

select NTP/RoC Public Meeting under "What's New?").

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Director, NTP.

## Report on Carcinogens

### *Proposed Listing/Delisting Procedures*

Nominations for listing or delisting (removing) an agent, substance, mixture, or exposure circumstance in the RoC should be submitted to the NTP<sup>1</sup> (footnotes are defined). Nominations must contain a rationale for listing or delisting as either a "known human carcinogen" or a "reasonably anticipated human carcinogen." Appropriate background information and relevant data (e.g., journal articles, NTP Technical Reports, IARC listings, exposure surveys, release inventories, etc.) that support the nomination should be provided or referenced when possible.

A nomination for listing or delisting in the RoC is evaluated initially by the NIEHS/NTP RoC nomination review committee, composed of scientists from the NIEHS/NTP staff, to determine if the information available for a nomination indicates the criteria for listing can be applied and warrants formal consideration by the NTP. This committee is provided with the information submitted with each nomination and any relevant supplemental materials identified by RoC staff. The committee reviews the information provided for each nomination and makes a recommendation for either continuing with the formal review for listing or delisting or not pursuing the nomination at this time. The rationale for dropping a nomination would be the lack of sufficient information for applying the listing criteria or, in the case of nominations for delisting, the absence of significant new information published since the original listing. The recommendations of this committee are submitted to the Director, NTP for approval. Those nominations not accepted for review will be returned to the original nominator who is invited to resubmit the nomination with additional justification, which may include new data, exposure information, etc. The NTP Executive Committee<sup>2</sup> and

the NTP Board of Scientific Counselors are informed of all nominations not accepted for review for listing or delisting in the RoC.

The NTP announces its intent to review and solicits public comments on all nominations accepted for review through announcements in the **Federal Register** and NTP publications. The NTP will initiate an independent search and review of the literature and prepare a background document for each nomination under consideration. The comments received in response to the public announcement are used to help identify issues that should be addressed in the background documents. The background documents are prepared with the assistance of an expert consultant(s) who have expertise and/or knowledge for the specific nomination. Background documents are prepared according to the following general format:

#### 1. Introduction

Information contained in this section includes chemical identification such as synonyms, trade names, CAS Registry numbers, molecular formula, molecular structure, etc. Also included are physical-chemical properties and identification of structural analogs or metabolites.

#### 2. Human Exposure

Information contained in this section can include use; production; analysis; environmental occurrence including environmental release, drinking water and food content and occurrence in consumer products; environmental fate in air, water, and soil; environmental and occupational exposures; biological indices of exposure; and regulations including occupational exposure limits and "other" standards and criteria.

#### 3. Human Studies

Information contained in this section can include traditional cancer epidemiology investigations including case control and cohort studies as well as data from clinical studies.

#### 4. Experimental Carcinogenesis

Information in this section can include experimental animal investigations of potential carcinogenesis including long term bioassays, experiments where the substance is administered in conjugation with known carcinogens or factors that modify carcinogenic effects, studies to investigate a defined precancerous lesion and experiments on the carcinogenicity of known metabolites and derivatives.

#### 5. Genotoxicity

Safety Commission (CPSC), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), National Center for Environmental Health of the Centers for Disease Control and Prevention (NCEH/CDC), National Institute for Occupational Safety and Health/CDC (NIOSH/CDC), Occupational Safety and Health Administration (OSHA), National Cancer Institute of the National Institutes of Health (NCI/NIH), and National Institute of Environmental Health Sciences/NIH(NIEHS/NIH)

Information in this section can include investigations of genetic and related effects including gene mutation and chromosomal damage.

#### 6. Other Data Relevant to Evaluation of Carcinogenicity and its Mechanisms

Information contained in this section can include metabolism, absorption, distribution and excretion of the substance, other toxic effects, and data derived from the study of tissues or cells from humans and/or experimental animals exposed to the substance in question, which can be useful for evaluating whether a relevant cancer mechanism is operating in people.

Data used in the preparation of Sections 3 through 6 of the background document must come from publicly available, peer-reviewed sources.

The final draft of the background document for each nomination will be reviewed by the NIEHS/NTP RoC Review Committee (RG1) that is composed of senior scientists from the NIEHS/NTP staff. The RG1 is asked to review the background document for content and determine if it is adequate for use in reviewing the nomination and applying the criteria for listing in the RoC. Upon determination of adequacy, the background document is considered the final document of record and is placed on the NTP RoC Web site. A notice is then published on the NTP list-server and the NTP Web site announcing the availability of the background document for a nomination. Notification of the availability of background documents by mail can also be requested by contacting the NTP.<sup>3</sup> The formal review of a nomination will not begin for at least 45 day after the announcement of the availability of the background document for that nomination. All comments received within this time period will be distributed to the RoC review committees and also become part of the public record.

### Formal Review Steps

Nominations under consideration by the NTP for listing in or delisting from the RoC undergo a multi-step, scientific review process that includes several opportunities for public comment. The following text briefly describes that process.

#### *NIEHS/NTP RoC Review Committee (RG1)*

The RG1 conducts a formal review of nominations for listing in or delisting from the RoC. The RG1 reviews the background document for each nomination and all public comments received in response to the **Federal Register** announcement of the intent to

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<sup>2</sup> Agencies represented on the NTP Executive Committee include: Agency for Toxic Substances and Disease Registry (ATSDR), Consumer Product

<sup>3</sup> Contact information provided in footnote 1.