

Experiences with the Swedish Environmental Classification Scheme

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the health care perspective

Long-term target:

**Protect drinking water from
contamination with synthetic chemicals**

Guiding principle:

**All patients should have the right to
best available treatment**

Pharmaceuticals (ng/L) in three water treatment plants in the Stockholm region, samples taken 2007-04-02

Generic name	Plant N intake	Plant L intake	Plant G intake	Plant N outlet	Plant L outlet	Plant G outlet
Citalopram	<0.3	1.4	0.5	<0.3	<0.3	<0.3
Atenolol	1.0	0.5	1.5	<0.3	<0.3	<0.3
Metoprolol	1.1	1.5	2.5	0.3	0.5	0.4
Naproxen	1.4	1.4	2.0	0.7	0.2	1.3
Ibuprofen	<0.2	0.4	1.2	0.5	0.3	1.3
Diclofenac	0.6	0.8	0.7	<0.1	<0.1	0.7
Trimetoprim	0.4	<0.3	0.4	<0.3	<0.3	<0.3

Pharmaceuticals in liver from perch caught in the Stockholm region in May, 2007

	Central Stockholm	10 km east	30 km east
Citalopram* (log K_{OW} = 3.74)	0.1 $\mu\text{g}/\text{kg}$	<0.1 $\mu\text{g}/\text{kg}$	<0.1 $\mu\text{g}/\text{kg}$
Propoxyphen** (log K_{OW} = 4.18)	0.25 $\mu\text{g}/\text{kg}$	0.16 $\mu\text{g}/\text{kg}$	<0.1 $\mu\text{g}/\text{kg}$

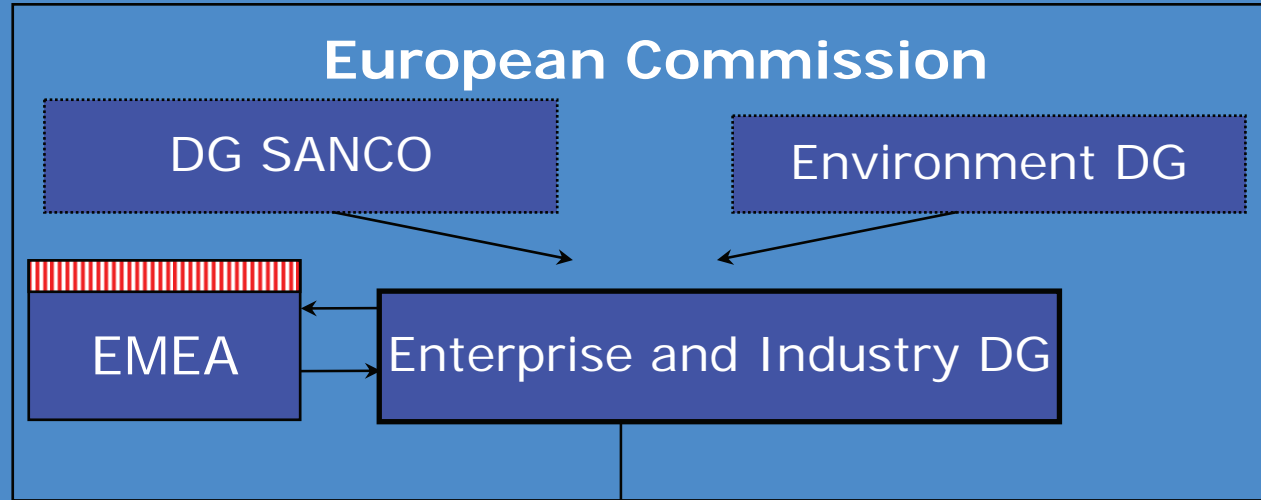
* recipient levels <1 ng/L

** recipient levels 0.1-0.6 ng/L

a global problem?

Sampling position	Number of detected pharmaceuticals
Perth	14
Singapore	8
Paris	7
Beijing	6
Edinburgh	4
Hamburg, Johannesburg	3
Brussels, Helsingborg, HongKong, Copenhagen, Lyon, Sophia	2
Dubai, Düsseldorf, Hoorn (NL)	1
Manchester, New York, Shipol	0

EU and pharmaceuticals



proposes



comments



decides

Environmental aspects in the new directive

New recital :

“Environmental impact should be assessed and, on a case-by-case basis, specific arrangements to limit it should be envisaged.”

Risk ass./environment:

“-any risk ...as regards patients’ health or public health..”(hum.)

“any risk of undesirable effects on the environment”(vet.)

Re. documentation to be added to the application:

- “Evaluation of the potential environmental risks posed by the medicinal product. The impact should be assessed.....”

Re. labelling of package.:

“Specific precautions relating to the disposal of unused medicinal products...”

“Member states shall ensure that appropriate collection systems are in place for medicinal products that are unused or expired.”



**This was good but not enough.
Also consider**

- to provide simple but accurate information to health care staff about environmental effects of pharmaceuticals
- to give doctors (and patients) possibility to a fair choice between medicines with similar effects but different environmental properties
- to provide an incentive for the pharma industry to develop future medicines with less environmental impact

The Swedish Association of the Pharmaceutical Industry

invited the Medical Products Agency,
Apoteket and representatives of the public
health care to jointly develop an
environmental classification system for
human pharmaceutical substances

The international reference group for "the Swedish initiative"



**Risk and hazard
assessment !?**

risk



Biking without brakes = risk
(connected to the use of the object)

risk assessment

PEC = predicted environmental concentration

$$\text{PEC}_{\text{SURFACEWATER}} = \frac{\text{sold amount of AI}}{\text{amount of water in which AI is diluted}}$$

PNEC = predicted no effect concentration
(highest concentration not toxic to aquatic organisms)

$$\frac{\text{PEC}}{\text{PNEC}} < 1 \quad (\text{good!})$$

$$\frac{\text{PEC}}{\text{PNEC}} > 1 \quad (\text{bad!})$$

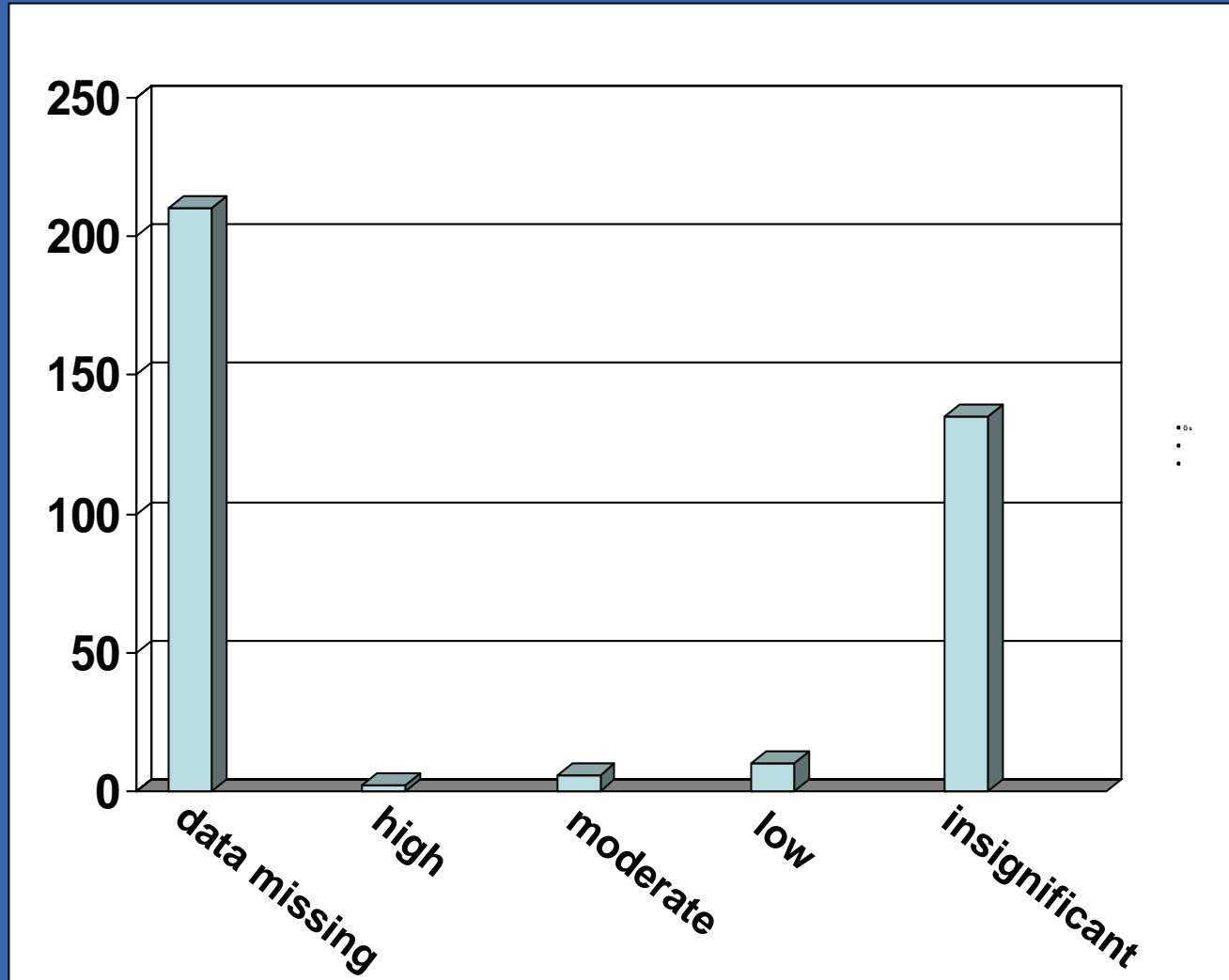
risk classification

Use of the medicine has been considered to result in

	PEC/PNEC
insignificant	<0.1
low	0.1 - 1
moderate	1 - 10
high	>10

environmental risk

Outcome of the risk classification



hazard



A bike without brakes = hazardous
(a property of the object)

hazard assessment

Persistence: The substance is

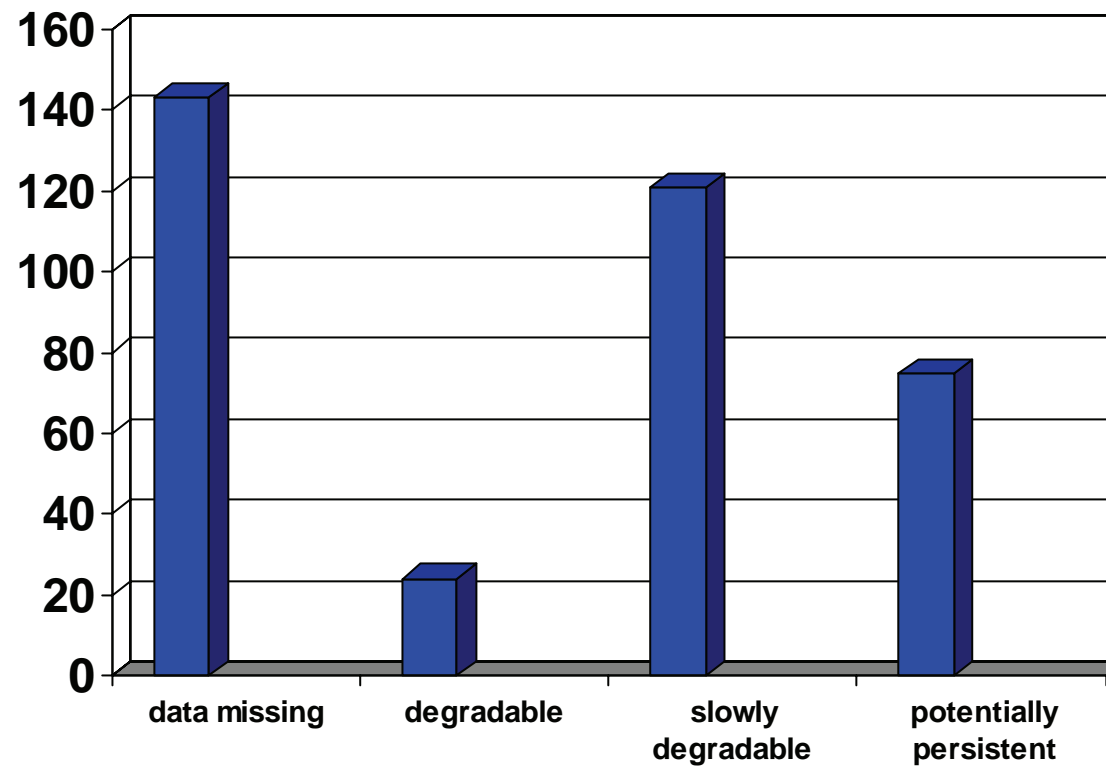
- *degraded* in the environment
- *slowly degraded* in the environment
- *potentially persistent*

Bioaccumulation

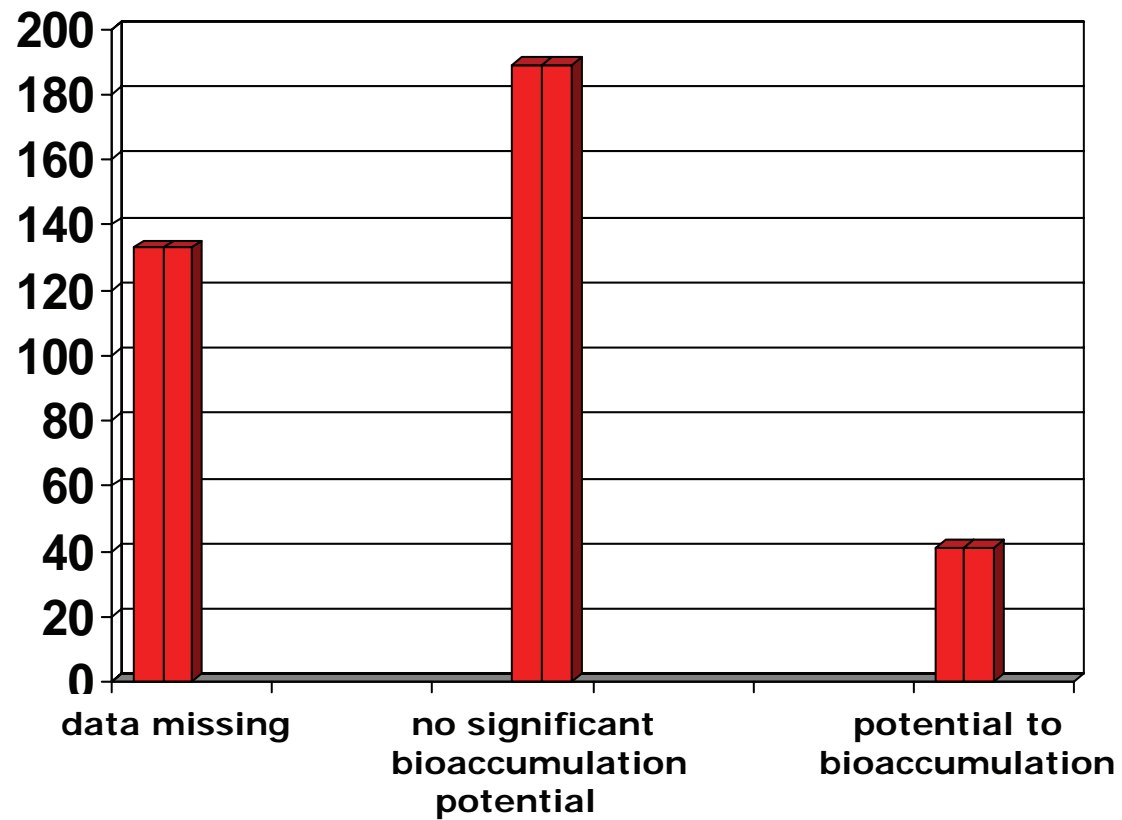
No significant bioaccumulation potential
Potential to bioaccumulation in aquatic organisms

Does the substance fulfill the criteria for PBT and/or vP/vB?

Outcome of the hazard assessment: persistence



Outcome of the hazard assessment: bioaccumulation



an environmental classification according to the Swedish model comprises

- **Risk assessment:**

- *"Use of the substance has been considered to result in low environmental risk"*

- **Hazard assessment:**

- *"The substance is slowly degraded in the environment"*

- *"No significant bioaccumulation potential"*

Application in daily health care of the environmental information on pharmaceuticals

- political target that outlet concentrations and recipient levels of pharmaceuticals should be lower 2011 than 2005
- environmental information on pharmaceuticals available on the web and in printed material
- all doctors and other prescribers regularly undergoing education on environmental effects of pharmaceuticals
- pharmaceutical committees integrate environmental aspects in their evaluation and recommendation reviews
- patient information sheets developed in collaboration with Apoteket AB

Pharmaceuticals in STP inlets and outlets, average concentrations from three major STPs in the Stockholm region, samples taken 2007-09-03

Substance	STP inlet, ng/L	STP outlet, ng/L	Elimination, %
acetaminophen	34400	1700	95
ibuprofen	4360	140	97
naproxen	2870	360	87
furosemide	1540	880	43
ketoprofen	1190	330	72
atenolol	1090	750	31
metoprolol	1010	1160	-14
codeine	670	200	69
diclofenac	495	220	56
losartan	370	140	62
tramadol	320	460	-44
cetirizine	220	280	-30
ciprofloxacin	200	54	73
sulphametoxazole	180	75	58

polycymaking in the EU; what are the next steps needed?

- risk assessment should include "public health" and "environment"
- information system on pharmaceuticals and environment in all EU countries
- improved techniques for elimination of pharmaceutical residues in sewage treatment plants
- activate EU legislation on recollection systems for unused pharmaceuticals in all member countries