International Agency for Research on Cancer

World Health Organization

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans

What is the IARC Monographs Programme?
The IARC Monographs Programme identifies environmental factors that can increase the risk of human cancer. These include chemicals, complex mixtures, occupational exposures, physical agents, biological agents, and personal habits. The Monographs Programme publishes a series of Monographs on the evaluation of carcinogenic risks to humans posed by these environmental factors.

What is an IARC Monograph?
An IARC Monograph is not a new study. It is a comprehensive and critical review and evaluation of the published scientific evidence on the carcinogenicity of human exposures. This review includes data on cancer in humans, cancer bioassays, and the mechanisms of carcinogenesis. National health agencies can use this information as scientific support for their actions to prevent exposure to potential carcinogens.

How are evaluations of carcinogenic risks performed?
An interdisciplinary Working Group of expert scientists meets at IARC in Lyon, France, for eight days. The Working Group reviews the published studies and evaluates the weight of the evidence that an environmental factor can increase the risk of cancer. After performing and discussing a critical review of the published scientific evidence, the Working Group formulates the evaluations. As a result, each agent is classified into one of five categories.

What are the categories into which an agent can be classified?
After evaluating the weight of the evidence that an agent can increase the risk of cancer, the Working Group classifies the agent into one of five categories: Group 1, carcinogenic to humans; Group 2A, probably carcinogenic to humans; Group 2B, possibly carcinogenic to humans; Group 3, not classifiable as to its carcinogenicity to humans; or Group 4, probably not carcinogenic to humans. Since 1971, more than 900 agents have been evaluated, of which more than 400 have been identified as carcinogenic, probably carcinogenic, or possibly carcinogenic to humans.

Who performs these evaluations of carcinogenic risk?
The evaluations are performed by an independent panel of international experts. Working Group members are selected on the basis of knowledge and experience, as well as absence of real or apparent conflicts of interests. They serve as individual scientists and not representatives of any organization, government, or industry. The interdisciplinary group of expert scientists who formulated this evaluation includes public health and cancer experts from North America, Europe, and Japan.

What is done to ensure that the evaluation is independent and unbiased?
Strong safeguards are in place to protect against potential conflicts of interest by experts that could influence outcomes. Each potential participant is required to report financial interests, employment and consulting, and individual and institutional research support related to the subject of the meeting. IARC assesses these interests to determine whether there is a conflict that warrants some limitation on participation. Interests related to the subject of the meeting are disclosed to the meeting participants and in the published volume.

Who participates in Monograph meetings?
Five categories of participants can be present at Monograph meetings. The Working Group of expert scientists performs the critical reviews and develops the evaluations. Invited Specialists are experts who have critical knowledge and experience but have a real or apparent conflict of interests. These experts contribute their knowledge but do not participate in the evaluations. Representatives of national and international health agencies often attend meetings, and Observers with relevant scientific credentials may be admitted to a meeting in limited numbers. Representatives and Observers do not draft any part of a Monograph or participate in the evaluations. The IARC Secretariat consists of scientists who are designated by IARC and who have relevant expertise. They serve as rapporteurs and participate in all discussions.

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What happens at a Monograph meetings?
During the meeting, the Working Group reviews the published studies and evaluates the weight of the evidence that an agent can increase the risk of cancer. The experts meet mostly in subgroups according to type of expertise during the first part of the meeting and in plenary session during the second part of the meeting. The objectives of the meeting are peer review and consensus. In the evaluation, the agent is classified into one of five categories.

Which data sources are reviewed to formulate the evaluations?
About one year before a Monographs meeting, IARC collects relevant biological and epidemiological data from recognized sources of information, including data storage and retrieval systems such as PubMed. Meeting participants who are asked to prepare preliminary working papers for specific sections are expected to supplement the IARC literature searches with their own searches. Before the meeting, these preliminary working papers prepared by meeting participants are distributed to Working Group members and Invited Specialists for review. All eligible studies published or accepted for publication in the scientific literature before the meeting are considered.

What is the scientific basis for the evaluation?
The categorization of an agent is a matter of scientific judgment. The strength of the evidence for carcinogenicity from human and experimental animal data is evaluated and classified into one of the following categories: sufficient evidence, limited evidence, inadequate evidence, or evidence suggesting lack of carcinogenicity. In plenary session, the Working Group combines the human and experimental evaluations to evaluate the carcinogenicity of the agent. The strength of the mechanistic data is characterized and can be pivotal when the human data are inconclusive. Finally, the body of evidence is considered as a whole, in order to reach an overall evaluation of the carcinogenicity of the agent to humans.

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