Regulatory framework for the registration of semiochemical-based PPPs in the EU

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Regulatory Framework

- Regulation (EC) No 1107/2009 of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

OBJECTIVE
"to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the ***competitiveness*** *of Community agriculture"*

- Regulation (EU) 283/2013 lays out the data requirements for AS
- Regulation (EU) 284/2013 lays out the data requirements for PPPs

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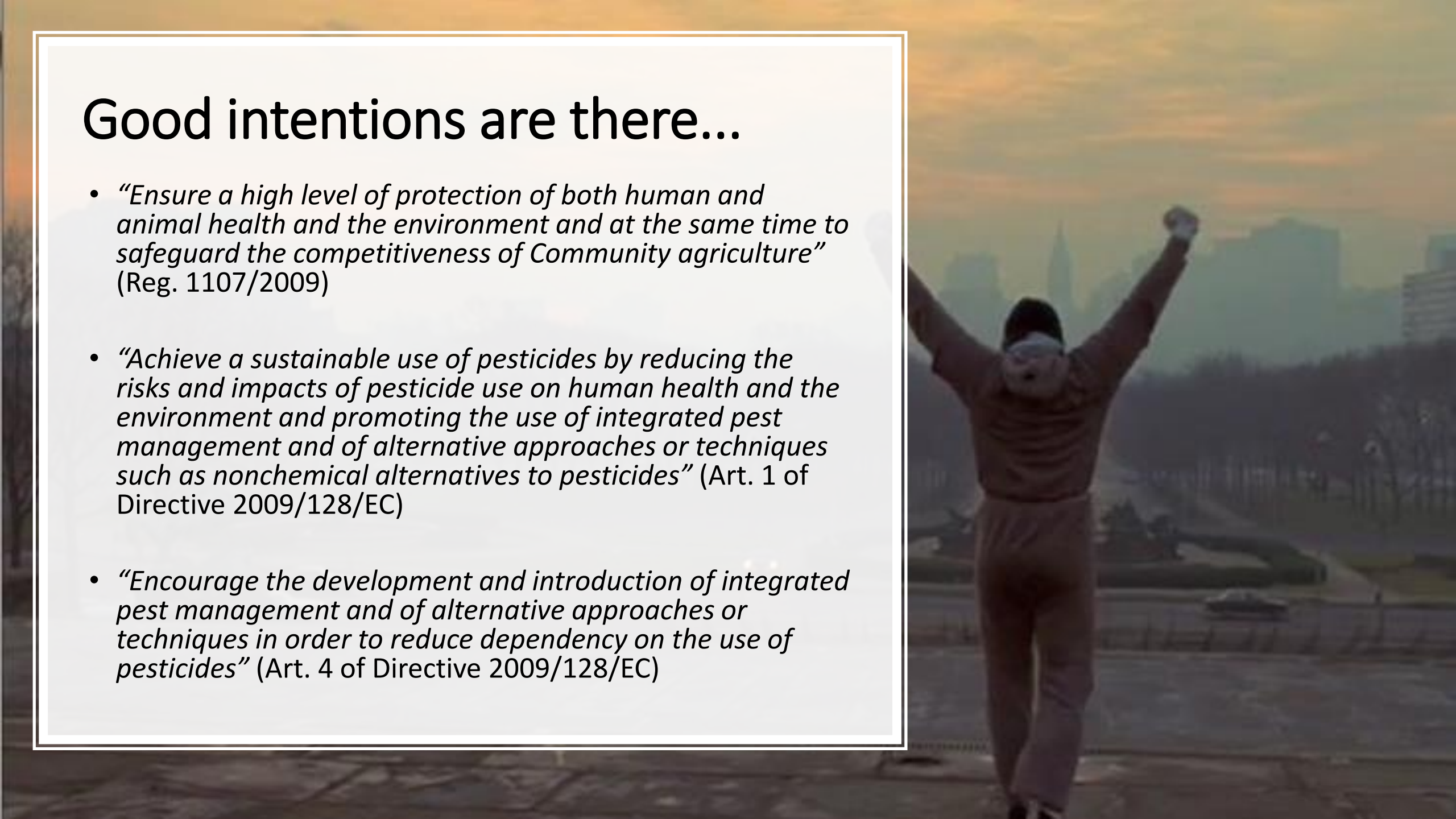
Good intentions are there…

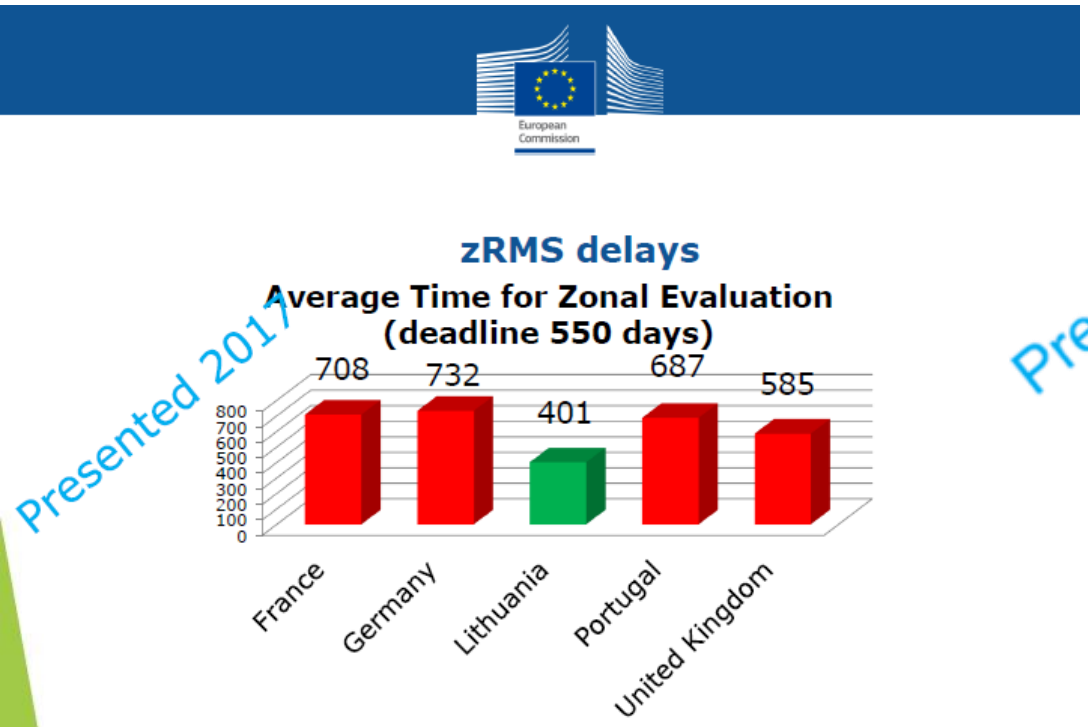
- *"Ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture"* (Reg. 1107/2009)

- *"Achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of integrated pest management and of alternative approaches or techniques such as nonchemical alternatives to pesticides"* (Art. 1 of Directive 2009/128/EC)

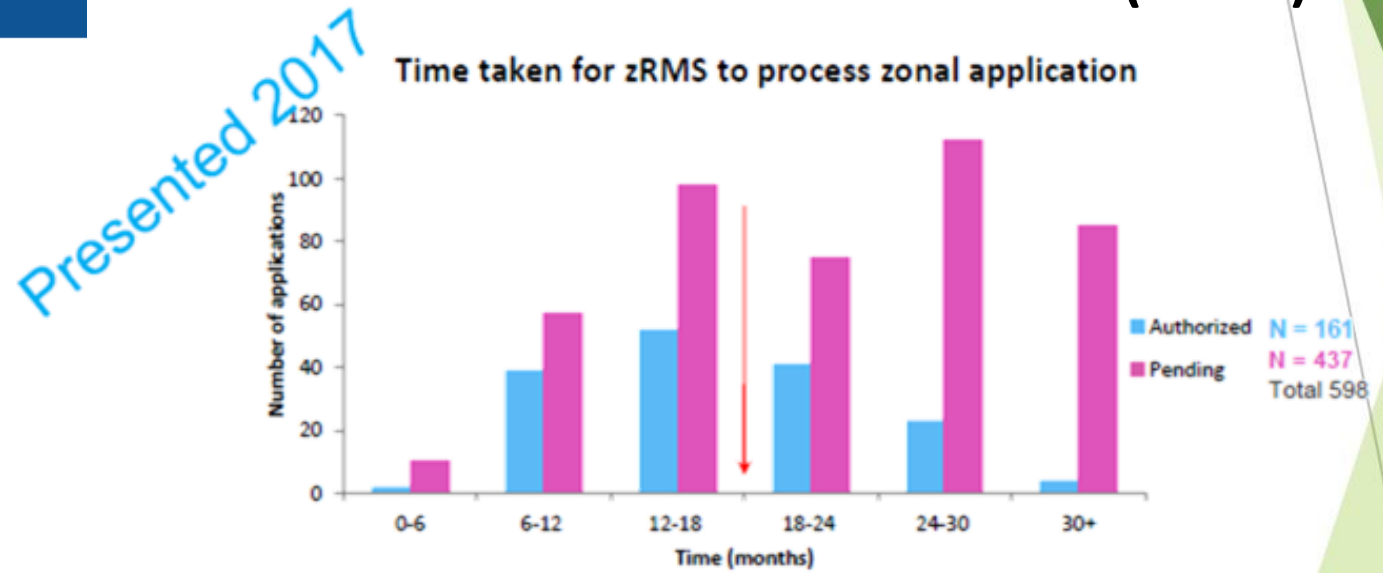
- *"Encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides"* (Art. 4 of Directive 2009/128/EC)



… is the objective of 1107 met?



Zonal evaluation of new formulations (zRMS)



- Granted Zonal authorisations within 18 months or less = 21%
- Pending Zonal evaluations already exceeding 18 months = 62%

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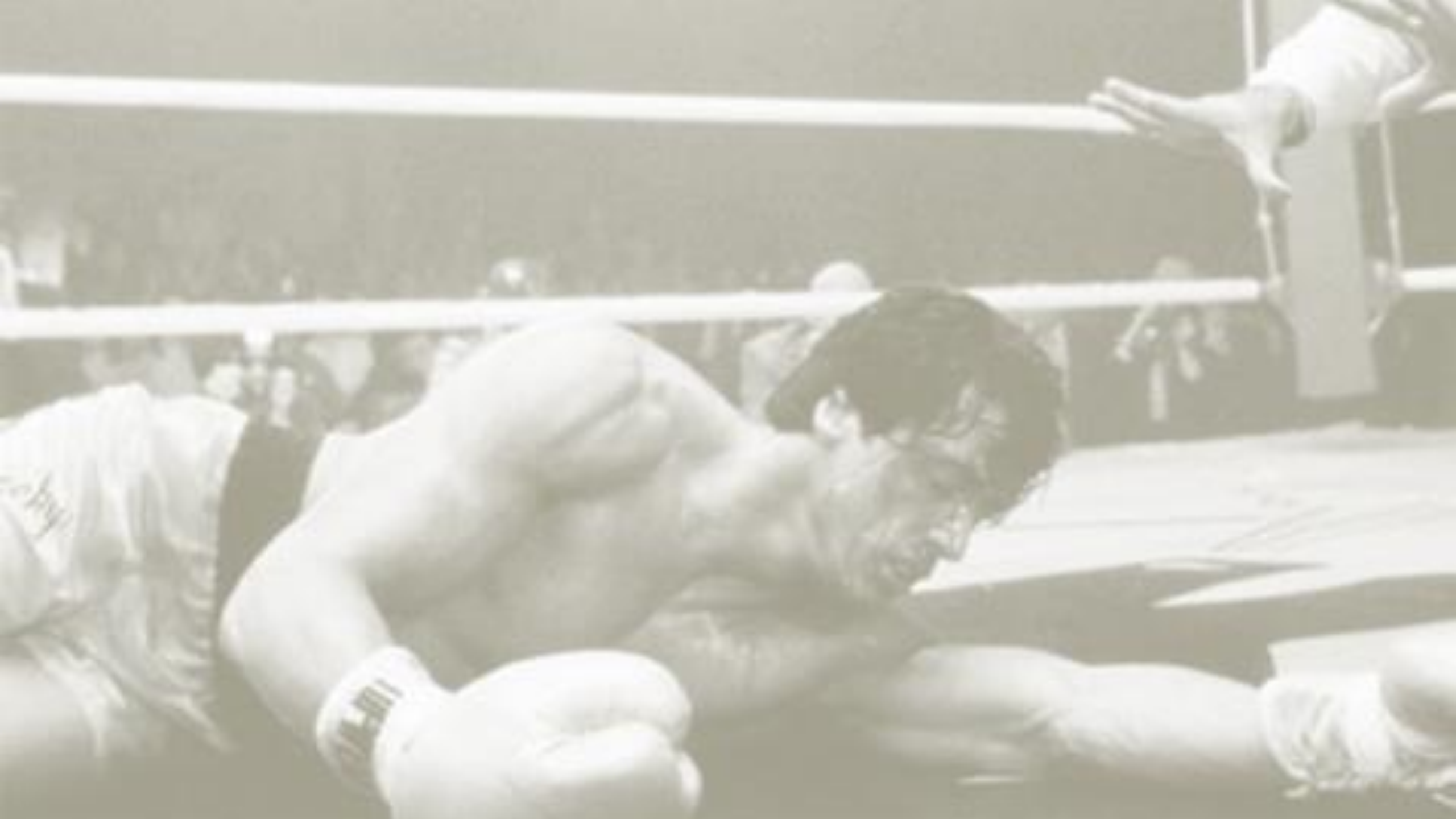

… but how easy is it to register ‘alternatives’?

- Semiochemical Active Substances and Semiochemical Plant Protection Products fall in the same framework and have the same data requirements and timelines as conventional pesticides.

Are reduced data requirements possible for semiochemicals?

- The only PPPs that benefit of a shorter evaluation timeline (120 days vs 12 months) are low-risk PPPs, i.e. PPPs that only contains low-risk active substances.

Are semiochemicals considered as low-risk active substances?

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- **SANTE/12815/2014**
  Guidance document on semiochemical active substances and PPPs

- **EPPO Standard PP1/296**
  'Principles of efficacy evaluation for low-risk PPPs'

- Motion for a Resolution on faster access to the European market for **low-risk pesticides** of **biological origin**

SANTE/12815/2014

- Applicable to all applications submitted from 01.01.2017 onwards
- Aims to provide practical solutions on how procedures and data requirements can be applied to facilitate the approval of semiochemicals active substances and PPPs

"When the exposure route is by the vapour phase only (retrievable dispensers, non-retrievable dispensers and dosable matrix) and where the exposure (by the same route) caused by the use of the plant protection product is similar (within one order of magnitude) to or lower than natural exposure levels of the semiochemical", **the risk characterization is limited to the physical-chemical properties, the analytical methods and the efficacy** of the product.

- Reduced data requirements based on:
  - Formulation type
  - Application rate

Physical-chemical properties
Analytical methods
Toxicological properties
Residues data
Efficacy data
Environmetal fate data
Ecotoxicological properties

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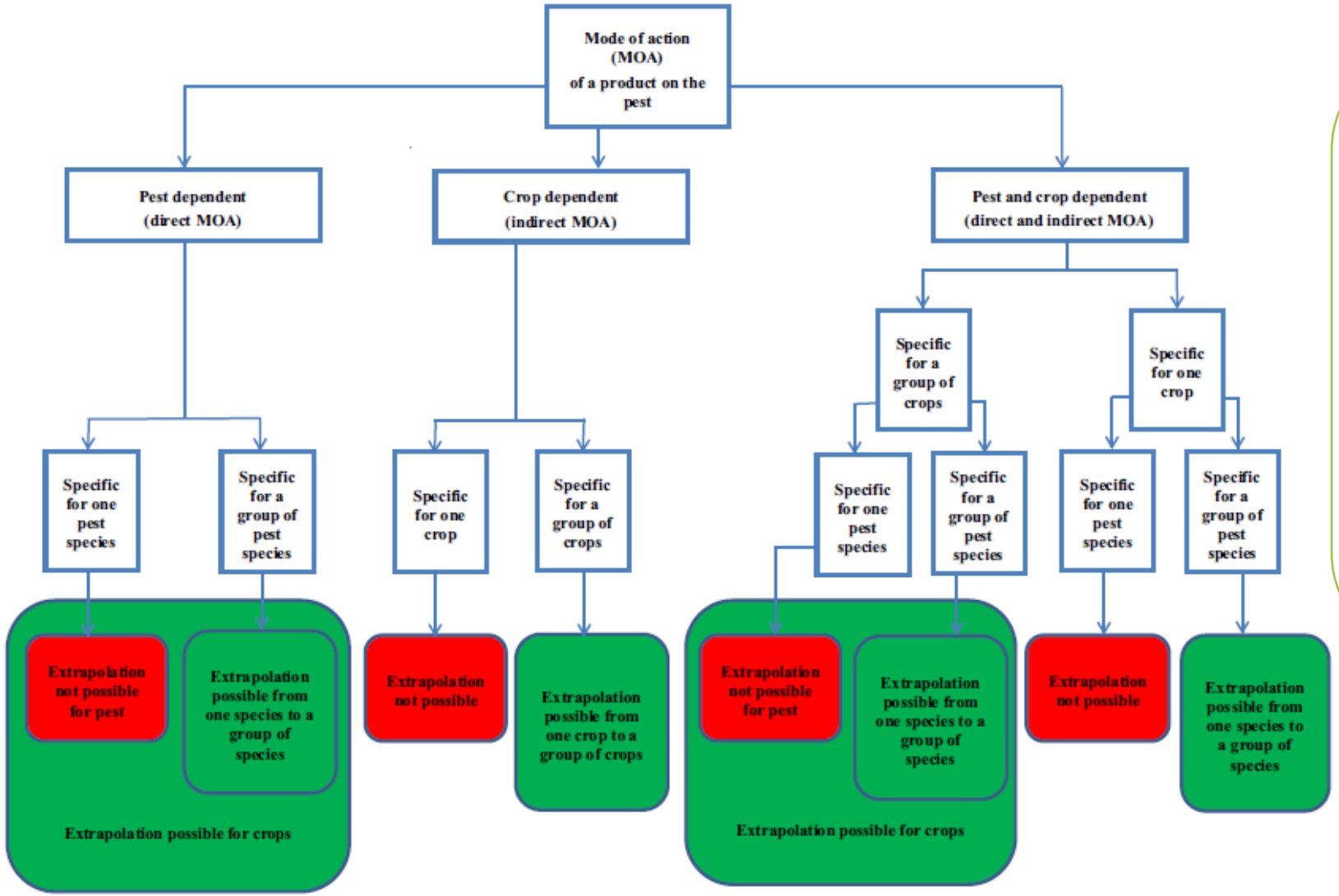
EPPO Standard PP1/296

- This standard has a specific section (section 9.3) dedicated to semiochemicals



"As the plant species is not relevant in relation to semiochemcial product's performance, extrapolation is possible to other crops in which the same pest appears. In the case semiochemicals that have multiple targets, extrapolation to a group of related species is possible".

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Low-risk status of semiochemicals 1/3

- *"Semiochemicals are substances emitted by plants, animals and other organisms which are used for intra- and inter-species communication, have a target-specific and non-toxic mode of action and are naturally occurring. They are generally effective at very low rates, often comparable to levels that occur naturally. In light of current scientific and technical knowledge* ***it is also appropriate to provide that semiochemicals should be considered as low-risk substances"*** (Regulation EU 2017/1432)
- However, the same exclusive criteria for AS other than microorganisms set out by this Regulation are applied to semiochemicals

Problems due to skin sensitisation potential and toxicity to aquatic organisms

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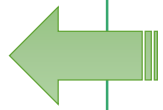
Low-risk status of semiochemicals 2/3

The reduced data package for semiochemicals PPPs emitting only to the air compartment and having an exposure similar (within one order of magnitude) to the natural exposure level set out by SANTE/12815/2014 is perfectly compatible with a 120 days evaluation timeline laid out for low-risk PPPs!

IBMA asks the Commission to issue an official statement legitimating the low-risk status of certain representative uses of semiochemical active substances, i.e. for semiochemicals PPPs emitting only to the air compartment and having an exposure similar to the natural exposure level.



IBMA Position Paper on Commission Regulation (EU) No 2017/1432 and low-risk status of semiochemical active substances and plant protection products

The International Biocontrol Manufacturers Association (IBMA) Professional Group on Semiochemicals prepared this position paper to address the low-risk status of plant protection products containing semiochemical active substances following the entry into force of Regulation (EU) 2017/1432.

Regulation (EC) No 1107/2009 lays down rules for the authorisation, the placing on the market, the use and the control within the Community of plant protection products (PPPs). Its purpose is *"to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture".*

Such competitiveness is becoming every day more difficult to achieve considering the more restrictive risk mitigation measures conventional pesticides are being subject to as they go through the AIR program and the evaluation timelines for PPPs, which often doubles or triples the timelines established by Regulation 1107/2009 (DG(SANTE) 2017-6250 – MR).

Low-risk status of semiochemicals 3/3

Inclusion of Straight Chain Lepidopteran Pheromones (SCLPs) in the first draft of the ‘Commission Notice concerning a list of potentially low-risk active substances approved for use in plant protection’ currently being worked on by the EU Working Group on low-risk substances/PPP.

“[..] Considering the physical and chemical properties of pheromones, since the criteria call for "appropriate standard tests", adapted to the properties of the substances (e.g. highly volatile) as foreseen also in ECHA guidance for CLH, this raises the question whether the current tests can be considered "appropriate standard tests" for SCLP's within the context of the low-risk criteria. Moreover, since the mode of ***application of SCLP's is by dispensers and at concentrations that do not exceed the background level, the sensitisation classification and the aquatic toxicity classification would pose no concern for SCLP's*** *applied in such a way.* ***This is supported by the Guidance Document on semio-chemical active substances and plant protection products (SANTE/12815/2014) that provides for detailed identification of cases where exposure is comparable to natural exposure levels and allows for a simplified non-testing strategy for these cases.***
For the reasons given above, SCLP's are included into the potentially low-risk category, but only when applied from dispensers. This restriction is indicated in the Commission Notice”.

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Consequences

- Reduced availability on the market of alternatives to conventional pesticides
- Use of ‘unconventional’ routes to place on the market semiochemical products
- Misuse of art. 53 and application of different arbitrary criteria in each Member State

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Conclusions

Some progresses have been made in the last couple of years towards a more proportionate regulation of semiochemicals, however much more needs to happen on the wave of the recently adopted Motion for Resolution to achieve the goals set out by Regulation (EC) 1107/2009 and by the Sustainable Use Directive.