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Exposure Assessment in the Context of the EU Technical Guidance Documents on Risk Assessment of Substances

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CONTENTS

SUMMARY

The ECETOC Task Force "Exposure Modelling" critically reviewed the EU Technical Guidance Document for Risk Assessment of New and Existing Substances and identified a number of specific exposure assessment issues which may require further consideration. These are described in this Document No. 35 which should be viewed as a status report. It should enable ECETOC to further prioritise activities in the area of exposure and risk assessment, which would form the basis for the further collaboration with the national competent authorities on the development of a mutually agreed risk assessment system in support of EU legislation. Although the basic principles of European risk assessment are scientifically sound and mutually accepted, the Technical Guidance Document in its present status of development often only allows risk assessments which are too generic and too conservative. Consequently, many details will need to be developed in order to tailor the risk assessment process more to the specific needs.

In several of its Technical Reports, ECETOC recommended that before proceeding with a risk assessment, the assessor should establish whether exposure of man or the ecosystem to the substance of concern is likely to occur. If so, a process for assessing environmental and human health-related exposure must be employed to enable a risk assessment to be carried out. This process is a practical step-wise risk assessment procedure which essentially consists of an iterative comparison of exposure to effects. Although the EU adopted the step-wise risk assessment approach, the Task Force concluded that in particular Tier 1 (or screening phase) of the risk assessment process fails to separate out those substances which are of no concern. Tier 1 needs to be designed to be sufficiently selective, so that substances of real concern can be identified, and these concerns addressed, quickly and efficiently. The Task Force also concluded that the current system or process as detailed in the Technical Guidance Documents is over-conservative and may lead to a large amount of unnecessary testing.

For both human and ecological risk assessments, a large number of factors and often complex pathways need to be considered when estimating exposure. For both assessments, a worst case analysis (maximum possible exposure) should be used only as a screening tool to establish whether exposure can be categorised as "insignificant" and not as the basis for predicting actual human or environmental exposure. Sole use of the worst case approach leads to an unrealistic characterisation of exposure conditions and merely expresses the precautionary principle rather than the facts.

Assessments should move from 'risk characterisation' by means of PEC/PNEC comparisons to 'risk estimation', i.e. the quantification of the likelihood of the incidence and severity of adverse effects, characterised in terms of a statistical distribution with a most probable value for the risk and some confidence interval and not by a single number. ECETOC has started a project entitled 'ECIMOS' with

the objective to develop an Integrated Modelling System or common modelling platform for exposure, effect and risk modelling using existing model algorithms or calculation modules which integrate state-of-the-art methods for sensitivity and uncertainty analysis for different aspects in the exposure, effect and risk assessment of chemical substances.

1. INTRODUCTION

The goal of a comprehensive risk assessment is to estimate the likelihood and the extent of an adverse effect occurring in man, animals or ecological systems from possible exposure(s) to substances or physical agents. The assessment of whether a substance presents a risk to the receiving environmental compartment is based on a comparison of the Predicted (or measured) Environmental Concentration (PEC) of the substance of concern with the Predicted No-Effect Concentration (PNEC) to organisms in that ecosystem. The assessment of whether a substance presents a risk to man is based on a comparison of the predicted (or measured) exposure for a human population of concern with a No-Observed Adverse Effect Level (NOAEL), generally derived from experimental animal studies.

Mathematical models have been developed as decision-support instruments for risk assessors which facilitate the performance of calculations, e.g. USES (RIVM, VROM, WVC, 1994) or HAZCHEM (ECETOC, 1994a). The development of the Technical Guidance Document for EU Risk Assessment of New and Existing Substances calls for a model which mimics the Document in every detail. Therefore, a European working group was established in 1994 with the aim of developing a "European Union System for the Evaluation of Substances" (EUSES).

To further explore when and how exposure assessment procedures and methods should be revised and improved, the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) formed a Task Force in 1994 with the following Terms of Reference:

- review in detail the USES model and identify elements needing modification and further development;
- develop proposals for an updated version (EUSES) which are in accordance with the concepts developed by ECETOC;
- define the applicability of EUSES to each tier of the risk assessment process;
- collaborate with the national competent authorities on the development of a mutually agreed risk assessment system in support of EU legislation;
- develop a data base for environmental parameters to be used in generic regional and local situations.

This Task Force carefully observed the EU activities of merging the Technical Guidance Documents for risk assessment of new notified substances with those of existing substances and provided input via the technical EU working groups at various stages of the process. The Task Force critically reviewed the assumptions and equations used to predict *exposure* to substances within the European risk assessment, and recommended some practical approaches to improve critical aspects within the environmental, consumer and occupational exposure assessment methodology. In addition, representatives of the Task Force participated in two EU Special Expert Meetings which were held in The Hague, NL, one on Biodegradation (31.5.-1.6.1995), the other on Release Estimation (19.-21.9.1995).

The Task Force also supported actively the development and testing of EUSES, the model based on the algorithms and tables provided in the new "Technical Guidance Documents in Support of Directive 93/67/EEC on Risk Assessment of New Notified Substances and Regulation (EC) No. 1488/94 on Risk Assessment of Existing Substances" (EEC, 1996).

This Document No. 35 was prepared for information of ECETOC member companies, particularly those which were not closely involved in the development of the Technical Guidance Documents for new and for existing substances and the subsequent merging process of the two documents. It will therefore focus on the critical assumptions used for the estimation of environmental, consumer and occupational exposure as described and recommended within the present EU Technical Guidance Documents. Underlying processes and mechanisms will be reviewed and suggestions will be made for improvements by the incorporation of recent scientific developments.

2. BACKGROUND

2.1 NEW CHEMICAL NOTIFICATIONS AND RISK ASSESSMENTS

Since 31 October 1993 all new chemicals notified to the EU authorities must comply with the 7th Amendment of the Dangerous Substances Directive 67/548/EEC (EEC, 1992). This implies that competent authorities are required to conduct a risk assessment for man and the environment for the chemical being notified according to the principles laid down in the Commission Directive on Risk Assessment of New Chemicals (93/67/EEC) which was published in the Official Journal and came into force on 31 October 1993, i.e. the same day as the implementation of the 7th Amendment of Directive 67/548/EEC.

The results of the risk assessment at each stage of the notification will form the basis for risk management decisions (e.g. no immediate concern, further testing at higher tonnage triggers, immediate further testing or risk reduction). As tonnage and/or use patterns change, the risk assessment must be revised and where a concern is identified, the competent authority is empowered to request additional data from the notifier (toxicity/ecotoxicity data or exposure data).

Although the time period for gaining experience has been relatively short, industry is finding that the different Member States are approaching the risk assessment requirement quite differently. Clearly, the sophistication of the risk assessment seems to depend on the resources available within the competent authority for handling a variety of data. Some authorities see the 7th Amendment as a tool for requesting further data in each case while others prefer to use the opportunity to better understand the potential risks in collaboration with industry.

2.2 EXISTING CHEMICAL SUBMISSIONS AND RISK ASSESSMENTS

Article 10(4) of the Council Regulation (EEC) No. 793/93 on the Evaluation and Control of the Risks of Existing Substances requires that a risk assessment be carried out according to principles later described in Commission Regulation (EC) No. 1488/94 for Risk Assessment of Existing Substances (1488/94/EEC).

The Council Regulation requires that dossiers be submitted on existing substances (i.e. those listed in the EINECS Inventory which contains about 100,000 substances) exceeding certain defined production volumes per year. All data pertaining to the ecotoxicological, toxicological and physico-chemical properties of the substance are collected in the format of the Harmonised Electronic Data Set (HEDSET) and will be included in the database IUCLID developed by the European Commission.

In accordance with Regulation 793/93, Phases I and II of the HEDSET submissions have been completed by industry in Summer 1995 for about 2,500 "high tonnage" existing substances (those produced or imported in quantities exceeding 1,000 t per year) in accordance with two official deadlines (4 June 1994 and 5 June 1995, respectively). These datasets were loaded into the IUCLID database of the European Chemicals Bureau (ECB) in Ispra, Italy. Copies of these data files were immediately given to the competent authorities of all EU member states for loading into their own IUCLID systems. In May 1996 the *non-confidential* parts of the *merged* datasets were made available by ECB to all interested parties (industry, consumer groups etc.). "Merged" means that datasets for one substance received from different submitters were combined. "Non-confidential" means that confidential data like production volume as well as data flagged as confidential by the submitter were removed. These datasets can be purchased on CD-ROM with IUCLID export files or as a so called "IUCLID low cost version" for those not having a IUCLID database. The IUCLID low cost version is a CD-ROM-based document retrieval system for searching IUCLID reports by name, CAS or EINECS Number but does not have the functionality of a database.

The final HEDSET submissions - Phase III - required for all other chemicals produced or imported in quantities exceeding 10 t per year must be completed by industry on 4 June 1998.

Using the IUCLID data bank, the EU and Member States will draw up priority lists of about 50 chemicals per year for risk assessment by the regulatory authorities. In principle, the submitted substance data will be used to rank the substances according to their relative risk based on an automated Informal Priority Setting method (IPS). Substances which have been prioritised will then be evaluated and assessed according to the principles laid down in the Risk Assessment Regulation.

The first priority list was published in May '94 and contained 42 substances. Several member states are preparing risk assessments on these priority substances. Recently, about 10 *draft* risk assessments were made available and were discussed during a Technical Meeting. The second priority list was published in September 1995. EU member states including the "new" member states can already begin the risk assessments for these substances, concurrent with the assessments of the first list. The second list contains 36 substances. A third priority list has been discussed and will be published soon in the Official Journal.

2.3 TECHNICAL GUIDANCE DOCUMENTS ON RISK ASSESSMENT

These documents are to provide harmonised guidance to all member state authorities on the procedures for conducting acceptable risk assessments for man and the environment. They are not legally binding but the intention and expectation is that European regulators charged with conducting a

risk assessment will use these documents for developing their conclusions concerning the potential risks of a chemical.

Since the introduction of risk assessment legislation in the EU, separate Technical Guidance Documents (TGD) have been prepared for the evaluation of both 'New' and 'Existing' Chemicals (EEC, 1993; 1994). Additional guidance documents were also developed on the use of QSARs (quantitative structure activity relationships) and on risk reduction and risk/benefit considerations.

The two sets of TGD for New and for Existing Substances respectively, were diverging in essential parts and hence could result in different risk assessment conclusions and consequently to different risk management strategies. Recognising this, the Commission decided to set up EU working groups in order to develop a uniform and consistent guidance package for new and existing substances. This harmonised guidance package for a comprehensive risk assessment of both new and existing substances was agreed on 8/9 November 1995 and published in 1996 (EEC, 1996).

Unfortunately, various changes were made during the amalgamation process which increased the conservatism of the risk assessment approach; new data were often not sufficiently considered and arguments were often not supported by solid science and/or peer reviewed literature. In addition, some controversial areas were not addressed with the probable result that the individual member states may conduct the risk assessment following their own national policies. Adoption of different risk assessment methods, assumptions and safety factors to produce so-called unique and 'precise' risk quotients will result in divergent "risk" conclusions, and is expected to lead to an inefficient use of available resources - within both competent authorities as well as industry.

3. RELEASE ESTIMATION

3.1 EMISSIONS

Estimating Releases or 'emissions' is one of the most important and also contentious areas of environmental risk assessment. This is the step that determines just how much of a substance actually enters the environment. In the TGD, various life-stages of a substance are identified, each of which may have its own associated release to the environment. These life-stages are production, formulation, processing (or use), recovery and disposal. For most substances the first three of these are usually considered and may or may not be significant in terms of the quantity released to the environment.

This information on releases is often difficult to obtain, particularly for the use or processing stage of a chemical's lifecycle, and different amounts and quality of release data are available for different types of substances.

In order to allow for this variability, a hierarchy of data type is given in the TGD, i.e. in order of priority:

1. specific information;

2. the emission scenarios as given in the TGD;

3. the estimated release factors from the release tables.

This hierarchy was agreed by both ECETOC and competent authorities and although there is overlap, the principle of the approach is sound. The new EUSES release module also reflects this and includes the basic 'flexible' approach proposed by ECETOC.

The greatest concern here is the interpretation of 'specific information'. The information to be considered may include measured release data or any factors that might affect the actual release to the environment. For example, the plant technology may use wet or dry processes in open or closed systems and these may be the main factors controlling the release to the environment. In addition, the number and location of production sites, number of days for emission etc. may be known, and this type of information should be used wherever possible to estimate the release. Therefore, 'specific information' should not be restricted to 'measured concentration values' and may include a combination of measured and estimated values.

When such specific release data are not available, it may be possible to utilise one of the 'emission scenario documents' referred to in the TGD. These documents identify typical release patterns for certain industry types (e.g. paints and varnishes, plastic additives etc.). The idea is that if it is known that a substance is used as a preservative in paints, for example, it should be possible to identify the pattern of release based on the pattern of production, formulation and use of paints which is provided in the document. Thus the emission scenario documents potentially provide a useful method to estimate release fractions.

However, it should be recognised that these emission scenario documents are based on varying degrees of information about the industries they represent and still only provide estimates of releases which may or may not reflect true release patterns. They usually do not take into account the state of technique used in manufacturing (e.g. BAT or dedicated units for mitigating releases) but assume conservative release figures. This will need to be corrected as more specific information becomes available. They also mostly fail to address the potential correlation between the sizes of the effluent stream and the receiving water. Further data collection is needed in the EU to substantiate such correlations.

The third option is to use the release tables provided in the TGD. However, this must be seen as a last resort when no other information is available. It should be emphasised that the release factors given in the TGD are not based on real release information and are deliberately conservative. Moreover, nearly all the recent industry assessments for priority list substances indicate that actual emission fractions, at least during production, are significantly lower than the fractions given in the release tables. For information, the default release fraction for existing substances (>1,000 t per year) at production and formulation is set at 0.3% release to wastewater, based on data provided by ECETOC for intermediates. For new substances the corresponding value for exposure assessment at base set (<10 t per year) is 2%, based largely on the experience of the UK Department of Environment. This 2% release value was made conservative in order to encourage industry to provide more specific information.

In terms of actual use, the different categories (industry/use/main) can be difficult to interpret, and it is not clear how these different categories might interact. There may be several use or industry categories that are applicable for one substance. Moreover, the release tables seem to be principally focused on the industrial categories, while the use categories are only taken into account to a lesser extent. Also, the current tables rely heavily on the influence of vapour pressure and water solubility for estimating the release during production, whereas recent investigations (ECETOC, 1994b) demonstrate that for intermediates there is, in practice, no such correlation between the properties of a substance and its release to the environment. Instead, the release is controlled primarily by the type of manufacturing or formulating process being used. It is essential that the user should be aware of these limitations when using the release tables.

3.2 CALCULATION OF $PEC_{regional}$

In environmental risk assessment, the Predicted Environmental Concentration (PEC) is used as a descriptor for the real environmental concentration of a given substance. While PEC_{local} characterises the concentration in the immediate vicinity of a point source, the $PEC_{regional}$ reflects the background concentration in areas not directly affected by point source discharges. There is an important difference which strongly influences the methodology to be applied in determining these values.

In the case of PEC_{local}, the concentration is always related to the strength of the point source and the various fate processes (e.g. advection, degradation) which can be measured and quantified. Hence the resulting concentration in the vicinity of a point source can be predicted by using an appropriate local model. The results of the model predictions can be scrutinised, provided that the analytical methodology is available.

With increasing distance from the point source, fate processes and contributions from other sources will become more important. In situations where no direct influence from point sources occurs, a steady-state concentration of a substance in the different environmental compartments is assumed. These steady-state concentrations, calculated by the fugacity approach, represent the $PEC_{regional}$ or background concentration. Analytical measurements in the environmental compartments concerned are generally feasible. Since the concentrations depend on the fate and release processes, the $PEC_{regional}$ may vary considerably in reality. Therefore, a stochastic approach could improve the estimation of the $PEC_{regional}$.

4. BIODEGRADATION

4.1 INTRODUCTION

The PEC may significantly be reduced by biological and/or physico-chemical processes and as a consequence may result in a reduction of the PEC/PNEC ratio. For most of the substances for which an exposure assessment has to be executed, the biological degradation processes are most important, particularly because the PEC/PNEC comparisons are based on the parent substance. Biodegradation (kinetics) and exposure predictions should therefore be related to primary biodegradation. In addition, it is important to acknowledge and accommodate the hierarchy in test results. In principle, should monitoring data for the chemical of interest be available, based on specific analytical measurement of the substance itself in an effluent under actual field conditions, then these data should take precedence over laboratory simulation tests and/or model predictions. Different approaches could be used for the interpretation and use of test results; knowledge gained on the extrapolation of results from laboratory tests to the field should be used to predict the fate and behaviour of the substance. It is therefore essential to clearly distinguish 1) use of expert judgement or simple calculation algorithms, 2) 'direct' extrapolation of biodegradation test results and 3) use of mathematical models which simulate competing fate processes and operations of Waste Water Treatment Plants (WWTPs) and other environmental compartments (river, soil).

4.2 PRIMARY, READY, AND INHERENT BIODEGRADATION

Mathematical models currently in use to predict environmental concentrations of substances also require knowledge of the kinetics of biodegradation. Ideally, the measurement of primary biodegradation requires specific analytical methods which are sensitive enough to determine concentrations relevant to the environmental compartment of concern. Such methods could well be difficult to develop within a reasonable period of time and it is therefore often necessary to assess primary degradation based on tests using non-specific methods.

Within the current framework of legislative test methodology, the methods for assessing ready biodegradability usually provide the only biodegradation information available at the base set level. These ready biodegradability tests may provide an indication of the completeness or extent of ultimate biodegradation of the substance, but do not always provide a good basis for the calculation of primary biodegradation rates. It is generally accepted that compounds meeting the "ready" criteria are totally mineralised and their biodegradation rates are fast enough to achieve a high removal in WWTPs.