

**COMMENTS BY THE CENTER FOR REGULATORY EFFECTIVENESS  
ON PROPOSED REVIEW PROCESS FOR THE 12TH ROC**

**71 Fed. Reg. 47507 (Aug. 17, 2006)  
(by e-mail: jameson@niehs.nih.gov)**

The Center for Regulatory Effectiveness appreciates the opportunity to comment on the NTP's proposed new procedures for the 12th Report on Carcinogens. The proposed new procedures are available online at <http://ntp.niehs.nih.gov/index.cfm?objectid=720162B0-BDB7-CEBA-FE2B27BBA2785BA5#>

**GENERAL COMMENTS**

The guidelines should state that nominations for RoC consideration will be publicly available online along with any information submitted in support of the nomination. Nominations should be published online as soon as possible after NTP receives the nominations.

The guidelines should emphasize the importance of consulting with substance-specific experts throughout the review process.

The guidelines should state that the RoC will consider and identify mode and level of exposure when classifying a substance with regard to cancer.

An appropriate NTP official should certify in the administrative record for each RoC that NTP has disseminated all information regarding that RoC in accordance with the requirements of the Information Quality Act, 44 U.S.C. 3516 historical and statutory notes. For example, an appropriate NTP official should certify in the administrative record for each RoC that the IQA pre-dissemination review requirements have been met. These certifications should be accompanied by a brief explanation of how the IQA requirements have been met.

We commend NTP for stating that the Agency will prepare a response to public comment on the 12th RoC. We recommend that NTP prepare a response to public comment on all RoCs.

It is not clear from the guidelines whether the public will have the opportunity to comment on:

- NTP's draft/proposed listing status for a substance; and
- NTP's draft/proposed RoC.

The public should have an opportunity to comment on the draft/proposed listing status and on the draft/proposed RoC.

## LINE-BY-LINE COMMENTS

### ***The propose procedures state:***

*"The reason for not going forward with review of a new nomination would be lack of sufficient information for applying the listing criteria. The reason for not proceeding with a nomination to reclassify a current listing would be the absence of significant new scientific information published since the original listing [footnote omitted]."*

### ***CRE Comment***

What does "lack of sufficient information for applying the listing criteria" mean? It should mean that a substance proposed for review will not be reviewed if internal staff review or external comment shows that the substance is neither known nor reasonably anticipated to be a human carcinogen. If this showing is made during the selection period, then there is no point in wasting time on formal review. The substance should not be selected for review.

### ***The proposed procedures state:***

*"Data used to prepare Sections 3 through 5 must come from publicly available, peer-reviewed sources."*

\*\*\*

### ***"1. Introduction***

*This section describes the properties (e.g., chemical, physical or biological) of the candidate substance and states the scientific rationale for review. For chemicals, it contains the following sections (1) chemical identification including synonyms, trade names, CAS Registry numbers, molecular formula, molecular structure, etc., (2) physical-chemical properties, and (3) identification of structural analogs or metabolites. For other types of agents (e.g., biological, exposure circumstances, or physical), it provides appropriate information to define the candidate substance."*

### ***CRE Comment***

This above quoted text refers to Section 1 of the Background Document . Under the proposed procedures, only "data used to prepare Sections 3 through 5 must come from publicly available, peer-reviewed sources." Data used to prepare section 1 should also have to meet these requirements. Why would NTP say they should not?

***The proposed procedures state:***

*" Data used to prepare Sections 3 through 5 must come from publicly available, peer-reviewed sources."*

\*\*\*

***"2. Human Exposure***

*This section provides a summary of relevant data documenting both present and past exposures. It typically provides information on use, production, environmental occurrence, and exposure (including release and fate in air, water, soil, and food), exposure to the general population (e.g., occurrence in consumer products or medical devices), occupational exposure, biological indices of exposure, and regulations and guidelines to limit exposure."*

***CRE Comment***

The above quoted text refers to Section 2 of the background document. Under the proposed procedures, only "data used to prepare Sections 3 through 5 must come from publicly available, peer-reviewed sources." Data used to prepare section 2 should also have to meet these requirements also. Why would NTP say they should not?

Sincerely,

Scott Slaughter  
The Center for Regulatory Effectiveness  
11 DuPont Circle  
Suite 700  
Washington, D.C. 20036  
202/265-2383