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Comments on the Report on Carcinogens Review Process and the NTP's Proposed Changes (68 FR 67692-96, Dec. 3, 2003) for its Jan. 27-28, 2004 Public Meeting

We commend NTP for again seeking public input on its RoC program in an effort to make its Reports as sound and useful as possible.

These written comments address only the RoC review process, not the listing criteria.

We request that NTP keep the record open on this matter for 30 days after this meeting for any additional public comments in response to comments or discussion at the January public meeting.

Significant Changes Proposed by NTP

As we understand the proposal, it would make the following significant changes. If there are other changes of significance that we missed, we hope that RoC program staff will clarify those changes and their significance at the public meeting.

1. **Nomination Review by New Committee Prior to RG1 Review**

There would be a new review group created called the Nomination Review Committee. This committee would review nominations for whether there is sufficient information to apply the listing/delisting criteria. After its review, this committee would make a recommendation to the Director, NTP regarding the sufficiency of the information to support the nomination. If the nomination information were found to be insufficient, the nominating entity would be advised and given an opportunity to provide additional justification. Although not stated in the proposal, if additional information were provided, there would presumably be another review and recommendation to the Director by the Nomination Review Committee.

Previously, reviews of nominations for sufficiency were conducted by RG1 as part of the RG1 review of the Draft Background Document (the "DBD", now referred to as the Background Document, or "BD"). In this process, it was not clear whether an RG1 conclusion that the nomination information was insufficient would end the review process. The proposed change would allow NIEHS/NTP scientists and the Director to determine that the formal review process would not begin unless sufficient information to support a nomination had been received.

2. **Release of the BD for Public Comment Before RG1 Review**

In the past, the BD was often released only after RG2 had conducted its review and made its recommendation and the RoC Subcommittee meeting had been announced with an opportunity for public comment. The review procedures stated only that the DBD would be posted on the NTP website and announced as available sometime after RG1 review. The proposed changes refer to RG1 review of any comments from the public on the DB, but the procedures to not state explicitly that the DB will be released for public comment a minimum period before the RG1 review to allow for public comments before RG1 review. This appears to be an oversight.

3. **Evolution of the BD Package as It Moves Through The Review Stages**

Previously, the listing procedures indicated that the DBD became the "final document of record" after RG1 determined that it was sufficient to support a listing nomination and before the RG1 conducted a review for the purpose of making a listing recommendation. The proposed changes, along with the actual contents of DBDs for the 10th RoC nominations, indicate that all of the review committees may comment on the BD, and that their comments and recommendations will be used to supplement the BD. Many of the BDs for the 10th RoC contain fairly detailed minutes of the RG1 and RG2 review meetings, issues raised, and their recommendations. At the same time, the language of the review procedures concerning the BD becoming the "final document of record" after RG1 has accepted a nomination is proposed for deletion. The implication of this is that the BD is now an evolving document (rather than a "final document of record") as it moves through the review process , and each review group will be reviewing additional materials, at least in the form of more detailed RG1 and RG2 review records containing their comments and recommendations which are made part of the BD package.

CRE Comments and Recommendations on the Proposed Changes and Additional Changes

1. **Transparency**

RoC listings are very influential. Every effort should be made to maximize and ensure their scientific rigor and objectivity. The RoC review committees are standing committees, and therefore outside experts with specific expertise regarding key aspects of an individual nomination are likely to be able to contribute substantially. For example, stakeholders may have unique information on the physical-chemical nature of a nominated substance or exposure circumstances. In addition, with the multi-stage format of the review process, there is an

increased likelihood that any inaccuracy or incompleteness at one review stage will be carried forward into the next review stage unless corrected. With the ease of posting information on agency websites, it appears that making available the maximum amount of information pertinent to a nomination and its ongoing review would promote the quality of the scientific underpinnings of the RoC and would not be burdensome. We note that during the reviews for the 10th RoC, NTP has been posting increased amounts of review information (such as public comments and review group meeting minutes and comments). We recommend maximum disclosure at each step of the review process. The specifics of this are set out in the next section.

2. **Opportunities for Public Comment**

Since it would not be burdensome to make available all pertinent information during the review process, it appears the only valid issues are when to release information, and how much information, in order to provide a sufficient basis for meaningful public comment that can then be provided to the next review group.

The first stage of the review process when outside information could improve the review is when a nomination is being reviewed. At this point in the review process, the object should be to ensure that the Nomination Review Committee has all relevant information, including particularly any specialized information on physical-chemical composition, the nature of exposures, and any studies that might be overlooked either because they were published outside the United States or because they are very recent. Such information is likely to be known best by stakeholders. When the agency first receives a nomination and plans a nomination review, it should post notice of the upcoming nomination review, the supporting justification received with the nomination, and invite submission of relevant information. (The proposed process provides only for public notification after a nomination is approved for review.) The agency should also invite recommendations for outside experts who would be likely to be able to assist the Nomination Review Committee and the Committee should be able to consult with outside experts – not for their opinions but for information of which they are knowledgeable.)

When a nomination is approved or found inadequate by the Nomination Review Committee and the Director, notice of this action should be posted along with any supplemental justification information that was reviewed by the committee in approving the nomination. If the nomination is approved, the notice should also advise that preparation of a BD will begin, and invite recommendations for outside experts who could assist in its preparation and invite comments on issues that should be addressed in the BD.

When a BD has been prepared and is ready for submission to the RG1, the BD should be posted along with an invitation to submit comments on the BD for the use of RG1.

After RG1 completes its review, the minutes of the review meeting, any review group comments, and its recommendations should be posted along with the date (or estimated date) of the RG2 meeting. Public comments received sufficiently in advance of the RG2 meeting should be supplied to the RG2. If one or more individuals on RG1 or RG2 wish to provide individual supplementary comments, whether in the form of a dissent or in the nature of additional support of the majority's views, they should be offered such an opportunity and their views should also be posted.

The current RoC Subcommittee review process, including the notice and comment opportunities, appear adequate, with one possible exception: On occasion, the RoC Subcommittee solicits the views of non-committee experts during the course of its meeting, either ones from a federal agency or otherwise, whom it has invited to participate. If this is planned, the notice of the meeting should identify such individuals and the issue they may be asked to participate in discussing..

3. **Preparation and Contents of the BD**

The procedures do not state who is primarily responsible for preparation of the BD; they state only that the BD is prepared by someone with the assistance of "an expert consultant(s)". We believe that the BD should be a model of scientific objectivity and should not contain a listing recommendation, as DBDs have in the past. The review committees can then discuss application of the listing criteria to that information and publish their comments and recommendations. Otherwise, the group that prepares the BD becomes a kind of secret review group rather than a group entrusted with gathering and cogently presenting all of the relevant scientific information. In addition, individuals should not assist in preparing the BD and then review their own work as a member of a review group, particularly if the BD contains a listing recommendation (which we recommend against). All of this suggests, indeed seems to require, that in order to preserve objectivity and an absence of any bias in the BD, the persons preparing the BD should be completely independent from any of the review groups and should not have any NTP or RoC programmatic responsibilities.

4. **Composition of Committees**

Although this subject is not addressed in the procedures, it is important and deserves some comment. There should not be overlap in the membership of the review committees, with an individual serving on one committee and then that same person, or a close associate, serving on a committee which must consider the comments and recommendations of the preceding committee – in effect thereby reviewing their own views or their own office's views.

In addition, to ensure scientific rigor, there should be adequate representation from each scientific discipline important for the particular review. In some cases this might mean adding additional expert consultants (either from an agency or academia) to assist the regular standing membership (as is done often by EPA in reviews by its Science Advisory Board). In particular, there should be sufficient expertise (i.e., more than one reviewer) from critical areas such as observational epidemiology.

5. **Role of the NTP Executive Committee**

The NTP Executive Committee, comprised of high-level officals from the agencies participating in the NTP, is usually regarded as a policy oversight committee. As such, it is unclear why it is part of the RoC review process. The Executive Committee clearly should have a role in establishing the review process; but since the RoC should be an objective and unbiased document, and since high-level agency officials often do not have expertise relevant to individual nominations, Executive Committee participation in the review process gives an appearance of policy intrusion. In addition, although the Executive Committee review is indicated to be a scientific review based on the BD, it has been reported that Executive Committee meetings often give very cursory consideration to individual nominations, and high-level officials probably do not have time to review the BD and all the review group comments and recommendations, and public comments, in preparation for such a discussion. We recommend that the Executive Committee review step be removed from the RoC review process.

Summary of the Review Procedure Recommended by CRE

Post announcement of nominations and supporting justification, and invite public to submit additional information, prior to Nominations Review Committee review. Also request recommendations for experts who should be consulted by the Committee to ensure as much as possible that the Committee has complete and accurate information. We agree that this new Committee and its process is a good idea.

Post notice of recommendation to Director by the Nominations Review Committee recommendation.

Post Director's action on Nominations Review Committee recommendation.

If a nomination is approved, post notice that preparation of Background Document will begin and invite public comments on the nomination and recommendations for expert consultants to assist with the BD.

Publish notice of availability of the initial BD when completed, and invite public comments, and announce date, or estimated date, of RG1 review. The procedures should make clear that the initial BD will be released to the public for comment prior to RG1 review. This is not clear in the current proposal.

Post comments and recommendations by RG1, invite public comment, and announce schedule for RG2 meeting. As an evolving document (i.e., with review committee meeting minutes, comments, and recommendations appended), the public should have an open opportunity to comment as it evolves.

Announce upcoming public RoC Subcommittee meeting and availability of BD and RG1 and RG2 comments and recommendations. Provide information on any non-committee experts expected to be asked to participate in discussion of any specific issues.

Additional Recommendations

The BD should be prepared by individuals who are not members of any review group and do not have any NTP or RoC programmatic responsibilities.

Background Document should be objective and should not contain a listing recommendation.

There should not be overlap in the membership of review committees, nor should individuals on one committee contain close associates of a committee whose views they are reviewing.

The NTP Executive Committee should not be a review committee, although it would be appropriate for it to have a role in reviewing the RoC procedures.

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Thank you for your consideration of these comments.

Sincerely,

/S/

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