Umwelt Bundesamt

Für Mensch & Umwelt

Lages, 27.07.2015

Environmental Risk Assessment of Plant Protection Products

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German Federal Environment Agency (UBA), IV 1.3

Environmental Risk Assessment of Plant Protection Products

structure

Environmental Risk Assessment of Plant Protection Products (PPP ~ pesticides)

I) Current regulatory situation

II) Introducing protection goals

III) Tasks for different authorities in Europe

IV) Risk assessment principles, how are risks resulting from pesticide use identified? From lower to higher tier assessment steps

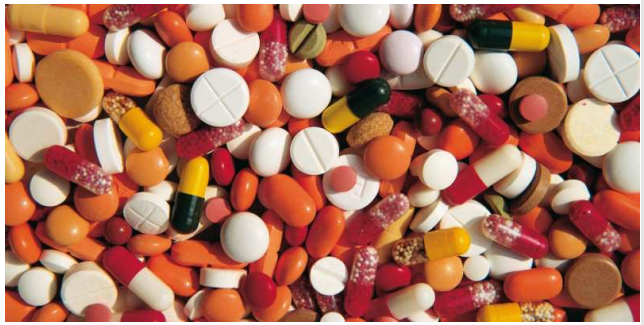
V) Why it is important to assess the risk form formulated PPP

I) regulatory background

Why specifically regulate pesticide use?

Chemicals:
REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) is the European Community Regulation on chemicals and their safe use

Human Pharmaceuticals, Veterinary drugs:
Regulation (EC) No 726/2004



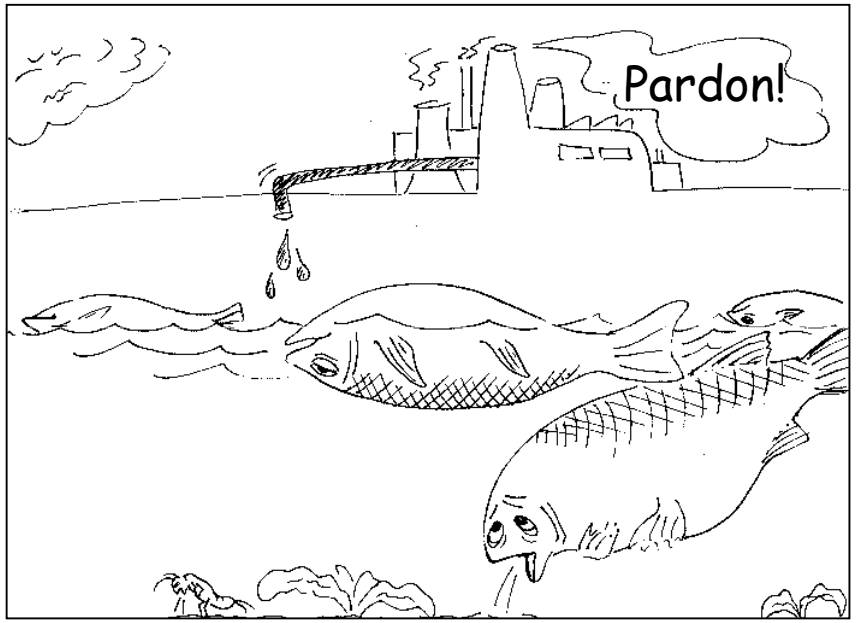
Detergents:
Regulation (EC) No 648/2004

Biocides:
Regulation (EU) No 528/2012

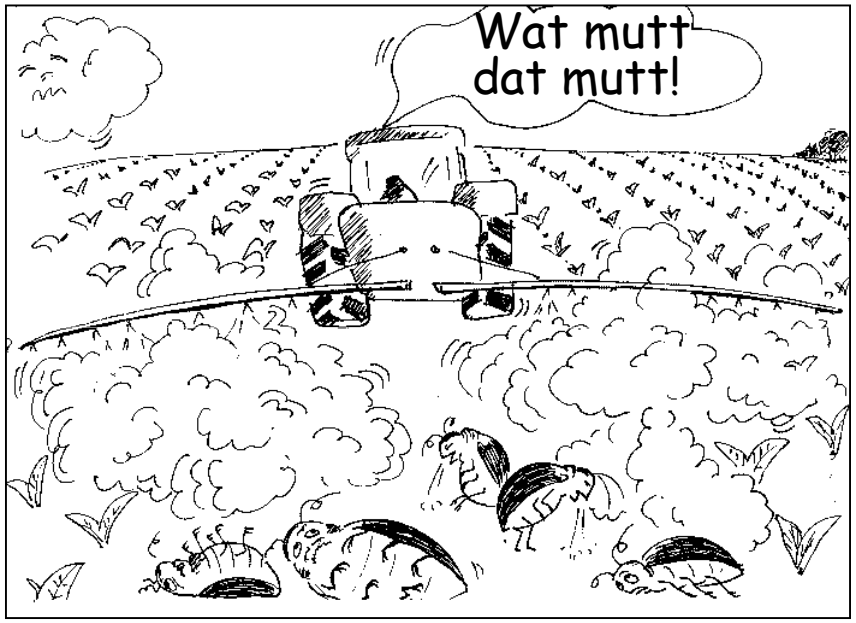
Plant Protection Products:
Regulation (EC) No 1107/2009

Why specifically regulate pesticide use

Chemicals



Pesticides



→ Pesticides are released in the (agricultural) environment **on purpose**, with the aim of controlling (pest) organisms populations

Why regulate specifically pesticide use

Statistics regarding PPP use in Germany

	absolute	*percentage*
Land cover DE	357 031 km²	—
Land use (agriculture)	120 455 km² [a]	34 %
Set aside area (% of agricutultual land)	—	ca. 2 % [a]
→ Area on wich PPP are used (DE)	117 931 km²	**33 %**
Amount of PPP-substances sold (DE)	46 000 t × a^{-1} [b]	
→ PPP active substances used (DE)	**3,9 kg × ha^{-1} × a^{-1}** [c]	—

[a] without grassland http://epp.eurostat.ec.europa.eu, agricultural census 2010
[B] BVL, 2013
[c] im wine ca. 30 kg /ha

Why regulate specifically pesticide use

→ **Effective against living organisms**

→ **Applied on purpose on a relevant share of the (terrestrial) habitat area / in relevant amounts in the treated areas**

Development of the market

→ **Pesticide sales increased worldwide by289% between 2000 and 2010**

→ **"The emerging agricultural powerhouse is in South America. Brazil, already one of the world's most potent agricultural producers, is expected to post growth well above the regional average, which itself is substantially faster than the global growth average."**

→ **"Brazil became in 2008 the world's top consumer of agriculture pesticides (ahead of the US)" (Worldwide Crop Chemicals 2012)**

Legislation

European level

**REGULATION (EC)
No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 21 October 2009
concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC**

considered

At Member States (MS) level e.g. Germany

Gesetz zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz – PflSchG)

Ausfertigungsdatum: 06.02.2012

Requirements and conditions for approval for pesticides

a) it shall be sufficiently effective;

b) it shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects .... or on groundwater;

c) it shall not have any unacceptable effects on plants or plant products;

d) it shall not cause unnecessary suffering and pain to vertebrates to be controlled;

Requirements and conditions for approval

e) it shall have no unacceptable effects on the environment, having particular regard to ..

(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;

(ii) its impact on non-target species, including on the ongoing behaviour of those species;

(iii) its impact on biodiversity and the ecosystem.

Requirements and conditions for approval

e) it shall have no unacceptable effects on the environment, having particular regard to its impact on biodiversity and the ecosystem.

Definitions in 1107/2009

→ 'environment' means waters (including ground, surface, transitional, coastal and marine), sediment, soil, air, land, wild species of fauna and flora, and any interrelationship between them, and any relationship with other living organisms

Requirements and conditions for approval

e) it shall have no unacceptable effects on the environment, having particular regard to its impact on biodiversity and the ecosystem.

(© Jason Hawkes)

Requirements and conditions for approval

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(© reuters)

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Definitions in 1107/2009

→ 'biodiversity' means variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems

Protection Goals

For pragmatically reasons, the assessment of the risk possibly posed by the use of pesticide (e.g. PPP) is performed

→ **By defining ‘groups’ of so called 'non-target organisms' (e.g. birds, aquatic organisms, mammals etc.)**

- **for which representative surrogates are tested**
- **for which it is possible to define exposure scenarios**

→ **By exactly defining the intended uses**

→ **By extrapolating to the overall protection goal by means of assessment factors**

Protection Goals

For pragmatically reasons, the assessment of the risk possibly posed by the use of pesticide (e.g. PPP) is performed by addressing groups of organisms exposed as a result of the intended uses of the pesticide

→ **The specific assessment of 'non-target organisms' in the different risk assessment schemes should not mislead over the fact that the protection goals are understood in a broader sense!**

II)

Protection Goals

How to define Protection Goals that are more precise?

→ **In Europe, remit of the European Food Safety Authority (EFSA)**

→ **Specific Protection Goals (SPG) are defined for the traditionally assessed groups of organisms**

→ **SPG shall help in defining precisely what to protect, when, to which extent…. More in the presentation this afternoon**

II)

Protection Goals

Definition of Specific Protection Goals

- → **According to the methodology of the Millennium Ecosystem Assessment (2005)**
- → **As a tool to clarify the monetary values of processes and structures in ecosystems, a 'new' concept is introduced: *ecosystem services***
- → **Ecosystem services are delivered by ecosystems and are valuable to mankind ('food', 'clean water' 'soil formation')**

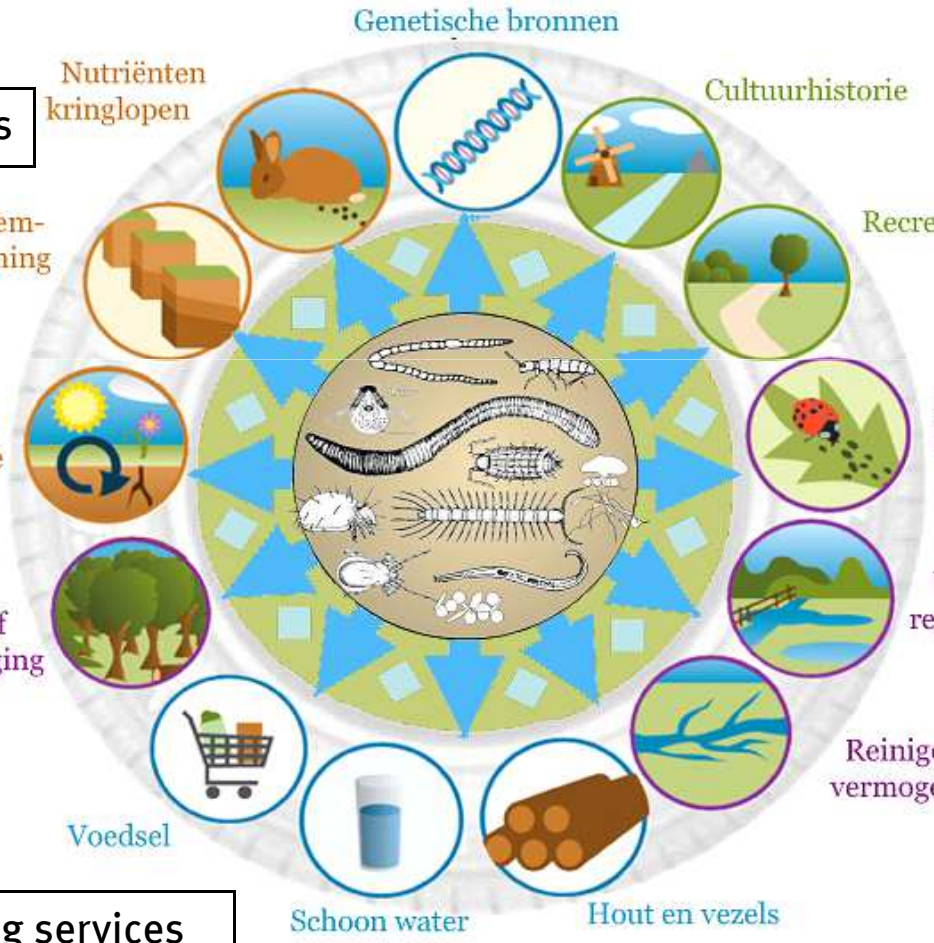
II)

Protection Goals

Ecosystem Services according to Millenium Ecosystem Assessment	
Provisioning services	Food , Fiber Genetic resources Biochemicals, natural medicines, pharmaceuticals Fresh water
Regulatory services	Air quality regulation, Climate regulation Water regulation, Erosion regulation, Natural hazard regulation Water purification and waste treatment Disease regulation, Pest regulation Pollination
Cultural services	Cultural diversity, Spiritual and religious values Educational values, Inspiration, Aesthetic values Social relations, Sense of place Recreation and ecotourism
Supporting services	Soil formation Photosynthesis, Primary production Nutrient cycling, Water cycling

II)

Protection Goals



Supporting services

Cultural services

Regulatory services

Provisioning services

(Rutgers et al. 2011)

III) Task for the different authorities

Data packages

one PPP dossier

III) Task for the different authorities

Data packages

COMMISSION REGULATION (EU)
No 283/2013
of 1 March 2013
setting out the data requirements
for active substances,
in accordance with Regulation (EC)
No 1107/2009 of the European
Parliament and of the Council
concerning the placing of plant
protection products on the market

Data requirements active substance

1. Identity of the active substance
2. Physical and chemical properties of the active substance
3. Further information on the active substance
4. Analytical methods
5. Toxicological and metabolism studies
6. Residues in or on treated products, food and feed
7. **Fate and behaviour in the environment**
8. **Ecotoxicological studies**
9. Literature data
10. Classification and labelling

III) Task for the different authorities

Approval of active substances at EU level

Peer reviewed, joint assessment of active substances (a.s.) in the European Union

→ Aim is to harmonize the assessment criteria and the market in the EU

Assessment is based on Legislation 1107/2009

→ The authorization of PPP with the active substace assessed is possible only if the a.s. is approved in the EU (positive list!)

→ Renewal of authorization every 10 years

III) Task for the different authorities

Approval of active substances at EU level

Up to now: decision based on the outcome of the risk assessment

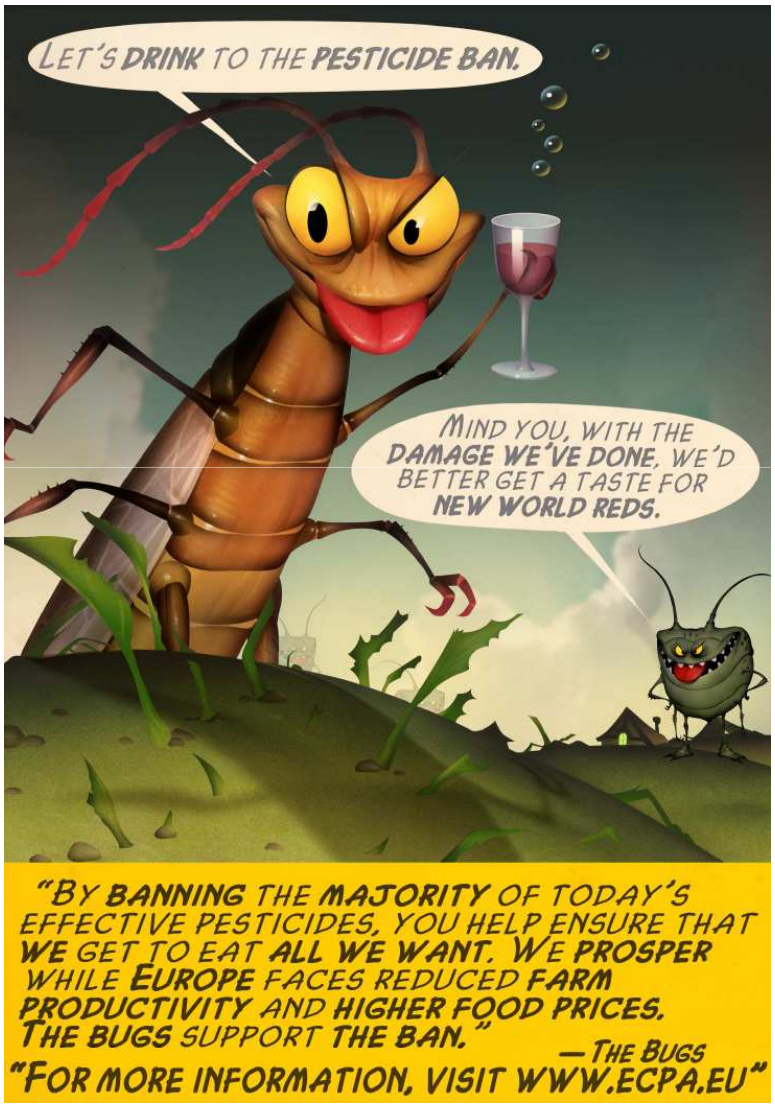
In future (1107/2009): hazard assessment bevore risk assessment:

- → **Mutagenic (M) cat. 1 od. 2**
- → **Carcinogenic (C) cat. 1 od. 2***
- → **Toxic for reproduction (R) cat. 1 od. 2***
- → **endocrine disruptor for humans (EDs)***
- → **endocrine disruptor for non target organisms***
- → **POPs**
- → **PBT**
- → **vPvB**

*** if exposure not negligible**

III) Task for the different authorities

Approval of active substances at EU level

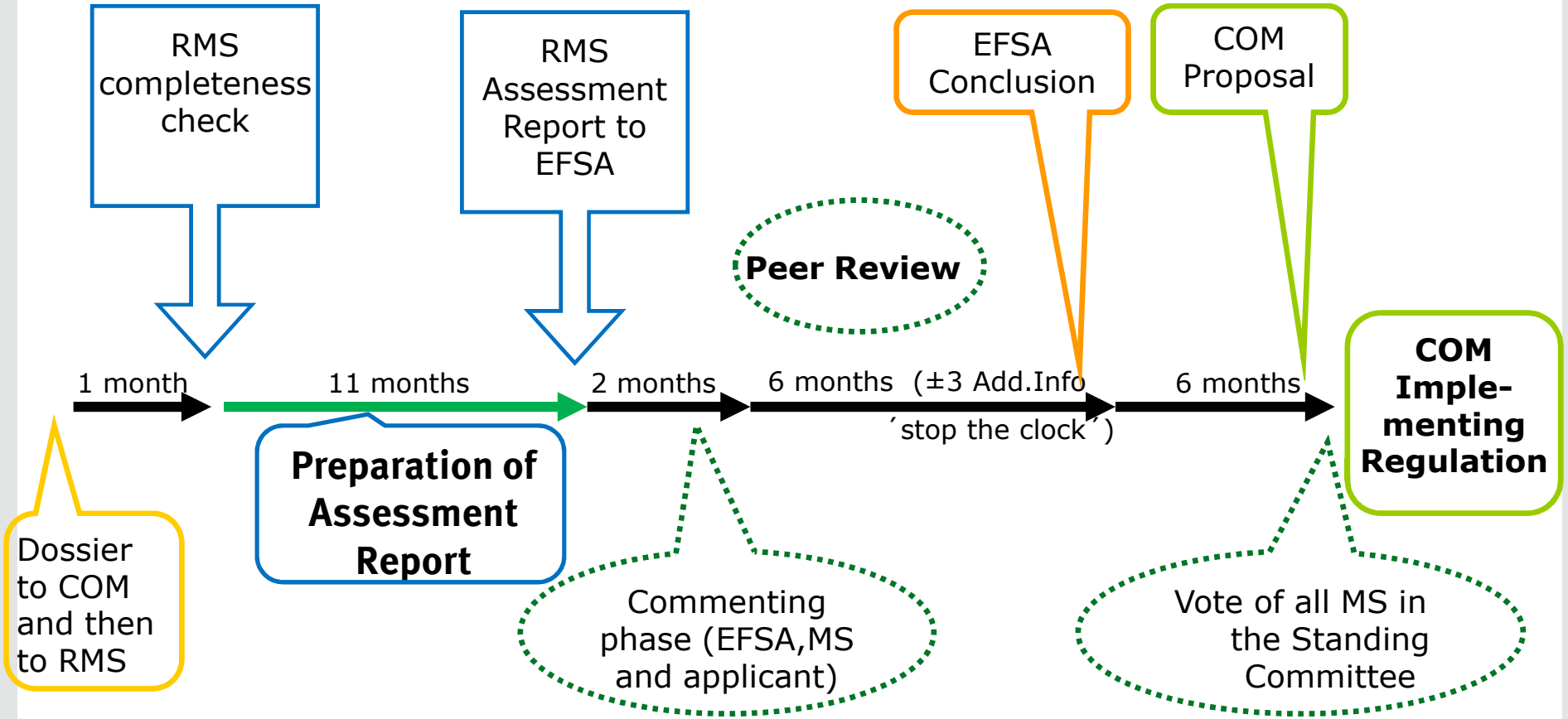


→ **The decision of having an hazard screening of active substances bevore risk assessment (cut off criteria) was preceded by a very controversial debate**

III) Task for the different authorities

Approval of active substances at EU level

Peer reviewed, joint assessment of active substances (a.s.) in the European Union



III) Task for the different authorities

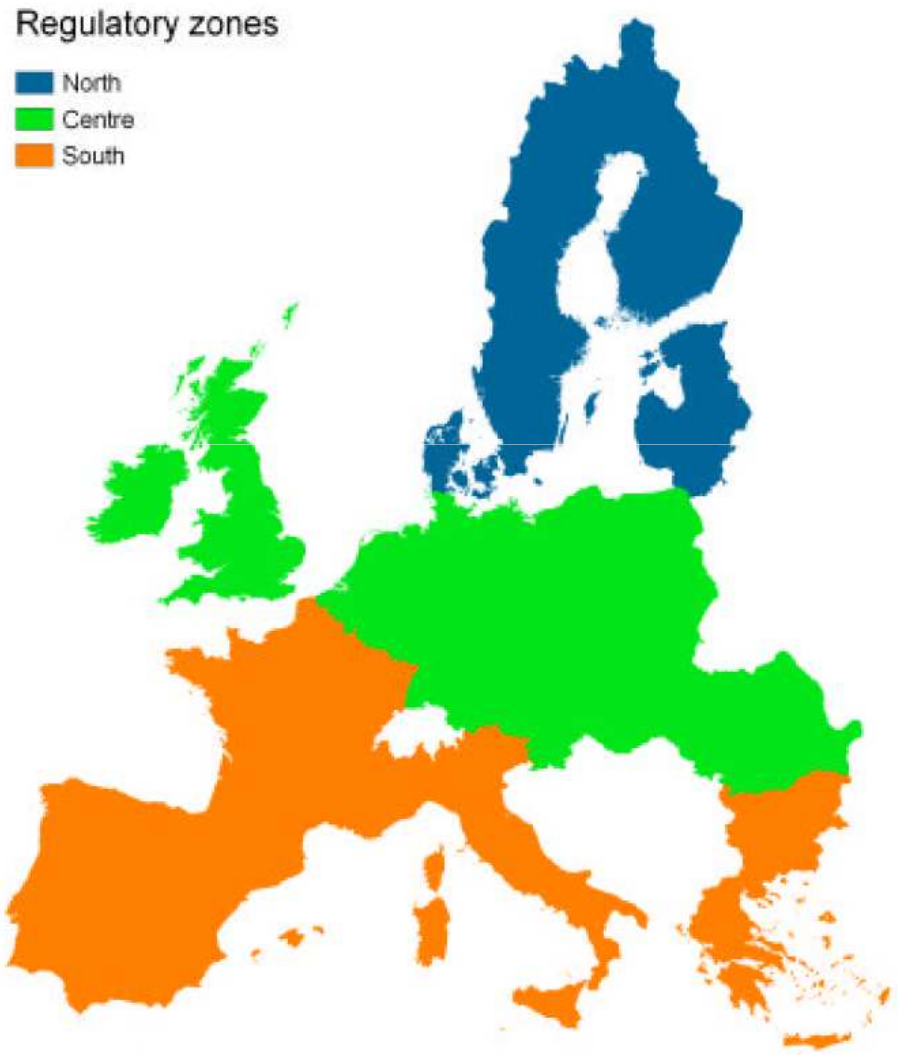
Authorization procedure for PP Products (!)

Zonal registration

according to EU 1107/2009

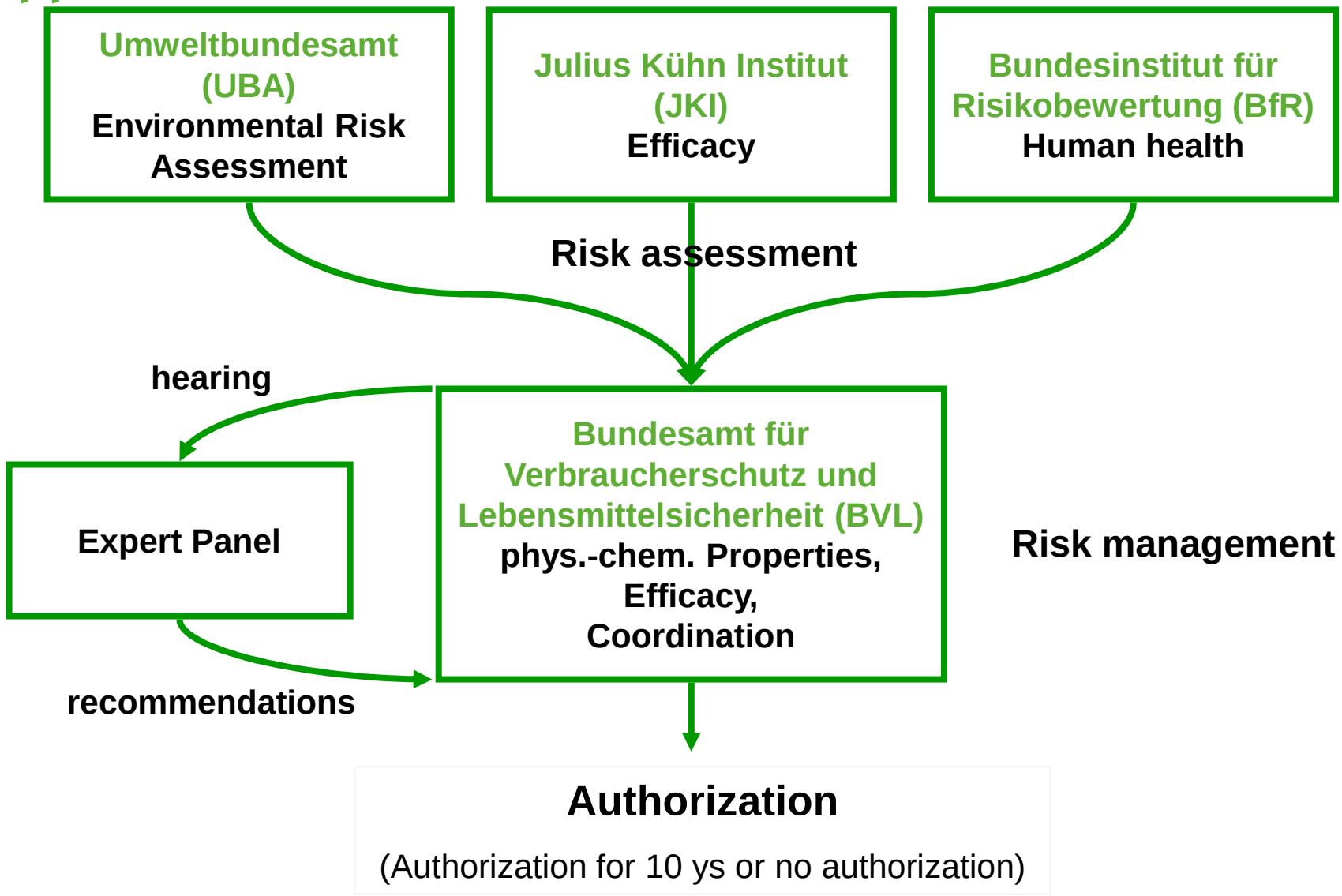
→ **Zonal Authorisation (1 Rapporteur, some co-Rapporteurs)**

→ **National Authorisation / Mutual Recognition**



III) Task for the different authorities

Approval of Substances / Authorization of PPP



Risk assessment

An acceptable risk for the environment is indicated if

1) In theory

$$\frac{\text{'real effect threshold'}\ ^{a}}{\text{exposure}} > 1$$

2) In the risk assessment practice

$$\frac{\textbf{measured}\ \text{ecotoxicological endpoint}\ ^{b}}{\text{exposure}} > \textbf{assessment factor}^{c}$$

[a] effect threshold for effects on populations
[b] e.g. LC50, NOEC, ECx...
[c] syn. Trigger value, acceptability criteria, safety factor..

Risk assessment

Assessment factor is specific for the organisms group evaluated

Toxicity to Exposure Ratio (TER)

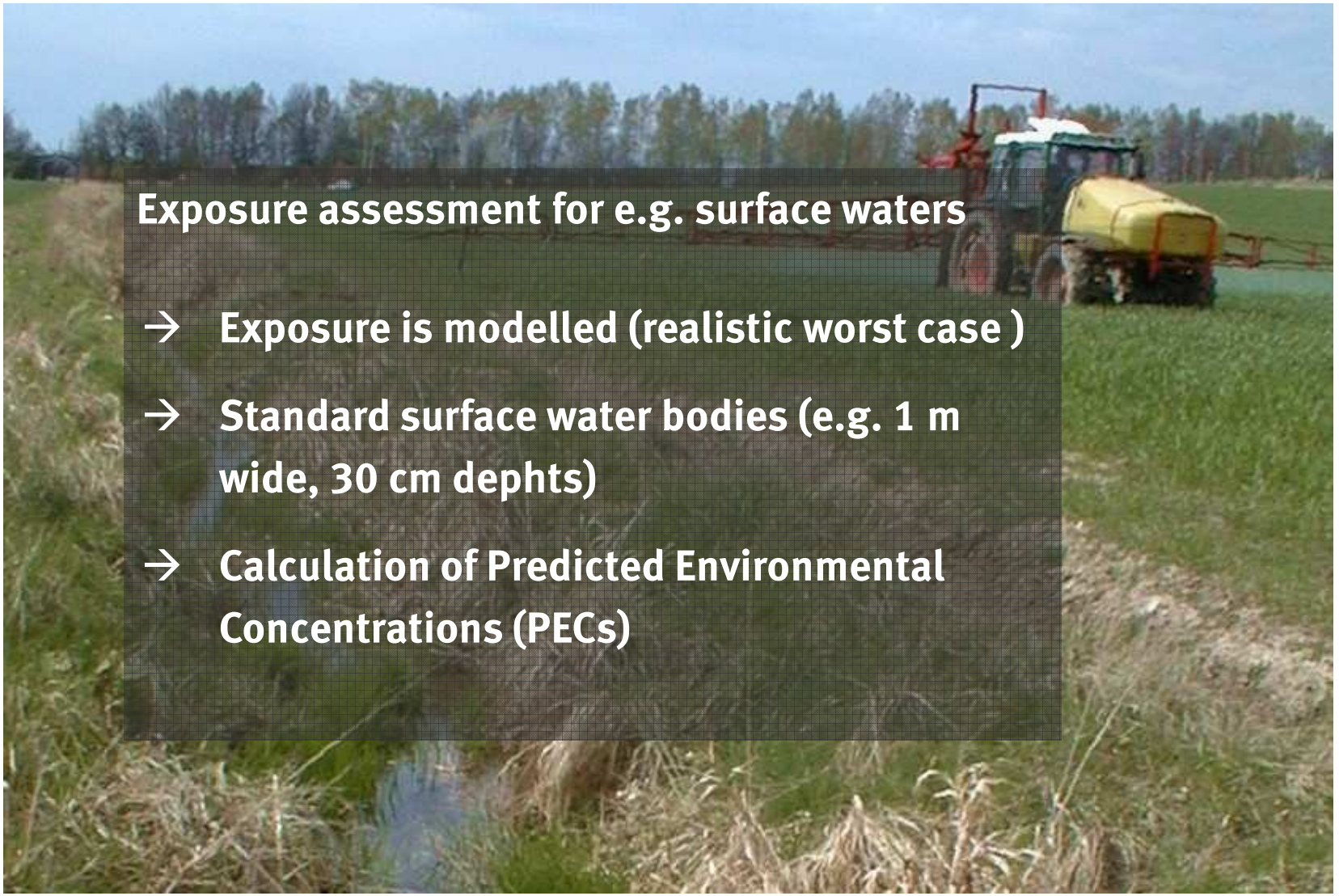
$$TER = \frac{\textbf{measured}\ \text{ecotoxicological endpoint}}{\text{exposure}} \rightarrow \textbf{assessment factor}$$

separated assessment for

→ **Short time exposure / acute toxicity**

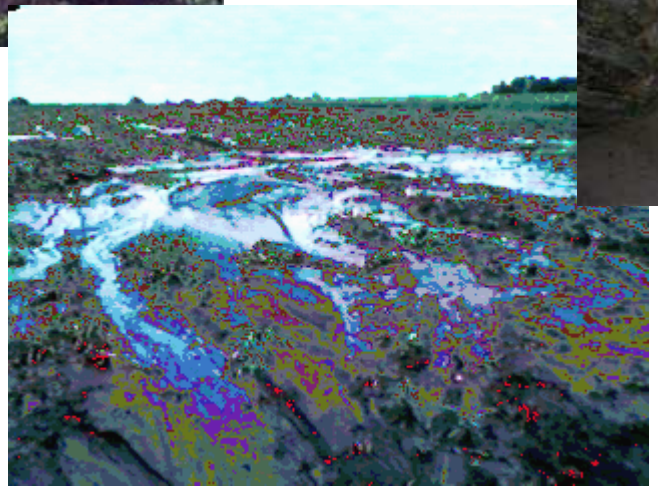
→ **Long term or repeated exposure / chronic toxicity**

Risk assessment : exposure



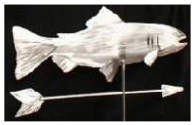
Risk assessment: exposure

Possible exposure routes



IV) Risk assessment principle

Risk assessment: ecotoxicological tests (e.g. aquatic)

assessment endpoints  **data required (e.g. for a fungicide)**

Effects on aquatic organisms

8.2.1.	acute toxicity for fish →	acute toxicity test with e.g. trout
8.2.2.	chronic toxicity for fish →	chronic toxicity test with fish
8.2.3.	bioconcentration in fish →	bioaccumulation in a fish species
8.2.4.	acute toxicity for invertebrates →	acute toxicity test with daphnid (*Daphnia* spp.)
8.2.5.	chronic toxicity for invertebrates →	chronic toxicity test with daphnid (*Daphnia* spp.)
8.2.6.	effects on algae growth →	growth test with an green algae
8.2.7.	effects on sediment dwellers →	chronic test with chironomid larvae in a water sediment system [1]
8.2.8.	[higher] water plants →	growth test with *Lemna* spp. [2]

[1] only a.s. accumulates in the sediment | as additional species [2] only for herbicides (incl. 2. algae)

Risk assessment: Toxicity to Exposure Ratio (TER)

Species / Test duration	*Endpoint*		*Value*	***Assessment factor***	
Oncorhynchus acute, 4 d	Mortality	LC50	10 µg/L	100	
Daphnia, 2 d	Immobilization	EC50	1 µg/L	100	
Scenedesmus, 3 d	Population Growth	EC50	0,5 µg/L	10	

Wich organisms group does drive the risk characterizationf for acute short term exposure?

Risk assessment: Toxicity to Exposure Ratio (TER)

Given an exposure of aquatic organisms
by a predicted environmental concentration (PEC) of 0,1 µg/L

TER calculation would be as follows:

$$\text{TER} = \frac{\text{Ecotox-Effect Value}}{\text{Exposure}} = \frac{\text{LC50}_{\text{Daphnia}}}{\text{PEC}} = \frac{1\ \mu g/L}{0{,}1\ \mu g/L} = \mathbf{10}$$

Is the risk indicated by the given values acceptable?

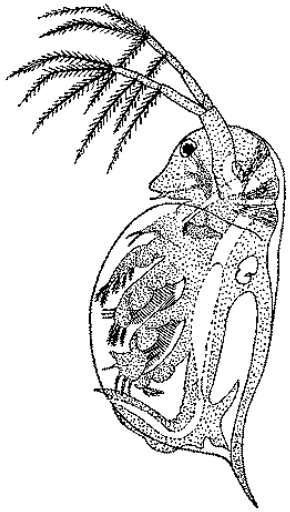
No – relevant assessment factor acute effects is 100

Risk assessment: sources of uncertainties

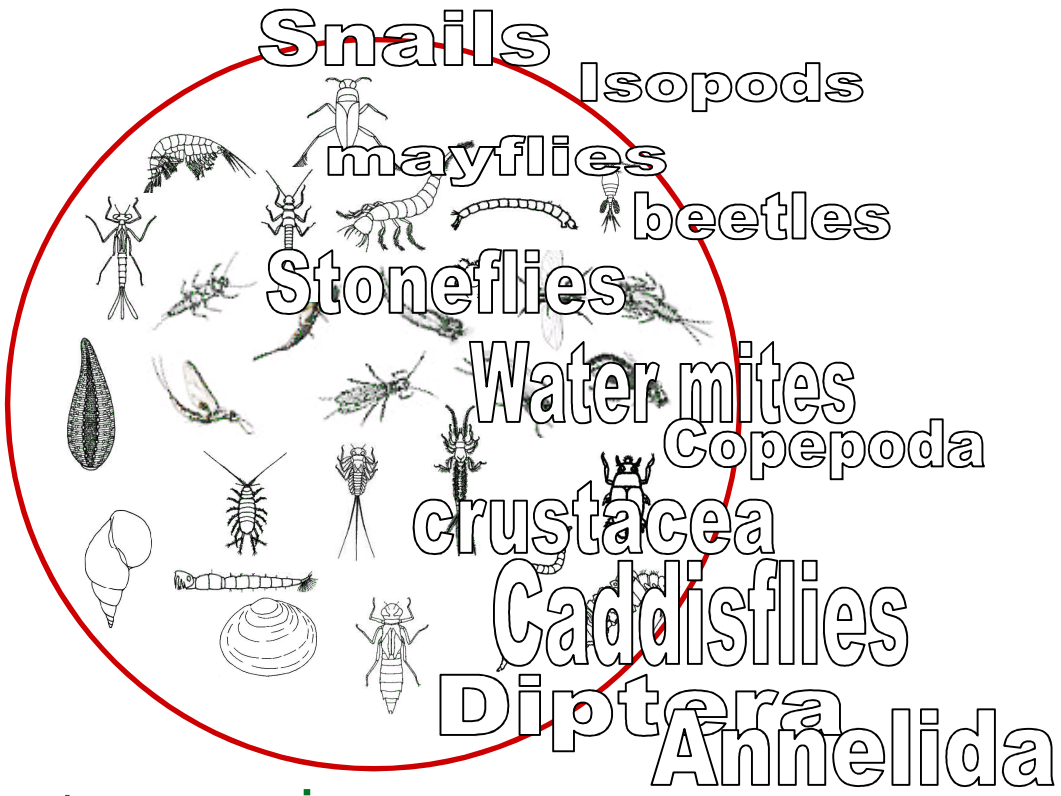
Extrapolation
„from lab to field“

Risk assessment: sources of uncertainties

tested



to protect



→test surrogate species

Risk assessment: sources of uncertainties

(1) Intra- and inter-laboratory variation of toxicity data

(2) Intra- and inter-species variation of toxicity data

(3) Short-term to long-term/chronic toxicity extrapolation

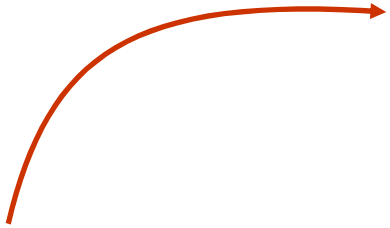
(4) Extrapolation of mono-species laboratory data to field impact on ecosystems

- more sensitive lifestages
- more sensitive endpoints
- delayed effects
- contaminated food source
- increase in effect by co-stressors
- exposure to mixtures
- amplification by interspecific competition (shift in coenosis composition)
- if recovery is considered: Species with a lower recovery potential

Risk assessment: adressing uncertainties

If an unacceptable risk is indicated by the TER calculation (Value below the assessment factor), then....

Risk unacceptable



Higher Tier

- Higher Tier tests
- less standardized, more expensive
- changed safety factors

Tier 1

- Standard Lab tests
- Standard safety factors
- fast and (relatively) cheap

Risk assessment: refinement and management

More realistic effect assessment

→ **higher tier tests (e.g. with mesocosms)**

More realistic exposure assessment

Inclusion of risk management options to reduce the risk

→ **Lower exposure through better techniques**

→ **management options regarding intended use (e.g. amount to be used, repeated applications, time of application)**

→ **Buffer strips to aquatic bodies or to terrestrial non-target habitats**

Inert formulants in PPP?

Data requirements for active substances clearly more comprehensive

Data requirements for products are sometimes rather vague – e.g. aquatic environment

next to singular acute tests

→ **"....additional studies [...] may be required for particular PPP where it is not possible to extrapolate from data obtained in the corresponding studies on the active substance"**

Inert formulants in PPP?

Example: Glyphosate as active substance and in formulated products

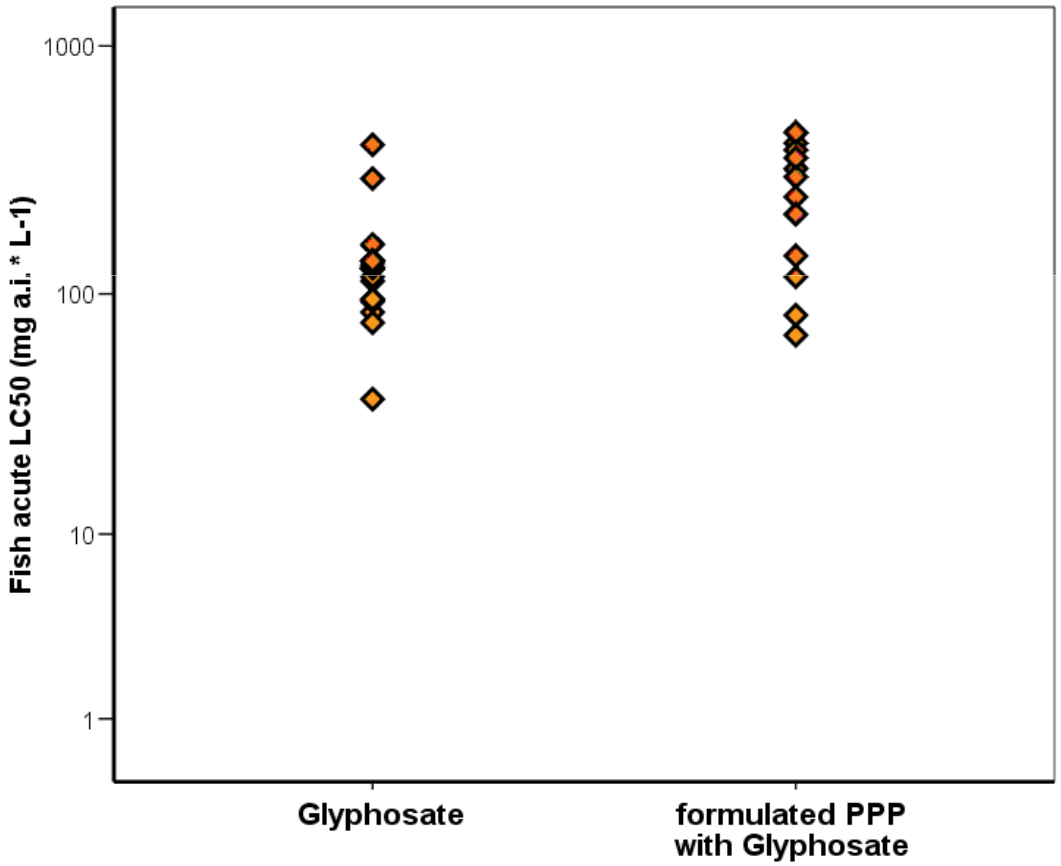
→ **diverging properties of active substance and formulants**

→ **availability of data**

→ **widespread use and questioned for unacceptable acute and long-term environmental effects**

Inert formulants in PPP?

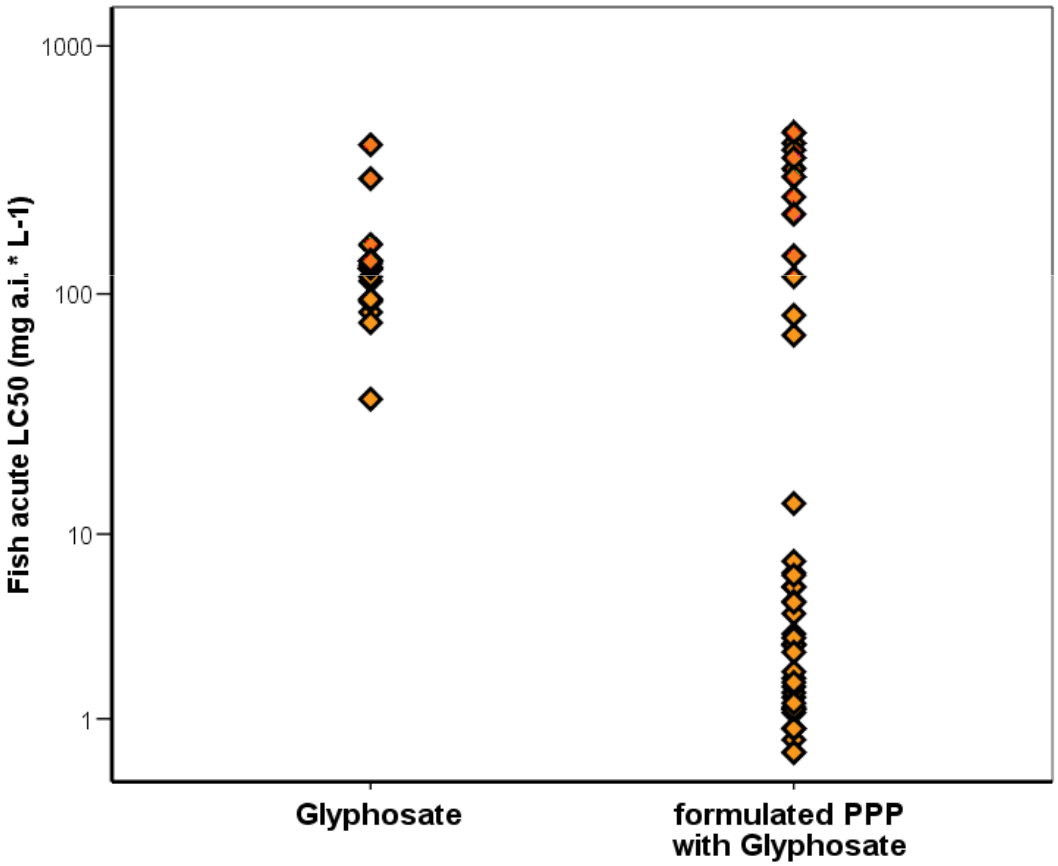
Example: Glyphosate as active substance and in formulated products



→Good match

Inert formulants in PPP?

Example: Glyphosate as active substance and in formulated products

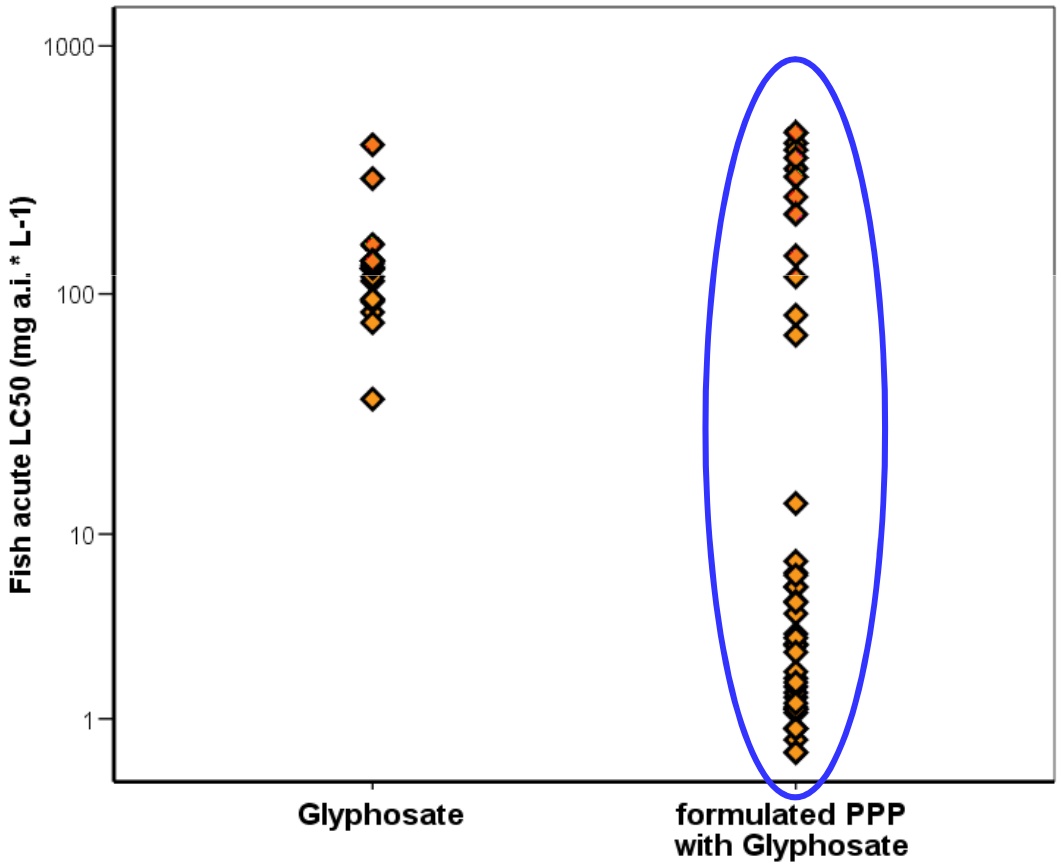


→Good match only for some products

→Some PPP clearly more toxic than others

Inert formulants in PPP?

Example: Glyphosate as active substance and in formulated products



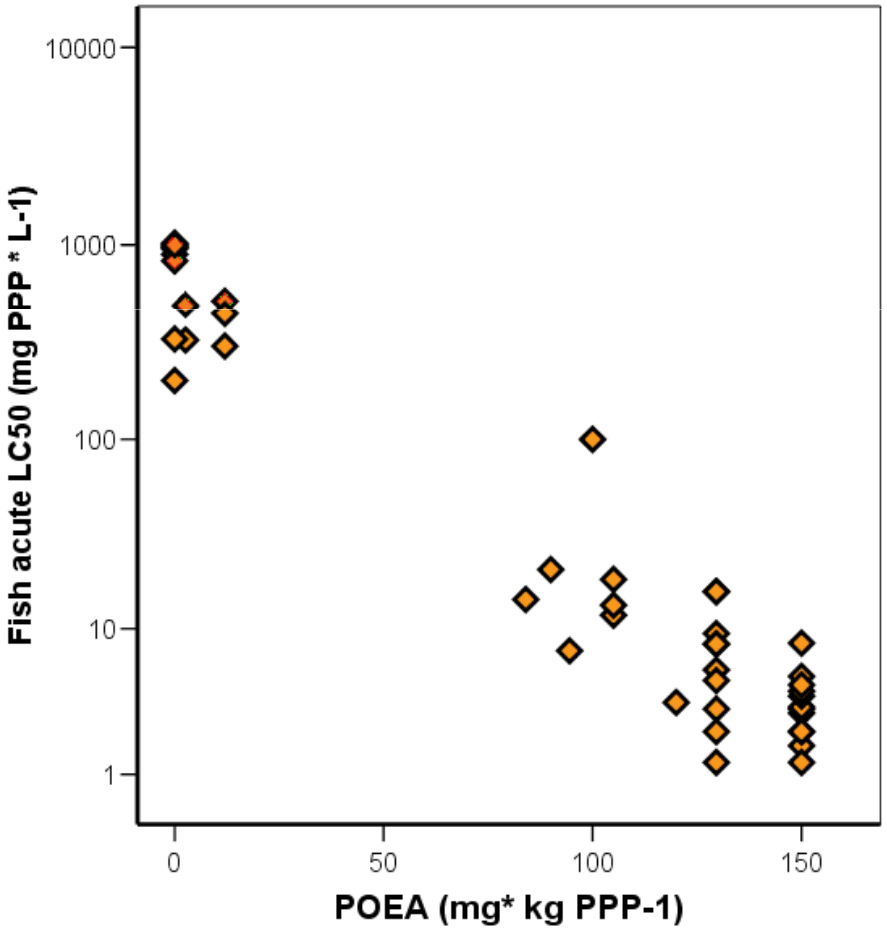
→Good match only for some products

→Some PPP clearly more toxic than others

→Is it possible to sort this out?

Inert formulants in PPP?

Example: Glyphosate as active substance and in formulated products

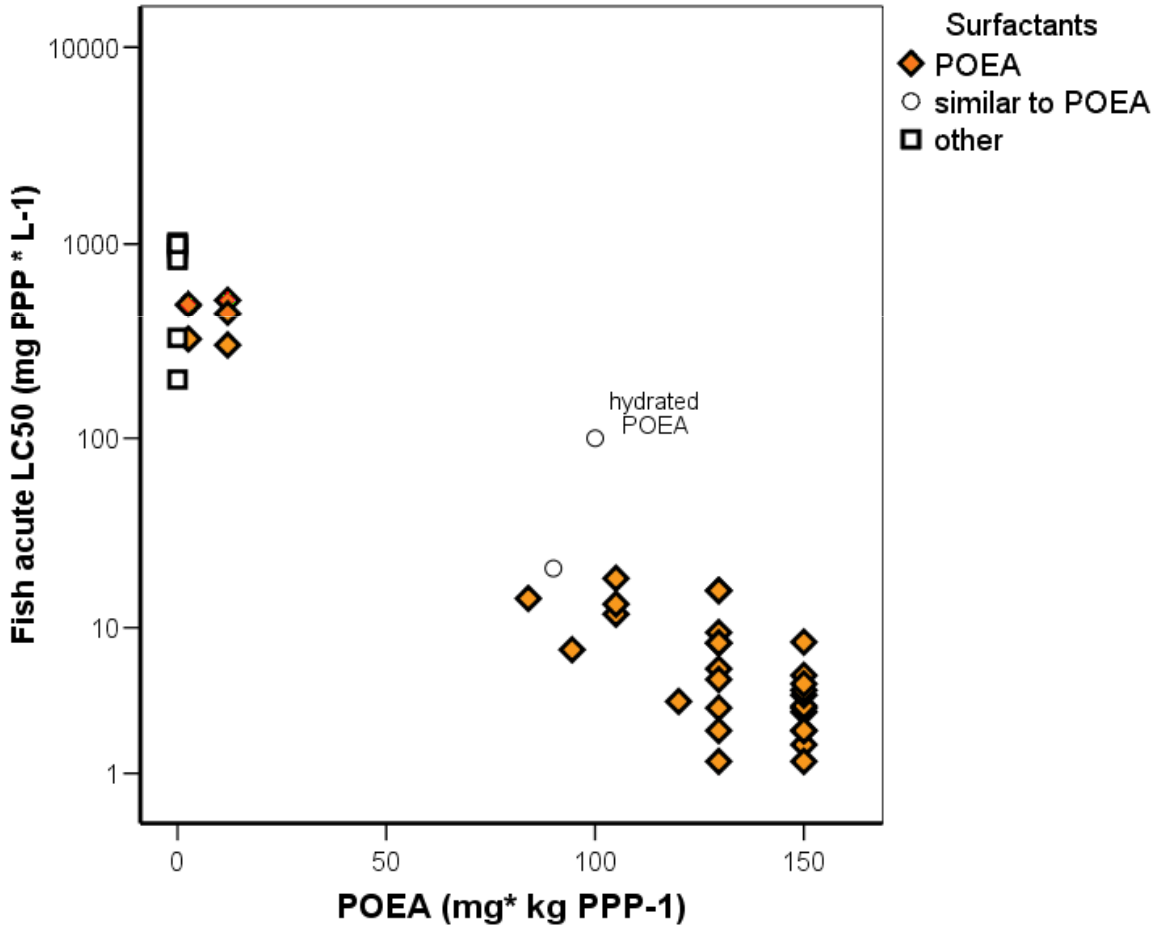


→Some PPP containing a specific surfactand group clearly more toxic than others

→Toxicity was plotted against the amount of the surfactant group 'alkylamine ethoxylates'

Inert formulants in PPP?

Example: Glyphosate as active substance and in formulated products



→Toxicity can be predicted along with the 'surfactant class'

→Alkylamine ethoxylates (POEA) in PPP are not allowed anymore in Germany (phased out)

Inert formulants in PPP?

- → **It is possible to ask for the substitution of very toxic surfactants from PPP and other products**
- → **It is possible to request specific data on formulants in a tiered approach without 'treating them as active substances' and 'sacrifice test organisms'**
- → **Unifying principles can only be seen if all available data is analyzed**
- → **New legislation will reform the listing of formulants ('unacceptable formulants')**
- → **Detection bias towards low toxicity active substances in PPP with and high toxicity formulants...**

Thank you

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