



EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH AND CONSUMER PROTECTION
Directorate C - Scientific Opinions
Unit C2 – Management of Scientific Committees; scientific co-operation and networks
Scientific Committee on Toxicity, Ecotoxicity and the Environment

Brussels, C2/JCD/csteep/TGD-EnvExpAss25012002/D(02)

**SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND
THE ENVIRONMENT (CSTEE)**

Opinion on the

**“Revision of the 1996 Technical Guidance Document (TGD) in support of Commission Directive
93/67/EEC on risk assessment for new notified substances and Commission Regulation (EC)
1488/94 on risk assessment for existing substances
[also being extended to provide guidance on risk assessment for biocides
under 98/8/EC (excluding human exposure evaluation)]”**

submitted for CSTEE opinion on 23 August 2001

Draft revision version on

PART 1 – ENVIRONMENTAL EXPOSURE ASSESSMENT

CSTEE opinion expressed by written procedure on 25 January 2002

General Comments

The document is substantially improved in comparison with the previous version. Many aspects are detailed better and the justification of many assumptions is scientifically sounder. It is also good to see that the total exposure is covered better in the present version than in its predecessor. The increased focus on the technosphere and dumpsites as sources is also welcomed.

As in the previous version, chapter numbering is quite confusing (the document is divided in parts and chapters, chapters are divided in subchapters, the same subchapter numbers appear in different chapters, etc). A small effort should be made to make it more user friendly.

Appendices II to XI are lacking in this version. Are they unchanged in comparison to the old version and is it supposed that there is no need for improvement? Probably some parts should be revised or added. As an example, Appendix XI dealt with the complex problem of ionising substances, but there is another problematic group of chemicals, apparently not addressed by the document, *i.e.* polymeric substances, for which definition of properties (even MW) is very complex.

Many scenarios need the application of default assumptions. This approach cannot be avoided, but sometimes the selected assumptions lead to very "unrealistic" scenarios (often very conservative, sometimes quite optimistic). Even if, for preliminary assessment, conservative approaches and an assessment based on "worst case" scenarios are to be preferred, in some cases an effort for less unrealistic scenarios could be made.

According to Directive 98/8/EC, biocides are among the substances this document is addressing. Biocides can be classified into various types (at least 23), which are extremely different particularly in relation to emission and exposure patterns (*e.g.* products used indoors for human hygiene and antifouling compounds). Procedures for "local" exposure assessment (usually the most relevant for assessing the occurrence of a risk) in the TGD are suitable mainly for point emission sources and refer to more or less steady-state conditions. It should be carefully checked if these procedures are suitable for all typologies of biocides. A relevant example is that of chemicals used in large amounts but with very discontinuous emission patterns (*e.g.* products used as antifouling in industrial or energy plants cooling systems). A careful check should also be carried out to control the consistency of the TGD with the Guidance Document on Data Requirements for Biocides.

About modelling, it should be clear whether conditions for emissions are steady or unsteady-state. The types of models underlined in the TGD are thought to work in typical steady state conditions, which may not be applicable to all situations. Or, in turn it must be explicitly "declared" that the conditions of emissions are steady state. It is like defining the type of sampling, analytical conditions when presenting measured data.

Additionally, it should be made clear **where** the intended target for exposure is when evaluating substances emitted at point sources. Numerous point sources (well distributed on the territory) emitting chemicals at a steady pace can as well be considered sort of "diffuse" sources and the emission considered at regional level. If the desire is though to observe the exposure (and therefore the effects) of a specific target located close to the point source, it might be needed to evaluate (and specify) the time course of the emission, or in other terms, an unsteady state emission (one shot type) of the amount "x" of a chemical produces of course a larger exposure compared to a prolonged (in time) emission of the same amount. In this situation, a worst case scenario with the "one shot emission" would probably be better.

A detailed procedure for assessing reliability and representativeness of monitoring data is described in this TGD. It would be useful if this procedure could be transferred or harmonised with other TGDs in order to reach a standard European procedure for using monitoring data in RA.

The transboundary input from local and regional into the continental model is not sufficiently addressed in the document. Continental concentration is a relevant item to assess predicted background levels and to check the meaning of some monitoring data. Some suggestions are reported under Specific Comments.

The groundwater compartment has been strongly overlooked. The proposed approaches are too rough and approximate for such a relevant compartment. This is also relevant in relation to biocides, because some biocide typologies may give rise to not negligible soil and groundwater pollution. Some suggestions are reported under Specific Comments.

The emission scenarios (Appendix I) have not been reviewed by the CSTEE, as this field is not covered by the expertise of the members of the committee, and it has not in the time given been possible to identify external experts.

SPECIFIC COMMENTS

Page numbers refer to the document Tgd_env_exp_rev041001

PART II

Chapter 3 Environmental Risk Assessment

2. Environmental Exposure Assessment

Chapter 2.1

Page 247

Insert underlined text at the 4th and 7th bullets:

- Industrial/Professional use (large scale use including processing (industry) and/or small scale use (trade));
- Waste disposal (including waste treatment, land filling and recovery).

Page 248, first paragraph

There is the need to be more precise about degradation products. The SCP has produced a document on Relevant Metabolites. Even if it is specifically referred to pesticides, some connections could be useful.

For LPV substances a qualitative and quantitative assessment of the degradation products should be done to determine if degradation products should be subject to RA.

Chapter 2.1.1

Page 248

One must be very careful in using monitoring data. If not specifically produced for a local or regional risk assessment procedure, they can be biased by sampling planning, chemical selection, etc. (see comments on Table 3). Value and limitations of monitoring data are described in the CSTEE document on "Exposure data in risk assessment".

Page 248, second para

The second sentence should also address the fact that the environment may act on the substance. Thus, the sentence may be rewritten:

"This range.....substance, and differences in environmental factors influencing degradation and distribution processes, or..."

Page 248-249

The term "site-specific" should be used with some care. A real "site-specific" risk assessment should be based on a detailed and complete description of the environmental conditions. In general, this is not the aim of the TGD, which should produce PEC figures to be reasonably applicable for a European-level risk assessment. Some site-specific data can be used instead of the default data characterising the standard scenario. This may allow producing less unrealistic "worst case" scenarios.

Page 249, lines 8-10

As a general rule, extrapolation from a site-specific condition should be allowed if the site is representative of a worst-case scenario.

Chapter 2.2.1

Table 3, pages 252-253

It is very important to make available necessary information for evaluation of the reliability and representativeness of the measured data. Some additional criteria could be added:

- How have chemicals to be monitored been selected?
- Which are the criteria for selecting sampling sites and frequency?

In the table, at the line "One shot or mean": include "x" in column 1.

A line should be added:

"Unit specified": "x" in both columns;

it should be referred to the following text in a note:

Units must be clearly specified and information given whether it has been normalised to *e. g.* C, lipid etc."

Page 253, Notes

To make an evaluation of the representativeness of the sample possible, it should be emphasised more strongly that information on sampling procedures as well as on both qualitative and quantitative aspects of the sample (characterisation) and info on handling of the sample should follow the measured data.

Page 253, Note 11

For modelling and trend analysis it will indeed be of great importance to know not only the year but more exactly the time of year of sampling both to take into consideration possible changes in release pattern and the fact that degradation and transport of the substance will vary with environmental condition/factors changing through the year. To reveal time trends it is very

important that sampling is standardised/normalised with regard to factors known to influence environmental concentrations. A minimum requirement should be at least year and season.

Page 253, Note 12

For some samples (especially air samples) basic climatic conditions should be added (temperature, weather conditions, rain, wind).

Page 255, Table

Analytical quality control should be added in the 5th column in the presentation suggesting how the measured data should be presented. Information on the analytical quality is not necessarily given when "relevant information on analytical method" is requested. Info on AQ is a demand for evaluating the limitations of the data.

Chapter 2.2.2

Page 256, last para

Use of biota. More information is needed to characterise the biota, the type of organism must be indicated. Moreover, biological variability should be kept in mind. Whenever possible, additional information (season, sex, dimension) should be provided.

Chapter 2.3.2

Page 260

In the **second/third paragraph** data for exposure models are mentioned and some description is given for how to correct partition coefficients for dissociating chemicals, according to the environmental pH. Some more warning should be given on the need for the assessor to classify the chemicals in "types" before proceeding in the modelling exercise. (Mackay *et al*, 1996). This would warn the "user" in the case the substance is involatile or speciating, for example.

Page 261, first para

"...it may be considered to obtain measured Koc ...". It would be better to put Kp instead, because Koc may not be an adequate descriptor for adsorption when organic carbon may not be responsible for the adsorption.

Chapter 2.3.3.1

Page 266, Figure 4

There needs to be an arrow from the bold horizontal line to the landfill.

Chapter 2.3.3.3

Page 267, bullets 3 and 4

Guidance needed when a non-dispersive use becomes a dispersive (100, 1000 or 10000 sources?)

Chapter 2.3.3.6

Page 278

The problem of potential leakage to groundwater should be addressed.

Chapter 2.3.4

Pages 279-281, Characterisation of the environmental compartments

There is a description of a "generic" EU environment. Since there is quite a variability in environmental properties across the Union, it should be recommended as part of a more "regional" but closer to specific "national average conditions" (e.g. temperature variations) to conduct a

sensitivity analysis on the main parameters in order to define the range of variation of the target response.

Page 280, Table 4

The groundwater compartment should be included in the table. A relevant parameter would be the depth of the water table.

Chapter 2.3.5 Partition coefficients

Page 281. Adsorption to aerosol particle

The proposed approach is based on the Junge-Pankow approach. There is a more recent approach, based on K_{oa} (octanol air partition coefficient) (Finizio *et al.*, 1997), which is a better descriptor than VP.

Page 282 Volatilisation: Second paragraph

There is a problem with water miscible compounds (such as acetone) and calculation of Henry's Law constant. In such cases a direct measurement of H should be recommended (Mackay *et al.*, 1992).

Page 283 Adsorption/desorption: fourth paragraph

The "nonhydrophobics" are described as chemicals for which log K_{ow} range is between -2 and 8. It sounds a bit too wide!

2.3.6 Biotic and abiotic degradation rates

Page 285 middle of page

Why should the positive screening test be considered valid when several results are available?

Page 287-288 Photochemical reactions in the atmosphere

Photodegradation data in the atmosphere must be evaluated with some care. Often highly persistent chemicals are reported as rapidly degraded in air. This is likely to occur in experimental conditions, where the chemical could be in large amount in the gas phase. In the real environment, most of the chemical may be associated to particles (lipophilic chemicals) or aerosol (very soluble chemicals) and the real atmospheric half-life could be orders of magnitude higher.

2.3.7 Elimination processes

page 297

Assuming for a standard regional scale that 80% of the wastewater is treated in a biological STP, is probably too optimistic, at least at present and at an average European level. Also data reported in Appendix XII, Table 1 are quite optimistic. In some cases they could refer to "planned", but not yet actually functioning (the STP of Milano was already "planned" in the '90s and included in the statistics, but it is not yet functioning). At least a couple of alternative scenarios should be proposed as a "best case" and "worst case" STP presence. This could be applied for a transition period to be realistically evaluated in function of the STP evolution.

Page 305, first para under Municipal

Organobromine should probably be organochlorine.

2.3.8 Calculation of PECs

Calculation of $PEC_{continental}$ is not mentioned in the introduction of the chapter (it is shortly mentioned at page 328). Even if it is not relevant for risk characterisation and for a PEC/PNEC calculation, it would be appropriate to add some short sentences to indicate its usefulness for an

assessment of a background concentration, at list as order of magnitude, and for assessing the meaning of some monitoring data.

Page 308, First bullet

The principle of considering dilution as the dominant “removal” process (see also page 315) is correct as a general rule, but exception must be taken into account in particular cases. For example with substances with very high H constant (*e.g.* VP at level of kPa, solubility at level of mg/L) volatilisation losses may occur in very short time. There are no reasons for introducing (properly) a correction factor for suspended solid sorption and not for volatilisation, at least for very volatile substances.

Page 308 Second bullet

Groundwater being a most important compartment should be presented in a separate bullet point.

Page 308 last para

Add “ground and” to “to surface water”...

PECl_{local} for the atmosphere

Page 311 first paragraph

Why volatilisation only from STP? There is no mention of many possible diffuse emissions. Relevant volatilisation losses may occur also from surface water, soil and landfilling.

Page 311-second paragraph

A PNEC for atmospheric exposure is difficult to assess. For higher vertebrates it could be correct to assume inhalation as a component of the total exposure, but for other organisms it could be different. In particular, for terrestrial plants, atmospheric exposure could be the most relevant, at least for some kind of chemicals. Information is lacking, but it could be useful at least to highlight the need for this kind of data.

Page 315, first para and Figure 9

Both text and figure should contain also other types of sources than the WWTP.

PECl_{local} for soil

Page 319 first paragraph

Additional soil exposure routes could be taken into account. Excluding intentional soil application (applicable to plant protection products but also to some biocides), spill (regular or accidental) from production, use and disposal sites should be taken into account. Moreover, some biocide typology, even if not directly applied on soil, may give not negligible soil deposition.

Page 321, Figure 12

Concentration in soil should be after 1 year instead of 10.

Page 324-325, Table 10

For non-agricultural soil, a soil depth of 10 cm, as for grassland, is probably more appropriate.

2.3.8.6 Concentration in groundwater

Page 326

The approach is too rough and approximate for a so relevant compartment like groundwater. Some better approaches, even if general and preliminary, could be taken from the plant protection product directive. As a preliminary classification of the leaching potential, the GUS index (Gustafson, 1989)

could be applied. For a risk characterisation, groundwater PECs should not be compared with ecotoxicological PNEC, but with drinking water standards or human health criteria.

2.3.8.7 Calculation of PEC regional

Page 326 and 327

There is some, but not adequate, consideration of long-range transport of chemicals such as POPs, which may enter even the continental scale environment.

Page 328

Model parameters for PEC regional and country specific parameters: some guidance should be given on the selection of parameter importance: temperature should be average, seasonal, max/min etc...Some “ecoregional “ environmental scenarios should be defined and proposed for a defined number of regions in order to allow the comparison of results.

2.5 Decision

Page 332

This paragraph is a key point in the whole risk assessment procedure. If substantial background info is available to make it possible to do a proper evaluation of the quality and representativeness of the measured data, the cases distinguished in the bullet point should be valid. Nevertheless, criteria must be carefully explained and better clarified.

It must be better highlighted that is not the **number** of data but their real **representativeness** (spatial and temporal) that makes a monitoring relevant.

In particular the second bullet is the most controversial. If $PEC_{calc} > PEC_{experimental}$ the most important question is:

Are monitoring data good and representative enough to exclude that higher concentrations are likely to occur in some possible European scenarios?

The second question is:

Is the PEC prediction enough refined and is the adopted scenario acceptable?

If it cannot be demonstrated that the worst-case scenario is unrealistically conservative, the calculated PEC should be preferred.

There is no mention of the “range of acceptability” of the PEC predicted/measured ratio. A factor of 5, 10?

In the sentence between the two groups of bullets it is mentioned that if the measured data are OK, further work is needed to elucidate the exposure situation. Is this really necessary if the PEC/PNEC is significantly below 1?

Appendix

Page 347

Aspects of formulation: Shouldn't multiplied be divided?

Page 349

Here is the use of processing and industrial use discussed. It is not clear which one is preferred.

Page 351

In the third para before Agricultural, references are made to TGD and EUSES, have better be cross-references within this document.

Page 374

The ideas that emissions that originate from another substance can be prioritised under ESR is difficult to accept. It is essential that the total exposure is estimated irrespective of the sources

REFERENCES

Finizio A., Mackay D., Bidleman T. Harner T. (1997) Octanol-air partition coefficient as a predictor of partitioning of semi-volatile organic chemicals to aerosol, *Atmospheric environment*, 31, 2289-2296

Gustafson D. I. (1989) Groundwater ubiquity score: a simple method for assessing pesticide leachability. *Environ.Toxicol. Chem.*, 8, 339.

Mackay D., Shiu W.Y., MA K.C. (1992) Illustrated Handbook of Physical-Chemical Properties and Environmental Fate for Organic Chemicals, Lewis Publishers, Boca Raton, FL, USA. P.697

Mackay, D.; Di Guardo, A.; Paterson, S.; Kicsi, G.; Cowan, C.E. (1996) Assessing the Fate of New and Existing Chemicals: A Five Stage Process *Environ. Toxicol. Chem.*, 15, 1618.