The future of microbial products and regulatory issues

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Microbial agricultural inputs

- Setting the scene
- Biocontrol products
- Plant biostimulants
- Biofertilizers
- Market developments
- Regulatory issues
  - Biostimulants
  - Biocontrol products
- Future outlook
What is IBMA?

• Industry trade association
• Established in 1995/96
• Over 235 members
• Global European focused association
• Diverse membership
  • SME’s to multinationals
  • Organic & biocontrol only to IPM & conventional
  • Principally involved in agriculture & horticulture
What “Non-chemical solutions” are currently available from the Biocontrol industry?

**Macrobials**
- Predators, parasites & nematodes
- Living organisms found to naturally protect crops

**Microbials**
- Viruses, Bacteria & Fungal Pathogens
- Found naturally in soil, used in food, feed & and unregulated uses

**Semiochemicals**
- Pheromones, Plant volatiles
- Communication tools found in nature with no killing effect

**Natural & Biochemical Products**
- Botanicals & Other Natural substances
- Products derived from nature

Usually regulated as PPPs
Not usually regulated as PPPs
What is the focus of IBMA?

- Ensuring proportionate regulation of members’ products
- Promoting the interests and activities of the sector and its’ members
- Promote members main interest – biologically based protection
- Accelerate the strong growth in the use of biocontrol products
- Maintain a strong European focus
- Assist in establishing a global network
- Promote diversification into other areas
Established October 2014 as a Global Federation of Biocontrol and Biopesticide Associations

Acronym: BioProtection Global

https://biocontrolglobal.com/

Founding Members
ABC Bio - Brazilian Association of Biological Control Companies
ANBP - Association of Natural Biocontrol Producers
BPIA - Biological Products Industry Alliance
IBMA - International Biocontrol Manufacturers
SABO - South African Bioproducts Organisation
Microbial agricultural inputs

- Biocontrol
- Biostimulants
- Biofertilizers
- Used in production of crops: protection and productivity
- Excluding microbes for food and feed, for carbon recycling, soil remediation, etc.
**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
- Organic acids are humic and fulvic acids used as soil amendments, formed by the microbial degradation of plant matter
- Microbials, primarily bacteria, often used as seed or soil treatment to aid in nutrient assimilation
- 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; Minerals & Others; PGRs; Semiochemicals; Organic Acids
- Seaweed Extracts is the largest segment in this group
- Semiochemicals (pheromones) has the largest actual number of products
- Challenges for Plant Extracts is manufacturing and consistent quality in the active ingredient(s)

**Microbials**
- Bacteria; Fungi; Virus; Protozoa; Yeasts
- Bacteria, followed by fungi make up the largest groups commercially (>90%)
- Microbials are the largest market of biopesticides at US$1.3 Bn
- Challenges for microbiologicals 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
Microbials for biocontrol of pests

• Origin
  • Bacteria
  • Fungi
  • Oomycetes
  • Yeasts
  • Viruses
    • Baculoviruses
    • Weak plant viruses
    • Bacteriophages
  • Protozoa

• Uses
  • Insecticides
  • Fungicides
  • Bactericides
  • Viricides
  • Herbicides
  • Nematicides
  • Elicitors for ISR, SAR,
  • Plant growth regulation
Microbials for biocontrol

• Crops
  • Protected crops
  • Soft fruit
  • Fruit crops
  • Vineyards
  • Field vegetables
  • Arable crops
  • Amenities
  • Vector control
  • Animal health

• Applications
  • Foliar sprays
  • Seed treatment
  • Root dipping
  • Soil application
    • Dripping
    • In-furrow sprays
    • In-soil mixing
  • Bee-Vectoring
  • Post harvest
  • Etc.
Microbials for plant biostimulants

- Plant biostimulants contain substance(s) and/or microorganisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and crop quality

- Source: EBIC
Microbials for biostimulants

- **Origin**
  - Bacteria
  - Fungi
  - Yeasts

- **Crops**
  - Arable crops
  - Fruit crops
  - Protected crops
  - Field vegetables
  - Soft fruit
  - Vineyards

- **Applications**
  - Foliar sprays
  - Soil application
    - Dripping
    - In-furrow sprays
    - In-soil mixing
  - Seed treatment
  - Root dipping
  - Endophytic use
Microbials for biofertilizers

• Uses as inoculants
  • nitrogen fixing
  • phosphate mobilizing
  • potassium mobilizing

• Origin
  • Bacteria
  • Fungi
  • Cyanobacteria

• Crops
  • Cereals
  • Grains
  • Oil seed
  • Pulses
  • Fruits
  • Vegetables
  • Turf

• Applications
  • Seed treatment
  • Soil application
    • In-furrow sprays
    • In-soil mixing

• Countries
  • USA
  • Canada
  • Brazil
  • Argentina
  • India
  • Europe
Market developments

• Biocontrol products
• Biostimulants
• Biofertilizers
Global Market Performance—Biocontrol

- Biological Control—Sustainable Growth—17%
  - **Latin American** market growing faster than any other region
  - Climate and crops grown in Latin America well adapted to use of biopesticides

- Green technology / Sustainable technology
  - **Consumer demand** for lower residues driving adoption
  - Key part of an integrated system for food production

- Biopesticide market still dominated by rapidly growing entrepreneurial companies, but consolidation has started
  - **New technology** & new companies continue to emerge

- Market access needs drive consolidation
  - Many existing small companies lack market access
  - Larger companies/investors will acquire & consolidate to eliminate inefficiencies in current market

**Global CAGR**
- 67% NAm & Euro Share of Global Market
- >16% Global CAGR

**58%** Microbials Largest Product Line
- >17% Microbials Product Line fastest Growing

**47%** Bioinsecticides Still Largest Use Segment
- 18% Bionematicides Fastest Growing Use Segment

**2020 Global Biocontrol—Segment Mkt Shares**
- Bio-Insect 47%
- Bio-Fung 3%
- Bio-Herb 1%
- Bio-Nemat 5%
- Others 3%

**2020 Product Line Mkt Share**
- Microbials 58%
- Macro-organisms 13%
- Biochemicals 30%

**2020 Global Biocontrol Regional Mkt Share**
- N.Am 16%
- EU 35%
- Asia-Pac 2%
- LatAm 15%
- ROW 32%
BioProducts Market: Global Landscape

- **Microbial Biocontrol Market**
  - Product Sub-Types CAGR:
    - **Bacteria**
    - **Fungi**
    - **Virus**
    - **Others**
    - **TOTAL**

- **Biochemical Biocontrol Market**
  - Product Sub-Types CAGR:
    - **Semio-chemicals**
    - **Other Bio-chem**

- **Global Macrobial Market**
  - Regional CAGR:
    - **EU**
    - **USA/Canada**
    - **ROW**
    - **LatAm**
    - **Asia-Pac**
    - **TOTAL**

**Key Points**:

- **Bacterial based products**, led by *Bacillus* sp. based products, dominate the market.
- **Fungi** make up a smaller, but substantial portion of this category.
- **Viruses** have gained significant share in selected markets for control of specific insects (e.g. *Helicoverpa armigera*: Brazil).

- **Pheromone** products highest in value, but made up of large number of small products.
- Other biochemicals mainly **plant extracts**.
- The **challenge** for plant extracts is **consistency in supply chain** from year to year.

- **EU** dominates market with significant use in key greenhouse markets in Netherlands & Spain.
- **US** second in size, with majority of use in greenhouse markets.
- Currently **very little use of macros in field crop markets**.
Product Type Comments

✓ Extract based products are fastest growing and gaining global share
✓ Acid based products are largest in size, but with less new product innovation, global share dropping
✓ Other products, e.g. microbials, are growing but remain much smaller in size
- Evaluated valuation of US$ 1,254.2 mn in 2016
- CAGR of 12.9% during the forecast period of 2017 to 2025
- Estimating it to be worth US$ 4,092.1 mn by 2025
BioProducts Market: Global Landscape

US$3 Billion Today

US$5 Billion 2020

US$11 Billion 2025
Definition and regulation issue for biofertilizer and biostimulants

- European Union: biofertilizers are included in biostimulant definition
  - Nutrient efficiency
  - Legislation in development

- Latin America
  - Biofertilizers regulated (o.a. nitrogen fixing, phosphate or potassium mobilizing)
  - Biostimulants: legislation being discussed

- USA
  - Both are currently regulated by state
  - Federal regulation under discussion in EPA

- India
  - Both independently regulated
Legislation for Biostimulants

• European Union: Revision of Reg. 2003/2003 - Fertilizers

  • Positive list for micro’s
    • Azotobacter spp.
    • Azospirillum spp.
    • Mycorrhiza
    • Rhizobium spp.

  • New micro’s
    • Regulated at strain level
    • CEN Standards
    • EU Expert group MICROBIOSTIM
      • Data requirements and guidance
      • Safety assessment
A 2-level definition in the future “fertilising products” regulation

Fertilizing products/plant nutrition products comprising

- PFC1: Fertilizers
  - Organic
  - Organo-mineral
  - Mineral
- PFC2: Liming materials
- PFC3: Soil improvers
- PFC4: Growing media
- PFC5: Agronomic additive/inhibitors
- PFC6: Plant biostimulants
- PFC7: Combination
CMC-specific requirements

- **CMC 2 (plant materials and extracts)** – Positive list of defined treatment and extraction processes. *We would like to see the list broadened to any process that does not trigger REACH registration.*

- **CMC 6 (Food-industry by-products)** – Positive list. Again, progress has been made in Council negotiations, but *original list is too limited.*

- **CMC 7 (Microorganisms)** – Positive list to be populated by delegated act following evaluation by an Expert Group. *EBIC is concerned that positive list cannot cope with innovation, large number of microorganisms and strain-level particularities.* *We advocate the development of a criteria-based evaluation supported by harmonized standards.*
Timeline for developing a European regulation recognizing biostimulants
Legislation for Biocontrol microbials

• European Union:
  • Reg. 1107/2009
  • Data requirements Reg. 283/2013 Part B for micro-organisms
  • Low-Risk active substances
    • Micro-organisms eligible for low risk a.s. status
    • L-R Status after full evaluation
    • Approval period 15 years (vs 10 years)
    • Data protection 13 years (vs 10 years)
  • Low-Risk Plant Protection Product
    • Authorization within 120 days (art. 47)
    • LR PPP allowed in advertisement, not on product label (art. 66)
Legislation for Biocontrol microbials

- Reg. 1107/2009 and Low-Risk criteria and procedure
  - Only referring and applicable to chemical substances
  - EU Expert group set up for incentives and criteria
  - Incentives: not further evaluated
  - Criteria amended and published including criteria for micro-organisms: COMMISSION REGULATION (EU) 2017/1432 of 7 August 2017:

  5.2. Micro-organisms

  5.2.1. An active substance which is a micro-organism may be considered as being of low-risk unless at strain level it has demonstrated multiple resistance to anti-microbials used in human or veterinary medicine.

  5.2.2. Baculoviruses shall be considered as being of low-risk unless at strain level they have demonstrated adverse effects on non-target insects.
IBMA view on Low-Risk procedure and criteria

- Incentives: approval period should be unlimited unless scientific evidence for negative impact → data call in system
- Total registration period: 4.5 - 5 years → too long for SMEs
- Data protection 13 years → often not relevant as many data published and patent not possible
- LR status should be allowed on PPP label: first hand info for farmers
- Low-risk criteria for m.o.: need guidance for applicant and evaluator on antimicrobial resistance
IBMA proposal for fast track LR procedure
Support for IBMA ‘fast track’ proposal

• Needs an amendment of Reg. 1107/2009: art. 22, 47, 66
• No support of EU COM, wait for REFIT procedure (→ 4,5,6 years??)
• Support in European Parliament:
  → European Parliament resolution of 15 February 2017 on low-risk pesticides of biological origin (2016/2903(RSP)
• Adopted with near unanimity over all political groups
• EU Com does not act on adopted resolution, but keeps referring to REFIT
• IBMA looking for support in EU Council, by Member States, and other stakeholders
Low-Risk actives and products

• Currently 11 a.s. approved as LR (out of total 494 a.s.)
• 8 micro-organisms
• Potential LR micro-organisms
  • AIR 4 list group 1: renewal procedure existing m.o.’s: expiry date 31/04/2019: “presumably low risk”: 30
  • In development: “non-binding list of LR a.s.”
• 3 recently approved micro-organism not approved as LR a.s.!!
  • 2 strains of *Beauveria bassiana*
  • 1 strain *Bacillus amyloliquefaciens*
Biocontrol and biostimulant

• What if both modes of action apply?
• Science does not determine but the law
• That means “what is claimed” in the market
• Double function/both uses: registration as PPP
Nagoya Protocol and ABS

• IBMA is involved since 2008, IBCA (macrobiotics) initiated
• IOBC working group: Preparation of Background Study paper 47  FAO
• REGULATION (EU) No 511/2014  of 16 April 2014: compliance in EU !!
• Development of sector specific guidance: biocontrol and biostimulants
• Compliance with ABS and EU regulation
  • R & D
  • Product development

  ▶ All microbiotics subject to ABS !!
  ▶ *Big hurdle for innovations in biologicals*
Future outlook

• Microbials will be used more and more as ag-inputs
  • Biocontrol products
    • Market driven
      • Retailers: residue free produce, organic production
      • Environment
      • Resistance
      • Fewer new chemicals
      • Loss of chemicals
    • Science driven
      • Microbiome
      • Production technology
      • Application (Precision Ag)
Future outlook

• Microbials will be used more and more as ag-inputs
  • Biostimulants/biofertilizers
    • Market driven
      • Need to increase productivity due to growth of population
      • Use of less fertile land
      • Constraints for artificial fertilizers
      • Climate change, water availability
    • Science driven
      • Microbiome
      • Production technology
      • Application (Precision Ag)
Future outlook

• Microbials will be used more and more as ag-inputs
  • Hurdles to overtake
    • Regulations are too complicated, too long, too expensive
    • Need for harmonization
    • Uptake by farmer community
    • Fear for microbes by public
Future Inputs in agriculture

- Artificial mineral fertilizers
- Biologicals
- Synthetic chemical PPPs
Vision of IBMA and EBIC

Joint vision
- Regulated in legal framework specially designed for innovative biological/natural agricultural inputs
- Have an easy access to a single EU market

Vision of IBMA
- Separate registration for Biocontrol products
- Away from conventional synthetic molecules

Vision of EBIC
- Separate registration for one single EU market
- Away from mineral fertilizers
Future outlook

• Agricultural Biologicals Industry keeps growing
• Heterogenous landscape
• SME’s to Ag-Multinationals
• Product range increasing
• New scientific discoveries
• Market demand growing
Future outlook

- EU → Precautionary principle blocks innovation
- Innovative products need innovative legislation
→ Industry view on a new legislative system
- Microbials need to be assessed on the risk they pose to humans and the environment
- Not based on their function
- Solution: new legislative framework for bio-inputs in agriculture
- EU Centralized assessment by experts
- Long term goal of ag-bio industry
Future outlook

• So far ........
  • Future of microbial
  • Regulatory issues

• Call on action from you:
  • Develop new microbials
  • Collaborate with industry
  • Tell your story to the general public about the benefits and safety of micro-organisms !!
Thank you for your attention

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