REFIT of Reg. 1107/2009 – Not another MISFIT:
Call for development of fast track authorisation following adapted data requirements for biological control agents (BCAs)
Refit Process

- PPPs are regulated in the EU by Regulation (EC) 1107/2009, including all microbial BCAs, pheromones and botanicals

- Evaluations and fitness checks are tools that are used to implement the **Regulatory Fitness and Performance programme (REFIT)**. REFIT is a rolling programme to keep the entire stock of EU legislation under review and ensure that it is 'fit for purpose'; that regulatory burdens are minimised and that all simplification options are identified and applied ([https://ec.europa.eu/food/plant/pesticides/refit_en](https://ec.europa.eu/food/plant/pesticides/refit_en)).

- Urgent need for a REFIT exercise of Reg. 1107/2009
Current tool box for biological control industry

Microbials
- Viruses
- Bacteria
- Fungi

Macrobials
- Predatory mites
- Insects
- Nematodes

Semiochemicals
- Pheromones
- Plant volatiles

Natural and Biochemical Products
- Plant extracts
- Seaweed products
- Basic chemical substances

Autorisation following EC Regulation 1107/2009, except macrobial BCAs
Potential

- Biological control can provide tools to substitute banned synthetic PPPs and/or replace or support those suffering from resistance development.
- Biocontrol preserves biodiversity and function of the antagonistic potential in agro-ecosystems.
- Biological control can help to reduce pesticide residues (MRLs).
Spain: 48,000 ha (Murcia und Almeria) shifted to biological control until 2010

Success: Healthier plants, higher yields, compliance with MRLs, safer environment for growers …..

Chance in paradigm: Today PPP salesmen are asked whether their synthetic products are safe for beneficials
Percentage of samples with PPP residues

German Agricultural Society's (abbreviated DLG), 2017

No (limited) regulation on insects, mites and nematodes enabled quick introduction
Problems

• All microbial BCAs, pheromones and botanicals are included in Regulation (EC) 1107/2009, although they do not fit.
• Due to exaggerating data requirements, BCA authorization can take up to 10 years until reaching the market
• Timelines are not met, neither for EU approval, nor for zonal approval or mutual recognition
• EFSA risk assessment causes more problems (risk assessment without weighing benefits and damage caused by keeping old technology in the market)
• Additional data requirements implemented without a prior consultation of relevant stakeholders and without a cost-benefit analysis of regulation
Since the introduction of Dir. 91/414 our industry demands adaptation

Ten years ago the REBECA Policy Support Action made proposals to the EC for improvements, which were ignored

Biocontrol suffers from increasing stringency on synthetic PPPs

We do not share the history of environmental damage and failure of the risk management like synthetic PPPs

BCAs do not fit, e.g. acute and long-term toxicology for MBCAs

Major problem for biocontrol industry: the long timelines

Therefore IBMA picked up the not yet well defined “low risk product” article

MBCAs = low risk when not pathogenic to humans and no antibiotic resistance
Realistic Timelines 1107/2009 for BCAs

Annex II AS submission

Active Substance

Final DAR

Approval AS

Annex III PPP submission ZRMS

PPP

Zonal Approval PPP

Mutual recognition Application

Mutual recognition Approval
Timelines 1107/2009 (proposed low-risk case)

- **Annex II AS submission**
- **Completeness Check**
  - Incl. low-risk status
- **Provisional low-risk a.s. approval**
- **DAR**
- **Full Approval AS**

- **Year 1**
- **Year 2**
- **Year 3**

- **Mutual recognition Application & approval**
- **Provisional Zonal Approval PPP**
- **Annex III PPP submission**
  - ZRMS

- **Full Zonal Approval PPP**
- **Low-risk BCA**

**Low-risk biocontrol agent**
European Parliament
2014-2019

TEXTS ADOPTED

P8_TA(2017)0042

Biological low-risk pesticides

European Parliament resolution of 15 February 2017 on low-risk pesticides of biological origin (2016/2903(RSP))
Motion brought forward by MEP Pavel Poc and DG ENVI
Almost unanimously accepted by all EP parties

14. Stresses the need to revise Regulation (EC) No 1107/2009 in order to foster the development, authorisation and placing on the EU market of low-risk pesticides of biological origin; is concerned that the current authorisation process for placing plant protection products on the market is sub-optimal for low-risk pesticides of biological origin;

15. Calls on the Commission to submit, before the end of 2018, a specific legislative proposal amending Regulation (EC) No 1107/2009, outside of the general revision in connection with the REFIT initiative, with a view to establishing a fast-track evaluation, authorisation and registration process for low-risk pesticides of biological origin;

Andriukaitis (Commissioner SANTE) refuses to take corrective measures during the REFIT process (which will take 6-8 years)
Biocontrol and regulation

• Growers have less PPP products available every year
• BCAs can fill their tool box
• Exaggerating regulation requirements are preventing biological products to come to the market
• Although NAPs, Reg. 1107/2009 and Dir. 128/2009 all talk about the support of non-chemical alternatives, MS do not translate this into national plant protection practice
• All lip service?
• Governments and politicians fail to follow their own objectives
Since the introduction of the 1991/414 we are demanding
- appropriate data requirements taking into consideration the real risks of BCAs
- science-based risk assessment and management
- acceleration of the authorisation process

What is going on? Why this procrastination?

REFIT will again mainly deal with synthetic PPPs

Take BCA authorization out of 1107/2009, develop adapted regulation

All microorganisms in agriculture in one regulatory system!!!
PPPs, biostimulants, fertilizers, feed additives, soil amendments, etc.