SCIENTIFIC ASSOCIATION OF EUROPEAN TALC INDUSTRY **EUROTALC**

Brussels, 29 November 2000

National Toxicology Program (NTP)
Dr C.W. Jameson
Report on Carcinogens
MD EC-14
PO Box 12233
Research Triangle Park
NC 27709 North Carolina
USA

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Dear Dr Jameson,

EUROTALC, the Scientific Association of the European Talc Industry, respectfully submits the attached comments in response to the "NTP Draft Report on Carcinogens Background Document for Talc-asbestiform and non-asbestiform".

Our comments will be completed by more detailed submission which will be sent separately by John Addison (John Addison Consultancy, Cottingham, England) and Dr Arthur Langer (Brooklyn College of the City University of New York).

Yours sincerely,

Dr Michelle Wyart Remy
Secretary General

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EUROTALC Response

to the NTP Draft Report on Carcinogens

Background Document

for Talc asbestiform and non-asbestiform"

November 2000

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Introduction

EUROTALC is the Scientific Association of the European Talc Industry. Through company ownership, the Association links much of the US talc industry as well.

Our organisation focuses on all non-commercial issues related to talc production, processing and use. In particular, occupational health is considered a priority by our members, who share the collected information with their customers. We therefore pursue, with NTP, the same objective of seeing the business conducted in a way that safeguards the health of those exposed to talc.

EUROTALC certainly welcomes the work of the NTP in constantly striving in improve public health. However it is essential that the deliberations of the NTP's Board of Scientific Counselors be based on the relevant information and a judicious weighing of it, so that the outcome reflects every credit on the Public Health Service.

The draft report, prepared for the NTP by Technology Planning and Management Corporation does not, in our view, provide the Board with the valid foundation it must have in order to construct a conclusion, which is helpful to the public and just to the industry. This is because the document is seriously flawed in a number of crucial respects.

Here follows a summary of the points at issue, on which EUROTALC has expertise:

1. Linking talc with asbestos

1.1 Guilt by association

There is a clear, but false, line of logic in the TPMC report that goes:

- Asbestos is a carcinogen
- Widespread contamination of talc products with asbestiform minerals is alleged
- Ergo, talc products should be regarded as carcinogenic

The conclusion is not true, because the middle statement is not true.

In our experience there are no credible analyses showing asbestiform fibers in either industrial or cosmetic talc products.

There are strict quality control requirements from the talc industry's customers, particularly in the CTF (cosmetics, toiletries and fragrances) sector, but also in paper, plastics and paints sectors, specifically precluding the presence of asbestiform fibers. For some applications, eg food additive, there are regulatory controls precluding the presence of asbestiform fibers.

Yet on page 28 section 3.3 para 2 it is stated:

".....because of the widespread contamination of talc and commercial talc products with asbestiform minerals, it must be assumed that "talc" without further specification of mineralogy or morphology may contain asbestos fibers. The weight of the evidence thus indicates that it would be prudent to regard such undifferentiated talc materials as carcinogenic."

And on page 56 section 4.3 para 2 it is stated:

"Italian and commercial talc (both presumably containing asbestos fibers)....." ".....asbestiform dusts (chrysotile, crocidolite, amosite, anthophyllite), as toxicological surrogates for asbestiform talc, caused tumors....."

These statements are, frankly, libelous to the American (and international) talc industry. This unscientific and anecdotal linking of talc with asbestos is a huge injustice to a high-technology processing industry with an excellent regulatory compliance and product quality record.

1.2 "Asbestiform talc" is a mineralogical curiosity

As pointed out in J. Addison and A. Langer comments on the NTP Draft Report for Talc Asbestiform and Non-asbestiform, for mineralogists, "asbestiform talc " does not mean talc containing asbestos, nor talc containing asbestos fibers. Talc crystals which would develop in an asbestiform habit would be called "asbestiform talc". It is considered as a mineralogical curiosity, with no industrial significance. With the exception of a few keen mineralogists there is no human exposure to that rare mineral.

1.3 "Asbestiform talc" (in the meaning of the draft Report) does not need to be listed by NTP

The draft Report erroneously use "asbestiform talc" to refer to talc containing asbestos or asbestiform fibers. J Addison and A. Langer comments address this aspect in depth. Regarding the pertinence of the evaluation of "talc containing asbestos", EUROTALC would like to stress the following:

a- All the mineralogical analyses quoted in the Report as giving evidence of the presence of asbestos fibers in talc were conducted before the 80's and these are inadequate to differentiate asbestos from its non-asbestos analogues. It is one of the prime responsibilities (and necessities) of the talc industry to ensure by adequate controls that the asbestos amphiboles and chrysotile are absent from its products.

b- In addition, asbestos is a listed carcinogen. As with many other carcinogens, it may contaminate naturally occurring ores or artificially prepared mixtures, preparations, etc., in various proportions, from traces to significant amounts. There is no objective reason to list specifically "asbestiform talc".

1.4 The relevant talc literature does not demonstrate talc carcinogenicity

Many of the papers in the literature, and relied upon in the draft report, on the occupational health effects of "talc" in fact relate to non-asbestiform tremolite ore and product, containing a minority of talc. They do not refer to talc products proper from the talc industry. Thus from the results one cannot attribute any observed health effects specifically to talc. Therefore all the literature regarding this product and cited in the draft report, is not relevant in the assessment of the possible carcinogenity of talc. Further, the experimental data reviewed in the TPMC draft report are exclusively taken from the asbestos literature.

A reference which **does** relate to talc proper, is "An Epidemiological Mortality Study in the Talc Producing Industry", Wild P., Institut National de Recherche et de Securité, June 2000, p1-73 (in French). A copy was submitted to NTP, preceded by an official Executive Summary in English. It was also submitted to IARC. This study was not cited by the TPMC draft report.

This study concerns the largest talc mine and milling plant in the world and mortality in the cohort is tracked from 1 Jan 1945 to 31 Dec 1996. It is the follow-up of a survey previously conducted on the same population, the results of which are published ("Survey of the respiratory health of the workers of a talc producing factory", Wild P. et al, Occup. Environ. Med., 1995, 52, p470-477). Although the last results are not yet published in the scientific literature – they are ready for submission – the independence of the report is

guaranteed by the reputation of INRS through ISO 9000 accreditation and peer-review of their reports by an external committee.

The draft report (p22, section 3.1.3, para 2) states " No available study of workers exposed to talc includes quantitative individual level data on the level of exposure.....". This is not correct. The above referenced study does do this, with a site specific job-exposure matrix (JEM). The same matrix was used in the preceding study of this same population (Wild, P. et al, 1995). This paper is not cited by the draft report either.

The findings of the research on this cohort, the largest and longest in the literature on talc proper, should have a significant place in the report.

In studies which are cited, in rubber, paper and ceramic plants, and also in the perineal use of powders, insufficient weight is given to the fact that the people involved were exposed to many other agents. Thus any effects observed cannot be reliably attributed to talc.

2. The animal inhalation study on talc is inadequate to demonstrate talc is a carcinogen

"Talc: Consumer Uses and Health Perspectives" 31 Jan-1 Feb 1994. Workshop cosponsored by the International Society of Regulatory Toxicology & Pharmacology and the United States Food and Drug Administration

This event brought together over 20 leading experts in epidemiology, safety assessment, toxicology and clinical medicine. They deliberated on the latest studies conducted on talc and its use in consumer products.

Some of the papers presented at the event are cited in the draft report but the event itself and its conclusions are not.

In the journal Regulatory Toxicology and Pharmacology Vol. 21, No 2, April 1995, the Executive Summary states:

Regarding the animal (Lovelace) study –

" In regard to the NTP talc bioassay in rodents, it (the expert panel) found that because of the extreme doses and the unrealistic particle sizes of the talc employed, because of the negative results in mice and male rats, because of the lack of tumor excess at the low doses, and because of the clear biochemical and cytological markers of excessive toxicity in female rats, the positive talc bioassay results in female F344/N rats are likely experimental artefact and non generic response of dust overload of lungs and not a reflection of a direct activity of talc."

EUROTALC fully supports the expert opinion of Dr Oberdörster, Dr Wehner and others, that the combination of very serious flaws in this study, clearly rule it out as an indicator of hazard to humans. Perhaps the report's authors were unaware of these previously identified problems.

No additional work has been reported since which demonstrates direct activity of talc.

3. Ovarian cancer evidence is not conclusive

The ovarian cancer epidemiology will be addressed in other submissions. While having no particular expertise in the ovarian cancer aetiology, EUROTALC however regularly benefits from the advice of the epidemiologists who take care of the talc workers cohorts under control. EUROTALC supports the views of qualified epidemiologists that there is no scientifically founded evidence of talc having a causal role in the occurrence of ovarian cancer. The weak association observed in some studies, and not confirmed in a large prospective survey, could be explained by chance, bias or confounding factors.

4. Myriad smaller errors

Experts we have communicated with, in the different technical areas spanned by the draft report, all find numerous smaller errors of fact, logic and interpretation. Although smaller they are frequently significant and their summation, coupled with the major issues addressed by EUROTALC and others, clearly demonstrate the inadequacy of the draft report.

The quality of the literature search, its review and discussion, and its synthesis and conclusions, do not provide NTP with a valid basis for making such important and far-reaching decisions. This draft report does not stand up in the "court" of scientific scrutiny.

In conclusion

The "talc containing asbestiform fibers" review is largely redundant given previous evaluations of asbestos and is irrelevant to the talc evaluation dossier.

EUROTALC respectfully requests the NTP Board of Scientific Counselors to re-consider the draft report conclusions that "talc not containing asbestiform fibers" (which should read "talc") is reasonably anticipated to be a human carcinogen.

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