



Center for Regulatory Effectiveness

Suite 700
11 Dupont Circle, N.W.
Washington, D.C. 20036-1231
Tel: (202) 265-2383 Fax: (202) 939-6969
www.TheCRE.com

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Via e-mail and regular mail

Dr. C. W. Jameson
National Toxicology Program,
Report on Carcinogens Program
National Institute of Environmental Health Sciences
79 Alexander Dr.
Bldg. 4401, Rm. 3118
P.O. Box 12233
Research Triangle Park, NC 27709

Dear Dr. Jameson:

Re: Comments on the revised RoC procedures and the two talc
nominations for the 12th RoC in response to 69 FR 62276-79,
Oct. 25, 2004

We appreciate the additional opportunity to comment on this subject in view of the recent posting of the revised RoC procedures and comments made during the public meeting of the NTP Board of Scientific Counselors ("BSC") on June 29, 2004 by both NTP/RoC staff and members of the BSC, as reflected in the minutes of the meeting posted on the NTP website.

These CRE comments supplement those previously submitted by CRE on both the RoC procedures and the talc nominations.

Procedures for any Revised Nominations

RoC program staff made it clear at the June 29, 2004 Board of Scientific Counselors meeting, as reflected in the minutes, that they might modify or revise the nominations for metalworking fluids and talc. (Minutes at 11, 14, 15.) If a nomination is revised or modified, it would constitute a new nomination, and the Agency must adhere to the nomination and review procedures for the 12th RoC which were recently posted on the NTP website. A proposed revised/modified nomination would be required to be submitted to the NIEHS/NTP Nomination Review Committee with supporting rationale and information. The Nomination Review Committee would then be required to make a

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recommendation to the Director, who would decide whether or not to accept the recommendation. If the Director accepted the revised/modified nomination, it would then have to be announced in the *Federal Register* along with an explanation of the rationale and supporting information for the new nomination and with a solicitation of public comments.

It is not an option for the Agency to announce a revised/modified nomination when it makes the background document available to the public. Nominations are not announced as “proposed” nominations on which public comment is sought in order to make a final decision on a nomination. The nominations are announced as final nominations at that time, and public comments are solicited not for the purpose of possibly revising the nominations; but, rather, as explained in the procedures for the 12th RoC, the public comments “are used to help identify issues that should be addressed in the background documents.” A revised/modified nomination would almost certainly result in different comments concerning the issues that need to be addressed in the background document and therefore would require a new announcement and opportunity for public comment.¹

The October 25, 2004 *Federal Register* notice on which we are commenting states that “[M]odifications to the nominations in the attached table may be identified and would be announced in future **Federal Register** notices.” At 62276 3d col. We expect that any such announcement would be made in accordance with our understanding of the requisite procedures as outlined above, and believe that this should be clarified by the Agency – perhaps in a footnote to the explanation of revised procedures for the 12th RoC which is posted on the NTP website.

Suggestions by BSC Members for Revision of the Talc Nominations

It is imperative that nominations be clear and scientifically precise in order to enable public comments and a valid scientific review.

In its comments to the Board of Scientific Counselors and the Agency on the talc nominations, CRE asserted that if the term “talc” were to be used to describe a nominated exposure, the nomination should reference the CAS Registry number (“CASRN”) and its associated scientific definition of the substance. During the June 29 meeting, a number of Board members appeared to agree with this CRE position (as reflected in the minutes), and the October 25 *Federal Register* notice states that “[t]he nominations are provided with their Chemical Abstracts Services (CAS) Registry numbers (where available).” There is a CAS number for “talc”, but it is not provided in the talc nominations, as it should be.

¹ It remains puzzling to us why the Agency does not announce proposed nominations for public comment before they are reviewed by the new Nomination Review Committee and then submitted to the Director for approval. In the case of metalworking fluids and talc, commenters were forced to address the wording of the nominations because the wording was so lacking in clarity that it was not possible to identify the scientific issues that should be addressed in the background document. In the case of talc, this was confirmed by the statements of Dr. Jameson during the June 29 BSC meeting to the effect that the term “talc” as used in the nominations did not mean “talc” as scientifically defined, but rather talc together with some other unspecified exposures. (Minutes at 15.)

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During the BSC meeting, Dr. Storer and Dr. Blair suggested that perhaps the nominations should be divided into three parts: one consisting of “pure talc” or talc “defined by the CASRN”, along with one for “cosmetic talc” and another for “occupational exposure to talc”. (The latter two are the same as the two current nominations.) Dr. Jameson, speaking on behalf of the Agency, explained that the CASRN was not used in the nomination because “the talc to which people were exposed is not pure talc as defined by the CASRN; thus, to evaluate talc as defined only by its CASRN would be misleading.” (Minutes at 15, emphasis added.)

Neither the suggestions by Dr. Storer and Dr. Blair nor the explanation by Dr. Jameson suggest or provide a viable solution to the problem posed by the current nominations. The current nominations are based on the term “talc”. “Talc” is, quite simply, “talc” in accordance with its scientific definition and understanding; and to call an exposure “talc” when what is really intended is not talc, but some mixture of talc and other unspecified substances, is what would be misleading. Describing the exposure as “pure talc”, as opposed to “talc” does not clarify the nomination, since under the scientific definition as indicated by the CASRN, “talc” is “pure talc”. If the Agency intends that “talc” should mean something other than pure CAS talc, without saying so, that is misleading. Particularly if the Agency intends that “talc” should include “talc” intermixed with asbestos, such a meaning is inappropriate because asbestos has already been listed as a “known human carcinogen”, and because it also appears that current exposures to “cosmetic talc” do not include asbestos (points which were made by members of the RoC Subcommittee during the 10th RoC review of asbestiform and non-asbestiform talc).

Defining Nominated Exposures as Current Exposures

It is clear from both the legislative history of the RoC authorizing legislation and the plain language of the statute itself that nominations and listings must be based on exposure (as to chemical and physical nature and circumstances) which are currently experienced by persons residing in the United States.

The legislative history indicates that the RoCs were intended by Congress to provide information that would be useful to U.S. residents. This can only be accomplished if the RoCs address exposures as they are at the time of listing, as opposed to exposures as they might have been at some time in the past.²

The statute (42 U.S.C. § 241(b)(4)) states that it applies only to substances “to which a significant number of persons residing in the United States are exposed.” (Emphasis added.)

It appears that the nominations for both metalworking fluids and “talc” (both nominations) may be based on exposures as they were at some point in the past. In the case of talc, this would

² This viewpoint is also expressed in Appendix A of the 10th RoC, where it is noted that certain types of exposures have not been reviewed because they “may differ in different parts of the world or may have changed over time.”

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apply especially to talcum powder prior to 1976, since it had been shown that some brands apparently contained varying amounts of asbestos. The change in the industry due to the 1976 CTFA purity standard was amply discussed in the RoC Subcommittee review for the 10th RoC, and was clearly one of the reasons the Subcommittee voted 8-2 against listing.³ Related to this issue of current vs. historical exposures is the issue of what "talc" means, as discussed above.

Public Comment on Sufficiency of Background Documents Prior to RG1 Review of Sufficiency

The revised procedures for the 12th RoC which have now been posted on the NTP website provide that RG1 will review a background document "to determine its adequacy for use in reviewing the nomination and applying the criteria for listing in the RoC." If RG1 determines the background document provides insufficient information to review the nomination, it will recommend to the Director that the review be stopped; if it determines that the background document is adequate, the background document will be made available to the public for comment prior to the beginning of the review process at the RG1 level.

We strongly urge a modification to this procedure. We believe that RG1 should have the benefit of public comments on the background document when it makes its determination on the adequacy of the document to support review of the nomination and application of the listing criteria, rather than after such a determination.

Application of the Data Quality Legislation and Guidelines

As discussed above, at least two apparent flaws in the talc nominations could raise issues of compliance with the Data Quality legislation and guidance: (1) If the nomination and listing are stated in terms of "talc" when something other than talc is reviewed and forms the basis for a listing, the listing and listing analysis would not be scientifically valid and would lack "utility" because they would be misleading to the public, the intended users of the information. (2) If the nomination and review encompass types of exposures which existed in the past but which have since changed, the listing and review would also lack "utility" in that they would not provide currently useful information to the public.

Conclusions and Recommendations

1. If a nomination previously announced is subsequently revised/modified, the new nomination must be announced in the *Federal Register* with an opportunity for public comment. We recommend that this be stated in the explanation of procedures for the 12th RoC which has been posted on the NTP website.

³ And this decisive vote included one member voting in favor of listing based on an inaccurate understanding concerning the quantity of asbestos which was reported to have been observed in some talc brand samples prior to 1976. The other member who voted in favor of listing did not provide an explanation.

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2. The explanation of the intent behind the talc nominations, and the suggestions for revision made by BSC members are not consistent with the scientific definition and understanding of the term "talc". "Talc" means pure talc as defined with its CAS Registry number and associated definition; it cannot mean a mixture of unspecified other substances and talc, especially if one of those substances is asbestos, which is already listed as a known human carcinogen. Since talc containing asbestos was addressed during the 10th RoC reviews, we assume that something different is intended, but the current nomination provides no indication of that intent. The nomination must be clear in order to permit public comments and a valid review, and in order to provide the "utility" required under the Data Quality legislation and guidance. The nomination for metalworking fluids poses similar problems.
3. Exposures which are nominated, reviewed, and listed in the RoCs must be current exposures, not exposures which were different in the past. Otherwise, a listing would lack the validity and utility required by the Data Quality legislation and guidance and would not comply with the RoC authorizing legislation.
4. Background documents should be made available to the public for comment prior to RG1's consideration of their adequacy.

Thank you again for this additional comment opportunity and for your consideration of these comments.

Sincerely,

[Redacted]

William G. Kelly, Jr.
CRE Western Representative