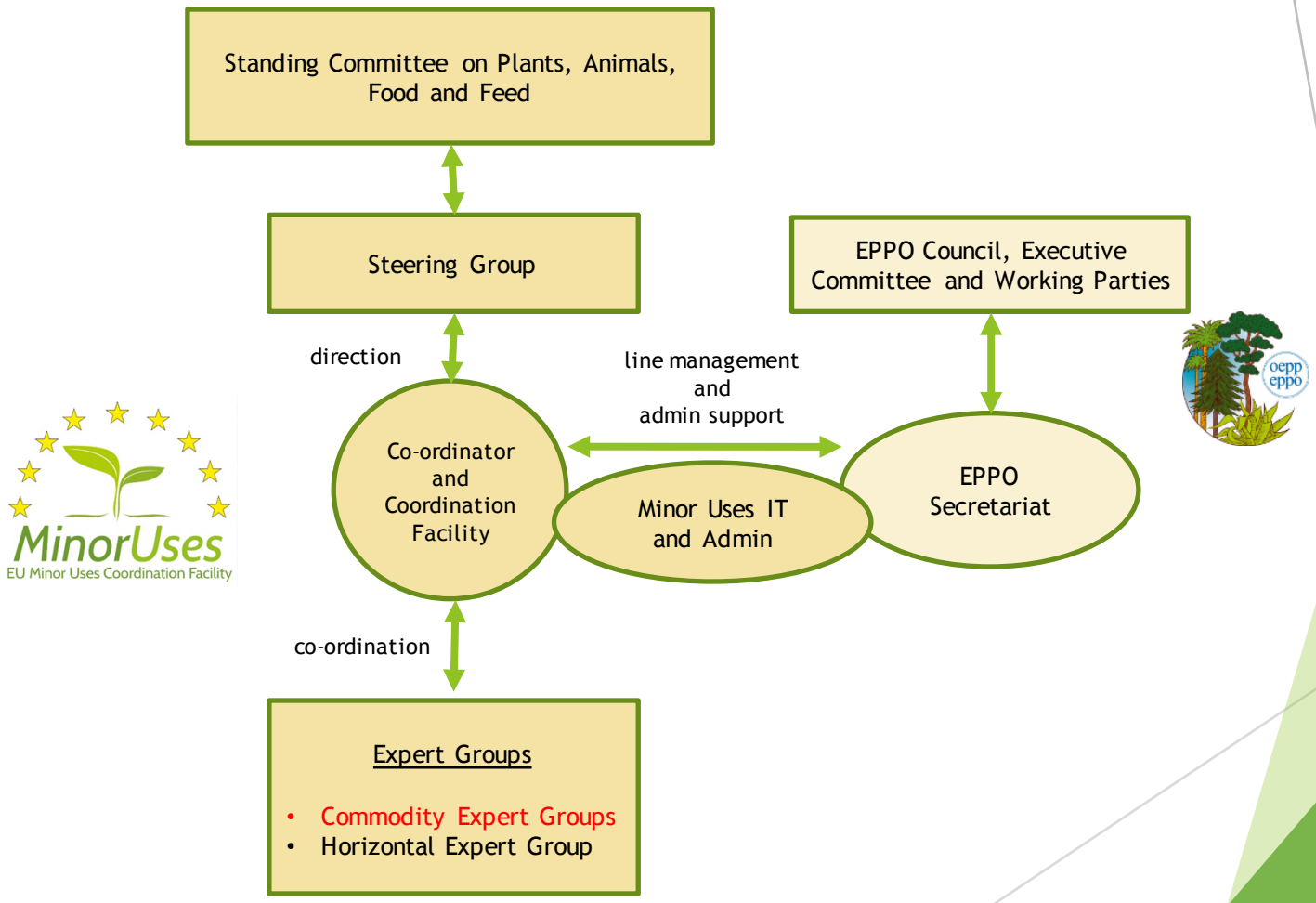
- Coordinator started 1 September 2015.
  Coordination Facility will work for all Member States.

Coordination Facility - Tasks

Tasks of the Coordination Facility:

- sharing of information and experience gained at national level.
- coordination of minor use work between Member States and stakeholders.
- creation and maintenance of a data base on minor uses.
- stimulation of harmonisation (e.g. crop group and pest group definitions, development of guidance).

Diagram of relationship



Commodity Expert Groups

Currently there are 6 Commodity Expert Groups (CEG):

- CEG fruit and vegetables
- CEG ornamentals
- CEG tobacco
- CEG rice
- CEG hops
- CEG seeds

- Focus in CEG is very much on **chemical solutions!**

Coordination Facility - Mission

The mission of the Facility is 'to enable farmers in the EU to produce high quality crops by filling minor uses gaps through efficient collaboration to improve availability of chemical and non-chemical tools within an integrated pest management (IPM) framework'.

Member States and Stakeholders

(growers, industry, international organisations)

OECD
BETTER POLICIES FOR BETTER LIVES

European Crop Protection

The IR-4 Project

AgroCare
ALINA ECCA CCPIA PMFAI
865 different individual companies

copa cogeca
european farmers european agri-cooperatives

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

freshfel
EUROPEAN FRESH PRODUCE ASSOCIATION

COCERAL

C-IPM

Content

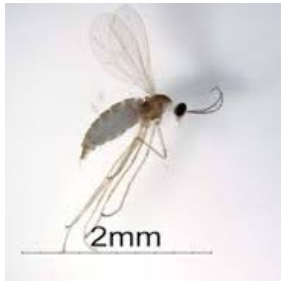
- Minor Uses
- The EU Minor Uses Coordination Facility
- Sustainable Agriculture
- OECD-Biopesticides Steering Group
- Biocontrol Solutions

MinorUses
EU Minor Uses Coordination Facility

We need to feed the World!

Obesity is now killing triple the number of people who die from malnutrition!

Pests and diseases in savoy cabbage



Sustainable Use (EU Directive)

Objectives at use level:

- Reducing risks and impacts of the use of pesticides
  - On human health
  - On the environment
- Promoting
  - The use of **Integrated Pest Management**
  - The use of alternative techniques such as **non chemical methods**

Integrated Pest Management (IPM)

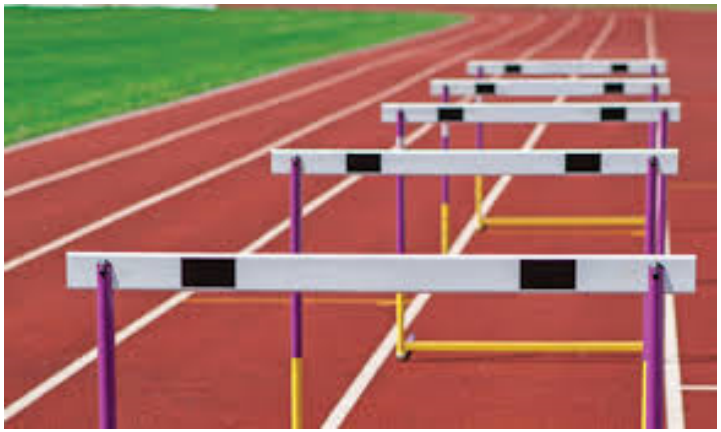
- IPM ≠ no (chemical) pesticides
- IPM =
  - Low pesticide input management;
  - Consideration of all available plant protection measures;
  - Pests and diseases kept at levels which are economically and ecologically justifiable;
  - Healthy crops with least possible disruption to agro-ecosystems.

Key Factors for Success

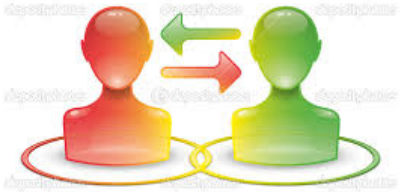
- Engagement, cooperation and collaboration across all sectors (growers, growers associations, industry, competent authorities, research and government).
- Adoption over wide area/most growers.
- incentives/support including financial.

Key Obstacles

- Multiple solutions/tools needed and cost of implementing tools.
- Limited number of IPM compatible products.
- Lack of information/knowledge of crop/pest biology/ecology.
- Not all growers are willing to accept.



Communication on IPM



Definition of "non-chemical methods"

- ‘Non-chemical methods’ means alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques, or physical, mechanical or biological pest control methods.

Increasing Interest in Biological Control

- It fits within IPM-strategies for a sustainable agriculture.
- To overcome problems with resistance. Applications with conventional chemicals can be alternated with biological control.
- Residues. More and more large supermarkets apply a zero-residue policy. When replacing the last chemical treatments by biological a zero-residue situation can be achieved.
- The lack of new chemical active substances.

Content

- Minor Uses
- The EU Minor Uses Coordination Facility
- Sustainable Agriculture
- OECD-Biopesticides Steering Group
- Biocontrol Solutions

MinorUses
EU Minor Uses Coordination Facility

A few words about OECD (1)

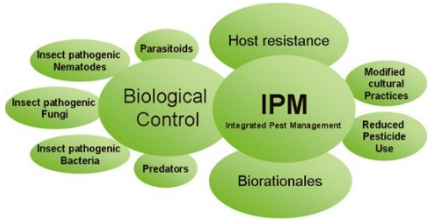
- The Organisation for Economic Co-operation and Development

A few words about OECD (2)

- Started after World War II
- Today the OECD has 34 member countries
- More than 70 developing and transition economies are engaged in working relationships with the OECD (Brazil, Russia, China and India)

How do pesticides fit in all this?

One of the fields in which OECD is actively involved is the sustainability of agriculture.



Biopesticides Steering Group (BPSG)

The Biopesticides Steering Group was established by the Working Group on Pesticides in 1999 to help member countries to harmonise the methods and approaches used to assess biological pesticides.

Biological Pesticides

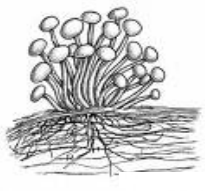
- Macro-organisms

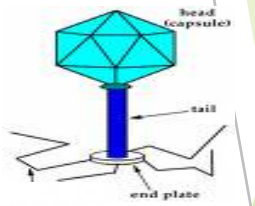
  (not covered by Reg.1107/2009)

- Microbial biopesticides

- Semiochemicals/Pheromones

- Plant extracts/Botanicals





Macro-organisms

- Registration requirements were reviewed for invertebrate biocontrol agents/IBCAs and published in the OECD Series on Pesticides No. 21: “Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCAs)”.
- Survey about the regulation of macro-organisms for pest and disease control in OECD countries is needed.

OECD-BPSG Publications on Microbials (1)

- Working Document on the Evaluation of Microbials for Pest Control (Series on Pesticides No. 43, 2008)
- Workshop on the Regulation of Biopesticides: Registration and Communication Issues; 15-17 April 2008, EPA, Arlington, USA (OECD Series on Pesticides No. 44, 2009):
- Report of Seminar on "Identity and Characterisation of micro-organisms", OECD Series on Pesticides No. 53, 2010)
- Report of Seminar on "The fate in the environment of microbial control agents and their effect on non-target organisms", OECD Series on Pesticides No. 64, 2011)
- Issue Paper on Microbial Contaminant Limits for Microbial Pest Control Products (Series on Pesticides No. 65, 2011)
- Guidance to the Environmental Safety Evaluation of Microbial Biocontrol Agents (Series on Pesticides No. 67, 2012)

OECD-BPSG Publications on Microbials (2)

- Report on Seminar on "*Trichoderma* spp. for the use in Plant Protection Products: similarities and differences", OECD Series on Pesticides No. 74, 2013)
- Workshop on Microbial Pesticides: Risk Assessment and Risk Management; 17-19 June 2013, Saltsjöbaden, Sweden (OECD Series on Pesticides No.76, 2014*)*
- Report of Seminar on "Application Techniques for Microbial Pest Control Products and Semiochemicals: Use Scenarios and Associated Risks", OECD Series on Pesticides No. 80, 2015)
- Guidance Document: Outline on Pre-Submission Consultations for Microbial Pest Control Products, Series on Pesticides No. 81, 2016
- Report of Seminar on "Hazard and Risk Assessment of Secondary Metabolites produced by Microbial Pesticides", *in publication*
- Report of an OECD survey on Regulatory and Testing Issues for the Sensitisation Potential of Micro-organisms, *in publication*
- Guidance document for the assessment of the equivalence of technical grade active ingredients for identical microbial strains or isolates, *in publication*

Workshop on Microbial Pesticides: Risk Assessment and Risk Management

- Micro-organisms are living organisms with biological properties that can die, survive or proliferate.

- As living organisms micro-organisms respond to the environment in different ways.

"Biology is the difference!"

Semiochemicals/Pheromones

- Registration requirements were reviewed for pheromones and other semiochemicals and published in the OECD Series on Pesticides No. 12: "Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control".
- Report of Seminar on "Application Techniques for Microbial Pest Control Products and Semiochemicals: Use Scenarios and Associated Risks", OECD Series on Pesticides No. 80, 2015)

Semiochemicals/Pheromones

- In the EU the "OECD-12" was used as guidance for preparing the SCLP-Draft Assessment Reports.
- More guidance needed for formulations other than solid matrix dispensers (e.g. sprayable microcapsule suspensions).
- The statement in OECD No. 12 that "application rates of up to 375 g ai/ha/year are generally understood to result in exposure levels which are comparable to natural emissions" should be reconsidered.
- EU is preparing a draft ". Guidance Document on Semiochemical Active Substances and Plant Protection products"

Botanicals/Plant Extracts

- Report of Seminar on "Characterisation and Analyses of Botanicals for the use in Plant protection Products", OECD Series on Pesticides No. 72, 2012).
- EU "Guidance Document on Botanicals". Based on the taxonomy and/or current knowledge of the botanical source three groups of botanical active substances can be distinguished.
- EU "Guidance Document on Botanicals" is in the process to be adopted as an OECD-document.




Content

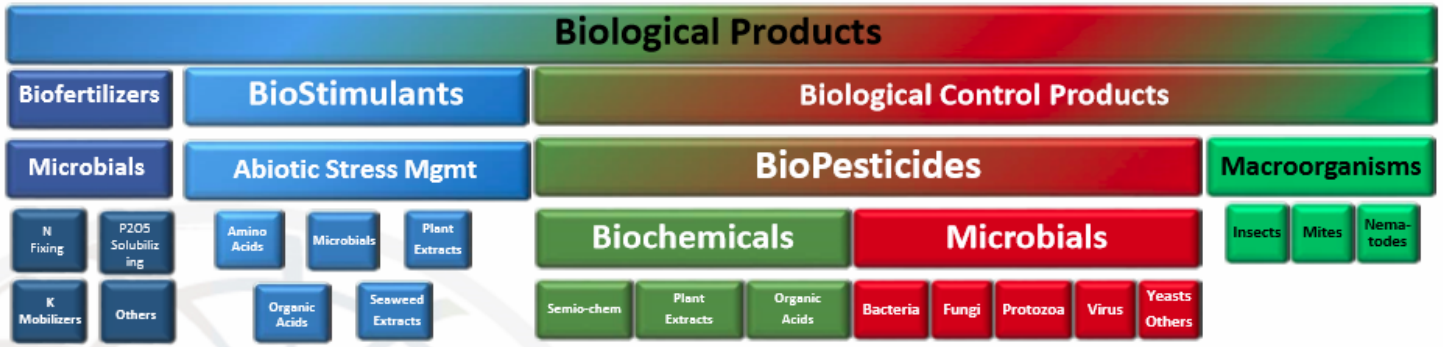
- Minor Uses
- The EU Minor Uses Coordination Facility
- Sustainable Agriculture
- OECD-Biopesticides Steering Group
- Biocontrol Solutions

MinorUses
EU Minor Uses Coordination Facility

TWO B MONTHLY
The Global Biocontrol & Biostimulants E-Newsletter

BIOLOGICAL MARKET OVERVIEW --INTRODUCTION—PRODUCT TYPES

DunhamTrimmer
International Bio Intelligence



Biofertilizers

- Microbials used to enhance plant nutrient uptake from soil
- Nitrogen fixing bacteria make up largest group
- Others include mobilizers of specific nutrients (zinc, sulfur) and mycorrhizal fungi
- Biofertilizers regulated under country/state fertilizer regulations

Biostimulants

- Seaweed Extracts make up the largest segment in this group
- Microbials, primarily bacteria, often used as seed or soil treatment to aid in nutrient assimilation
- Organic acids are humic and fulvic acids used as soil amendments, formed by the microbial degradation of plant matter.
- Definition and regulation of biostimulants is still under development in most parts of the world

BioPesticides

- Biopesticides are derived from natural materials, such as plants, bacteria and certain minerals. Biopesticides target specific pests and are inherently less toxic than synthetic pesticides.

Biochemicals

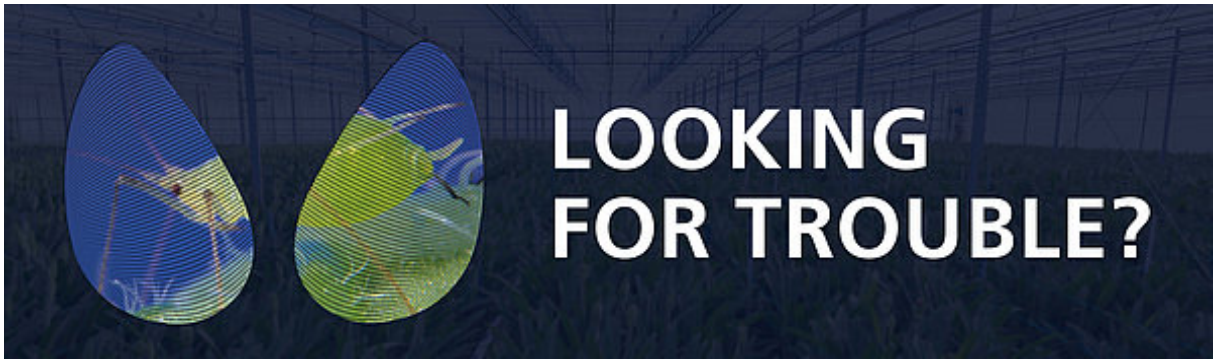
- Plant Extracts; Semiochemicals; Organic Acids
- Plant Extracts make up the largest segment in this group
- Semiochemicals (pheromones) has the largest actual number of products
- Largest challenge for Plant Extracts is manufacturing and consistent quality in the active ingredient(s)

Microbials

- Bacteria; Fungi; Virus; Protozoan; Yeasts
- Bacteria, followed by Fungi make up the largest groups commercially (>90%)
- Microbials are the largest market of biopesticides at US$1.3 Bn.
- Biggest challenges for microbials are formulation related: 1) Shelf-life; 2) Stability; 3) Performance enhancement

Macroorganisms

- Insects; Mites; Nematodes
- Insects followed by mites makeup the largest groups
- Unique in that the live organism in the form of eggs, larvae, pupae or adult is used.
- Most important challenge for Macros is logistics—shipping live organisms that have to have special care to survive
- Normally not classified as a Biopesticide—only as Biological Control Products



Early detection of the pest by a powerful task force of five different parasitic wasps, each with its own field of expertise.

KOPPERT
BIOLOGICAL SYSTEMS

Novel Technologies

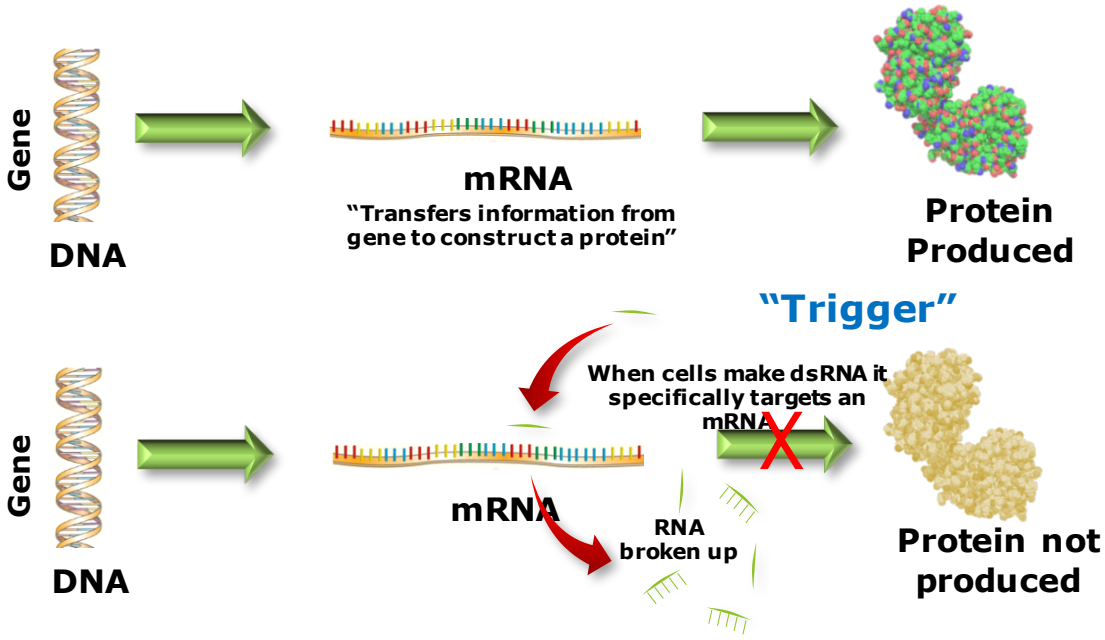
- Endophytes are organisms, often fungi and bacteria, that live between living plant cells. They can act by inducing resistance, plant growth stimulation, resistance against abiotic stresses, etc.

- Non-living substances of microbial origin. Non-spore formers where the cells lose viability on completion of the fermentation process, to the extent that when the formulated product is packaged, living cells are not present in the product.

- Engineered insects containing a lethal gene. To avoid that the gene will be spread throughout the natural population it is a 'self-limiting gene' which prevents offspring from developing into reproductive adults.

Novel Technologies
RNA interference (RNAi)

RNA interference (RNAi) is an important pathway that is used in many different organisms to regulate gene expression.



Public Debate necessary…

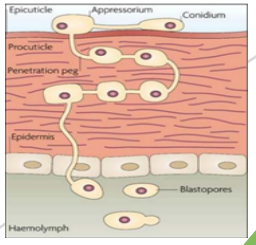
Public Debate is necessary

- Despite widespread debate on public acceptance of genetically modified organisms, several unique features support the safety profile of RNAi-enhanced products, including the ubiquitous nature of siRNAs in plants; the history of safe use and consumption of naturally occurring and transgene-derived RNAi crops; high species specificity that minimizes off-target effects; and lack of toxicity and allergenicity, resulting from the fact that no transgenic protein is produced by such plants. Clearly, RNAi holds tremendous potential for producing healthier crop plants with enhanced nutritional value *The Scientist, June 1, 2015*
- People on a *company's* public relations staff told me they hoped to communicate better on RNA sprays than they had on GMOs. *MIT Technical Review, Aug 11, 2015*
- RNA may be natural. But introducing large amounts of targeted RNA molecules into the environment is not. *MIT Technical Review, Aug 11, 2015*

Recommendations:

Knowledge and availability of biopesticides:

- Increase knowledge Crop-Pest-Predators: biology and interactions.
- Consider the whole ecosystem of a plant (crop-pest-predators/natural enemies).
- Aim for an integrated approach as biologicals support IPM programs to meet demands from the food chain, regulators and consumers.
- Production of biopesticides: Quantity, quality and logistics.
- Bigger portfolio: aim to cover all pests and diseases in a specific crop.
- Do not forget minor uses as they offer a lot of opportunities for biocontrol!



Recommendations:

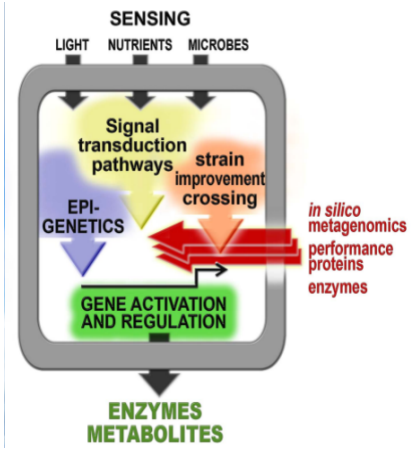
Communication:

- Communicate about (advantages of) 'sustainability' and IPM to consumers, retailers, farmers and other stakeholders.
- Increase information sharing and communication. Currently knowledge and research is fragmented; Increase role of growers and agricultural advisory services.

Novel technologies:

- Be prepared for new techniques of biocontrol. Start a public debate about novel technologies as early as possible.
- *'Regulators are always lagging behind'*: when developing a novel technique industry should contact regulators already in an early stage.

"Biology is the difference!"



Understanding Interactions between Plant and Biological Product for a Sustainable Future Agriculture

"Biology is the FUTURE!"

Conclusion

Biological solutions can provide excellent tools for sustainable agriculture and to fill minor use gaps!

Minor Uses
a Place for Biocontrol Solutions

THANK YOU FOR YOUR ATTENTION

ANY QUESTIONS

Jeroen Meeussen
Coordinator
European Union Minor Uses Coordination Facility
21 boulevard Richard Lenoir
75011 Paris
FRANCE

T +33(0)1 84 79 07 55
M +33(0)7 60 82 22 36
E jeroen.meeussen@minoruses.eu

website: www.minoruses.eu

MinorUses
EU Minor Uses Coordination Facility