

World Health Organization
International Agency for Research on Cancer

28 October 2005

**IARC Monographs on the Evaluation of Carcinogenic Risks to Humans -
Comments on the draft Preamble**

Dear Ladies and Gentlemen,

We are referring to your invitation for comments on the draft Preamble that was posted on your website on 31 August 2005. The attached paper contains detailed comments that ECETOC has received from Member Companies and compiled into a summary document. This document has been reviewed by the industry members of the ECETOC Scientific Committee and are presented for your consideration. In particular, we draw your attention to our comments on the

- apparent expansion of the IARC charter beyond hazard identification to include dose-response assessment
- new selection procedures for Working Group members that could effectively prohibit industry scientist participation
- consideration of a positive response in second sex of an animal bioassay as 'sufficient' evidence of carcinogenicity in animals
- ability to elevate a category 3 [not classifiable] to a category 2B [possible] based solely on genotox/mechanistic data
- inclusion of abstracts in monograph discussions

In submitting these comments, however, we believe IARC may wish to consider establishing a process that would enable a more consensual and open discussion of the principles upon which IARC decisions are made. For example, this might involve setting up an expert meeting to review the implications of the more significant proposed changes before finalising their incorporation into the Preamble, in a format previously adopted for discussions involving species-specific mechanisms. In the interim, the existing IARC proposals could be indicated as 'proposed' changes, but such a process would allow for a more considered review.

Sincerely,

Dr. Michael Gribble,
Secretary General

PS: ECETOC is a scientific, non-commercial association. Please, see a short description of our membership portfolio and vision / mission statement attached. ECETOC did not receive (nor will receive) any compensation for these comments.

2 Attachments