Are standard avian risk assessments appropriate tools addressing the risk to reptiles?

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Overview

⇒ Some regulatory background
⇒ Vertebrate risk assessment (RA)
⇒ Relevant exposure routes and scenarios
⇒ Acute, long-term and secondary RAs
⇒ Conclusion and future directions
Registration of plant protection products in Europe (EU)

**OLD:** Directive 91/414 EWG

SANCO 11802/2010 Data requirements active substance
SANCO 11803/2010 Data requirements formulation

SANCO 11802/2010:
‘available and relevant data, including data from the open literature for the active substance of concern, regarding the potential effects of an active substance to birds, mammals, reptiles and amphibians should be presented and taken into account in the risk assessment.’
**Data requirements birds + mammals**

- **Acute tests**
  (e.g. OECD test guideline no. 223)
- **Chronic Tests**
  (e.g. OECD test guideline no. 206)
- **Literature data**

**Data requirements amphibia**

- **Amphibian metamorphosis assay**
  (OECD test guideline no. 231)
- **Literature data**

**Data requirements reptiles**

- **No official guideline published**
- **Literature data, only**

According to draft SANCO 11802/2010
Risk assessment (RA) vertebrates

TER = Toxicity / Exposure

Risk assessment birds + mammals according EFSA guidance document (2009)

\[ \text{TER}_A = \frac{\text{LD}_{50} \ [\text{mg a.s. / kg b.w.}]}{\text{daily dietary dose [mg a.s. / kg b.w.]}}, \]

\[ \text{TER}_{LT} = \frac{\text{NOAEL} \ [\text{mg a.s. / kg b.w./ day}]}{\text{daily dietary dose [mg a.s. / kg b.w.]}}, \]

Is it possible to conduct a reptile risk assessment based on the EFSA GD?
Potential exposure routes in reptiles

- dermal absorption
- diet
- drinking water
- inhalation
  (soil ingestion)

(Fryday & Thompson, 2009)
Habitat
Reptiles often live in field margins (e.g. marginal strips or the edge of forests) and only few species are found in crops (e.g. vineyards, olive groves and orchards)

⇒ Direct dermal or inhalation exposure appears to be less significant
⇒ Dermal and inhalation exposure in the EFSA GD Data gap

Food
Snakes: mainly small mammals, but also birds, amphibia, reptiles and fish
⇒ Exposure via secondary poisoning
⇒ Fish-scenario available – but not for birds, mammals and amphibia Data gap

Lizards: mainly arthropods, but also annelids, gastropods and small vertebrates
⇒ Exposure via contaminated arthropods + secondary poisoning (earthworm)
⇒ Both exposure scenarios are available in the EFSA GD Risk assessment possible
How to conduct risk assessment for lizards?
(according to EFSA GD, 2009)

\[
\text{TER} = \frac{\text{Toxicity}}{\text{Exposure}} = \frac{\text{LD}_{50} \text{ or NOAEL}}{\text{DDD}}
\]

⇒ Only few reptiles studies available (mostly Crocodilia und turtles)
⇒ Fryday and Thompson (2009)
  - Acute und chronic endpoints (reptiles) of 19 active substances
⇒ Weir et al. (2010)
  - Acute endpoints (reptiles) of 15 active substances
⇒ Pauli et al. (2000)
  - RATL: A Database of Reptile and Amphibian Toxicology Literature (>2000 entries, different substance groups)

⇒ Luttik (2010)
  - Compared the sensitivity of birds and reptiles. The substances differ up to factor of 1000
  - Use bird endpoints + safety factor of 10, 100 and 1000

Most active substance are not Annex I listed
**How to conduct risk assessment for lizards?**

*(according to EFSA GD, 2009)*

\[
TER = \frac{Toxicity}{Exposure} = \frac{LD_{50} \text{ or NOAEL}}{DDD}
\]

**Acute and long-term risk assessment**

\[
DDD = \text{Application rate} \times \left( \frac{\text{FIR/b.w.} \times \text{RUD}}{\text{b.w.}} \right) \times \text{MAF} \times \text{TWA}
\]

- **DDD:** Daily Dietary Dose
- **Application rate:** Active substance [kg a.s./ha]
- **FIR/b.w.:** Food intake rate / body weight [g fresh weight/day/g]
- **RUD:** Residue unit dose [mg a.s./kg]
- **MAF:** Multi application factor
- **TWA:** Time weighted average factor

**Secondary poisoning**

\[
DDD = \text{FIR/b.w.} \times \text{PEC}_{\text{earthworm}}
\]

- **PEC\textsubscript{earthworm}:** Concentration in earthworms (=PEC\textsubscript{soil twa 21 d} x BCF\textsubscript{earthworm})
- **PEC\textsubscript{soil twa 21 d}:** Time weighted PEC over 21 days
- **BCF\textsubscript{earthworm}:** Bioconcentration factor earthworms
How to conduct risk assessment for reptiles?

FIR = 34.6 * W^{0.65} (Avery, 1978)

Common wall lizard
(Podarcis muralis)

**Habitat**
Vineyards, field margins, rocks/walls, riparian zones, grasslands, boges, garden/parks, forests and forest edges

**Diet**
Arthropods, juvenile reptiles, fruits
Screening acute risk

Vineyard (12 active substances)*
Fungicide:
Boscalid, Folpet, Metrafenone, Metiram, Pyrimethanil, Pyraclostrobin, Abamectin
Insecticide:
Imidacloprid, Methoxyfenozide
Herbicide:
Glyphosate, Carfentrazone-ethyl, MCPA

Cereals (11 active substances)*
Fungicide:
Tebuconazole, Epoxiconazole, Fenpropidin, Propiconazole
Insecticide:
Beta-cyfluthrin, Dimethoate, Thiacloprid
Herbicide:
Pendimethalin, Glyphosate, Isoproturon, MCPA

*Based on product authorizations in Germany and bird LC₅₀/NOEL values provided in EU documents
Screening long-term risk

**Vineyard** (12 active substances)*

Fungicide: Boscalid, Folpet, Metrafenone, Metiram, Pyrimethanil, Pyraclostrobin, Abamectin

Insecticide: Imidacloprid, Methoxyfenozide

Herbicide: Glyphosate, Carfentrazone-ethyl, MCPA

**Cereals** (11 active substances)*

Fungicide: Tebuconazole, Epoxiconazole, Fenpropidin, Propiconazole

Insecticide: Beta-cyfluthrin, Dimethoate, Thiacloprid

Herbicide: Pendimethalin, Glyphosate, Isoproturon, MCPA

*Based on product authorizations in Germany and bird LC/NOEL values provided in EU documents
Screening 2\textsuperscript{nd} poisoning risk

**Vineyard** (6 active substances)*
- **Fungicide:** Folpet, Metrafenone, Pyraclostrobin, Abamectin
- **Insecticide:** Methoxyfenozide
- **Herbicide:** Carfentrazone-ethyl

**Cereals** (7 active substances)*
- **Fungicide:** Tebuconazole, Epoxiconazole, Fenpropidin, Propiconazole
- **Insecticide:** Beta-cyfluthrin, Thiacloprid
- **Herbicide:** Pendimethalin

*Based on product authorizations in Germany and bird LC\textsubscript{50}/NOEL values provided in EU documents
Conclusion

- Based on data generated for birds, effects of PPP on reptiles are possible
- Contaminated food seems to be a major route of exposure
- Dietary RA of birds can be used to conduct risk assessment for lizards
  - Scientific effort is needed to gain more information on focal species, their diet composition and specific food intake rates
- EFSA GD (2009) is less suitable to assess the risk of PPP on snakes
  - Future work should focus on secondary poisoning (e.g. field studies or body burden modeling), but also the determination of focal species, their diet composition and food intake rates
- Dermal and inhalation exposure appears to be less significant in most crops (except for vineyard and orchards)
  - Future work should explore the significance of dermal exposure in reptiles
  - Development of dermal exposure scenarios
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