

## Environmental Policy

# The EU Existing Chemicals Regulation

## A Suitable Tool for Environmental Risk Assessment and Risk Management?

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### 1 Risk Assessment Within the EU

The legal framework for the risk assessment of chemicals was established in the EU by a directive carried out during the beginning of the 1980s which was transformed into a national chemical acts by the member states. It describes the extent of information industry has to present before marketing a newly synthesised substance. Since 1993 in the European Union, a regulation on the evaluation and control of existing substances ensures that a uniform and mandatory procedure is applied for the assessment of existing chemicals in all member states as well. Due to the large number of these chemicals (100,000 are compiled in the European Inventory of Existing Commercial Substances, EINECS), a risk assessment can only be performed for those substances which have been identified as being of high priority in a priority setting process.

The procedure followed in environmental risk assessment consists of comparing the concentration in an environmental compartment with the highest concentration at which no effects on organisms or ecological systems representative of that compartment are expected to occur. Therefore, after the initial step of compiling and validating all available information, comprehensive exposure (based on modelling or monitoring) and effect assessments have to be performed before the results of the two are compared in the risk characterisation step (AHLERS and DIDERICH, 1998; BEULSHAUSEN and AHLERS, 1997).

In all cases in which risk assessment has shown the need for emission abatement measures, a risk reduction strategy has to be drawn up by the reporter. When it is necessary to impose restrictions on marketing and use, the existing chemical regulations require that the associated advantages and drawbacks be discussed and that possible substitution products be taken into account.

On the basis of the risk evaluation and the recommendation for an appropriate risk reduction strategy, the Commission decides, whenever necessary, to propose Community measures in the framework of Council Directive 76/769/EEC or in the framework of other existing, relevant Community instruments.

### 2 Discussion

The outline above shows that a high-input process has to take place before the risks posed by a potentially dangerous substance can be limited. It usually takes several years to complete the journey from priority-setting, publication of

priority lists, environmental risk evaluation, the merging of it with the evaluations for the sectors health and occupational safety, discussion with EU and OECD member states, formulation of risk reduction strategies, to an EU-wide directive mandating restrictions.

A particular problem encountered is that industry in most cases submits the necessary information "drop by little drop", and only whenever the worst-case assumptions which have been used as a makeshift showed a need for regulation. Every time this happens, it is necessary to carry out comprehensive revisions, thereby slowing the process. Another obstacle to the derivation of regulatory measures is the widespread lack of knowledge about emissions to the environment which arise from the downstream use of chemicals.

The first three EU priority lists were published in 1994, 1995 and 1997, and comprise a total of 110 existing chemicals. Discussion within the EU has started on 44 substances, among them eight for whose evaluation Germany was responsible. A final agreement on 21 substances has already been reached at EU level, with the following result:

- three substances were found not to require action at present
- fifteen substances were found to require risk reduction measures
- three substances were found to be in need of further data to improve the data base.

### 3 Acceleration of the Existing Chemicals Assessment Process

The speed of the work on existing chemicals (only a minute number of the total of existing chemicals have been worked on, only few risk assessments completed and no risk reduction measures initiated so far), coupled with the magnitude of the problem (100,000 substances in the European Inventory of Existing Commercial Substances, EINECS; 15,000 to 20,000 substances with annual production volumes of between 10 and 1,000 tonnes and almost 2,700 substances with annual production volumes in excess 1,000 tonnes in Europe), have caused competent authorities in Germany and in the other European countries to give increased thought to the question of how the process can be accelerated. In our opinion there are several possibilities to speed up and improve the process of risk assessment and risk management. Such improvements are possible for each of the individual steps of the risk assessment/risk management process: *data collection*, *priority setting*, *risk assessment* (exposure as well as effect assessment), *risk management*.

In considerations of this kind, it should always be remembered that the various steps (e.g. priority setting and risk assessment) are not ends in themselves. Rather, the purpose of the exercise is to find out which substances pose a risk and then reduce this risk as quickly as possible.

**Data collection:** Regarding the first step, data collection, we think that there is the general need to have at least a minimum set of data available on all substances with an annual production/import volume of more than 1,000 tonnes. This set must also include exposure data of good indicative value. Only with this as the basis is it possible to carry out systematic priority-setting.

**Priority setting** is a very important step in the whole risk assessment process. When the total number of existing chemicals is compared with the number of substances actually assessed, the need to choose the "right" chemicals is evident. We suggest that an extended priority setting be performed (→ Fig. 1), to which expert judgement makes an important contribution and where, in a tiered process involving simple evaluation aspects such as generic exposure estimations or the application of structure-activity relationships, those substances should be identified which are to undergo comprehensive assessment. These will essentially be substances which in all likelihood are in need of regulation. And for these, a comprehensive risk evaluation is justified and necessary. It would also be important to be given the option of initiating simple regulatory measures (e.g. labelling, occupational health and safety

measures) during the extended priority setting without waiting until the whole risk assessment process has been completed. Using the initial data set and applying SAR methods and simple exposure calculations, the experts should be able to assign the approximately 2,600 chemicals produced on an industrial scale in different categories, as follows:

- Substances which are obviously of low priority.
- Substances for which additional exposure and/or effects data have to be compiled prior to further treatment. This proposal is to help avoid a problem we currently have in the case of many substances, namely that, rather than being able to take a decision as to the necessity of emission reduction measures directly upon completion of a lengthy assessment, more information must first be requested from industry. This causes delays of several years and unacceptably high additional burdens.
- Substances for which a targeted risk assessment appears to be sufficient. A targeted risk assessment focuses on a specific protection goal or an application area of potential concern. Substances having specific properties (persistence, bioaccumulation and/or a high biological effect such as carcinogenicity and reprotoxicity), as a rule, would be candidates for a targeted risk assessment. Targeted risk assessments would also be appropriate in cases where presumably only one area of concern (e.g. occupational health and safety) is at risk or where sufficient measures have already been taken to reduce the risk to specific areas of concern. A targeted assessment might also suffice when the substance concerned is strictly an intermediate product or when only certain regions are expected to be exposed to it.
- Substances likely to be in need of regulation. This need will then have to be verified and quantified in a comprehensive assessment.

In extended priority setting, substances, where possible and appropriate, should be treated in clusters according to structural similarities or identical uses (use clusters). The use cluster approach means that all substances serving the same purpose (e.g. pickling) are subjected to a comparative assessment. It has the added advantage that possible alternative products are assessed on the basis of identical criteria.

**Risk assessment:** Such an extended priority setting is a prerequisite for enhancement of the subsequent step, the *Risk Assessment*, as only chemicals and problems have to be assessed which have a high probability of concern. In addition, more flexibility should be allowed to choose an appropriate assessment factor according to the available information (expert judgement).

**Risk management** is the decisive step in the whole process. Priority setting and risk assessment are more or less useless if we are not able to draw the right conclusions from the results. This means that necessary risk reduction measures should be implemented as quickly as possible. From our point of view, the aim of the subsequent risk reduction strategy is to reduce the PEC to levels lower than the PNEC and to evaluate the most efficient way to achieve this goal.

We believe that the EU Existing Chemicals Regulation will indeed become a suitable tool for RA and RM by the incorporation of these improvements.

As in quantitative terms too little progress has been made under the existing EC's Chemicals Regulation, in the debate

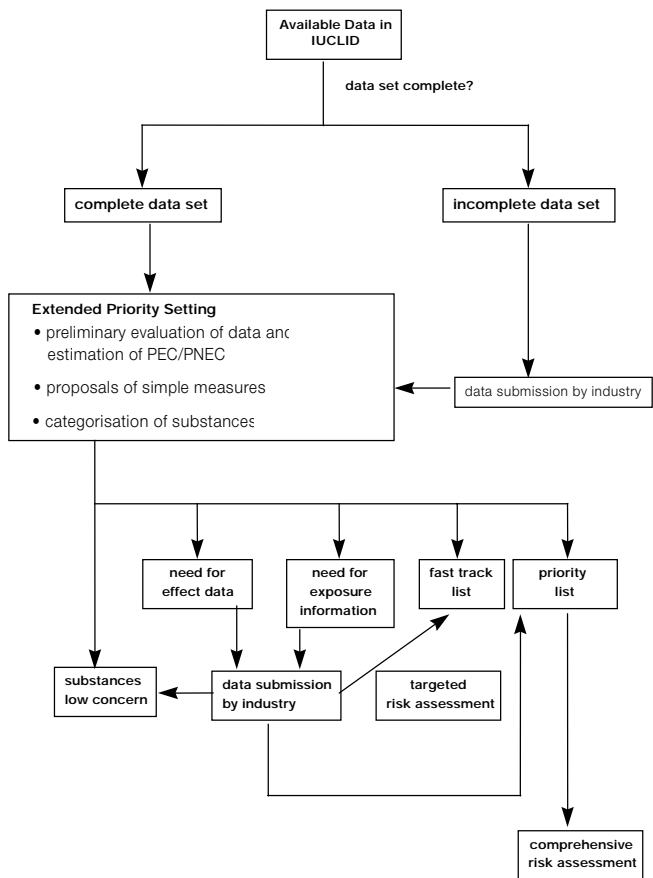


Fig. 1: Acceleration of the risk assessment process

over chemicals policy thought has however also been given to the question of whether one should adopt an altogether different approach to protecting human beings and the environment against the risks posed by hazardous substances.

One possible approach could be to carry out hazard assessment rather than a risk assessment, as envisaged as the future procedure under the OECD Existing Chemicals Programme. The advantage of this approach is that arduous exposure analysis work is not carried out initially. This would save a lot of time, so that work on the most critical substances could be completed within a reasonable time span. As only intrinsic properties are used in hazard assessment, the result is of global validity. The drawback of this approach is that regulatory measures cannot be formulated on the basis of a hazard assessment exercise, since these always take the form of emission abatement measures and, hence, presuppose knowledge about the emission. If a risk is suspected, relevant exposure considerations must be undertaken, again delaying the attainment of the ultimate goal.

Alternative considerations for streamlining the assessment process are focused on substances which are to be considered as particularly hazardous in the light of certain properties and thus as requiring regulation without in-depth assessment. Properties considered to be particularly problematic with respect to the environment are persistence, bioaccumulation and high toxicity (PBT substances). Several possibilities exist to pay attention to such dangerous chemicals. For example, PBT substances should not undergo assessment if results from a chronic test (multi-generation assay) are not available. In addition, an ap-

proval procedure for persistent and bioaccumulating substances might be of advantage since, with this, it would be possible to evaluate whether the benefit to be derived from the substance in question is greater than the associated risk on the basis of information to be submitted.

Finally, a complete ban or at least a ban on open-system uses (zero emission) is proposed. This alternative seems to be somewhat problematic, though, as there might not be any substitutes available for certain applications or the substitutes might be more critical than the substance itself.

A number of proposals which move along these lines have been discussed of late (e.g. SANTILLO and JOHNSTON, 1998; SCHERINGER et al., 1998).

#### 4 References

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## UNEP Corner

*James B. Willis, Director UNEP Chemicals, Executive Secretary for the Rotterdam Convention, and ESPR-Editorial Board, to Our Readers:* How countries respond to the challenge of implementing the new agreement will shape the future public health and environmental safeguards that communities around the world receive from trade in highly dangerous chemicals and pesticides.

### Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

The Convention was adopted and opened for signature at a Conference of Plenipotentiaries in Rotterdam, the Netherlands, on 10 September 1998. It was signed on 11 September 1998 by 86 countries. The Convention is open for signature until **10 September 1999** at United Nations Headquarters in New York. It enters into force 90 days after the submission of 50 instruments of ratification. The United Nations Environment Programme (UNEP) and the Food and Agriculture Organisation (FAO) are jointly operating the Interim Secretariat – before the Convention enters into force – to support governments in implementation.

The Convention incorporates, with some changes, the **Prior Informed Consent (PIC)** procedure which 154 countries have been implementing voluntarily since 1989. This procedure prevents export of 27<sup>\*</sup> harmful pesticides and industrial chemicals that have been banned or severely restricted or are causing problems under conditions of use in developing countries, unless the importing country agrees to accept them. In addition, a country seeking to export a chemical subject to a ban or severe restriction on its own territory must in-

form the importing country before the first shipment and then annually. In such ways, exporting and importing countries share responsibility for notification and monitoring to safeguard human health and the environment from the harmful effects of these chemicals. Significantly, countries meeting in Rotterdam agreed to carry out the revised PIC procedure on an interim basis voluntarily until the Convention enters into force.

**The new Convention includes the hazardous substances subject to the voluntary PIC procedure, and will encompass additional industrial chemicals and pesticides in the years ahead.**

**Asian Region Workshop**, Bangkok, Thailand, 8-11 December 1998: 17 Asian countries\*\* participated in the first *Regional Awareness Raising Workshop* on the Rotterdam Convention. The Asian region workshop sought to promote implementation and ratification and raise awareness about the details of the obligations of the Convention. Proceedings of the Bangkok workshop will contribute to the 6<sup>th</sup> session of the Intergovernmental Negotiating Committee (INC), 12-16 July in Rome, Italy\*\*\*.

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\*\* Bangladesh, Bhutan, China, India, Indonesia, Japan, Korea, Laos, Malaysia, Mongolia, Myanmar, Pakistan, Philippines, Sri Lanka, Thailand, Vietnam

\*\*\* ESPR informs on this event in No. 4 (October)

\* **Pesticides:** 2,4,5-T, aldrin, captafol, chlordane, chloridmeform, chlorobenzilate, DDT, dieldrin, dinoseb, 1,2-dibromoethane, fluoroacetamide, hexachlorocyclohexane, heptachlor, hexachlorobenzene, lindane, and mercury compounds, and certain formulations of monocrotophos, methamidophos, phosphamidon, methylparathion, and parathion. **Industrial chemicals:** crocidolite, polybrominated biphenyls, polychlorinated biphenyls, polychlorinated terphenyls, tris (2,3-dibromophenyl) phosphate