Section 1. Exposure data

Section 1 identifies the agent, describes its measurement, main uses, and production volume and summarizes the prevalence and level of human exposure worldwide. Methods of measurement and regulations are noted where relevant. Information is obtained from research studies, government reports and other publicly available sources, with all statements of scientific fact substantiated by a fully referenced article, report or web site. The data should present a representative overview, but all the available data are not comprehensively reviewed.

1.1 Identification of the agent (half a page for a single chemical; 2–3 pages for mixtures, occupations or industries)

The agent being evaluated is unambiguously identified. For chemicals, provide the Chemical Abstracts Service Registry Number, the latest primary name and the IUPAC systemic name and other names in common usage. Briefly describe physical and chemical properties relevant to occurrence, identification and biological activity and occurrence (e.g. liquid, solid or gaseous state; volatility, etc. for chemicals; composition, crystal structure and morphology for minerals; energy transfer for radiation, etc.). For a mixture, describe the main components, their sources and their relative proportions. Note impurities, contamination, bioaccumulation or transformations that may have an impact on the carcinogenicity evaluation (e.g. dioxin contamination of 2,4,5-T, or weathering of polychlorinated biphenyls in the environment). For an occupation or industry, describe the nature of the work and the agents involved with a focus on exposure to potential carcinogens. If the material tested in animals or in-vitro systems is different from that to which humans are likely to be exposed, note the relevant differences.

1.2 Production & use (1–2 pages; may be modified or omitted if covered in 1.1.)

1.2.1 Production

When relevant, indicate production quantities and countries where the agent is produced. Note if nationally or internationally classified as of high production volume. Indicate production processes with significant potential for occupational exposure. If significant exposures have occurred historically, note when production or exposure began and describe important changes in production processes, volume, or locations.

1.2.2 Uses

Describe the principal uses; if possible, indicate the amount or proportion attributed to each. Include minor or historical uses with significant exposure potential or that may aid interpretation of available epidemiological studies. A tabular summary may aid presentation if major and minor uses are numerous.
1.3 Measurement and analysis (up to 1 page + 1 optional table; may be omitted or modified according to relevance for the agent.)

An overview of analytical methods for research and regulatory purposes is provided as appropriate for the agent and specified in the Monograph outline. Describe in terms accessible to general readers the measurement methods for media that are important sources of human exposure. Address sampling issues (e.g. location, duration, personal versus environmental) pertinent to estimating population exposure. A tabular summary with standard references may optionally be used for multiple analytical methods or sample matrices. NB: Technical details of chemical analyses are no longer required.

1.4 Occurrence and exposure (up to 5 pages each of text and tables for 1.4.1, 5 pages and 1 table for 1.4.2)

Quantitative information regarding the prevalence and level of exposure is summarized for a concise overview of human exposure worldwide.

1.4.1. Exposures

Briefly describe the principal sources of population exposure (e.g. air, drinking-water, food, personal habits, or workplace). For those sources that are significant, representative exposure data from research studies, government reports and web sites, and other citable, publicly available sources are tabulated. It is important to search for and include data from low- and middle-income countries to the extent possible. Where data are lacking for important regions or countries, this is noted.

Organize tabulated data by source (environmental medium, occupation, use of the agent, etc.) and then by world region and country. Provide the year of sampling, mean or median, and range of exposure and other relevant parameters, such as the number of samples, sample duration, measurement method or type of site as appropriate (sample tables for environmental and occupational exposure are provided to the authors). The Monograph outline may provide a more specific or detailed organizational approach.

NB: Current exposures are of primary interest, but historical exposures may be as relevant for interpreting epidemiological studies and when agents are persistent or have long-term effects (cf. previous Monograph – if available). Data regarding environmental media, plants or wildlife that are not important sources of direct human exposure can be excluded. Similarly, data concerning remote, unpopulated sites (“background” exposures) may not be pertinent.

1.4.2 Exposure assessment and biological markers

When pertinent for the interpretation of studies of cancer in humans, describe and assess strengths and limitations of exposure measurement methods used in pertinent epidemiological studies. Such methods might include, for example, questionnaires, expert assessment, job-exposure matrices, exposure modelling, or biological markers. A table may be included to summarize methods and their strengths and limitations.
1.5 Regulations and guidelines (up to 1 page and 1 optional table; may be omitted if not applicable)

If regulations or guidelines have been established for the agent, the approach taken is described in a brief narrative. The applicable populations, the media concerned, and the basis on cancer risk, other health risks, or environmental considerations may be relevant. National and international bans on production, use, and trade are noted. If exposure limits have been established, these may optionally be tabulated if informative for the interpretation of existing or historical exposure levels (Section 1.4).