

November 24, 2004

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VIA FAX AND MAIL

Fax: 1-919-541-0144

Dr. C.W. Jameson
National Toxicology Program
Report on Carcinogens
Building 4401, Room 3118
79 Alexander Drive
P.O. Box 12233
Research Triangle Park, N.C.

Re: Comments In Response To NTP's *Federal Register*
Notice of October 25, 2004, Regarding Nominations
To the 12th RoC and Review Procedures

Dear Dr. Jameson:

These comments are submitted on behalf of Luzenac America in response to the NTP's republication of nominations for the Report On Carcinogens, 12th edition ("12th RoC") and announcement with respect to the procedures that will be used for review of those nominations which appeared in the *Federal Register* on October 25, 2004, 69 *Fed. Reg.* 62276. Luzenac America is a leading producer of high-quality talc products. We presently produce over 50% of the talc which is mined and milled in the United States. As set forth in the comments which we submitted on July 16, 2004, in response to NTP's initial publication of the nominations for the 12th RoC on May 19, 2004, 69 *Fed. Reg.* 28940, Luzenac is especially concerned about the nominations regarding talc. We are also concerned more broadly about the procedures that will be used by NTP for the review and evaluation of nominations, including the procedures used to evaluate particular studies and comments.

These comments focus primarily on the review procedures, including specifically the Nomination Review Process listed on the NTP web site (last updated 10/20/04) referred to in the October 25 *Federal Register* Notice and will also briefly comment on some critical threshold issues regarding talc. As the review goes forward, Luzenac anticipates submitting additional comments.

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1. It Is Essential That the Review Procedures Followed By NTP Be Clear, Transparent and Fair In Order To Maximize the Likelihood of a Scientifically Sound Result.

A. The NTP Needs To Publish the Background Documents for Nominations Under Review for Public Comment Before the NIEHS/NTP RoC Review Committee (RG1) Determines the Adequacy of Those Documents for Review of a Nomination.

The RG1 is composed of senior scientists from the NIEHS and the NTP who may or may not have specific knowledge or research expertise in the animal and/or epidemiological studies regarding a nominated substance. Nonetheless, RG1 serves as the "gatekeeper" in deciding whether the Background Document ("BD") is adequate or inadequate for conducting a review and determining whether the review is stopped or proceeds. If the decision of RG1 is that the BD is adequate, the document is placed on the NTP website and outside comment is invited. According to the Nomination Review Process after the comment period, the BD apparently is not revised, regardless of the nature of the comments, and it is used as the scientific foundation for the ensuing acceptable review of the health effects of the substance for the remaining NTP review process. See Nomination Review Process document at p.3.

We urge the NTP to modify the procedure to accommodate a period for outside review and comment on the draft BD, along with appropriate revision of the BD based on the comments, prior to the RG1 making a decision as to whether the review should proceed or be stopped. Such an open process with constructive public comment would serve to strengthen the scientific content of the BD and might reduce the number of documents rejected by the RG1 as unacceptable. In fact, in the National Toxicology Program's Response to Public Comments and Discussion on the Preparation and Review of the Report on Carcinogens Received at the January 27, 2004, Public Meeting at pp.4-5 (posted on NTP's web site), NTP states that it will:

... place the background document for a nomination on the NTP web site at least 30 days before any of the scientific review committees meet to evaluate a nomination and make a listing recommendation. The NTP believes that this will provide the public an opportunity to review the background documents and, if desired, to provide comment or other information prior to initiation of the formal review of the nominations.

NTP states that this procedure is designed to "enhance communication and transparency." However, the Nomination Review Process document published on your web site does not expressly provide for this public comment period.

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**B. The NTP Needs to Cease Its Procedure of Having an
NTP Staffer or Member of RG2 Make a Presentation
on Nominated Substances to the RoC Subcommittee.**

It is customary during the external peer review open meeting for an NTP staffer, or member of RG2, to make a presentation to the RoC Subcommittee as a review of the scientific studies for each substance being reviewed prior to the public comment period and the subsequent subcommittee's discussion. If the RoC Subcommittee is to truly function as an independent peer review group, neither NTP scientists, nor other government scientists, should have an opportunity to influence the subcommittee's thought process, for or against listing, by presenting a review of the scientific studies. We would recommend that the Chairman of the RoC Subcommittee appoint the most knowledgeable scientist on the subcommittee for a particular substance to provide a review presentation to the subcommittee of the science for each nominated substance prior to public comments.

**2. It Is Essential That NTP Utilize Safeguards To Minimize the Prejudice
Which Would Result From Reliance on Hearsay
or "Scientific" Opinions Which Lack A Proper Foundation.**

In an "informal" administrative proceeding such as such as those which are used in connection with the review of nominations by NTP for listing in a RoC, scientific reports, comments and other documents may be admitted into the administrative record even though they may contain "hearsay" if they were offered in a formal evidentiary proceeding. The risk of prejudice to interested and affected parties which can result from this is that there is usually no opportunity to question the author of the statements and thereby challenge or evaluate the basis on which they are made or their accuracy. To minimize this risk of prejudice, based on fundamental principles of due process of law and fairness, agencies routinely provide opportunity for comment by interested parties and members of the public. While this is not a complete substitute for cross-examination of the author, it does enable interested and knowledgeable persons to raise before the agency questions and potential problems with such statements so that the agency itself may determine what if any weight to give the statements, and what if any further investigation to make to determine their reliability or accuracy.

There is also a risk that undue weight may be given to verbal or written opinions or conclusions where the scientific foundation is unclear or inadequate. The data may be unreliable. Scientifically sound procedures may not have been followed in gathering the data, the person proffering an opinion or conclusion may lack the necessary expertise in the relevant discipline, tests may not have been properly conducted - any of a virtually infinite number of deficiencies could exist. There is a grave risk that NTP in conducting its review could put undue weight on opinions or conclusions which lack a proper scientific foundation. This could result

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in a mistake by NTP in concluding that a substance either should or should not be listed.

Such mistakes can have major adverse impacts in terms of over- or under-protecting human health, needlessly removing products from the marketplace, altering consumer purchasing habits and availability of choices, and irreparably damaging an industry with consequent severe economic and social consequences. The stakes are especially high where the decision making involves branding a substance as a carcinogen.

In light of these potentially major impacts, NTP needs to be especially careful to avoid making an erroneous decision. In particular, NTP needs to take all reasonable measures to minimize the likelihood that a decision may be based on hearsay information which is unreliable or purported "expert" opinions, conclusions or scientific studies which lack a proper foundation. To do this, it is essential that NTP ensure maximum opportunity for members of the public and other interested parties to review, evaluate and comment on all material which is considered or may be considered by the NTP in reaching a decision. A procedure which maximizes transparency and the opportunity for public comment is an essential safeguard.

Translating these important principles into specifics will involve making sure that all materials and information which the NTP is considering are made available for public comment and response. Adequate time for comments must be provided. Then NTP, in considering such comments and responses, must evaluate very carefully the scientific soundness, relevance and persuasiveness of any opinions, conclusions, studies or comments which are proffered. This includes any studies which provide the basis for the background document or any subsequent evaluation thereof. The goal must be to make sure that any nomination is clearly and unequivocally supported by scientifically sound, relevant and persuasive evidence.

3. With Respect To Talc, We Recommend That the NTP Expressly Limit Its Consideration To "Pure" Talc and Not Talc Which Is Contaminated By Asbestiform Fibers or Other Contaminants or Impurities.

The NIEHS nominated Talc (Non-Asbestiform) and Talc (Containing Asbestiform Fibers) for review for possible listing in the 10th RoC. The NTP's initial review of talc found that "there is some confusion in the scientific literature over the mineral nature and consequences of exposure to talc, both containing asbestiform fibers and not containing asbestiform fibers."

We agree with the NTP regarding the confusion in the scientific literature over the characterization of the mineral talc and the consequences of exposure.

We would also submit that for the Talc BD used for the 10th RoC review there was confusion by the authors of the document regarding the characterization of the

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mineral talc and the health outcomes of exposure. This confusion could have likely been avoided by a public review and comment period as suggested in paragraph 1.B. above. Because it was not, the confusion over the mineralogy and health effects of talc was passed along from one review step to the next. Ultimately, the Board of Scientific Counselors Subcommittee voted to not list talc not containing asbestiform fibers.

The NIEHS has submitted talc for review for listing in the 12th RoC and has divided the review into Talc (cosmetic and occupational exposure). As noted in our comments of July 16, 2004, we take exception to these unscientific classifications of the mineral. Talc is defined mineralogically as a hydrated magnesium sheet silicate with the chemical formula $\text{Mg}_3\text{Si}_4\text{O}_{10}(\text{OH})_2$ and has a specific CAS Registry Number 140807-96-6. The non-talc components of industrial talc products can include dolomite ($\text{MgCa} \cdot 2\text{CO}_3$), calcite (CaCO_3), magnesite (MgCO_3), chlorite ($3\text{MgO} \cdot 4\text{SiO}_2 \cdot \text{H}_2\text{O}$), quartz (SiO_2), and occasionally serpentines and amphiboles. In commercial applications, talc products include "cosmetic" grades and "industrial" grades.

Talc specifications for cosmetic applications are issued by the Cosmetic Fragrances and Toiletries Association (CTFA). The CTFA specification focuses on the purity of the talc. Additional product parameters are generally specified by the customer. The CTFA talc specification includes the requirement that the product does not contain asbestos. Talc utilized in cosmetic and personal care products normally contain greater than 90% talc and most present-day consumer products contain 96-99+% talc.

Industrial grade talc products can vary considerably in actual talc content. Product specifications for industrial talc products are application oriented and are generally established by market and customer requirements. Since the mid-1970's there has been an ever increasing demand for supplier "certifications" that the talc is asbestos-free. It is imperative that the current categorization of cosmetic talc and occupational exposure to talc refer to exposure to the mineral talc itself and not to other minerals that talc might be associated with in a mineral matrix. The mineralogical definition for talc does not include asbestos and consideration of the medical literature of exposure to asbestos minerals in a review of talc is scientifically unjustified and unfair. The NTP has already listed asbestos as a known human carcinogen in its 1st Annual Report on Carcinogens and any material containing asbestos is already covered by that listing. Minerals that might be associated with talc as minor constituents of the ore body should not be reviewed in the 12th ROC and if it is the intention of the NTP to review and classify specific minerals other than talc then that should be the subject of a future review.

Crystalline silica in the form of quartz can be a non-talc component of mined talc but that alone does not justify including the crystalline silica cancer studies in a review of talc. In that crystalline silica of respirable size is listed by the NTP, if a talc product were to contain threshold quantities of crystalline silica, then the

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OSHA HAZCOM standard would be automatically triggered and public health provisions to control occupational exposures to silica through warnings and labeling to downstream users would be required. Hypothetically, if talc were to contain $\geq 0.1\%$ of a regulated asbestos mineral the material would rightly be regulated as asbestos by OSHA, as well as other regulatory agencies with standards for asbestos. In addition to the OSHA HAZCOM standard, the provisions of the OSHA substance specific asbestos standard would be triggered. The RoC is a listing of substances that potentially pose a cancer risk. Talc is a specific substance with its own chemical, physical and morphological properties and it is this mineral alone that should be the subject of the NTP review for its appropriate cancer classification.

We appreciate the opportunity to provide these comments and request that they be considered.

Sincerely yours,

[Redacted]

Jon Godfa
President
Luzenac America, Inc.

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Luzenac America, Inc.

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