

Dear Sirs,

herewith I want to send two points of comment on the new IARC draft preamble.

I declare that neither I nor the organization I am affiliated to received (or will receive) compensation for my comments.

Comments

i) It should be made clearer which monograph chapters an invited specialist may draft:

In the document DRAFT Preamble 2005.doc, chapter 5, page 4, l. 42 ff. an invited specialist may not draft text that pertains to cancer data. This implies that an invited specialist may draft other monograph chapters ? (e.g. mechanistic section). It is not clear which monograph chapters specifically "pertain to cancer data".

On the other hand, in document Discussion of Changes, chapter 5, page 2 it is mentioned that "To assure public confidence in the impartiality of such determinations, the mechanistic sections, like the sections on studies in humans and studies in experimental animals, are written by experts with no links to the parties that have a financial interest in the evaluation."

The former sentence implies that an invited specialist may not draft text at all.

ii) document DRAFT Preamble 2005.doc, chapter 9 (c), page 14, l. 42 ff., evaluation of studies of cancer in experimental animals: it is mentioned that a relevant factor for the evaluation is a low variability of the historical controls.

However, there are further important factors when using historical controls for the evaluation of studies of cancer in experimental animals:

e.g.

- the available historical control data should be from the same lab
- the available historical control data should be from the same animal strain (or even the same breed)
- the available historical control data should be from an adequate comparable timeframe (maximally 5 yrs in the past in relation to the evaluated study)

How does the IARC preamble recommend to include these factors? There is no respective information given.

Best regards
Tom Gebel

