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Unit C2 – Management of Scientific Committees; scientific co-operation and networks
Scientific Committee on Toxicity, Ecotoxicity and the Environment

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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

CSTEE general comments on the draft revised version of the TGD

CSTEE opinion expressed by written procedure on 25 January 2002

The Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances requires under Article 10 that the real or potential risk for man and environment of priority substances to be assessed using principles which have been laid down in the Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances. The risk assessments are carried out by competent authorities designated by the responsible Member States that act as *rapporteurs*.

Within this framework a number of risk assessments have been performed. The CSTEE has been reviewing some forty of these reports and is generally impressed by the high quality of the assessments. One of the reasons for the good quality is probably the Technical Guidance Document (TGD), which has been used in most assessments done so far. This document is now being revised and the CSTEE is in the process to review the new version of it.

It is, however, very resource and time consuming to produce these assessments and it will take a very long time to deal with even just the substances that are produced in high volumes. This is probably one of the reasons why the European Commission issued a White Paper suggesting a new chemicals policy in the EU. In it the Commission proposes to shift responsibility to enterprises, for generating and assessing data and assessing the risks for use of the substances. It also suggests that producers of preparations and other downstream users will be obliged to assess the safety of their products for the part of the life cycle to which they contribute, including disposal and waste management.

A large number of actors may thus be doing risk assessments of substances in the future. The TGD will probably play an important role in this process and improve the quality and streamline the format of the reports. It is therefore important to make the document as user friendly as possible. The review of the revised TGD by CSTEE so far has been focussed on the scientific aspects and several working groups have been looking at specific sections, and not on the overall structure of the document. Nevertheless some general remarks can be made, and these may be useful in the final efforts in bringing the different parts together. These comments are therefore simply given as bullets, and if any further explanations are needed, the committee will be happy to expand these views.

- The number of a section is not unique (section 3.1.2 may appear in different chapters). The use of the chapter (or appendix) number as the first character would improve the readability, and make it easier to do cross-references.
- Several of at least the shorter appendices could be included directly in the text to improve the readability of the document.
- Clear warnings for the limitations (*e.g.* limits for Kow) of suggested models to predict exposure.
- At some critical points in a risk assessment references to already published risk assessments for existing and new substances may be a good help to see how the problems have been handled earlier.
- Appendices with useful data sources should be added.
- As well as appendices with glossary/definitions used in the whole document.
- A common chapter on the quality of measured exposure data to avoid different approaches in different chapters is also necessary. This may also be useful for the use of test results. In both cases a tiered approach can be suggested.

- The experiences gathered during several years of use of the TGD could be described somewhere to point at difficulties and, ideally, ways to come around these. This chapter could also point at research needed to improve the whole process.
- Chart diagrams could be useful to give overviews of the different processes.