



# An Industry View of the REFIT of Reg. (EC) No 1107/2009 and the Future

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# Legislative basis of the REFIT for PPP legislation

**Review Clauses** in Reg. (EC) No 1107/2009 articles 62(5) & 82  
[and in Reg. (EC) No 396/2005 article 47]

**Commission shall present a report to EP and Council by 14 Dec. 2014**

on mutual recognition, national restrictions, comparative assessment, zonal system, approval criteria and their impact on agriculture, human health and environment.

*“The report **may be accompanied, if necessary, by the appropriate legislative proposals** to amend those provisions.”*

In November 2016, COM published a **Roadmap** with five main evaluation criteria:

Effectiveness

Efficiency

Relevance

Coherence

EU added value

# Mission for a Consultancy Agency: Terms of Reference & Objective

- **Terms of Reference** [03/2017]: Evaluation criteria of the Roadmap were taken up and expanded on in 28 evaluation questions
- **Mission:** Perform an **evidence-based** assessment of the implementation of PPP legislation concerning the placing on the market and pesticide residues and deliver a **study report** which will be **used by COM to issue the report to EP and Council.**
- ECORYS was asked to **focus the study report on functioning and implementation** of PPP legislation, not on proposals for legislation.

ECORYS conducted mission from 28th June 2017 to 27th June 2018.



# REFIT Stakeholder Consultation - Online

**Objective:** collecting factual information

136 questions, final one for free commenting

Note: 244 Stakeholders responded

- IBMA secretariat had prepared guidance for IBMA members
- IBMA exchanged with COPA COGECA and EU MUCF, also considered comments by ECPA

## IBMA in free Additional comments

- Commits to: developing **innovative high-quality efficacious tools sourced from nature** for use by European farmers in sustainable agriculture
- Stresses: **current legislation** restricts availability of innovative green PPPs & is **not suitable** for BCAs
- Supports: assessment at a level **proportionate to** their nature and level of **risk**
- **Demands:** A **new regulation** for biological inputs into agriculture, or at the very least, a **dedicated stream** with appropriate data requirements & expert evaluators

### Including

- Single one zone authorisation
- Fast-track system
- Time unlimited authorisation
- Provision for data call-in



# ECORYS Stakeholder Interview with IBMA

27<sup>th</sup> March

## **Objective:** clarify specific aspects related to SH online consultation

- ECORYS issued guidance with 25 open questions: **Answers in writing** by IBMA

**Open, free discussion in meeting.** Opportunity used by IBMA to highlight:

- Shortcomings of current approach to biocontrol AS and products, inappropriateness of data requirements, lack of expertise of certain evaluators and consequences
- Poor alignment of Reg. (EC) No 1107/2009 with SUD
- Importance of speeding up process for biological low-risk AS and products
- **Need for separate regulation**

or at least specific rules, data requirements and a separate fast-track stream for biocontrol products

Note: ECORYS conducted about 60 SH in-depth interviews



## REFIT Workshop 2 (1) - Preliminary findings – effectiveness and efficiency

16th May 2018 in Brussels

60 attendees of all categories: COM, MSs, Stakeholders, farmers, industry, NGOs

Identified **shortcomings** of Reg. (EC) No 1107/2009 **concerning effectiveness** include:

- **Zonal system** not working due to insufficient trust [of CAs] and national requirements
- **Mutual recognition** not sufficiently harmonised
- **Legal timelines** exceeded
- **Emergency Authorisations** increasing
- No substitution resulting from **Comparative Assessment**
- Complaints about timelines inappropriate for **low-risk substances**

ECORYS: No common agreement among stakeholders on the **efficiency** of the risk assessment and the risk management processes.

## REFIT Workshop 2 (2) – Preliminary findings: Issues discussed

- Number of AS: **No** significant change but AIR3 and AIR4 not considered!
- Number of PPPs: Increase, but MSs [correctly] stress: number of uses decreased!
- Health effects: diverging views among SHs on health costs and effectiveness of cut-off criteria

### IBMA perception

- Impressive work collecting a great number facts and views.
- In many respects, the intermediate findings reflect observations made by IBMA.
- Intermediate report makes **no proposals for specific approach to BCAs**, but mentions that “*Data requirements and procedures are not considered as appropriate and proportional to non-chemical solutions, which particularly affects SMEs.*”

## REFIT Workshop 2 (3) - Preliminary findings – Relevance and coherence

### Relevance

*“There is a growing societal and consumer demand for an EU agriculture that is more sustainable, with reduced impact on the environment.”*

- Based on the Open Public Consultation i.e. almost 10,000 responses
- **91 % of citizens responding:** the way pesticides are applied / used does **not sufficiently reduce the impact on environment**
- *“Farmers fear a decrease of the availability of PPPs in the coming years”*

### Coherence:

*“Overall, the Regulation succeeded **to some extent** to establish a coherent policy in the area of pesticides.”*



## REFIT Workshop 2 (4) - Preliminary findings – EU added value

### **EU added value**

*“There is widespread agreement among stakeholders and Competent Authorities at the national and EU level that the regulatory framework and work sharing between Member State Competent Authorities, EFSA, and the Commission are necessary and beneficial [...].*

*Stakeholders in particular appear to be in favour of further harmonising and strengthening the role of the EU with regards to certain aspects of the Regulations.”*



# Situation of ECORYS' Final Study Report

In Workshop 2:

**COM promised**

Full ECORYS report will be published

End of June 2018:

ECORYS delivered draft study report

10<sup>th</sup> October 2018

**ECORYS issued full final study report in EN**

Executive summary in EN

Translations into FR and DE

Next step:

“Regulatory Scrutiny Board” [RSB]

= an independent body within COM

End of 2018

or

1<sup>st</sup> half of 2019:

Study report published **separately** by COM

or

**integrated** in COM Report to EP & Council



# Any future action following REFIT

- EU COM REFIT report to EP and Council – March 2019
  - Conflicting comments on content
  - Conflicting interests of stakeholders
- EP elections – May 2019
- New EU COM – October 2019
- EP mfR on low-risk biological PPPs



# Does the Biocontrol industry have to wait for REFIT?



Are we alone?  
**Copa and Cogeca  
Roadmap 2018-  
2025**  
Uncertainty has led  
to work in the  
summer  
**Arche Report on  
EU Regulation**  
then  
**IBMA Vision Paper**



# Last year prediction – action now required

- Renewal of EU COM
- Priorities of new EU COM
- Renewal of EU Parliament
- Renewal of EP Committees
  - ENVI
  - AGRI
  - Intergroup

• Need for Champions





The precautionary principle  
as interpreted by some

# Concluding remarks

IBMA see a need to change the way biological PPPs are regulated within Europe

IBMA have and will continue to engage in the REFIT process

Like the EP and the MS with the EU Expert Group on Sustainable Plant Protection, IBMA see a need to amend the regulatory process as soon as possible either within the legislation or by making amendments

IBMA call on EU COM to carry out without delay the EP Motion for Resolution of 15<sup>th</sup> Feb. 2017 on *low-risk pesticides of biological origin*

IBMA call for a new regulatory pathway for biological PPPs

- Dedicated to biologicals

- Experienced in relevant specialities

- Appropriate data requirements

- Appropriate interpretation of the precautionary principles

IBMA offer to be fully engaged in the development of a relevant pathway

# IBMA Document Trilogy: White Paper, Arche-IBMA Report, IBMA-C & C Roadmap



INTERNATIONAL BIOCONTROL  
MANUFACTURERS ASSOCIATION



With a different approach  
by shredding the current  
inappropriate rule book we  
can retain confidence of all  
stakeholders and increase  
value

Thank you  
Ulf and David



## Sources

- [EU REFIT webpage](#)
- [IBMA REFIT webpage](#)
- [Roadmap \(11/2016\)](#)
- [Terms of reference \(03/2017\)](#)
- ABIM 2017, presentations by [COM \(P. Pitton\)](#) and [IBMA \(U.Heilig & D. Cary\)](#)
- [IBMA Global response](#) to the Stakeholder online consultation (12/2017)
- REFIT Workshop 2 - [Agenda and Preliminary Findings](#) of the study
- Workshop 2 – [Minutes](#)