

Q&A on the updating of the Preamble to the *IARC Monographs*

The <u>Preamble</u> to the <u>IARC Monographs</u> describes the principles and procedures used in developing <u>IARC Monographs</u>, including the scientific criteria that guide the evaluations.

On 12–14 November 2018, the Advisory Group to Recommend an Update to the Preamble will convene at IARC to review and update the current Preamble.

Why is an update to the Preamble being proposed?

The Preamble to the *IARC Monographs* has been reviewed and updated regularly since its introduction in the 1970s. Scientists with a wide range of expertise have been invited to discuss and make recommendations to IARC in an open and transparent way.

The Advisory Group to Recommend an Update to the Preamble is being convened to consider scientific and procedural advancements that have occurred during the 12 years since the Preamble was last amended, in 2006. In particular, there have been important scientific developments in the area of cancer mechanisms. The recommendations of the Advisory Group are anticipated to encompass these advancements, and to also take account of any other scientific input received by the *IARC Monographs* programme in response to a "Call for Public Comments" announced via its website, in advance of the in-person Advisory Group meeting.

Dr Wild completes his second 5-year term as IARC Director in December 2018. Why does not IARC delay the meeting of the Advisory Group to Recommend an Update to the Preamble until after the Director-elect Dr Weiderpass takes up office on 1 January 2019?

The Preamble is updated at approximately 10-year intervals. The last update was in 2006, meaning that an Advisory Group meeting is now due. Dr Wild and Dr Weiderpass are cooperating in the preparations for the meeting. This close cooperation will ensure an efficient transition in leadership and in the timely adoption of an updated Preamble.

How will the review and update take place?

In order to take into account scientific input from all stakeholders, in the most comprehensive and transparent way, the process is threefold:

(1) Online submission of scientific comments

Before the Advisory Group meeting, IARC will solicit comments on the Preamble so that the Advisory Group can take account of the scientific views of a variety of different stakeholders.



Scientific comments on the Preamble may be submitted online via the Public Comments Form on the *IARC Monographs* website (closing date, 7 September 2018). Pertinent comments will be made available to the Advisory Group, and no material will be treated as confidential. Submitted comments are to be accompanied by a completed WHO Declaration of Interests form.

(2) A scientific webinar

IARC will also solicit expert input during a scientific webinar, to be held before the Advisory Group meeting. Presenters generally should have published significant research related to the carcinogenicity of environmental factors that can increase the risk of cancer in humans. Public nominations of presenters (see Call for Public Comments) will be combined with those identified by IARC. Attention will be given to achieving a balance of presentations from constituencies with differing perspectives (i.e. national or international health agency or scientific advisory committee, academic institution, industry, nongovernmental organization). The names and principal affiliations of the presenters, together with pertinent disclosures from the WHO Declaration of Interests that they will be required to complete, will be available in advance of the webinar on the *IARC Monographs* website, and will also be included in the final report of the Advisory Group.

All presenters will agree to provide a brief (up to 5 minutes) scientific presentation during a webinar of no more than half a day in total length, to be scheduled in September 2018, 1–2 months before the in-person meeting of the Advisory Group. The presentations will encompass general principles and procedures and/or scientific review and evaluation, as per the Preamble.

(3) The Advisory Group meeting

A group of international experts will be invited to be part of the Advisory Group tasked with reviewing and recommending updates to the Preamble to the *IARC Monographs*. These expert Advisory Group members prepare and review preliminary pre-meeting materials and participate in the 3-day meeting to be held on 12–14 November 2018 in Lyon, France.

Who are the members of the Advisory Group? How are they selected?

The expert Advisory Group will include approximately 20 scientists. Eligible scientists will generally have published significant research related to the carcinogenicity of environmental factors that can increase the risk of cancer in humans. They may also have expertise in carcinogen testing and/or in carcinogen-hazard evaluation. Through its "Call for Experts", IARC is especially interested in finding: (a) scientists whose relevant work may not be found through standard literature searches; and (b) scientists who work in countries that have been under-represented in past Advisory Groups.

Before an invitation is extended, each potential participant, including members of the Secretariat, completes the WHO Declaration of Interests to report financial interests, employment and consulting, and individual and institutional research support related to any agent that may be reviewed by the *IARC Monographs* programme.



IARC will establish an interdisciplinary Advisory Group on the basis of: (a) knowledge and experience; and (b) absence of real or apparent conflicts of interests, also taking into consideration nominations from various stakeholders and self-nominations. Consideration will also be given to gender balance and demographic diversity. The names and principal affiliations of the experts selected as members of the Advisory Group will be available on the *Monographs* website approximately 2 months before the Advisory Group meeting.

Can experts from industry or nongovernmental organizations be selected as members of the Advisory Group?

Before an invitation is extended, each potential participant, including the Secretariat, completes the WHO Declaration of Interests to report financial interests, employment and consulting, and individual and institutional research support related to any agent that may be reviewed by the *IARC Monographs* programme. IARC assesses these interests to determine whether there is a conflict that warrants limitation on participation, irrespective of the sector (academic, industry, nongovernmental, or other) in which the potential participant is working. The declarations are updated and reviewed again at the opening of the meeting. Interests related to the subject of the meeting are disclosed to the meeting participants and the public.

Will there be Observers, and what are the different roles of the people taking part in the Advisory Group meeting?

Five categories of participants can be present at the Advisory Group meeting:

- (i) The *Advisory Group* is responsible for making recommendations to IARC on updates to the Preamble to the *IARC Monographs*. The Advisory Group members are selected on the basis of: (a) knowledge and experience; and (b) absence of real or apparent conflicts of interests.
- (ii) *Invited Specialists* are experts who have valuable knowledge and experience, but also have a real or apparent conflict of interests. These experts are invited when necessary to assist in the Advisory Group by contributing their unique knowledge and experience. Invited Specialists do not serve as meeting chair or subgroup chair, draft any text, or otherwise contribute to the recommendations.
- (ii) *Representatives* of national and international health agencies may attend the meeting because their agencies sponsor the *IARC Monographs* programme or are interested in the recommendations of the Advisory Group. Representatives do not serve as meeting chair or subgroup chair, draft any text, or otherwise contribute to the recommendations.
- (iv) *Observers* with relevant scientific credentials may be admitted to the meeting by IARC in limited numbers. Attention will be given to achieving a balance of Observers from constituencies with differing perspectives. They are invited to observe the meeting and should not attempt to influence it. Observers do not serve as meeting chair or subgroup chair, or draft any text. At the Advisory Group meeting, the meeting chair and subgroup chairs may grant Observers an opportunity to speak, generally after they have observed a discussion. Observers agree to respect the Guidelines for Observers at *IARC Monographs* meetings.



(v) The *Secretariat* is made up of scientists who are designated by IARC and who have relevant expertise. They serve as rapporteurs and participate in all discussions. When requested by the meeting chair or a subgroup chair, they may also draft text or prepare tables and analyses.

What will be the focus of the review?

The meeting will focus on the Advisory Group recommendations concerning the major sections of the *Preamble* (general principles and procedures and/or scientific review and evaluation), and as such the agenda for the meeting may be organized to allow time for subgroup as well as plenary discussions.

Will IARC change its system for classification of carcinogens?

It is the role of the Advisory Group to make any recommendations, including on the classification categories that are described in the Preamble.

What is the expected outcome?

The expected outcome is for the Advisory Group to make concrete recommendations for updates to the Preamble to the *IARC Monographs*. The discussions and conclusions of the Advisory Group will be published as a report on the *IARC Monographs* website.

When and how will any possible changes to the Preamble be implemented?

IARC will take forward the recommendations of the Advisory Group into an updated Preamble, to be published on the *IARC Monographs* website in early 2019.

Will the World Health Organization (WHO) be involved?

IARC is part of WHO. The Secretariat for the Advisory Group meeting will comprise both IARC staff and WHO staff with pertinent expertise.

Is this review and update linked to the evaluation of glyphosate or of red and processed meat?

No, that is not the case. The Advisory Group to Recommend an Update to the Preamble is being convened in line with the principle that scientific and procedural advancements that have occurred since the last amendment to the Preamble are considered regularly. Several important scientific advancements, specifically in the area of cancer mechanisms, have occurred during the 12 years since the Preamble was last amended, in 2006. It is anticipated that the recommendations of the Advisory Group will encompass these advancements, and will also take account of any comments or other scientific input that IARC is soliciting via its website and via the scientific webinar to be held before the meeting of the Advisory Group.