

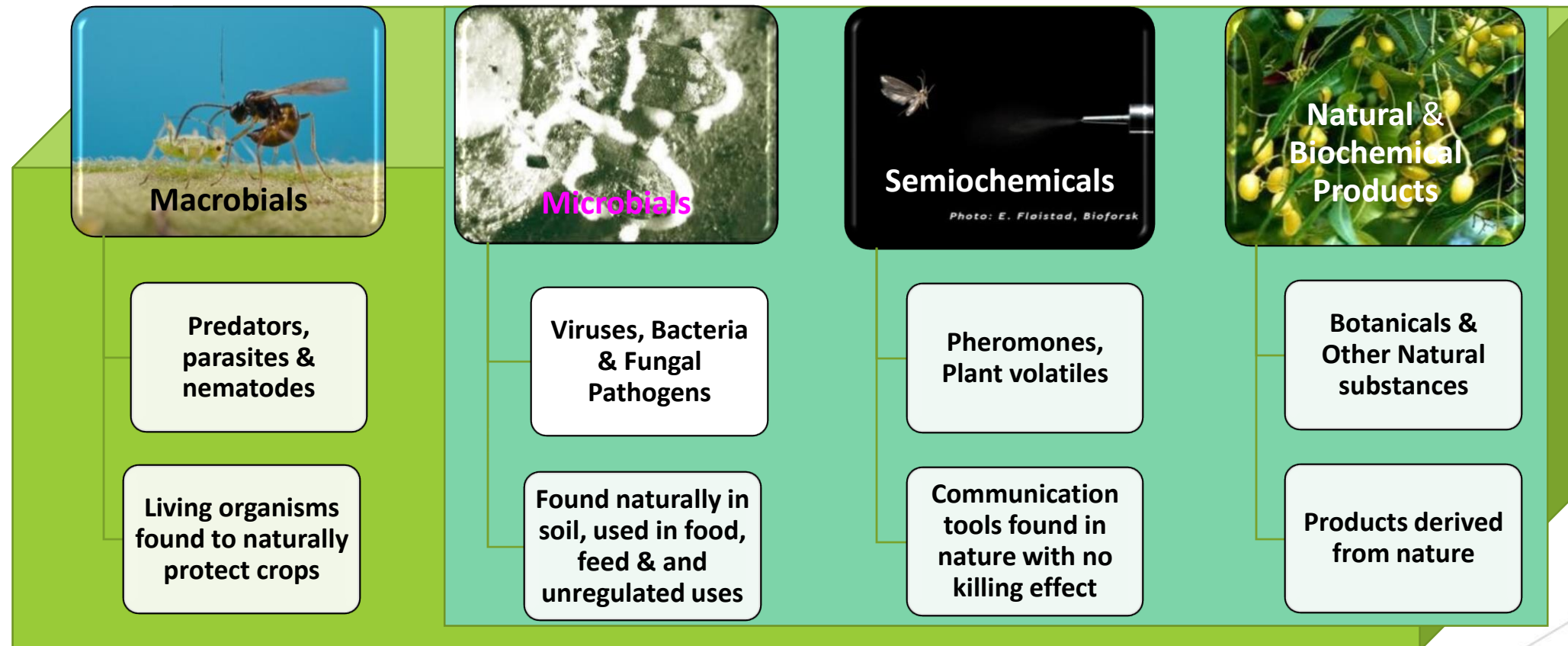


Low-risk Criteria and Procedures Development in Europe

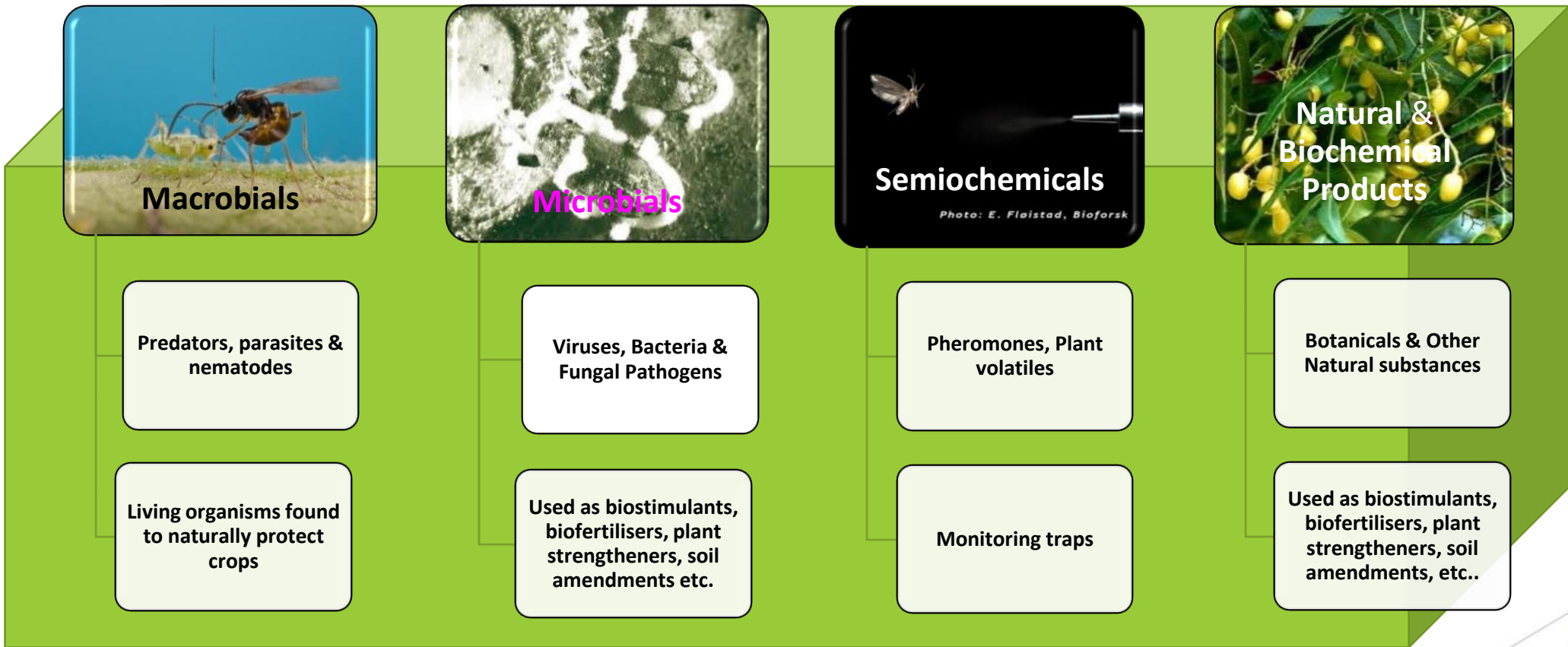
David Cary, Executive Director, IBMA



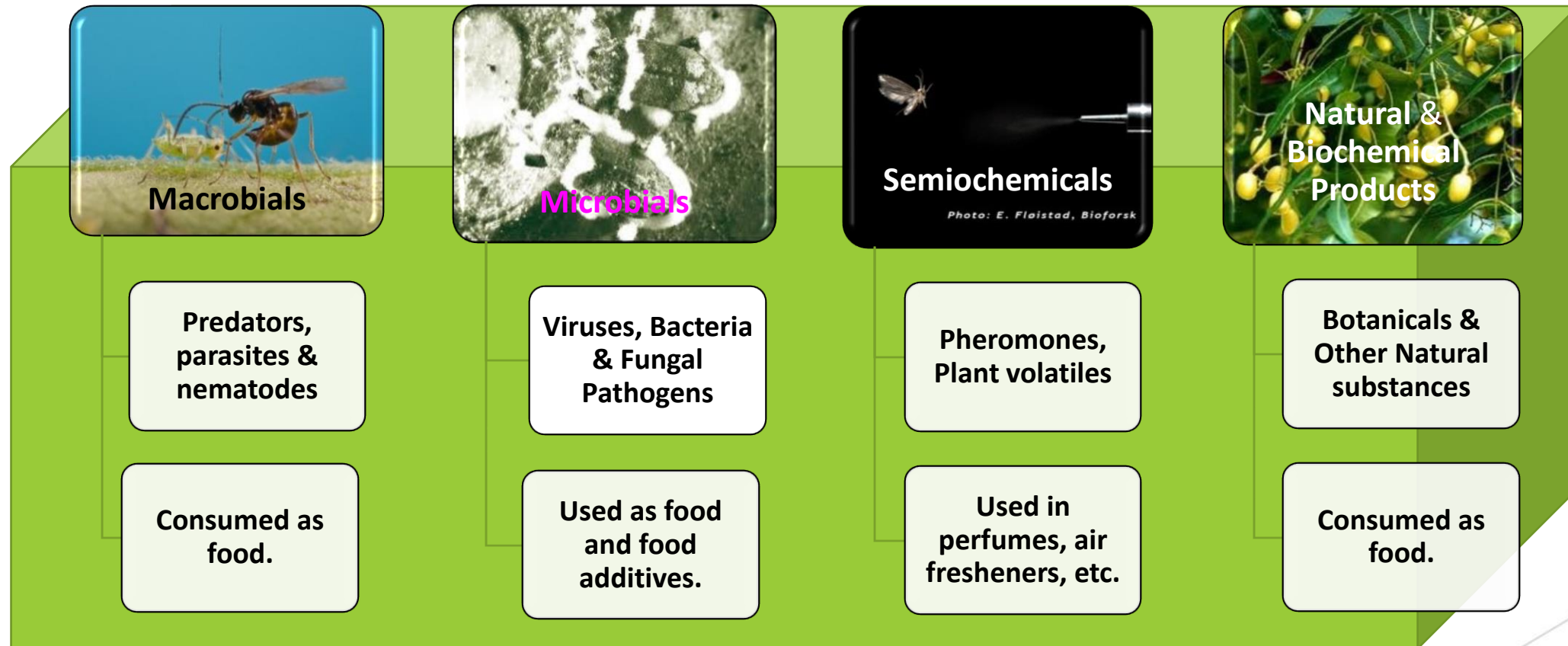
What “Non-chemical solutions” are currently available from the Biocontrol industry?



What range of non or minimally regulated products are currently available to the farmer?



What non or minimally regulated products are currently available to the consumer?



Current list of low-risk active substances

- Cerevisane
- COS OGA
- Feric phosphate
- *Isaria fumosorosea* Apopka strain 97
- Pepino mosaic virus strain CH2 isolate 1906
- *Saccharomyces cerevisiae* strain LAS02
- *Trichoderma atroviride* strain SC1





*Low-risk criteria
development*

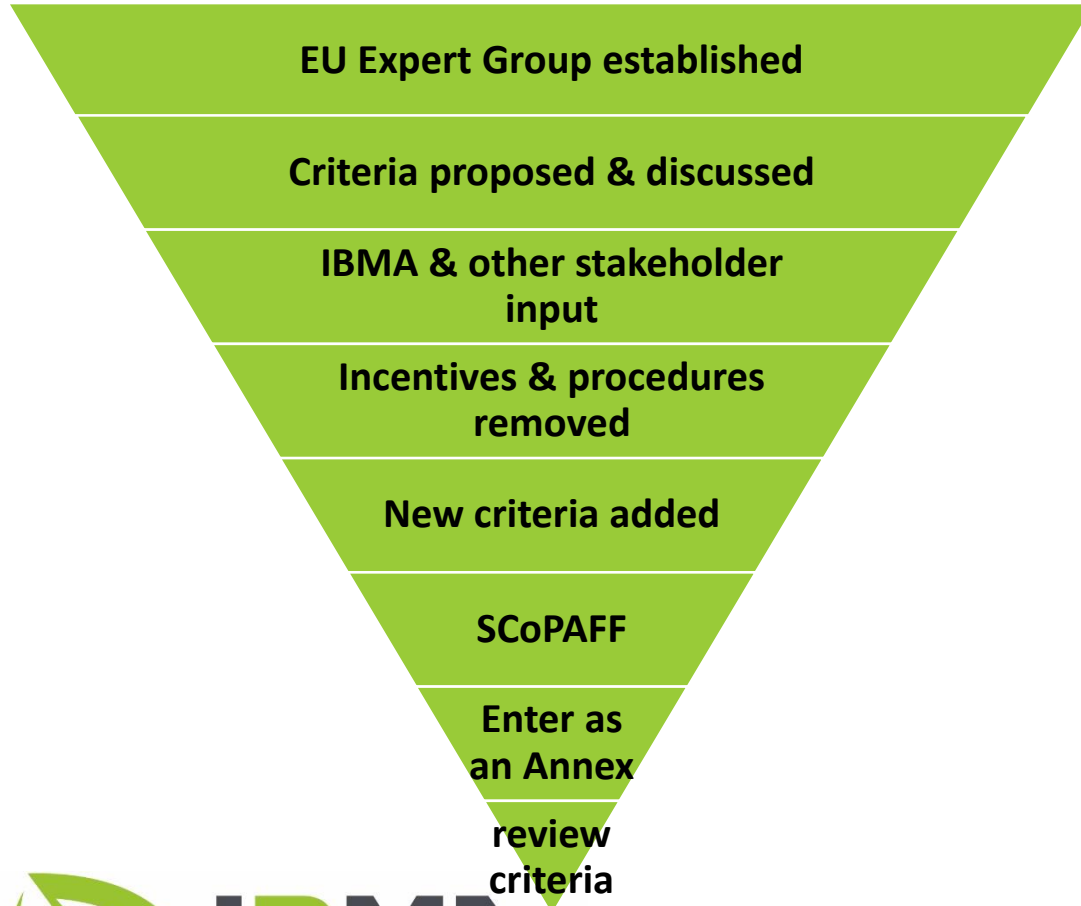


Low-risk Plant Protection Products Criteria Development



- IBMA input
 - From Professional Groups
 - Criteria and incentives
 - Different criteria to conventional chemistry solutions
- IBMA Chair of sub-group on incentives
 - Proposal of revised Incentives and Procedures

Low-risk Plant Protection Products Incentives and Procedures Development



IBMA need to separately handle incentives & procedures

Stakeholders identified & approached

Consultant PA Europe engaged

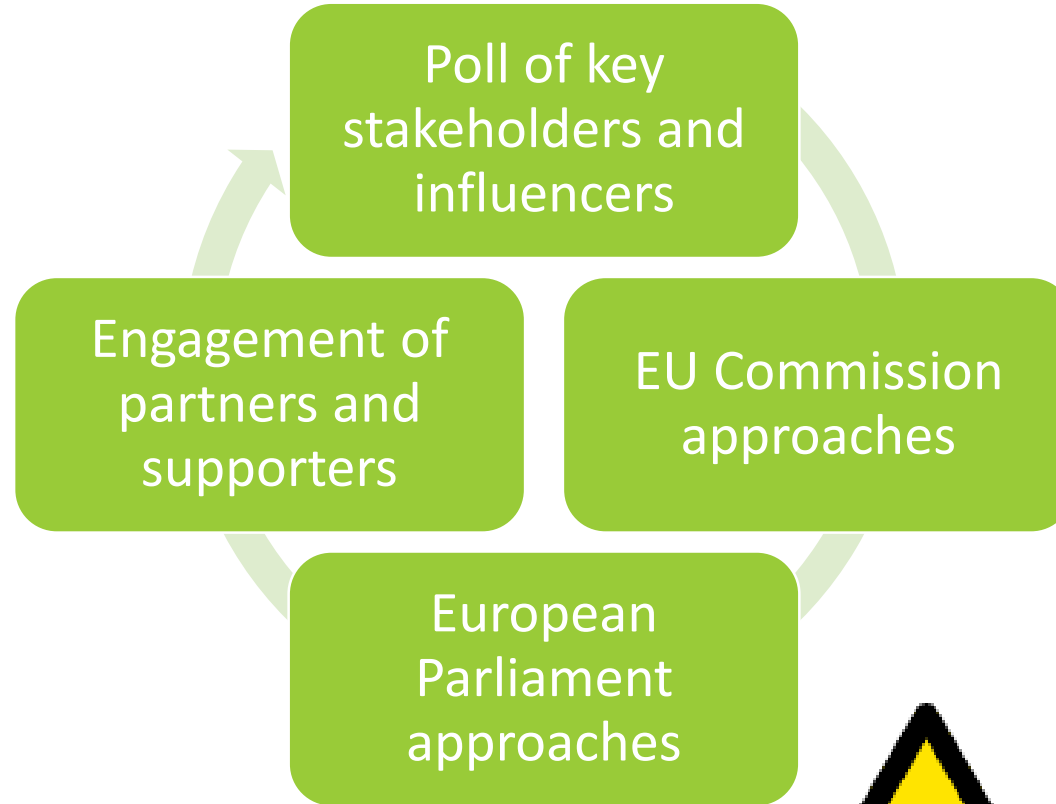
Activities of PA Europe, IBMA & Copa and Cogeca



*Low-risk procedures
and incentives
activities*



Approach to amend Incentives and Procedures



Full Agreement Among All Stakeholders

- Formal letter European Commissioner for SANTE Dr Vytenis Andriukaitis 01/08/16: “The Commission shares the same interest to promote low risk solutions for plant protection”
- Since 12/10/16 Draft LRP Resolution Supported by ALL PARTIES in the European Parliament – No Opposition Left!!!
- Elite Poll of 5/5/15: **93%** of all experts want the European Commission to facilitate and accelerate the approval procedures of low-risk bio-pesticides
- EU Council of Ministers: Unanimously support implementation plan of EU Sustainable Plant Protection EG on 28/06/16

OQ/MfR Co-Sponsors

- Mr Herbert Dorfmann (EPP)
- Mr Pavel Poc (S&D)
- Ms Julie Girling (ECR)
- Ms Frédérique Ries (ALDE)
- Ms Lynn Boylan (GUE/NGL)
- Mr Bart Staes (Greens/EFA)
- Ms Mireille D'Ornano (ENF)

Biological low-risk pesticides Resolution Time Table

- Oral Question in ENVI 28/11/16: Call on EC to immediately provide access for LRP to market through specific protocol
- Motion for Resolution in ENVI 23/01/17: Demand Specific Access Procedure for LRP to be available via these modified procedures in two-three years
- Vote in European Parliament Plenum: 13/02/17

Additional contributions to low-risk procedures

- 40 point Implementation Plan developed by EU Biopesticides Expert Group
- Harmonisation in interpretation eg. Human toxicology
- Development of EPPO Efficacy Guidelines
- Adherence to Mutual Recognition & Zonal Reviews
- Biopesticide stream similar to US EPA Biopesticides Unit
 - Evaluation by dedicated individuals with expertise and mindset
- Netherlands CtgB in bilateral discussions and implementation



Low-risk procedures and incentives possible outcomes



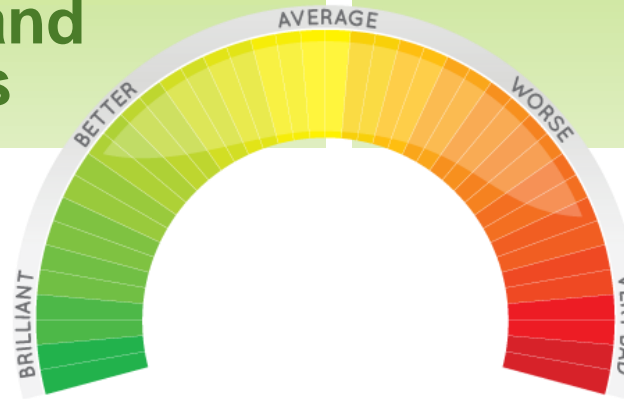
Possible outcomes

• REFIT ONLY

- No benefits for 8-10 years
- One of several issues wrong with legislation
- Lack of focus on our issue
- Little chance of total support for the full package of changes
- Low-risk is firmly on the agenda at EUP, Sante, stakeholders, EU Sustainable PPP Expert Group and Council of Ministers

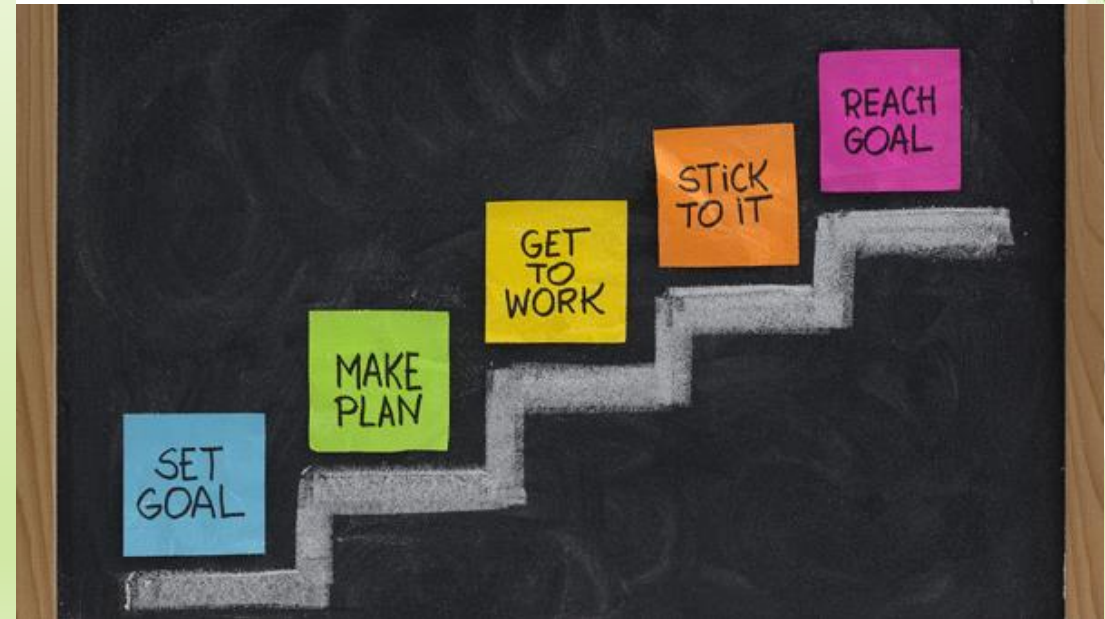
• REFIT + EU Sustainable EG PPP recommendations

- 40 recommendations
- Specific action to accelerate I-r PPP authorisations
- Provisional listing (**non legally binding**) of existing approved low-risk ais
- Advice to utilise the list to authorise I-r PPPs in 120 days



Preferred outcome

- **Simple Fitness check of EC Reg 1107/2009**
 - Low-risk substances reviewed via modified fast track procedure through simple modification to articles 22 and 66
 - Guidance developed to ensure low-risk PPPs reviewed within 120 day period
 - Work with EU Sustainable Plant Protection EG to implement additional means of acceleration





Many thanks – any questions?

David Cary

