

# Current challenges for pesticide risk assessment

Jos Boesten



# Outline

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- 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

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- 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

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- 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

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## 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 ?

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- 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

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- Challenge description
- History/background
- Example cases
- How to overcome ?

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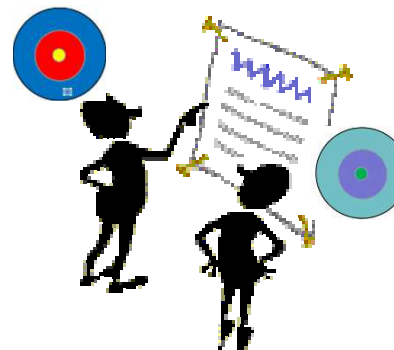
# Definition of EAGs: *challenge description*

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- 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”

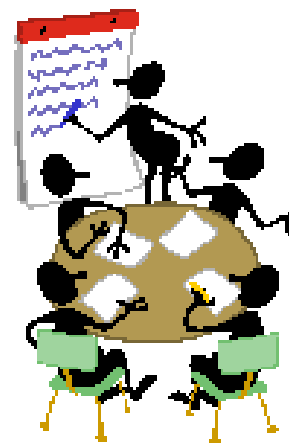


# Definition of EAGs:

## *history/background*

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- Until 2010 only vague EAG descriptions
  - e.g. FOCUS groundwater: 90<sup>th</sup> 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 ?*

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- 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 ?

# Q1: which type of concentration ?

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example:  
leaching to  
groundwater

## 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

## Q2: which temporal dimension of this concentration ?

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example:  
leaching to  
groundwater

### Examples

- daily values
- monthly averages
- yearly averages

## Q3: what spatial unit ?

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example:  
leaching to  
groundwater

### Examples

- 1m<sup>2</sup> of agricultural field
- whole agricultural field
- one drainpipe from an agricultural field
- all drainpipes from an agricultural field
- drinking-water abstraction well

spatial unit defines also surface  
areas or elements over which  
concentrations are averaged



## Q4: what spatial population of units ?

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example:  
leaching to  
groundwater

### Examples

examples for  
spatial unit = agricultural field

- 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

# Q5: what temporal population of concentrations ?

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

example:  
leaching to  
groundwater

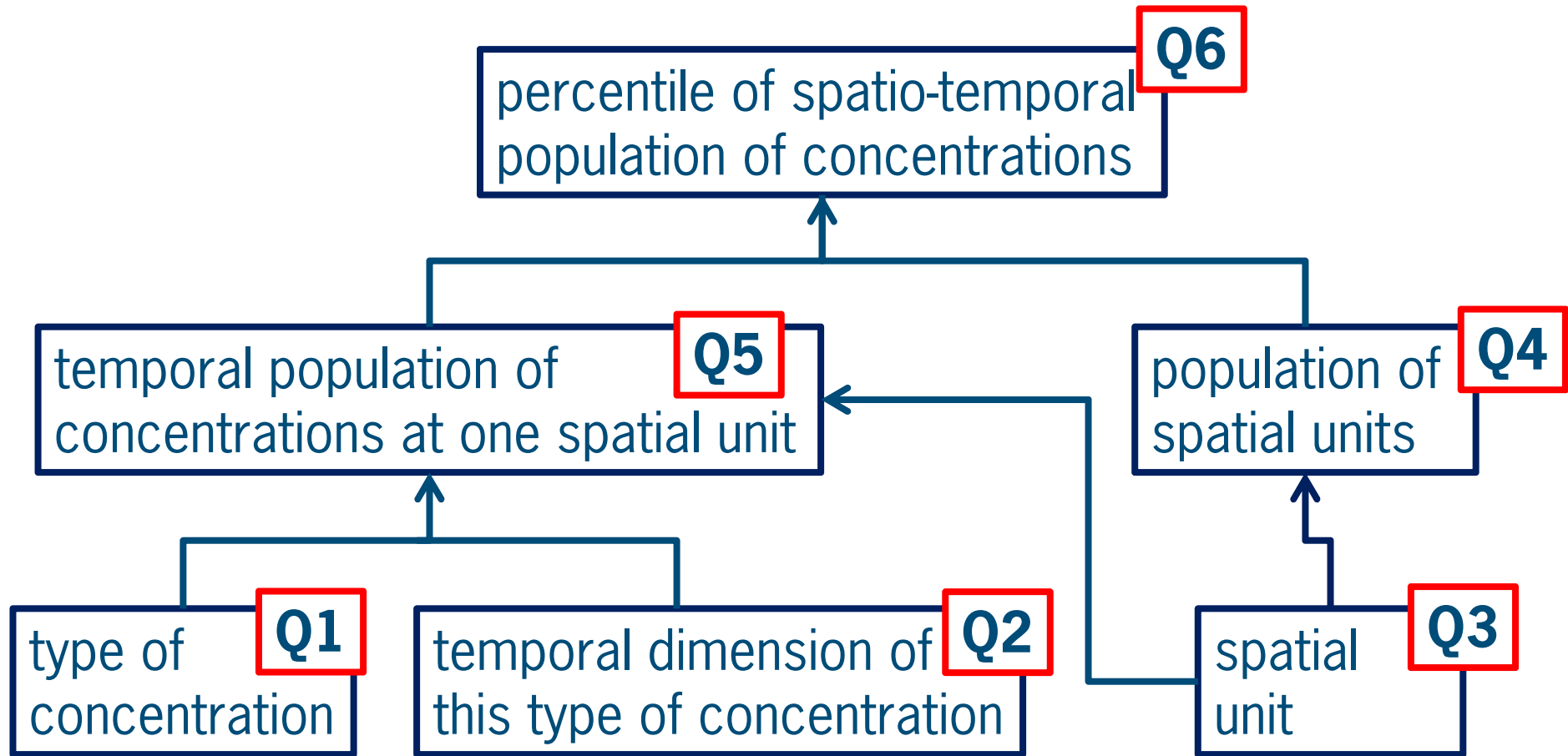
## Examples

(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

# Hierarchy in the 6 Qs

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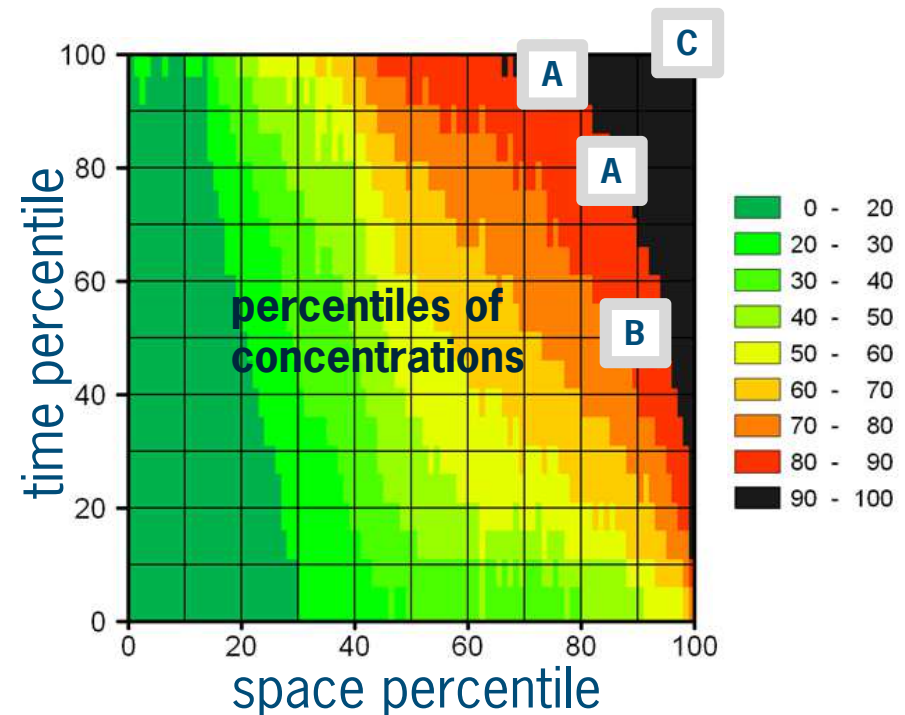


# Q6: which percentile from spatio-temporal population of concentrations ?

example:  
leaching to  
groundwater

## Examples

- A: overall 90<sup>th</sup> percentile based on appropriate combination of space and time percentiles
- B: 90<sup>th</sup> percentile in space combined with 50<sup>th</sup> in time
- C: 100<sup>th</sup> percentile in space and time
  - all-time high anywhere



# Definition of EAGs:

*examples of well defined goals*

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- 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



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# Coherent exposure and effect assessments goals: *challenge description*

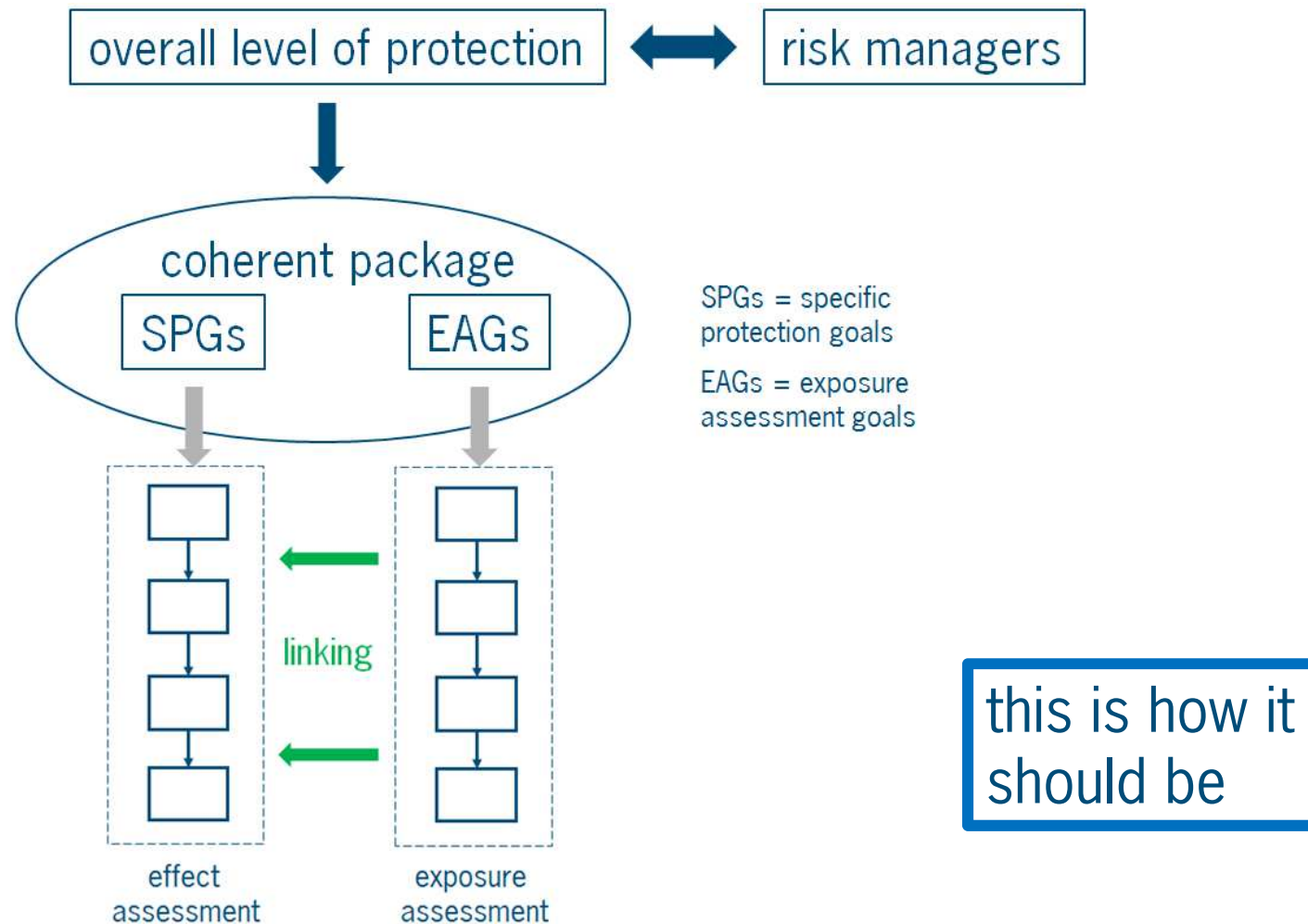
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- Organisms (aquatic + soil + bees + NTA + NTP):  
risk assessment = [effect + exposure] assessment
- Effect and exposure assessment goals are often not defined in a coherent way
- Nevertheless level of protection is 50/50 determined by combination of two
  - this level is 'the' key aspect of the risk assessment



# Coherent exposure and effect assessments goals: *challenge description*

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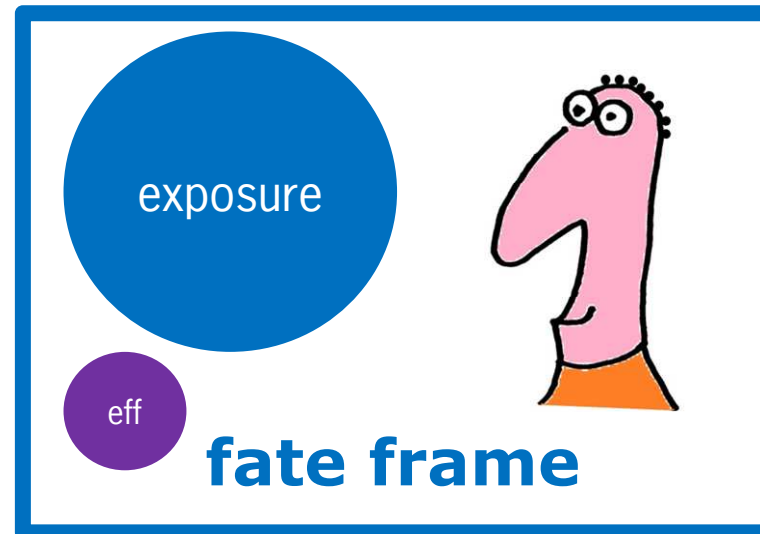
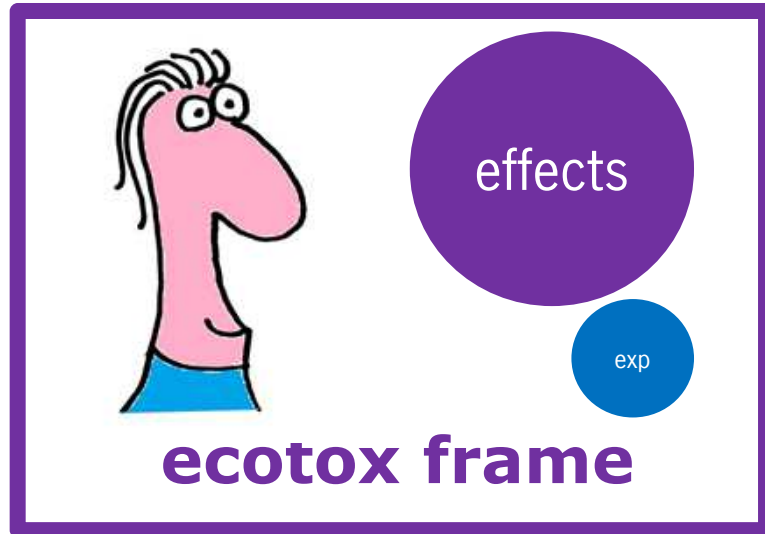




# Coherent exposure and effect assessments goals:

*history/background*

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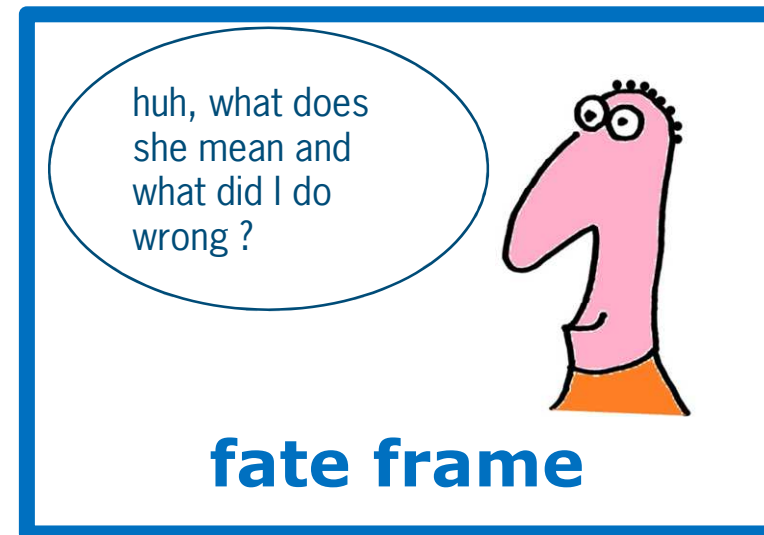
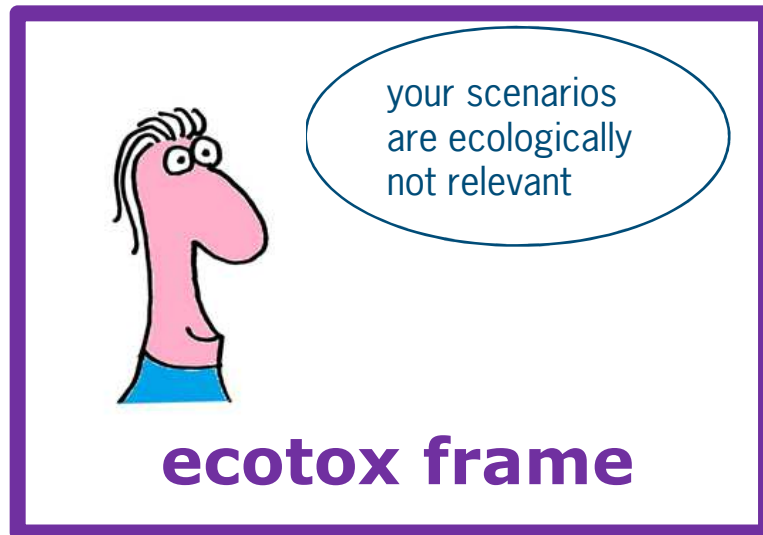
- Ecotox and fate experts have only seldomly drive for working across frames
  - working in own frame gives much more credits than stepping out of your frame
  - communication with other frame is mostly difficult
    - people in other frame often do not behave 'appropriately'



# Coherent exposure and effect assessment goals: *background*

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2005: typical example of difficult communication



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

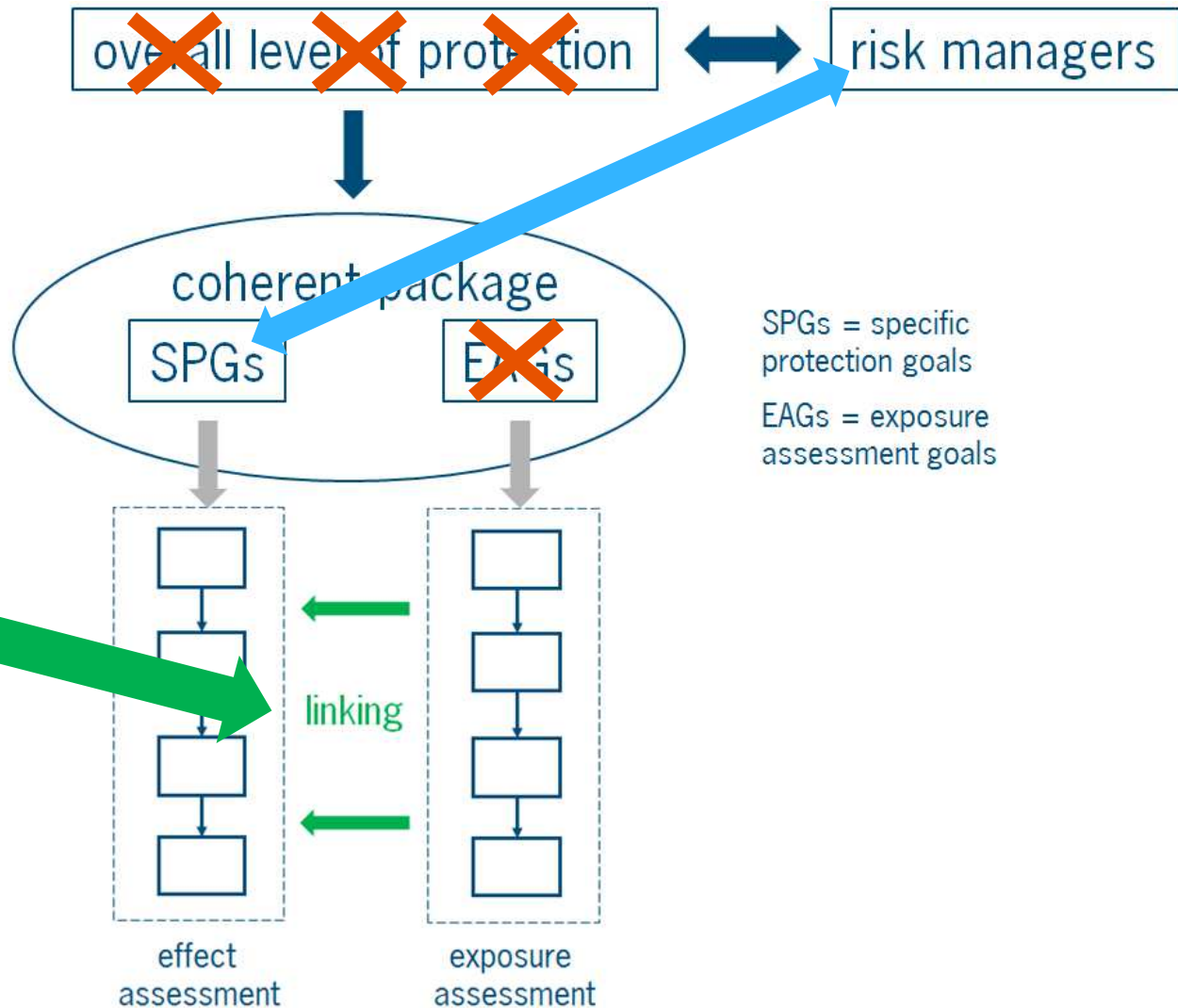
it is **NEVER** fault of one of two

(assuming mentally healthy people)

# Coherent exposure and effect assessment goals:

*example*

EU aquatic risk assessment in 2016 (NOW)



# Coherent exposure and effect assessment goals: *example*

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Dutch guidance development  
for aquatic organisms



2007	2008	2009	2010	2011	2012	2013
		effect workgroup				
exposure workgroup						

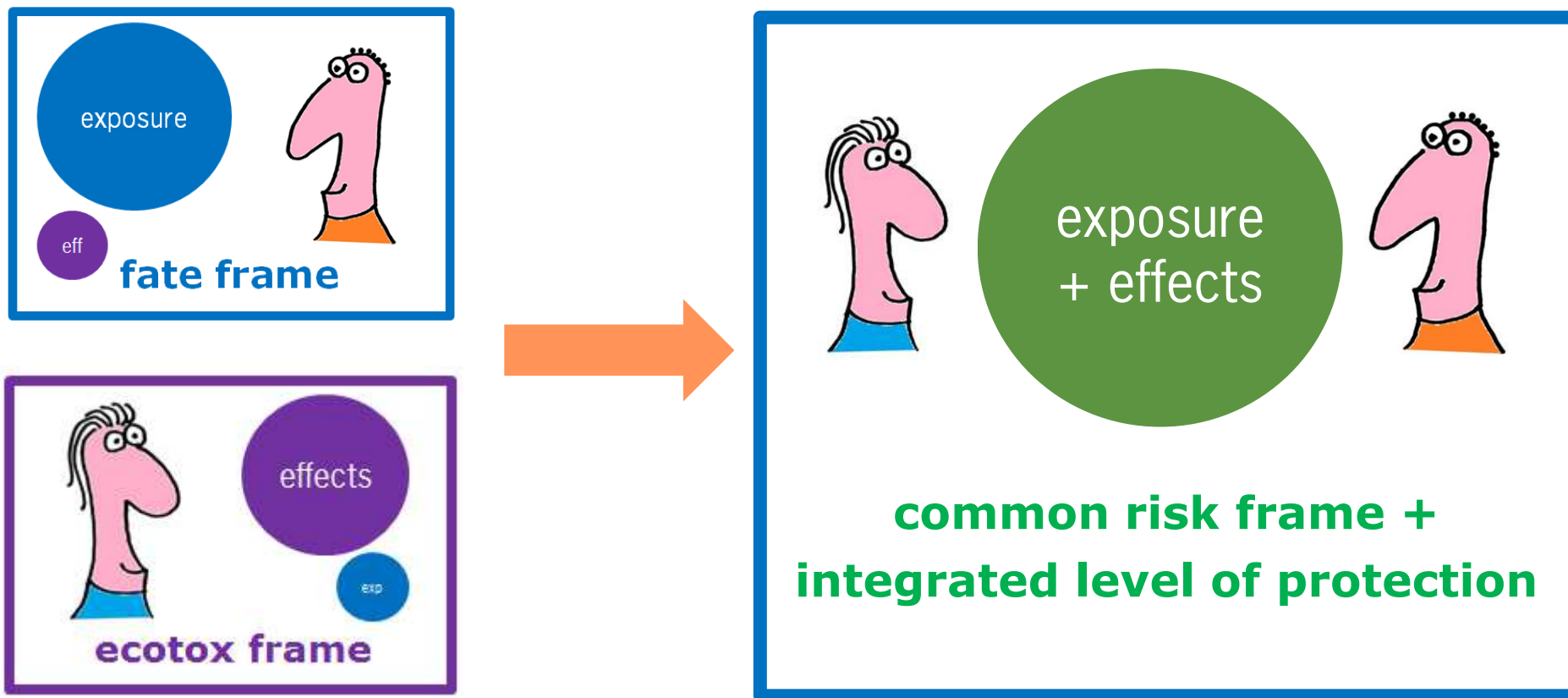
EFSA aquatic guidance:  
effect assessment is only  
fit for purpose for  
permanent water bodies

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

Dutch exposure WG still has  
to redo scenario selection  
based on only permanent  
ditches .....

# Coherent exposure and effect assessments goals: *how to overcome ?*

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# Coherent exposure and effect assessment goals: *how to overcome ?*

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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

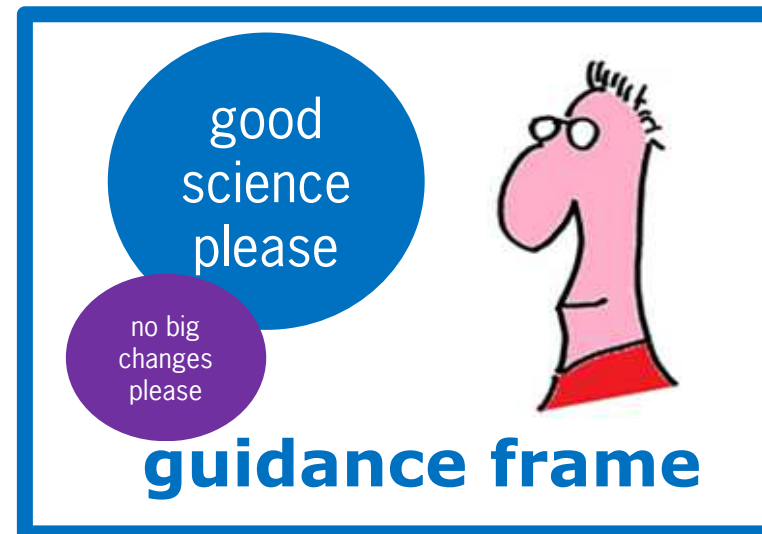
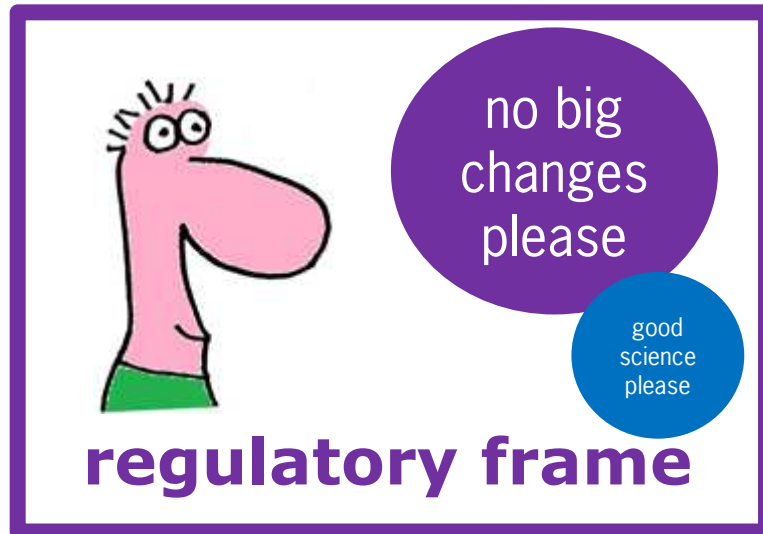
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# Overcoming regulatory resistance to scientific improvements: *challenge description*

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





# Overcoming regulatory resistance to scientific developments: *history/background*

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## 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*

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- 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 ?*

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- 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

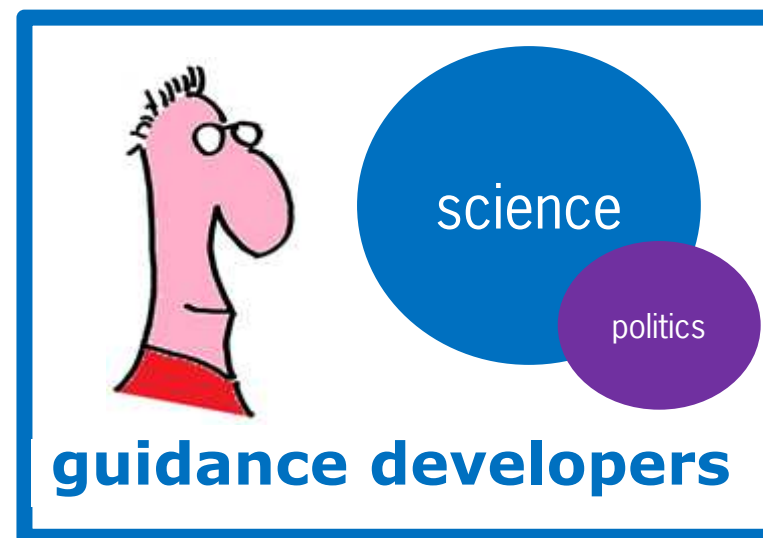
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# Communication between risk managers and guidance developers: *challenge description*

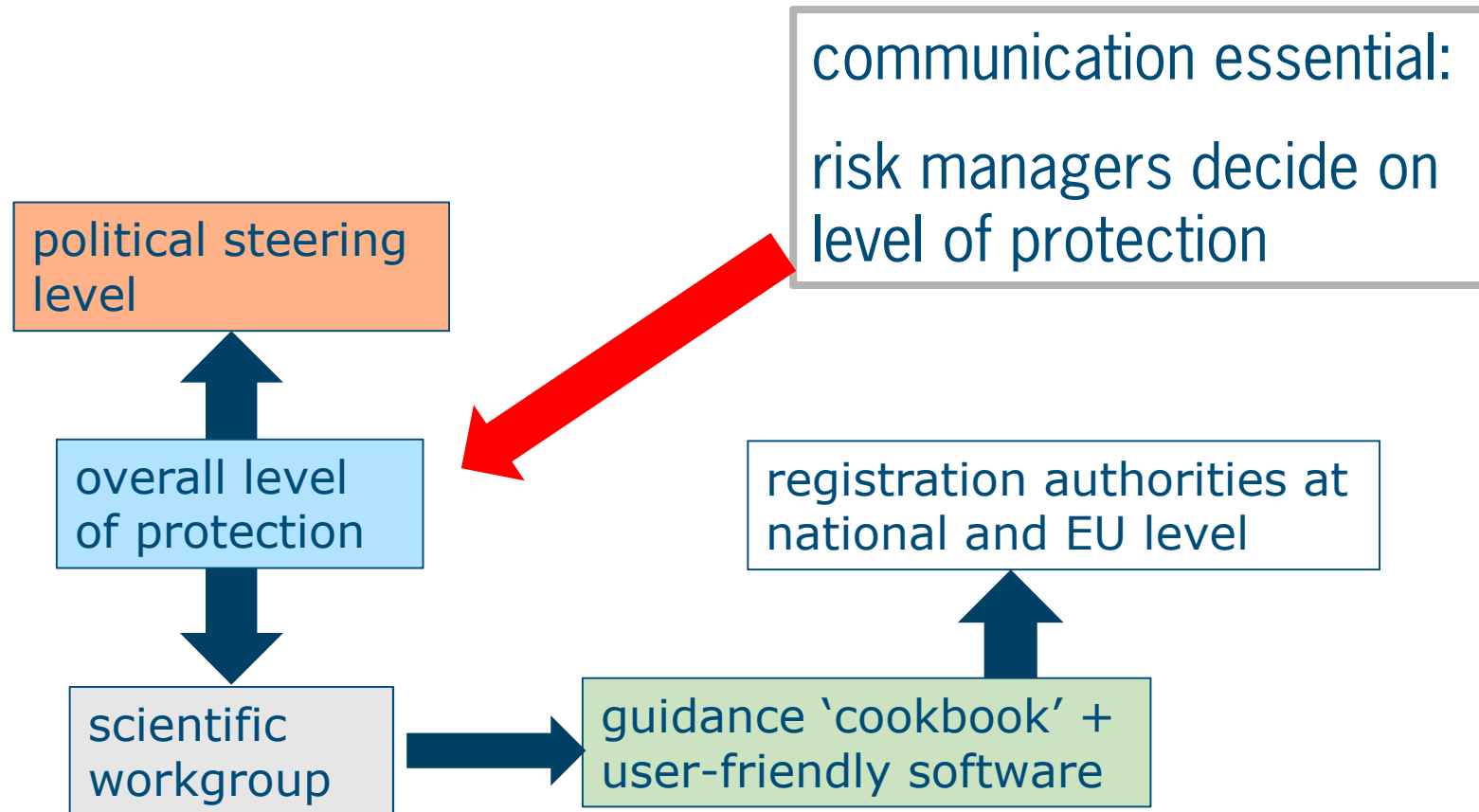
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- risk managers and guidance developers live in different frames



# Communication between risk managers and guidance developers: *challenge description*

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# Communication between risk managers and guidance developers: *background*

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- 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 ?*

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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:

Element	Type of language
Description of SPG – EAG combinations	Scientific
Overall level of protection (qualitative)	Political
Consequences for registration (how many pesticides will pass ?)	Political





# Communication between risk managers and guidance developers: *how to overcome ?*

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level of protection in  
RM/political language



Scientific definition of  
SPGs and EAGs



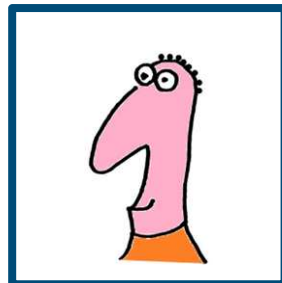
communication gap  
to be bridged by  
offering to RM  
options that do  
work scientifically:



# Conclusions

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- 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 linked 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 !



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Thank you for your attention !

