Section 5. Summaries

Section 5 combines summaries of the data reviewed in Sections 1 to 4. Each subgroup (members of the Working Group assigned to a particular Section) is responsible for writing the summary of the text they reviewed. Summaries are composed *during the meeting*, and are the product of the entire subgroup and, subsequently, of the entire Working Group.

Overall comments

Summaries are the sections most read in the entire volume. In that sense, it is extremely important to provide essential and relevant information, and yet remain concise.

The summaries should not contain studies or other elements that have not been mentioned before, in the main text.

Summaries must be understandable by the lay public. Avoid technical jargon.

No references should be quoted.

Section 5.1

The agent and its use are briefly described. Human exposure is summarized on the basis of the data on production, use and occurrence.

Section 5.2

A concise summary should be provided of the epidemiological studies considered to be of adequate quality for use in making an evaluation of carcinogenicity to humans. Those considered uninformative and not used in making the evaluation need not be brought forward to the description of studies in the summary.

A statement should be made of the type and number of studies (cohort, case–control) and whether an association was found between the exposure and the occurrence of cancer at different sites and under what circumstances. Quantitative data are not given. Any limitations should be mentioned.

References should not be cited, but information such as geographical location should be given to allow the reader to identify a study.

Section 5.3

A concise summary should be provided of those studies considered to be of adequate quality for use in making an evaluation of carcinogenicity to animals. Studies with critical weaknesses and not used in making the evaluation need not be brought forward to the summary.

A statement should be made of the number of experiments, the species and by what routes the agent has been tested adequately and with what qualitative results, including the main organ sites at which tumours were observed. Studies in which tumours were produced following single doses should be identified. Dose–response relationships should be noted. Several studies of the same type and/or with concordant results may be summarized together. Any limitations should be mentioned. Studies in which the agent was given in combination with known carcinogens should be summarized only briefly. Studies on preneoplastic lesions may be described if relevant to the evaluation. Cancer bioassays with major metabolites may be summarized.

Section 5.4

Information on biological effects in humans relevant to an evaluation of carcinogenicity is summarized, e.g. kinetic and metabolic considerations, evidence of DNA binding, persistence of DNA lesions or genetic damage in exposed people. Similarly, data on kinetics and metabolism in experimental animals are given only if considered relevant. The results of tests for genetic and related effects are summarized for exposed humans, other mammalian species, cultured human and mammalian cells and non-mammalian systems. Other mechanistic considerations may be included.