Current challenges for pesticide risk assessment

Jos Boesten
Outline

■ Introduction

■ Definition of exposure assessment goals (EAGs)

■ Coherent effect and exposure assessment goals

■ Overcoming regulatory resistance to scientific improvements

■ Communication with risk managers

■ Conclusions
Introduction: basics of pesticide risk assessment

- Pesticide use may lead to undesirable adverse environmental effects
- Leaching to groundwater solely exposure issue
  - 0.1 μg/L
- Organisms (aquatic + soil + bees + NTA + NTP): risk assessment = [effect + exposure] assessment
Introduction: basics of pesticide risk assessment

risk assessment = [effect + exposure] assessment

two elements: effect & exposure
work only well if correctly combined
Introduction: terminology for ‘fate’ part

- Fate is too vague in this context

- Fate and ecotoxicology are fields of expertise
  - fate expert, ecotox expert

- **Exposure assessment** indicates target
  - groundwater or organisms
Introduction: large progress in past 30 y

- I started developing regulatory exposure assessment in 1980s
  - first Dutch regulatory work
  - FOCUS-EU workgroups in 1990s
  - EFSA workgroups since about 2005

Example 1

1988: Dutch leaching scenario based on 1 soil profile and 1 weather station

Now: GeoPEARL with 500 soil profiles and 20 weather stations
Introduction: large progress in past 30 y

Example 2
Terminology of risk assessment and risk management unknown to me until about 2000 (vague separation between science and politics)
Now: clear RA/RM conceptual framework based on effect protection goals and exposure assessment goals (EFSA PPR Panel)

Example 3
Until 2005 almost no attention in effect assessment on how to link effect and exposure assessment flow charts
Now: clear conceptual framework for this linking (EFSA PPR Panel)
Introduction: what are my interests?

- Enormous personal influence on what is perceived as main challenges

- Usual attitude: challenges >80% in own field of expertise
  - caused by brainwash called ‘university education’
  - driven by self-interest
    - research budget, membership of workgroups, etc.

- Jos: developer of exposure methodologies (since 1988) paid for >95% by Dutch Ministry of Economic Affairs (on yearly-budget basis)
  - keeping research budget important drive for me
Introduction: approach for each challenge

- Challenge description
- History/background
- Example cases
- How to overcome?
Definition of EAGs:

- EAGs are not explicitly defined, only vague definitions

without such a definition

- exposure assessment cannot provide desired result

- scientific debate on exposure methodologies not meaningful: “moving target”
Definition of EAGs:

**history/background**

- Until 2010 only vague EAG descriptions
  - e.g. FOCUS groundwater: 90\textsuperscript{th} percentile leaching vulnerability within climatic zone
  - no problem because scenarios were selected based on expert judgement

- Need emerged in EFSA soil exposure WG 2007-2010
  - first explicit GIS-based scenario selection procedure
  - WG members disagreed on procedure at end because they had different EAGs in mind (without knowing !)

- EFSA (2010) opinion of soil exposure WG

- EFSA (2010) specific protection goals
  - one page about exposure (p. 47)
Definition of EAGs:  
*how to overcome?*

- Since 2010 simple technical solution: answer 6 questions
  - same for leaching, aquatic and soil organisms, bees, etc. etc.

6 Qs
- Which type of concentration?
- Which temporal dimension of this concentration?
- What spatial unit?
- What spatial population of units?
- What temporal population of concentrations?
- Which percentile from spatio-temporal population of concentrations?

example: leaching to groundwater
Q1: which type of concentration?

Examples

Concentration in:

- pore water passing 1 m depth (FOCUS GW scenarios)
- upper meter of water-saturated zone
  - e.g. 0.5-1 m below soil surface in winter
- water flowing out of drainpipes
- groundwater at 10 m depth

example: leaching to groundwater
Q2: which temporal dimension of this concentration?

Examples
- daily values
- monthly averages
- yearly averages

example: leaching to groundwater
Q3: what spatial unit?

Examples

- 1m² of agricultural field
- whole agricultural field
- one drainpipe from an agricultural field
- all drainpipes from an agricultural field
- drinking-water abstraction well
Q4: what spatial population of units?

**Examples**

- all treated fields in area of use
- only treated fields in area of use that generate percolation water that can be used for drinking water purposes
  - e.g. exclude fields with brackish groundwater or upward seepage

**example:** leaching to groundwater

**examples for spatial unit = agricultural field**
Q5: what temporal population of concentrations?

Q5 addresses multi-year issues such as application to rotational crops and application of same substance in different crops in a rotation.

**Examples**
(assuming that temporal dimension is defined as annual average of concentration)

- each annual value irrespective of application frequency
- average over 1, 2 or 3 years if application is every 1, 2 or 3 years
  - as in FOCUS GW scenarios

Example: leaching to groundwater
Hierarchy in the 6 Qs

Q6: Percentile of spatio-temporal population of concentrations

Q5: Temporal population of concentrations at one spatial unit

Q4: Population of spatial units

Q3: Spatial unit

Q2: Temporal dimension of this type of concentration

Q1: Type of concentration

Q0: Temporal population of concentrations at one spatial unit
Q6: which percentile from spatio-temporal population of concentrations?

**Examples**

- **A**: overall 90\textsuperscript{th} percentile based on appropriate combination of space and time percentiles
- **B**: 90\textsuperscript{th} percentile in space combined with 50\textsuperscript{th} in time
- **C**: 100\textsuperscript{th} percentile in space and time
  - all-time high anywhere

*example: leaching to groundwater*
Definition of EAGs:

*examples of well defined goals*

- 2012 Dutch exposure assessment for aquatic organisms
- 2015 EFSA bee risk assessment
- 2015 EFSA exposure assessment for soil organisms in annual crops
- 2015 EU modelling workshop: leaching to groundwater
Outline

- Introduction
- Definition of exposure assessment goals (EAGs)
- Coherent effect and exposure assessment goals
- Overcoming regulatory resistance to scientific improvements
- Communication with risk managers
- Conclusions
Coherent exposure and effect assessments goals:

*challenge description*

- Organisms (aquatic + soil + bees + NTA + NTP): risk assessment = [effect + exposure] assessment

- Effect and exposure assessment goals are often not defined in a coherent way

- Nevertheless level of protection is 50/50 determined by combination of two
  - this level is ‘the’ key aspect of the risk assessment
Coherent exposure and effect assessments goals: 

*challenge description*

```
overall level of protection ➔ risk managers
```

coherent package

- **SPGs** = specific protection goals
- **EAGs** = exposure assessment goals

effect assessment ➔ linking ➔ exposure assessment

this is how it should be
Ecotox and fate experts have only seldomly drive for working across frames

- working in own frame gives much more credits than stepping out of your frame
- communication with other frame is mostly difficult
  - people in other frame often do not behave ‘appropriately’
Coherent exposure and effect assessment goals:

**background**

2005: typical example of difficult communication

- **ecotox frame**: your scenarios are ecologically not relevant
- **fate frame**: huh, what does she mean and what did I do wrong?

In case of communication/frame problems, **ALWAYS** both parties are to blame.

It is **NEVER** fault of one of two (assuming mentally healthy people)
Coherent exposure and effect assessment goals:

*example*

EU aquatic risk assessment in 2016 (NOW)

linking works well
Coherent exposure and effect assessment goals: example

Dutch guidance development for aquatic organisms

<table>
<thead>
<tr>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- ditches that fall dry temporarily included in spatial population
- these give highest exposure (due to drift); RM wanted most conservative option

EFSA aquatic guidance: effect assessment is only fit for purpose for permanent water bodies

Dutch exposure WG still has to redo scenario selection based on only permanent ditches ....
Coherent exposure and effect assessments goals: how to overcome?

- Exposure
- Effects
- Fate frame
- Ecotoxicology frame

Common risk frame + integrated level of protection
Coherent exposure and effect assessment goals: *how to overcome?*

Difficult, difficult; only some suggestions

- at some point during revision/development of risk assessment procedure establish workgroup with equal numbers of ecotox and fate experts for producing coherent sets of goals

- to be imposed by management level (EFSA, MS governments)
  - it will not work bottom-up!

- make this workgroup responsible for interaction with risk managers for providing options for level of protection

- for longer term: support research projects that develop toolkits for such coherent approaches
Outline

- Introduction
- Definition of exposure assessment goals (EAGs)
- Coherent effect and exposure assessment goals
- Overcoming regulatory resistance to scientific improvements
- Communication with risk managers
- Conclusions
Overcoming regulatory resistance to scientific improvements: *challenge description*

- Regulatory agencies have ‘natural’ aversion against new guidance
  - undesirable that level of protection (= status quo) changes
  - changing the system increases work load

![regulatory frame](image1)

![guidance frame](image2)
Overcoming regulatory resistance to scientific developments: *history/background*

### Regulatory agencies
- Often overloaded with duties/dossiers and under time pressure
- Usually trust existing procedures (while sometimes based on poor science)
- Treat improved procedures (e.g. complicated higher tiers) with suspicion (while usually more realistic)

### Guidance WGs (EFSA or MS)
- Sensitive to criticisms from colleague experts
- Drive for scientific consistency
- When in doubt adopt often conservative choices (afraid to be accused of being too industry-friendly)
- Result: Often complicated and sometimes conservative guidance
Overcoming regulatory resistance to scientific developments: *examples*

- SETAC Nantes 2016 ‘Tendency towards higher complexity in environmental risk assessment: to accept or to avoid?’
  - special session by UBA+ANSES

- **flavour**: do not go for more realism, instead better stop with higher tiers

- debate driven by political considerations (my perception)
  - agencies put themselves in ‘centre of universe’
  - scientific world will never agree to ignore reality
    - research budgets would go down
Overcoming regulatory resistance to scientific developments: *how to overcome?*

- User-friendly software for higher tiers based on expert-system approach
  - sometimes huge efforts needed for development
  - workload may still be too much

- Provide agencies with more manpower and expertise
  - NL: Ctgb steadily growing over past 5 years, now at 130

- Political steering
  - without political drive for keeping a ‘sufficient’ package of pesticides on market, this problem cannot be solved
Outline

- Introduction
- Definition of exposure assessment goals
- Coherent effect and exposure assessment goals
- Overcoming regulatory resistance to scientific developments
- Communication with risk managers
- Conclusions
Communication between risk managers and guidance developers: *challenge description*

- risk managers and guidance developers live in different frames
Communication between risk managers and guidance developers: *challenge description*

- **Political steering level**
- **Overall level of protection**
- **Scientific workgroup**
- **Guidance ‘cookbook’ + user-friendly software**
- **Registration authorities at national and EU level**

Communication essential: risk managers decide on level of protection
Communication between risk managers and guidance developers: *background*

- Asking open questions to political level does not work
  - what level of protection do you want?

- RM give answers based on intentions
  - UP: no unacceptable impact on environment
  - never any environmental impact then no pesticides left
    - designed to kill organisms

- Assessment goals have to be precisely defined (e.g. 6 Qs)

- Solution: guidance developers develop options A-B-C-D
Communication between risk managers and guidance developers: *how to overcome?*

Approach for options:

- include full range of options of potential interest to risk managers
  - step out of comfort zone for some scientists

- description of option should include:

<table>
<thead>
<tr>
<th>Element</th>
<th>Type of language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of SPG – EAG combinations</td>
<td>Scientific</td>
</tr>
<tr>
<td>Overall level of protection (qualitative)</td>
<td>Political</td>
</tr>
<tr>
<td>Consequences for registration (how many pesticides will pass?)</td>
<td>Political</td>
</tr>
</tbody>
</table>
Communication between risk managers and guidance developers: *how to overcome?*

<table>
<thead>
<tr>
<th>Level of protection in RM/political language</th>
<th>Scientific definition of SPGs and EAGs</th>
</tr>
</thead>
</table>

Communication gap to be bridged by offering to RM options that do work scientifically:
Conclusions

- Toolkit for defining exposure assessment goals available
  - I can be hired for help 😊

- Coherent effect and exposure assessment goals important challenge for future
  - no easy solutions

- Issues at level of regulatory agencies strongly liked to political drives

- Toolkit for better communication with risk managers available
  - but still not commonly used

- Improvement of co-operation/understanding between groups in different frames is biggest challenge!
Thank you for your attention!