



Koppert

ABIM 2023: Session 3 - Regulatory Environment

EU study on the IBCA Industry vs Regulators

Challenges and Opportunities

Wohlfarter M.

Senior Regulatory Affairs Specialist

Maes P.

Director and Chief Strategy Officer



Koppert



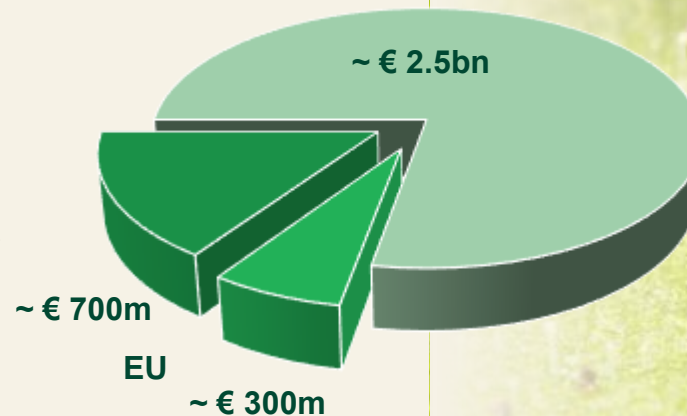
EC report in context: Brief facts & figures (2020 data)

- Biocontrol market ~ € 3.5bn (5% of total crop protection market).
- EU BC market ~ € 1bn (30% of global market).
- IBCAs ~ € 300m (30% of EU BC market).
 - 1-2% need reduction.
 - 10.5% replacement *potential*.
- Biocontrol industry CAGR ~ 15-17% (Crop Protection market ~ 4.66%).
- Annual growth of agriculture ~ 3.3% (slowing to 1.5%).
- Even at a 3-4x higher CAGR the Conventional Crop Protection Industry still grows 5x faster.
- **Doubling of the industry annually...**

Biocontrol share of Global Market (€70bn)



IBCA share of Biocontrol Market (€3.5bn)



Previous reg. initiatives and key findings of the EC

- 1996 ISPM 3 - Guideline for export/import, shipment & releases.
- 1997 EPPO/CABI Safety & Efficacy.
- 1999 EPPO Guideline on import of exotics - R&D.
- 2000 EPPO Guideline on import & releases of exotics.
- 2002 EPPO Positive-Use list (5th rev. 2021).
- 1998-2002 ERBIC; Efficacy & Safety.
- 2003 OECD guideline on required information.
- 2003-current: IOBC Commission on Harmonization of IBCA's (CHIBCA).
 - Further input on EPPO 6/3 Positive-Use List.
- 2005 ISPM 3 revised.
- 2006 Bigler Framework for ERA & IBCA's.
- 2006-2007: Registration of Biological Control Agents (REBECA).

- Regulation is a reoccurring topic.
- **'EC study'**;
 - Origin (Portuguese presidency of the EC).
 - Execution (widely consulted).
 - Findings;
 - Too little data to make a decision on regulation.
 - Proposals by the contractor;
 - Weak, focus on EFSA governance, instead of industry experts (EPPO).
- Outcome – whereto from here?
 - **Commission opinion**;
 - Insufficient data presented to make a decision on harmonized regulation. Lack of capacity to develop and enforce regulation.
 - **Industry opinion**;
 - Non-harmonized approached often are ill-fitting, and slow attainment of approvals. Often MS NPPOs seem insufficiently equipped to constructively objectively (positively) handle dossier.



Regulatory challenges

- Inconsistencies between MS.
- Direct comparison to a PPP.
 - Extensive data requirements (efficacy & non-related, non-target effects).
 - Ill-fitting dose recommendation requirements.
 - Lack of understanding at NPPO level.
- Arbitrary Native vs Non-native 'boundaries' for natural enemies, while pests roam free.
- Over cautionary application of the 'precautionary' principle;

More than 7,000 introductions involving almost 2,700 species of exotic arthropod agents for control of arthropod pests in 196 countries or islands during the past 120 years rarely have resulted in negative environmental effects...

(Van Lenteren 2012)

- Non-sensical Veterinary vs Phytosanitary policies and certifications.
- Non-harmonized approach to exemption.
 - Comprehensive EPPO guidelines available, yet NPPOs often consider it *too liberal*.



Unforeseen consequences of over ambitious policy in absence of support mechanisms

- 2030 goals and the Green Deal set ambitious targets.
- Crop Protection remains a necessity.
 - Restricting disruptive conventional products requires mechanisms for active replacement with softer alternatives.
 - Impact on yield (grower income), food security, and downstream quality.
 - Reliance on delayed effects with efficient supply chains.
 - Lacking continued consumer education.
 - Grower and eventually consumer resistance.
- Protection by doing nothing (...*as little as possible*...) is a farce.
 - Agricultural environments are disturbed (non-natural).
 - Positive effect of IBCAs on biodiversity.
 - Reduction of disruptive pesticides.
 - Reintroduction of natural enemies.



Harmonization through industry 'self-regulation'

- Utilize the EPPO guidelines.
 - Basic product dossier according to EPPO standards and guidelines.
- Industry self-interest to grow by continuous improvement.
 - Proof is in the market; continued sales (use).
- Expertise and voluntary contribution to industry bodies, panels, etc.
 - Understanding grower needs and which products fit.
- Impact of extraordinary claims/requirements; real value add?
 - Testing the unknown unknowns (just in case).
 - Comparative measured against conventional PPPs.





What the caterpillar calls the
end of the world,
the master calls a butterfly.

Richard Bach



Koppert

Martin Wohlfarter

Senior Regulatory Affairs Specialist

mwohlfarter@koppert.nl

+31 (0)61 258 9493