IBMA strategy for EU regulation of biocontrol

Ulf Heilig and **David Cary** - **ABIM 2017**

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Commission's legal obligation

Review Clause in Reg. (EC) N° 1107/2009, article 82:

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

on MR, 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."*

Commission initiated the REFIT process in 2016

- Presentation by P. Pitton in Plenary Session 1 ☞ today
- Information on COM website ☞ here
- Roadmap in November 2016 ☞ here
- Terms of Reference in March 2017 ☞ here

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IBMA approach to REFIT

- **Member survey**

  IBMA internal questionnaire developed in May

  Launched end of May via PG heads, closing 13th July

  Summary presented in IBMA RegSem, on 23rd October

- IBMA meeting at **DG SANTE** on 3rd July 2017
- IBMA meetings with **ECORYS**:

  Preliminary meeting on 12th July and
  Stakeholder WS on 12th September

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Objective and scope of consultant's mission

- **Objectives**
  - ✧ Perform an **evidence-based** assessment of the **implementation** of both, the legislation on PPPs and the one on pesticide residues
  - ✧ The study will be used by EU COM to draft the report to the EP and the Council on the **functioning and implementation** of the regulations
- **Scope**
  - ✦ **Effectiveness** of the intervention (Q1-13)
  - ✦ **Efficiency** in relation to the resources used (Q14-17)
  - ✦ **Relevance** in relation to identified needs and problems (Q18-20)
  - ✦ **Coherence** with other interventions / common objective (Q21-24)
  - ✦ **EU added value** compared to what could have been achieved at MS or international level

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REFIT evaluation questions in COM ToR

All to be addressed by **Consultant**

Effectiveness	1	1107/2009	Animal testing and data sharing
	2	1107/2009	Zonal system and authorisation
	3	1107/2009	Criteria for approval of AS - impacts
	4	1107/2009	Candidates for substitution (CfS)
	5	1107/2009	Impact on agriculture
	6	1107/2009	Impact AS approval on availability
	7	396/2005	Human health and internal market
	8	396/2005	Procedures
	9	396/2005	Trade impacts
	10	1107/2009	Enforceability
	11	396/2005	Enforceability
	12	1107/2009	Treated seeds
	13	396/2005	Fish, feed, processed products
Efficiency	14	396/2005 and 1107/2009	Efficiency of timelines
	15	396/2005	Efficieny of procedures
	16	396/2005 and 1107/2009	Efficiency risk assessment/ management
	17	396/2005 and 1107/2009	Costs/benefits for economic sectors
Relevance	18	396/2005 and 1107/2009	Pertinence of specfic objectives
	19	396/2005 and 1107/2009	Transparency and confidentiality
	20	396/2005 and 1107/2009	Adaption to technical and scientific progress
Coherence	21	396/2005 and 1107/2009	Internal coherence
	22	396/2005 and 1107/2009	Unambiguous translation of objectives
	23	396/2005 and 1107/2009	External coherence (international law)
	24	396/2005 and 1107/2009	External coherence (EU law)
Added Value	25	396/2005 and 1107/2009	AV vis-à-vis national/ international level
	26	1107/2009	Unacceptable co-formulants, safeners, …
	27	396/2005	Harmonised processing fators
	28	396/2005	Administrative review

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REFIT evaluation questions in Commission's ToR

All to be addressed by **Consultant**

IBMA identified subjects relevant for biocontrol in:

- Heads of PG meeting (13th July)
- Joint meeting ExCom & Nat Group heads (4th Sept.)

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REFIT Stakeholder Workshop

- On 12th September in Brussels
- **Attendees**: Limited to 40 people → 43 in total

  All stakeholder categories represented

  Member States (10), EU COM (13!), EFSA (1), MUCF (1), NGOs (4), industry (4), farmer (4), ECORYS / consultants(6)

- **Agenda**:
  - ✧ Presentation by ECORYS of their mission with scope and objectives; overall approach; consultation strategy
  - ✧ Discussion about relevance of questions and text of questionnaires for surveys
  - ✧ Case studies were proposed but no decision was taken

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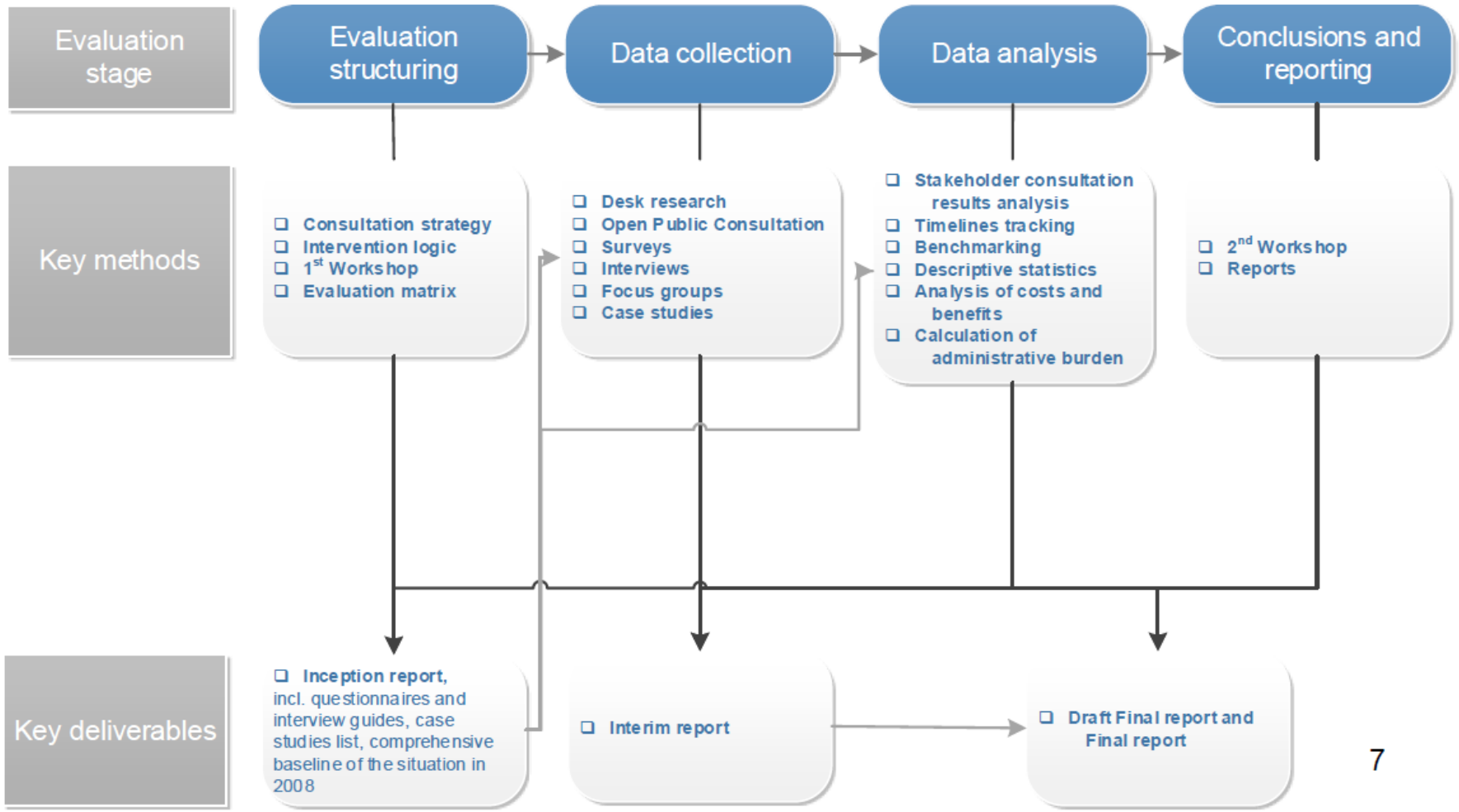
Overall approach of the ECORYS



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Options for input by IBMA and its members

• Stakeholder **online survey** (~ 85 questions)	Launch in early November, 5 weeks: **all members** + National Groups + IBMA Global
• Open **public consultation**:	**all members** + National Groups? + IBMA Global?
• **Interviews**:	IBMA Board and Secretariat
• **Focus Groups**:	? No information available
• **Case studies**:	? No information available
• **Final Stakeholder Workshop**	Expected in April: **Might be too late** to address relevant issues

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Outcome of REFIT

Final evaluation report by ECORYS by 28th May 2017:

- ✧ Shall answer questions of the **Terms of Reference**
- ✧ Shall assess **implementation** of provisions, **functioning** in practice, meeting of **objectives** of PPP legislation
- ✧ Shall identify **positive elements and shortcomings**
- ✧ **Quantification of costs** is key (**efficiency**): dossiers, workload, duplication of work, delays, use restrictions etc.
- ✧ **SMEs** specify their status

Report is not required to deliver solutions or legislative proposals

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Way forward after the REFIT Evaluation Report

- EU Commission needs to prepare its REFIT report.
- Possible submission in 2018/2019, but …

What can be done…?

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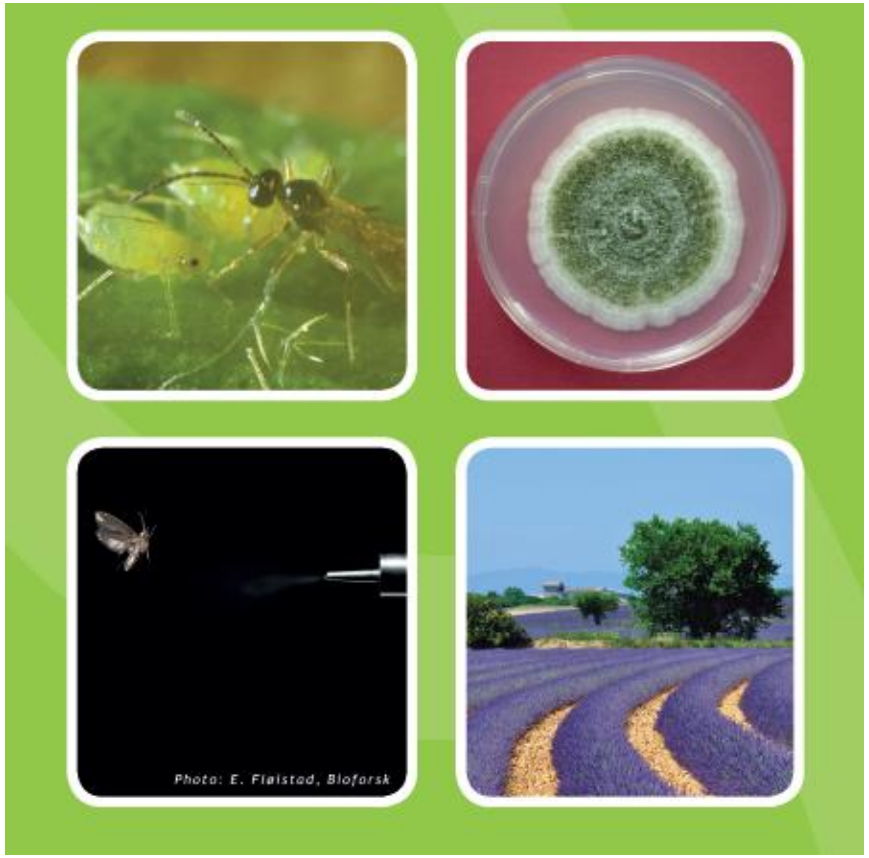
Any future action following REFIT



- New legislative proposal
- Source
  - EU COM
  - European Parliament
- Timelines
  - Effect of new EU COM & new EU Parliament
  - Type of legislation

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Timelines effected by:

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

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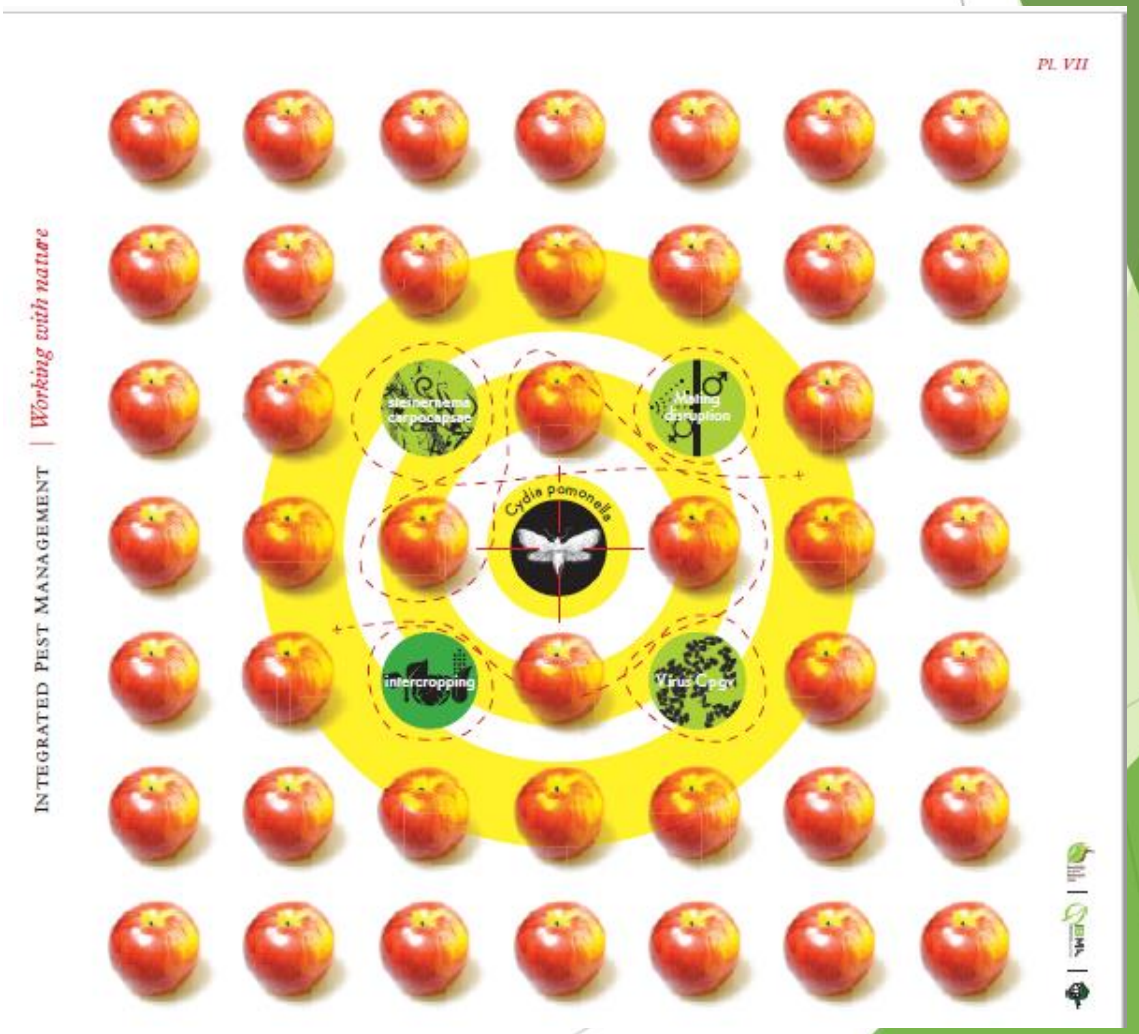
European Parliament possibilities

- Existing mfr
  (motion for resolution)
- New proposals
  - Separate legislation
  - Separate stream
  - Separate data requirements



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Objectives of IBMA & Members

- Centralised EU wide registration
- Proportionate registration
- Dedicated evaluators
- Experienced evaluators
- Predictable timelines
- Appropriate data requirements
- Not a barrier to market entry
- Provision for minor uses
- Provision for highly specific solutions
- Protection for SMEs
- Harmonised global approach

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New PPP active substances

A majority of new PPP active substances being approved in the EU from today will be biological and a majority of these will pose low risk

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Is low-risk the ultimate objective?

or

A pragmatic intermediate step to deliver a more appropriate and proportionate regulatory framework?

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Concluding remarks

If policymakers around our world including in Europe are in agreement and favour of greening agriculture using IPM as the standard practice and bringing more low-risk biological products to the market – what are we waiting for?

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Thank you for your attention

David Cary and Ulf Heilig, IBMA

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