European Food Safety Authority (EFSA): Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target terrestrial plants

Presentation part I: General approach of EFSA opinion

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EFSA NTTP Opinion: Background

Authorship

- EFSA Panel on Plant Protection Products and their Residues
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Objective

- To develop a scientific opinion to support development of a risk assessment scheme for plant protection products on NTTPs in the EU
- To provide recommendations for improving current guidelines and risk assessment scheme
- To support development of the subsequent EU Guidance Document
- Literature review of the factors influencing phytotoxicity testing & risk assessment of NTTPs

Timelines

- Opinion adopted in July 2014 (EFSA Journal 2014;12(7):3800)
- Subsequent Guidance Document scheduled for delivery “2 years after agreement on protection goals”
- Deadline expected to be in 2017

Protection Goals

Definition of NTTPs

- All terrestrial plants growing outside fields
- All terrestrial plants growing within fields that are not the intended target

Specific protection goals in relation to ecosytem services

- Off-field NTTPs – nutrient cycling, water regulation, food web support, aesthetic values and genetic resources, biodiversity
- In-field NTTPs – food web support, aesthetic values and genetic resources
- Endangered species

New in EFSA opinion:

- Effect assessment on biodiversity (not in existing guidance)
- Strict in-field protection goals (food web support: food and habitat provision)
- Focus on whole life cycle
- 95 % protection level

Attributes

- Populations (individuals - endangered species)
- Biomass, reproduction, growth, abundance

Current risk assessment scheme (herbicides & PGRs)

EU data requirements

- 6 to 10 (crop) species tested under glasshouse conditions
- Tier 2 seedling emergence & vegetative vigour tests

Current risk assessment scheme

- Toxicity Exposure Ratio (TER) = ER_{50} / Predicted Environmental Rate (PER)
  - PER based on drift for a single application
  - TER trigger = 5

- TER = HC_5 / PER
  - TER trigger = 1

Knowledge gaps

The Opinion raises the following uncertainties over the current risk assessment scheme:

- Is current risk assessment using crop species protective for effects on wild species, mosses, liverworts, ferns, shrubs, trees ?
- Is current risk assessment using vegetative vigour data protective for effects on reproductive parameters (flowering, seed set and viability of F1 generation) ?
- How can data from field and community studies be used in the risk assessment ?
- Is exposure to multiple applications covered ?
- Are effects from exposure via dust drift, volatilisation and run-off covered ?
- Is effect of plant age at time of exposure covered ?
- How can recovery be assessed ?
- How can mixture toxicity be assessed ?

Some of these uncertainties covered by new proposed endpoints and extrapolation factors between vegetative and reproductive endpoints for use in risk assessment