Perspectives on future risk assessment and prevention for control of POP's

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1. RISK ASSESSMENT PROCEDURE IN THE EUROPEAN UNION

The production, distribution, use and disposal of substances lead almost inevitably to their presence in the environment. The management of the risk involved of these substances represents an international challenge. It occupies a prominent place on Agenda 21, Chapter 19. The development and harmonization of risk assessment methods is a necessary prerequisite to successful risk management. Recent developments in the legislation of the European Union (Council Directive 92/32/EEC[1] on new substances; Council Regulation 793/93/EEC[2] on existing substances) have accelerated the need to define the principles and practical considerations of this process. In the scope of new and existing substances the Commission Directives laying down the principles of risk assessment (Commission Directive 93/67/EEC[3] and Commission Regulation 1488/94/EEC[4]) were implemented in the practice of evaluating substances. Technical guidance documents (TGD's) were developed to provide a helpful tool in performing risk assessment and to facilitate harmonization in the technical process. On the EU level the former separate TGD's for both new and existing substances are consolidated to one integrated TGD[5]. In parallel to the consolidation of the TGD's the attunement of on national level developed computerized systems to support the risk assessment were prepared and upgraded to a European system consistent with the consolidated TGD (EUSES 1.0[6]).

2. GENERAL PRINCIPLES OF THE RISK ASSESSMENT IN THE EU

Since mid eighties scientific methods were used in The Netherlands to predict and assess systematically the potentially hazard effects for environment and indirectly for man related to production and use of notified substances. The essential information for risk assessment were environmental exposure and effect data. To evaluate all possible effects a set of tools, like emission scenarios, predictive models and extrapolation methods were available. These tools were based on the concept that the EU harmonized minimal set of data at base set level was sufficient for risk assessment. The results of the already developed tools are joined together in the risk assessment model for the evaluation of new chemical substances based on causality between emissions and effects (fig. 1).

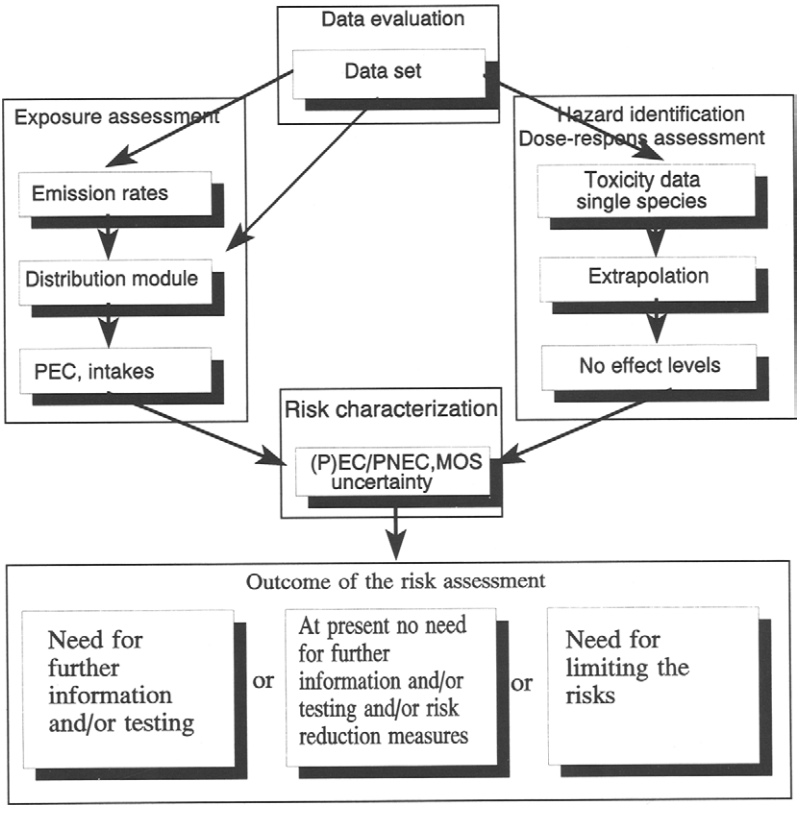

Figure 1: Principle of Risk Assessment

The exposure assessment is formed by models describing the processes as they occur in nature to predict the environmental concentration (PEC). The effect assessment shows the extrapolation of the toxicological test resulting into one or more predicted no effect concentrations for the distinguished biological endpoints (PNEC). Risk assessment for ecosystems takes place by comparing the predicted environmental concentration (PEC) and the predicted no effect concentration for ecosystems (PNEC-eco). The risk assessment for man compares the predicted no-observed-adverse-effect concentration derived from subacute, subchronic or chronic animal tests with the total predicted daily human intake. The ratio showing the margin-of-safety (MOS) is a quantitative result of the risk assessment to predict the risk in a specific situation. In the risk assessment for man no extrapolation factors and/or safety factors are used so far because of differences of opinion between the member states concerning the magnitudes of these factors.

The applied model (see figure 2) is a concise reflection of the major emission and distribution pathways for substances as they move through the environment in the European Union. The potential groups considered to be at risk are:

- bacteria in a waste water treatment plant.
- aquatic organisms;
- human beings on the workplace;
- the general public exposed directly via consumer products;
- the general public exposed indirectly via the environment.

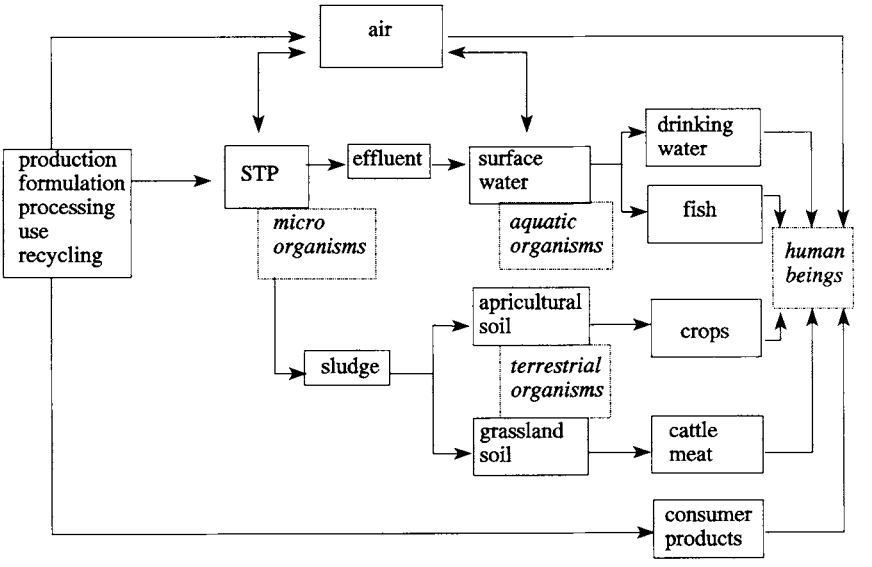

Figure 2: Elements of the emission/exposure assessment

In this model a substance is assumed to enter the surface water only via a sewage treatment plant (STP). The effluent of the STP is diluted in the surface water, where it is available for uptake by aquatic organisms. Each box reflects data resulting from previous processes and are, in its turn, input data for the following processes. The arrows reflect processes modelled using fixed and variable data.

For aquatic organisms, the predicted dissolved concentration of the substance in surface water is compared with the predicted no effect level that is obtained from extrapolation of toxicological tests. The tests, however, give only information about the effects of the substance on single species. For a more realistic risk assessment, the effects was extrapolated from single species to ecosystems. The sludge from the STP is considered to be used as fertilizer on grass- or arable land. Consequently the substance reaches human beings through the crops, the meat of cattle, fish and via drinking water. The total daily dose for human beings is compared with the dose without effect. If inhibition test results are available, a comparison is made between the concentration of the substance in the STP and the extrapolated no inhibition concentration for bacteria.

Potential pathways of the substance entry into the environment and its emission points are presented in the hazard assessment model. Only the emission to the influent of a STP is considered. All direct emissions to the soil are excluded because in most of the EU member states only so called "controlled dumping" on landfills is allowed and ecotoxicity data of terrestrial test organisms are mostly not available. Only after receiving additional ecotoxicity data other environmental compartments will be assessed. Emission to the air is evaluated when it is likely that the air concentrations will exceed the no effect levels. The air concentration will be evaluated in relation to the inhalation exposure of man.

When the risk characterization leads to the conclusion "need for limiting the risks", risk reduction measures will be recommended. The risk reduction measures will be based on a risk-benefit analysis taking into account (a) technical feasibility, (b) economical factors, (c) social/cultural factors, (d) legislative/political factors, and (e) research to reduce the uncertainties in methodologies and measurements. This is the most difficult step in the risk management process, because it is a multifactorial task. On the EU level a guidance concerning the applied methodologies to develop proposals for risk reduction measures is nearly finished. It will become available as chapter 6 to the TGD on risk assessment of new and existing substances.

3. EXPERIENCES WITH THE EU EXISTING CHEMICALS PROGRAM

Assuming that high volume chemicals may lead to high exposure, the OECD developed a list of HPVC chemicals based on the criteria > 1000 tons production per annum in more then one country or > 10,000 tons per annum in one country. Based on the present overall list containing approximately 2500 chemicals working lists in batches of about 50 chemicals for every phase of the program were developed given initially priority to chemicals lacking critical information ("data poor" chemicals) and since 1994 also priority to potentially high risk chemicals. The EU Existing Substances Regulation is the basis for the EU contribution to the OECD high production volume chemicals (HPVC) program. While the HPVC-program was initially focused on completing data of "data

poor" HPVC's, the EU program is mainly focused on potentially high risk HPVC's.

The EU existing substances regulation comprises of required delivery of available information of chemicals produced/imported > 1000 tons per annum in the first phase (ended in June 1994) and delivery of available information for chemicals produced/imported > 10 tons per annum in the second phase (deadline June 1998). The first phase realized data delivery of some 2500 substances whose datasets vary in completeness. The working lists for preparing risk assessments have been selected from the 2500 HPVC's given priority to potential high risk for man and the environment. Since 1993 three priority lists have been published, the first list of substances in 1994, the second list of substances in 1995 and recently in 1997 the third list containing substances.

The planning of the EU existing substances program was based on the optimism in the possibility to cover a working program of about 20 selected substances per year itemized over the 15 EU member states in function of rapporteur responsible for preparing the risk assessment. However, the practice of preparing risk assessment reports learned very soon from the start that (a) harmonized scientific quality standards and a harmonized format for reporting the risk assessment were needed before risk assessment reports could be prepared in a harmonized way, (b) a critical review procedure must be set up to get international acceptance, and (c) substantial human and financial resources in each member state must be made available to fulfil these criteria. Preparing the harmonized preconditions before the EU risk assessment procedure of priority substances could start led to^Ia delay of several years. Already during the development of the third priority list it was made clear that because of limited resources and major delay in developing risk assessments of the previous lists many member states were not able to take substances of the third list on board. At this moment the EU existing substances program is still waiting for the first risk assessment reports to reach the level of EU agreement. A more realistic proposition of the EU existing substances program in final risk assessment reports could be 5 substances per year.

The situation is even more critical because the regulation also requires recommendations for risk reduction based on criteria of the still to approve missing chapter 6 of the TGD with respect to cost-benefit analysis and risk reduction methodology. Because the priority

were made for potential high risk chemicals and risk reduction recommendations could already be foreseen, the first draft risk assessment reports still need to be completed with recommendations for risk reduction before formal adoption can be reached. So, the outlook on the progress of the existing substances program is none too bright.

We must conclude that the present schemes in developing risk assessment reports for priority substances is not a ideal working method to implement also for future POP's. It is only a question of time before the EU member states call for reconsidering the whole existing substances procedure because of the involved human and financial resources and the lack of effectiveness in the final aim to develop a acceptable risk management for chemicals in general.

4. A MORE EFFECTIVE RISK MANAGEMENT APPROACH: EXAMPLE PAPER CHEMICALS

4.1. Background

In the European Union, Directive 92/32/EEC[1] requires a risk assessment to be carried out on new notified substances. A major part of the new notified substances are dyes, which are predominantly used in the paper industry. Based on the results of the risk assessments there was serious concern for most of the notified substances that the aquatic environment was at risk at processing and recycling of paper. In discussing specific notified substances on EU level the assessment of the emission from production and processing paper was improved by agreement on a harmonized set of emission parameters based on detailed analysis of the emission from the paper industry. Because the production and processing processes in the paper industry were quite uniform, we explored the idea to develop simple aquatic environmental criteria for the assessment of paper chemicals based on harmonized models concerning emission and distribution in the environment[6]. The aquatic environmental criteria pertain to parameters which are important for the estimation of emissions (use category, function of the substance. and specific physical-chemical properties) and the aquatic toxicity of the substance {classified as R50 (L(E)C50 <= 1 mg/l), R51 (10 <= L(E)50 < 1 mg/l) or R52 (10 <

L(E)50 <= 100 mg/l)}. In addition the environmental criteria should follow the accepted risk policy in The Netherlands and the accepted EU risk assessment methods. The environmental criteria should be transparent and usable without the help of computers.

4.2. General overview of the results

A "standard scenario" which includes a fixed quantity level, Henry's law constant, octanol-water partition coefficient and fixed aquatic toxicity were used to calculate potential PEC/PNEC ratios for the function categories coloring agents, reprographic agents and other types of agents (see table 1; only the category coloring agents is presented as an example). Next, aquatic environmental criteria were derived, which describe the critical range of physical-chemical and aquatic toxicity properties for which paper chemicals belong to the classes of "low risk: no immediate concern" (PEC/PNEC <= 1, "immediate risk; concern - risk assessment required" (PEC/PNEC < 1000) or "high risk: high concern - restriction in use required" (PEC/PNEC >= 1000). Taking together the readily and non-readily degradable paper chemicals (see table 2; only coloring agents are presented as an example), the classes following the environmental criteria corresponded for 97% with the PEC/PNEC ratio for the aquatic environment for all life cycle stages of the notified paper chemicals. The results show that univocal and generally applicable aquatic environmental criteria can be derived based on an accepted risk policy and accepted risk assessment methods for chemicals grouped in use categories with a quite similar emission pattern.

Table 1: Estimated emission and potential PEC/PNEC ratios at different aquatic toxicity values for paper chemicals (assuming 100% release to the sewage treatment plant.

Use category/life cycle	Release estimate (fraction)	Daily emission rate (kg/d)	Potential PEC (mg/l)	Pot. PEC/PNEC dependent on L(E)C50 (mg/l)		
				R52 10 - 100 Mean 31.6	R51 1 - 10 Mean 3.16	R50 0.1 - 1 Mean 0.316
Reprographic agents						
Production	0.02	20.0	1	31.6	316	3165
Formulation	0.02	3.33	0.17	5.27	52.7	527
Processing:						
- Printing and allied processes	0.0005	0.50	0.025	0.79	7.91	79.1
- Others	0.815	815	40.75	1290	12896	128960
Recovery						
- cardboard/sanitary	0.01	0.33	0.02	0.53	5.27	52.7
- others	0.14	4.67	0.23	7.38	73.8	738

Table 2: Aquatic environmental criteria for paper chemicals used as reprographic agents

Reprographic agents	**R52** **10 - 100 mg/l**	**R51** **1 - 10 mg/l**	**R50** **0.1 - 1 mg/l**	**R50** **< 0.1 mg/l**
Production	concern + RA required if logH<=2 and logKow<=4, unless logH=2 and logKow=4	concern + RA required	high concern + restrictions in use if logH<=2 and logKow<=4, unless logH=2 and logKow=4	high concern + restrictions in use
Formulation	no immediate concern	concern + RA required	concern + RA required	concern + RA required /high concern + restrictions in use
Processing:				
- printing and allied process	no immediate concern	no immediate concern	concern + RA required	concern + RA required
- others	high concern + restrictions in use if logH<=1 and logKow<=3	high concern + restrictions in use	high concern + restrictions in use	high concern + restrictions in use
Recovery:	no immediate concern	concern + RA required	concern + RA required	concern + RA required /high concern + restrictions in use
- cardboard/sanitary	no immediate concern	no immediate concern	concern and RA required	concern and RA required
- others	no immediate concern	concern and RA required	concern and RA required	concern + RA required /high concern+ restrictions in use

Table 3: Comparison of environmental criteria and risk assessment results for notified paper chemical in The Netherlands.

No	L(E)C50	Class according to the environmental criteria				PEP/PNEC calculations			
	mg/l	pd	f	pc	rc	pd	f	pc	rc
1	1.88	II	II	II	II	458	51	1207	51
2	2.8	II	II	I	II	893	60	8.9	60
3	3.15	II	II	II	II	794	53	1254	53
4	3.24	II	II	I	II	768	51	7.7	51
5	10.7	II	I	II	I	29	1.9	46	1.9
6	11.63	II	I	II	I	69	4.5	409	4.5
7	16.7	II	I	II	I	180	10	237	10
8	25	II	I	I	I	100	6.7	1.0	6.7
9	34.6	II	I	II	I	25	2.8	67	2.8
10	46	II	I	II	I	33	3.6	30	3.6
11	115	I	I	I	I	26	1.5	34	1.4
12	225	I	I	I	I	11	0.7	18	0.7
13	532	I	I	I	I	4.7	0.3	7.4	0.3
14	>1	I	I	I	I	-	-	-	-
15	>1	I	I	I	I	-	-	-	-
16	>1000	I	I	I	I	-	-	-	-
17	>1000	I	I	I	I	-	-	-	-
18	>1000	I	I	I	I	-	-	-	-
19	26.1	II	I	II	n.a.	13	0.7	49	n.a.
20	0.23	III	II	II	II	2527	421	63	842
21	0.33	II	II	II	II	286	48	7.2	95
22	0.73	III	II	I	II	1348	222	34	452
23	2.6	II	II	I	II	152	25	3.8	51
24	10	II	II	I	II	100	17	2.5	33
25	>0.1	I	I	I	I	-	-	-	-
26	>0.1	I	I	I	I	-	-	-	-
27	>100	I	I	I	I	-	-	-	-
28	>1000	I	I	I	I	-	-	-	-

5. CONCLUSION

The idea to develop a more effective risk management based on accepted risk policy and accepted risk assessment methods seems to be successful for paper chemicals. It needs further discussion, but the approach could be explored for other groups of substances, like POP's. Because the main concern of POP's in the environment are predominantly related to persistency and environmental toxicity, and furthermore the distribution in the environment is quite similar for POP's, we would suggest not to follow the way of detailed risk assessment reports for each POP, but to develop derived environmental criteria for POP's based on "standard emission" scenarios. This approach only needs well improved emission scenarios for the relevant use categories of POP's.

REFERENCES

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6. G.B. Janssen and E.H. Hulzebos: Aquatic environmental criteria for paper chemicals; National Institute of Public Health and the Environment (RIVM); Report no. 601505001, February 1997.