

How to determine concentrations of hazardous substances tolerable for humans and/or aquatic ecosystems

Dr. Ulrike Schuhmacher-Wolz

FoBiG, Forschungs- und Beratungsinstitut Gefahrstoffe GmbH

Freiburg

www.fobig.de

Berlin, 17 June 2015

Hazardous substances

- Xenobiotica
 - E.g. (veterinary) drugs, hormones, sunscreens, cleaning agents, flame retardants, active ingredients and degradation products of PPP, BP,...
- Environmental contaminants
 - (heavy) metals (e.g. Pb, Hg, As, Cr), PAH, ...

Legislation

■ **Drinking water directive (DIRECTIVE 98/83/EC)**

‘Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean.’

- **‘is free ... from any substances which, in numbers or concentrations, constitute a potential danger to human health’**

→ Defence and Precaution

Legislation

- **Water framework directive** (Directive 2000/60/EC)
- ‘Framework for protection of inland surface waters, transitional waters, coastal waters and groundwater which **prevents further deterioration and protects and enhances the status** of aquatic ecosystems and, with regard to their water needs, terrestrial ecosystems and wetlands directly depending on the aquatic ecosystems’

➔ **Defence and Precaution**

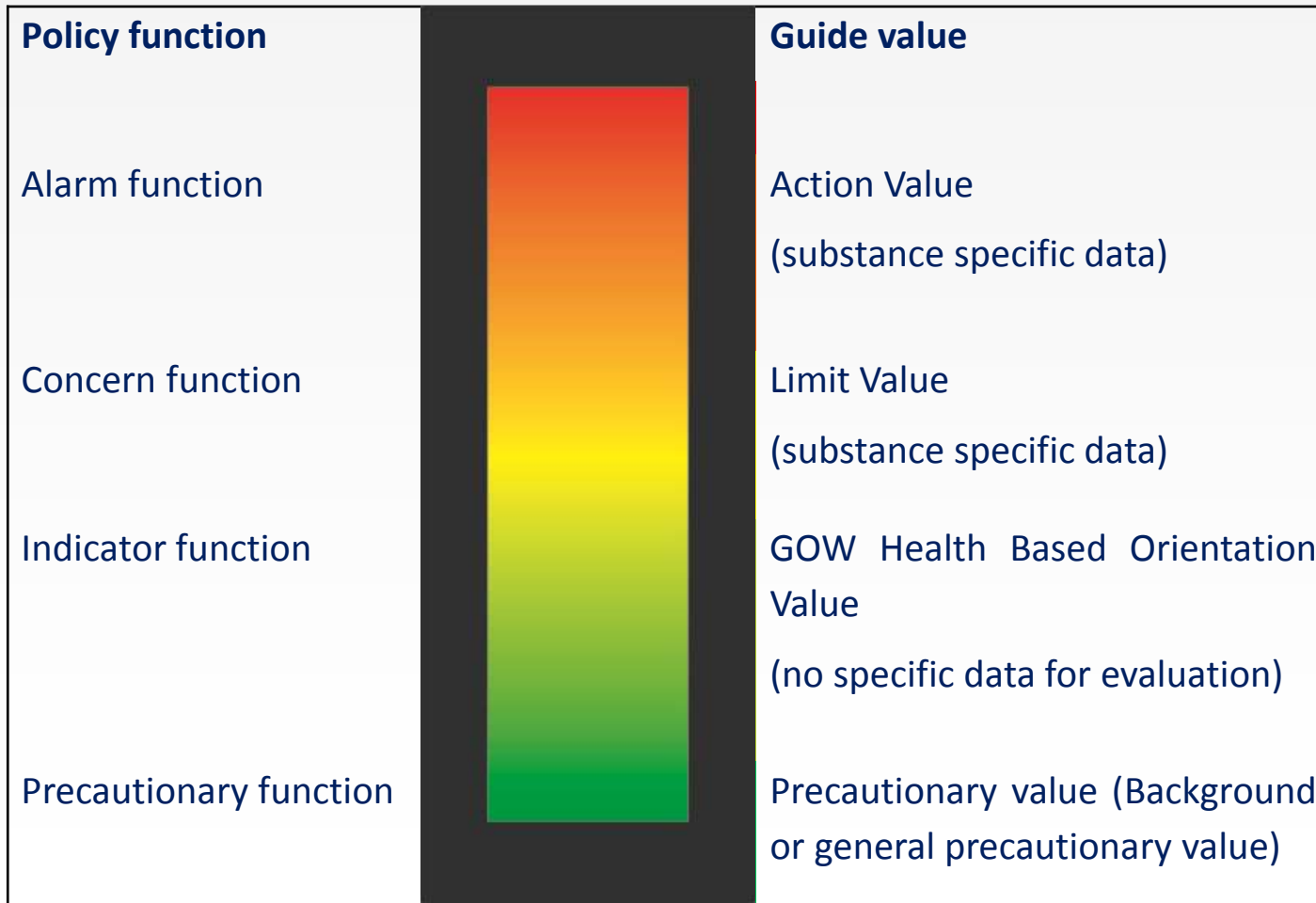
Limit values for water

- Drinking water
 - Ground water
 - Surface water
 - Coastal waters/transitional waters
-
- A) **Legally binding values**
 - B) Non-legally binding recommendations

Legal status of limit values

- DW
 - Limit values of national drinking water regulation
 - GOW Health Based Orientation Values
- GW
 - Limit values of national ground water regulation
 - GFS Negligibility Threshold
- SW
 - EQS Environmental Quality Standards of SW regulation
 - E.g. ICPR (International Commission for the Protection of the Rhine) target values

Hierarchy of DW Values



GOW - DW

- GOW = 0.1 µg/L
 - No / insufficient data for evaluation of human health risk
 - No limit value available

GOW scheme

	Test Strong genotoxic? Yes	Test Weak/not genotoxic? Yes	Immun- and neurotoxicity tested? No	Subchronic toxicity tested? No	Chronic toxicity tested? No	Chronic toxicity tested? Yes
GOW (µg/L)					1.0-3.0	> 3.0
				0.3-1.0		
			0.1-0.3			
		0.01-0.1				
	< 0.01					

Limit values - DW

- Substances with threshold
 - Acceptable/Tolerable Daily Intake (ADI/TDI)
 - NOAEL
 - Assessment factor (100)
 - 10% allocation
 - Consideration of background

- Substances without threshold
 - Aim: 1×10^{-6} additional risk (precautionary principle)

Action Value (AV)

- Time limited exceedance of limit values
 - $AV = IF \times ADI/TDI$
 - Often 10 % allocation

- Permanent not transient exceedance of ADI/TDI might be associated with an increased probability of health risks

Environmental Quality Standards (EQS)

- ‚EQSs should protect freshwater and marine ecosystems from possible adverse effects of chemicals as well as human health via drinking water or ingestion of food originating from aquatic environments.‘
 - Water column (AA-EQS and MAC-EQS)
 - HH via DW
 - Sediment
 - Biota
 - Secondary poisoning of predators
 - Human health via eating fish

Assessment factors for setting EQS

e.g. Freshwater

Available data	Assessment factor
At least one short-term L(E)C50 from each of three trophic levels (fish, invertebrates (preferred <i>Daphnia</i>) and algae) (i.e. base set)	1000 ^{a)}
One long-term EC10 or NOEC (either fish or <i>Daphnia</i>)	100 ^{b)}
Two long-term results (e.g. EC10 or NOECs) from species representing two trophic levels (fish and/or <i>Daphnia</i> and/or algae)	50 ^{c)}
Long-term results (e.g. EC10 or NOECs) from at least three species (normally fish, <i>Daphnia</i> and algae) representing three trophic levels	10 ^{d)}
Species sensitivity distribution (SSD) method	5-1 (to be fully justified case by case) ^{e)}
Field data or model ecosystems	Reviewed on a case by case basis ^{f)}

Data Gaps/Research Needs

- GOW
- EQS
- PMT

GOW - Data Gaps/Research Needs

Substance	GOW ($\mu\text{g/L}$)
Benzotriazole	3.0
Carbamazepine	0.3
Clofibrate	3.0
Diclofenac	0.3
Gabapentine	1.0
Ibuprofen	1.0
Metformin	1.0
Phenobarbital	0.3
Primidone	3.0

Improvement strategies for GOW

- Usage of substance/group specific data
- Usage of information on MRDD (maximum recommended daily dose)
- Usage of information on LTD (Lowest Therapeutic Dose)
- Usage of information on genotoxicity and carcinogenicity
- Usage of considerations on species specific toxicity

EQS - Data Gaps/Research Needs

- Currently no EQS for drugs
 - No routine monitoring
 - Watchlist: EE2, E2, E1, diclofenac, macrolide antibiotics
 - > 2500 drug active ingredients
 - Commission strategy on the prevention of water pollution by drugs announced for 2015
 - Do we need a monitoring campaign to identify problematic (veterinary) drugs or their metabolites?
 - Do we need additional EQS for (veterinary) drugs?
- Biota EQS – do they cover all relevant PBT-Substances
 - E.g. no Biota EQS for e.g. pentachlorobenzene
 - Does REACH or other PBT evaluations point to relevant substances?

PMT substances - Data Gaps/Research Needs

- PMT properties –
 - **P**ersistent
 - **M**obile
 - **T**oxic

- identification of relevant substances in raw water/drinking water
- ? Monitoring program for identification
- ? Regulatory measures

Summary and Conclusions

- Existing limit values are protective for human health and aquatic ecosystems.
- Exceedance of limit values for a certain period of time and to certain concentrations do not represent a health /environmental risk.
- GOW methodology can possibly be improved for certain substances/substance classes.
- Environmental risk of drugs only insufficiently addressed.
- PMT might be a risk for raw water.

Thank you for your attention.

