

COMMITTEE ON CARCINOGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Technical guidance for derivation of DNELs and risk characterisation of non-threshold effects in the context of REACH

Introduction

1. REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) is a new European Regulation which is intended, among other objectives, to ensure the protection of human health and the environment from industrial chemicals. It is due to come into force on 1 June 2007.
2. In order to ensure a smooth implementation of REACH, numerous guidance documents have been/are being developed by consortia and stakeholder expert groups. In many cases, in these documents, it has been necessary to take a pragmatic approach in order to deal with the large number of chemicals covered by the legislation (approximately 30,000 overall). In the UK, the HSE is appointed as the REACH Competent Authority and COC members have already had the opportunity to comment, at HSE's request, on the technical guidance document (TGD) on the carcinogenicity testing strategy. Both the COC and COT have now been asked for views by HSE on the draft guidance on the derivation of Derived No Effect Levels (DNELs: defined as the level of exposure to a substance above which humans should not be exposed) and risk characterisation of non-threshold effects. At Annex A to CC/07/4 is the latest version of the TGD on this subject. An earlier version of this document was discussed by the COT on 6 February and the covering paper which went to the COT is also attached (TOX/2007/02).

COT comments

3. At the COT meeting it was explained that DNELs/DMELs (Derived Minimal Effect Levels: see attached paper) would apply to substances subject to registration and exceeding the 10 tonnes per annum manufacture/importation/usage threshold, which is likely to include a significant number of the chemicals covered by the legislation.
4. The COT commented that the technical guidance would benefit from greater consideration of certain important aspects, such as the impact of study design on the assessment of NOAELs, and the choice of mathematical model used to derive benchmark doses. There was concern that the limited data requirements for substances in the 10 tonnes p.a. band would result in inadequate end points being analysed. The proposal to extrapolate from a 28 day study to generate a limit for lifetime exposure was not considered sufficiently robust. The COT also considered that the section on allometric scaling is unclear and that the TGD lacked convincing justification for treating workers differently to the rest of the population.

Issues on which comments are invited

This is a draft paper for discussion. It should not be quoted, cited or reproduced.

5. As stated in the COT covering paper, the draft TGD has been provided mainly for information but views from Members will be fed into the further development of the TGD for consideration by members of the working group developing this guidance. Members are invited to comment in particular on the aspects below:

- i) The proposed approaches to developing DMELs for genotoxic carcinogens;
- ii) The TTC approach to setting DMELs for somatic cell mutagens with no cancer data.

COC Secretariat
February 2007

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Annex A to CC/07/4

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Attached is the latest version of the working draft of the REACH TGD on derivation of DNELs and DMELs for consideration by Members.

Note: The draft document is still being developed and in need of further work. It will be published after it has been finalised.

COC Secretariat
February 2007