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Towards a
proportionate
regulation for
semiochemicals:
how far did we get?

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Regulatory Framework

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

Regulation (EU) 283/2013 laying out the data requirements for AS

Regulation (EU) 284/2013 laying out the data requirements for PPPs

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 Dir. 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 Dir. 2009/128/EC)*

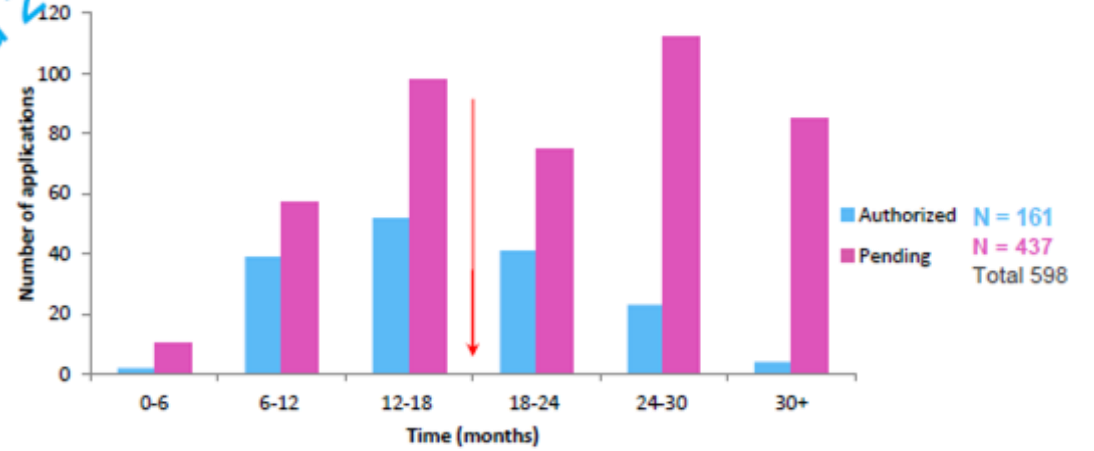


... are those objectives met yet?



Presented 2017

Time taken for zRMS to process zonal application

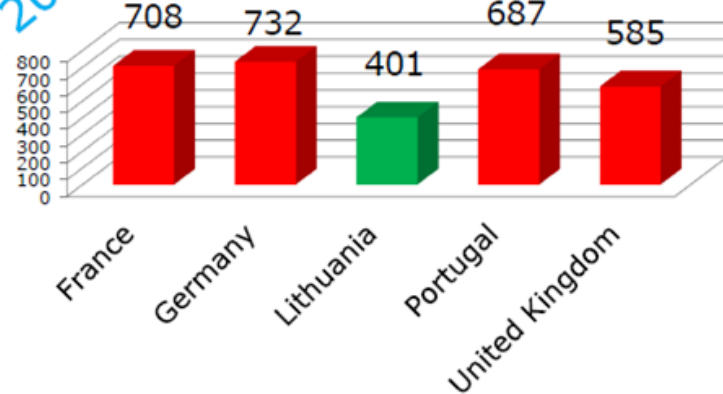


- Granted Zonal authorisations within 18 months or less = 21%
- Pending Zonal evaluations already exceeding 18 months = 62%

Presented 2017

zRMS delays

Average Time for Zonal Evaluation (deadline 550 days)



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?

work in progress



- **SANTE/12815/2014**

Guidance document on semiochemical active substances and PPPs

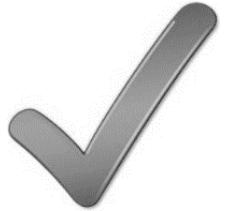
- **EPPO Standard PP1/296**

Principles of efficacy evaluation for low-risk PPPs'

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Are semiochemicals considered as low-risk active substances?



Commission Regulation (EU) No 2017/1432

*“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**”*

However, the same exclusive criteria for AS other than microorganisms set out by this Regulation are applied to semiochemicals

17th October 2018



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

Commission Notice concerning a list of potentially low-risk active substances approved for use in plant protection

The Notice provides a list of active substances approved under Directive 91/414/EEC that are expected to meet the low-risk criteria.

The list is established for informative purposes and was filled by the Commission with the assistance of the Working Group on Low-risk substances and products. The list is without prejudice to the outcome of any forthcoming evaluations, and it does not grant the listed substances the status of "low risk substance".

A man in a grey long-sleeved shirt and grey pants is running down a busy market street. He is wearing a red headband and white gloves. The street is filled with people, stalls, and goods. The background shows a bustling market scene with various stalls and people.

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 Motion for Resolution to achieve the goals set out by Regulation (EC) 1107/2009 and by the Sustainable Use Directive.

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Naturally.

Thank you!

