

A proposal for review from Kemi

– Rational environmental risk assessments

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Background

The decision criteria in uniform principles as proxies for general protection goals are gradually lost with increasingly complex and specific environmental risk assessments. The authorisation processes should be developed to improve the protection of the environment and increase its value for applicants and farmers.

Authorised products should pose lower risks for unacceptable effects than those that are not authorised on the basis of risk. A prerequisite for this is that risk assessments are comparable, i.e. standardised and compared to a common reference point. Detaching generic uncertainty from risk assessments of individual products would increase the value and efficiency of the

authorisation process. The process should instead contain fewer, robust and high-quality factors appropriate for the general protection goals.

With calibrated assessment factors the first-tier risk assessment could considerably faster deliver the same results as today in terms of risk levels for authorised products. Generic uncertainty could be handled in a process for regular review of assessment factors by efficiently take into account the accumulating general knowledge of occurrence and effects of pesticides in the environment. Stakeholder involvement is essential in this review as the authorisation process is only one of several options on the way towards sustainable use of pesticides.

Future? Calibrated tier 1

Objectives

- Facilitated market access.
 - Faster and more predictable evaluations (applicants perspective).
 - Remove obstacles for market access (farmers perspective).
 - Improved harmonization (applicants and farmers perspective).
- Continuously improve RA from validating data (protection goal perspective).
- Improved transparency (general stakeholder perspective).

How?

- Update and improve product risk database according to input from MS.
- Calibration of tier 1 based on all stakeholders' perspectives with regularly reviewed assessment factors based on environmental occurrence and effects of PPPs.



Long-term goals

- A more effective protection of the environment.
- A more effective handling, with shorter processing times and lower costs per application.
- Increased trust and confidence for the authorization process of plant protection products.

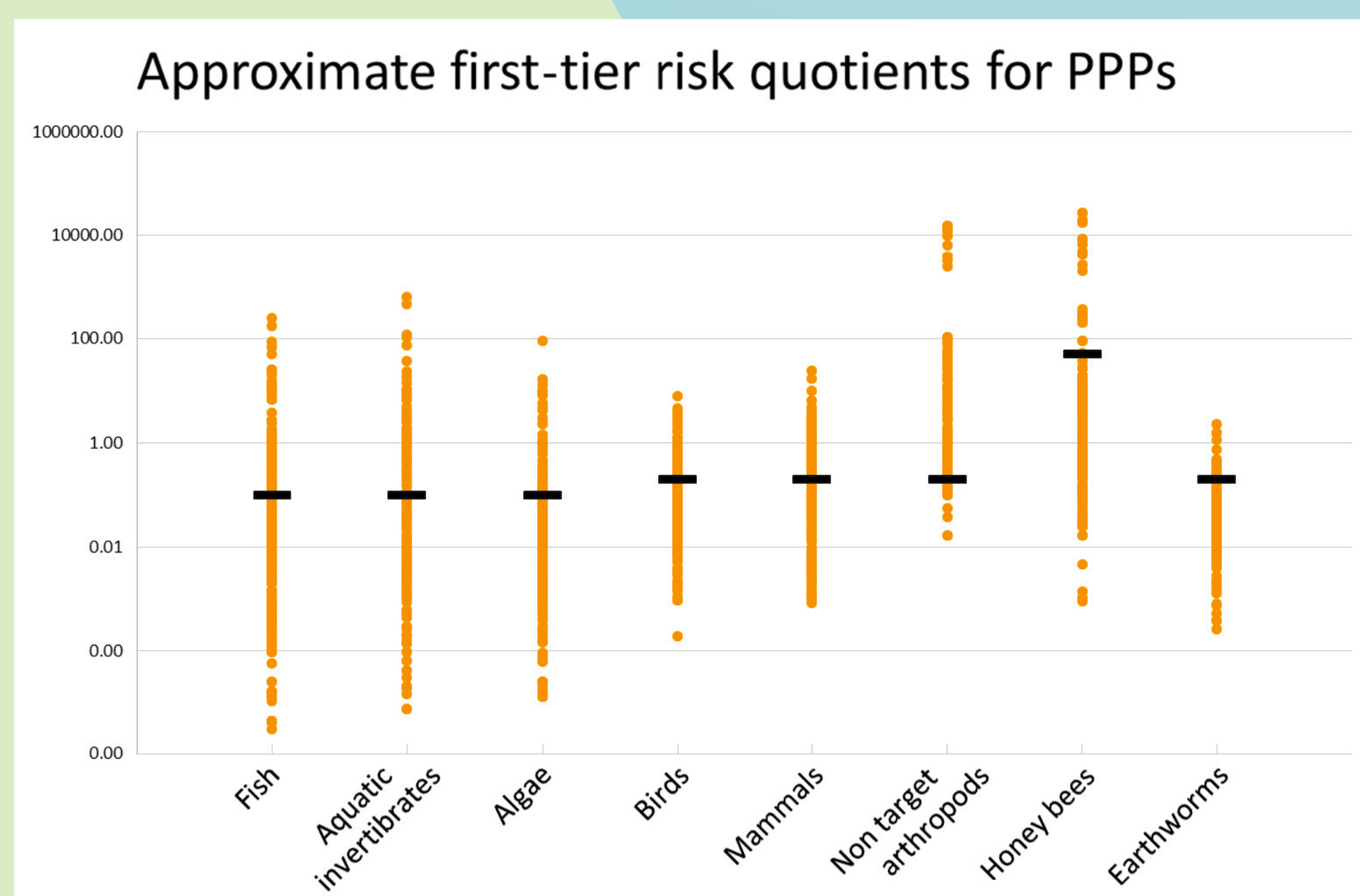
New: Database visualizing the overall level of protection (DaRP)

Objectives

- Overview of work-load and risk level (regulatory perspective).
- Faster evaluation.
 - Support for planning and focusing evaluation resources (regulatory perspective).
- Option for harmonized efforts to handle article 43 application peak (regulatory perspective).

How?

- Database of Risk levels for Products (DaRP) makes standardized risk assessments for all products based on tier 1-factors.
- No change in data requirements from applicants.



Approximate first-tier risk quotients (RQs) for all authorised uses of products available on the Swedish market (orange dots). Black lines represent the decision criteria (trigger values) in uniform principles. All RQs are expressed as exposure/effect.

Ongoing: Enhanced risk management at national level

Objective

- Continuous reduction of risks.

How?

- Improved environmental monitoring.
- Farm level risk mitigation management.
 - Information and training.
- Strategic mitigations and reductions of risks.
 - Screening tool for vulnerable situations.
 - Compensation areas.
 - Collaboration between stakeholders.