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Report on Carcinogens
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Research Triangle Park, NC 27709

NOV 30 2000

From Mr. J Addison and Dr. A.M. Langer

Re: Substances Under Review for Possible Listing in the Report on Carcinogens, Tenth Edition (65 Federal Register 17889) : Asbestiform Talc and Non-asbestiform Talc

Dear Dr Jameson,

On behalf of Eurotalc, the Scientific Association of the European Talc Industry, we appreciate the opportunity to provide comments on the Draft Report on Carcinogens Background for Talc asbestiform and non-asbestiform. We enclose a review of the Draft Report and urge the NTP to recognise the deficiencies in it when they consider listing talc in the 10th Report on Carcinogens. We believe that there is insufficient scientific evidence to justify such a listing and hope that the NTP will take the opportunity to correct the previous misapprehensions about talc.

Yours faithfully,

John Addison

Draft Comments on the NTP Draft Report on Carcinogens Background Document for Talc Asbestiform and Non-asbestiform.

John Addison, Arthur M. Langer

November 2000

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Comments on the NTP Draft Report on Carcinogens Background Document for Talc Asbestiform and Non-asbestiform.

These comments on the NTP Draft Report on Carcinogens were written by Mr John Addison, of John Addison Consultancy, Cottingham, England, and Dr. Arthur M. Langer, Professor and Director of the Environmental Sciences Laboratory, Brooklyn College of the City University of New York.

Mr Addison, a mineralogist, worked in the Institute of Occupational Medicine in Edinburgh from 1978 to 1993 where he was Head of the Mineralogy Section involved in studies of minerals and their biological potential etc. He also participated in experimental animal studies with Dr. JMG Davis where he was responsible for characterising materials before use. He has co-authored reports concerning the biological potential differences of cleavage fragments and their asbestos analogues. He has served for many years as an expert on UK Health and Safety Executive working groups, drafting the UK methods for the identification and determination of asbestos minerals, and on the oversight committees for the proficiency testing of laboratories involved in asbestos analysis and fibre counting. Mr Addison has published extensively in the area of minerals in the environment and their impact on public health, including chapters on asbestos for encyclopedias on behalf of major publishing houses in the USA and the UK. He is currently working internationally as a consultant mineralogist for a number of industrial clients.

Dr. Langer, also trained as a mineralogist, served as the Associate Director of the Environmental Sciences Laboratory in the Mount Sinai School of Medicine in New York from 1965 - 1985. He has written some 150 papers that focus on the health effects of inorganic dusts, many dealing with the properties that impart biologically important qualities to the powder. The materials studied include the asbestos fiber types, talc, silica, the titania polymorphs rutile and anatase, fibrous clay minerals, sepiolite, man-made vitreous fibers, and others. This expertise, developed over 35-years of professional commitment, has been sought by, and shared with, international and national agencies while serving on select committees, including IARC, IPCS, US NAS-NRC, EPA, OSHA, MSHA, FDA, NIOSH, NIEHS, among many. Talc has been among the minerals of interest. In 1968, with Dr. Irving J. Selikoff, Dr. Langer gave a seminar at the FDA concerning the mineralogical complexity of consumer talcum in the marketplace at that time and its possible ramifications concerning human health.

Comments on the NTP Draft Report on Carcinogens Background Document for Talc Asbestiform and Non-asbestiform.

John Addison, Arthur M. Langer

November 2000

Introduction

The Draft Report on Carcinogens Background Document for Talc Asbestiform and Non-Asbestiform is a review of the relevant information necessary to the proposed listing of those substances as carcinogens by the National Toxicology Program Board of Scientific Counselors. It was prepared for the NTP by Technology Planning and Management Corporation for discussion. This document is a review some of the mineralogical and other aspects of the Draft Report.

Review

The report gives an entirely wrong impression of the nature of the asbestos issue in the talc industries by implying that there is widespread contamination of talc products by asbestiform minerals, and that therefore talc products should be listed as carcinogens in the Tenth Report on Carcinogens. There is no widespread contamination of talc products by asbestiform minerals. There are substantial regulations in place that preclude that possibility, and industry-wide agreement on the testing of products that is necessary to ensure that the regulations are met.

In general the terminology used by the Draft Report in its assertions is at times confusing, misleading, inappropriate and incorrect. In particular the Draft Report uses the term 'asbestiform' in different ways. In one definition it seems to mean that a mineral so described has all of the properties of asbestos; in another usage it means containing asbestos or asbestiform fibres. It can not be used in both ways. These are precisely the sort of misappropriations of established mineralogical terms that has led to the confusion surrounding asbestos in the past. They should be avoided now.

It is recommended that the practical definition for the physical characteristics of asbestos proposed for use by the American Society for Testing Materials (ASTM 1990), and cited by The Health Effects Institute (HEI 1991), should be used. They refer to *asbestiform* as follows:

"Asbestiform mineral fiber populations generally have the following characteristics when viewed by light microscopy: (1) many particles with aspect ratios ranging from 20:1 to 100:1 or

higher (greater than 5 μm in length); (2) very thin fibrils generally less than 0.5 μm in width; and (3) in addition to the mandatory fibrillar crystal growth, two or more of the following attributes: (a) parallel fibers occurring in bundles, (b) fibers displaying splayed ends, (c) matted masses of individual fibers, and (d) fibers showing curvature.

The term asbestiform describes a mineral habit and is applied to a wide range of minerals, generally meaning that the minerals occur as fibre bundles or matted masses that are easily split into long thin flexible fibres. Asbestos minerals display the asbestiform habit, but in addition they are characterised by the physical properties of enhanced strength and flexibility, durability, diameter-dependent strength and unique crystallographic surfaces. Gypsum, brucite and anhydrite are examples of non-asbestos minerals that sometimes occur in the asbestiform habit (asbestiform brucite is called nemalite). Even when they occur in the asbestiform habit these minerals are not asbestos.

An amphibole such as tremolite, actinolite or anthophyllite occurring in the asbestiform habit is correctly referred to as asbestos, and terms such as *asbestiform tremolite* are synonymous with tremolite asbestos. However, it is tautological to refer to any asbestos mineral as asbestiform, as in *asbestiform crocidolite or asbestiform chrysotile*: the use of the term asbestiform in this context is redundant.

The term *asbestiform talc* could only be applied to the mineral talc only if it occurred in the asbestiform habit. *Asbestiform talc* can not be meaningfully applied to talc products that contain asbestos or asbestiform minerals. If it was the intention of the NTP to regulate for talc containing asbestos then it is advised to use the term asbestos or asbestos minerals and to define the targeted minerals accordingly. Similarly the application of the term non-asbestiform to talc that does not contain asbestiform fibres is ill-advised; it is simply talc.

Talc containing asbestiform fibres should not be described as a human carcinogen because there are many asbestiform mineral fibres, including those of gypsum, anhydrite and brucite (nemalite) that are not carcinogenic and to include them by implication in the listing would be a presumption.

If there is still an argument as to whether 'asbestiform talc' actually exists at all then it is because of the lack of clarity in the definitions used. If 'asbestiform' means 'resembling asbestos' or 'having the morphology of asbestos' (following the ASTM definition), then asbestiform talc does exist as an extremely rare mineralogical curiosity.

In contrast, if 'asbestiform' means 'having all the properties of asbestos' (as in the NTP Report Definition) then asbestiform talc does not exist.

The many other minerals with rare fibrous varieties such as brucite, muscovite etc do not have all the properties of asbestos but they have often been described as asbestiform. These are some of the reasons why the ASTM definition of the term 'asbestiform' is preferred.

The question of whether true asbestiform talc (ASTM definition) would require listing as carcinogenic to humans is not addressed in the report but, given the extreme rarity of talc in the asbestiform habit there would be little need to do so. Exposure to dust from asbestiform talc could only ever be minimal and of short duration, and the exposed population would consist of a handful of mineralogist who, out of curiosity, have collected small samples. Furthermore the implantation experiments by Stanton et al (1981) showed that the mesothelioma potential of talc fibre was zero.

IARC have made the same errors in their documentation. They started correctly by describing the minerals that may be found in some talc deposits, which included *amphibole minerals (asbestiform and non-asbestiform).* They correctly referred to *asbestiform tremolite* in talcs to which some miners and millers may have been exposed in a very limited number of areas, but then erred in their evaluation by referring to talc containing asbestiform fibres. They had no evidence whatsoever to generalise the evaluation beyond the asbestos minerals and one can only assume that this mistake was the result of insufficient mineralogical information, or that the mineralogical advice was ignored.

Talc containing asbestos may reasonably be concluded to be carcinogenic to humans, but then so would any other mineral product or material containing asbestos. It is absurd to suggest that all mineral products containing asbestos should be listed separately by the NTP, especially since the asbestos minerals are already listed.

If the NTP is uncertain about the minerals that should be included in the definition of asbestos minerals then it should seek advice. The current legislative definition of asbestos includes chrysotile, amosite, crocidolite, tremolite asbestos, anthophyllite asbestos and actinolite asbestos but excludes the prismatic forms of the last three minerals. This list may be considered to be sufficient for the purposes of the NTP. However, there are other species of amphibole asbestos minerals that might also be included on the grounds that they belong to a structurally-related class of substances whose members are listed in a previous Report on Carcinogens as 'known to be human carcinogen'. These additional amphibole asbestos minerals include richterite asbestos, winchite asbestos, arfvedsonite asbestos and perhaps any other amphibole mineral in an asbestos habit. One of us (AML) proposed that these be included in the OSHA Asbestos Regulations in 1984.

The authors need to ensure that there is a clear distinction made between the mineral talc and the commercial products that are given the same name but which may be entirely different in composition. (Rohl et al 1876)

Detailed Comments

There are many inaccuracies and errors throughout the report that lead to the impression that it was not sufficiently well researched. The following are some examples.

1. Statement: -*Talc is a hydrous mineral consisting of magnesium silicate ($3MgO.4SiO_2.H_2O$) and is generally identified as either containing asbestiform fibers (asbestiform talc) or not containing asbestiform fibers (non-asbestiform talc).*

Response: -Talc is not commonly identified as containing asbestiform fibers or not containing asbestiform fibers, nor is it known as asbestiform talc or non-asbestiform talc. Talc is occasionally known by grades: pharmaceutical, cosmetic and industrial. In fact it has been common practice for a number of years in the talc industries to test products very carefully so that they do not contain asbestos minerals. The FDA notes that cosmetic grade talc is at least 85% talc and 5% chlorite and/or carbonate mineral. Cosmetic talc products that do not meet this standard are not marketed.

2 Statement:- *"Asbestiform talc" generally refers to talcs containing asbestiform*

tremolite/actinolite, anthophyllite, or chrysotile. These are the predominant asbestiform mineral species found in talcs.

Response:- "Asbestiform talc" does not generally refer to talc containing asbestiform tremolite/actinolite, anthophyllite or chrysotile: the term refers to the minerals with the asbestiform habit. We stress that the use of the adjective 'asbestiform' in this case modifies talc, not the minerals that might be present in it.

3 Statement:- *Unlike many chemical substances that are discrete entities definable by a fixed chemical structure, asbestiform fibers comprise a group of materials that are not easily defined. They have a broad range of chemical compositions and crystal structures, sizes, shapes, and properties, and have been described with diverse terminology.*

Response:- Asbestiform fibres are well defined. The list of minerals that may occur as asbestiform fibres is extensive and includes minerals from many disparate groups. However, it is not an easy matter to define them all simply in one blanket phrase or statement. Asbestiform minerals do not form a group in any mineralogical sense other than possessing the same habit, and possession of a common habit emphatically does not place two otherwise unrelated minerals in the same group. For example, asbestiform amphiboles are not in the same mineral group as asbestiform brucite; their unit fibrils are both structurally and chemically dissimilar.

4 Statement:- *The basic properties of minerals usually do not vary with different crystallization habits, but a noteworthy exception is the asbestiform habit.*

Response: The basic properties of the unit fibrils constituting minerals with asbestiform habit are generally the same as those of the minerals in the normal habit. Hardness, specific gravity, refractive indices, colour, chemical composition, basic crystal structure, crystal system etc are all unaffected by the possession of asbestiform habit. However, the bundles of fibrils found in asbestos do exhibit optical properties and the special properties of asbestos (high tensile strength etc.) that are markedly dissimilar to the non-asbestiform crystal forms. It is also clear that the normal varieties of amphiboles possess different toxicological properties, having lower carcinogenic potential than the asbestos varieties.

5 Statement:- *Although talcs can be virtually free of fibrous materials, they also have been*

reported to contain asbestos fibers in quantities sometimes constituting almost half the total product weight (Dement and Zumwalde 1979). Surveys published in the late 1960s and 1970s reported that talcum powders contained measurable amounts of chrysotile, tremolite, and anthophyllite fibers that may be of asbestiform nature (Rohl et al. 1976,).

Response:- The historical record of asbestos in talc products is of little relevance today. There are strict quality control requirements from the talc industry's customers, particularly in the cosmetics sector, but also in the paper, paints and plastics sectors that specifically preclude the presence of asbestos minerals. For some applications, e.g. food additives, there are regulatory controls that preclude the presence of asbestos minerals.

Most of the analyses of talcs that were carried out in the 1960s and 1970s were carried out using X-Ray Diffractometry, a method which is incapable of differentiating between the asbestos form and the normal forms of amphiboles, so the "quantitative" analyses of asbestos contents are not to be accepted without question. In fact Dement and Zumwalde (1979) state that much of the tremolite detected by XRD in their analyses was of a non-fibrous habit.

6 Statement:- *Natural talc deposits and commercial talc products sometimes are found to contain serpentines (chrysotile, antigorite, and lizardite) and fibrous and non-fibrous amphiboles (Rohl et al. 1976). This form is also known as asbestiform talc, talc (containing asbestos), or talc containing asbestiform fibers.*

Response:- This statement is increasing the confusion in equating the terms asbestiform talc, talc (containing asbestos) and talc containing asbestiform fibres. Talc that contains asbestos or asbestiform fibres is not known as asbestiform talc. *Asbestiform talc* is the mineral talc in the asbestiform habit: *talc (containing asbestos)* is simply commercial talc that contains one or more of the regulated asbestos minerals: *talc containing asbestiform fibres* would be a commercial talc that contained one or more of the asbestiform minerals, including the asbestos minerals, but also possibly, asbestiform brucite or any other asbestiform mineral. We stress again that true asbestiform talc is extremely rare, that modern analytical techniques are more than adequate for the control of commercial and industrial minerals, and are in common use to preclude or minimise the presence of asbestos.

7 Statement:- *Conflicting views have been expressed regarding the extent to which these fibrous constituents are asbestos. Table 1-3 summarizes information about the use of the term "asbestiform talc."*

Response:- Most of the views regarding the extent to which the fibrous components of talc are asbestos or not have in fact been resolved. Most have been found not to be asbestos. In raising *conflicting views* this report seeks to reverse the progress in descriptive mineralogy by re-inventing issues that have mostly been settled, certainly among mineralogists and materials scientists. Furthermore, Table 1–3 does not summarise information about the use of the term "asbestiform talc", it simply lists the asbestos minerals.

8 Statement:- *3.1.3 Summary The results of recent epidemiologic studies of the cancer risks associated with exposure to talc are largely consistent with the data evaluated by IARC in 1987. Occupational studies continue to suggest a moderate increase in lung cancer mortality among workers exposed to talc dust in talc mining and milling operations and in other industrial settings where talc was used, including the rubber and paper industries. Studies of facilities where the talc was known to have contained asbestos or been of fibrous form give the strongest evidence of risk (IARC 1987a, Lamm et al. 1988).*

Response:- Occupational studies do not continue to suggest a moderate increase in lung cancer mortality among workers exposed to talc. The only suggestions of such a risk comes from workers exposed to talc containing small amounts of asbestos. Almost all of the studies carried out on talc alone have shown no increased risk from talc. The authors of the report have consistently sought reasons to dismiss those studies finding no excess cancers while accepting as valid any study, however flawed, finding excess cancer.

9 Statement:- *Some studies of workers exposed to talc also identified other potentially carcinogenic occupational agents in the workplace. Talc miners in Vermont and Norway were potentially exposed to radon daughters in addition to talc dust; hardrock miners may also have been exposed to silica. Both agents are associated with increased risk of lung cancer and classified as carcinogenic by the IARC and the NTP, but the studies considered here did not adjust for these exposures.*

Response:- It is interesting that these studies found low or no elevated cancer risk even when there were possible exposures to known carcinogens. Are the authors suggesting that the discovery of higher risks would somehow have convinced them that talc was or was not carcinogenic, or simply that the studies were flawed and therefore must be discounted. In that case every negative study for every known substance would be discounted and everything would be classified as carcinogenic since every working population could probably be shown to have experienced some potential exposure, however slight, to a known carcinogen.

10 Statement:- *Only occupational studies of workers in talc mining and milling operations and pottery production provide sufficient information to identify asbestiform talc. The evidence, derived largely from observations of excess lung cancer in these settings, indicates that talc containing asbestiform fibers is carcinogenic.*

Response:-This is emphatically not the case. Only a careful mineralogical assessment of the materials will provide sufficient information to identify talc containing asbestos. Talc containing asbestos would expected to be carcinogenic. The evidence derived from the observation of excess lung cancer in industrial settings where talc containing amphiboles was used could never indicate that talc containing asbestiform fibres was carcinogenic.

11 Statement:- *However, 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.*

Response:-There is no widespread contamination of talc or commercial products with asbestiform minerals. It is unwarranted to assume that 'talc', without further specification or mineralogy or morphology, contains asbestos fibres. Nor is there any weight to the argument that such undifferentiated talc should be regarded as carcinogenic. This is a sweeping generalisation that is so utterly wrong as to be breathtaking in its absurdity.

12 Statement:- *4.1.1 Inhalation exposure in rodents This inhalation bioassay provided evidence for carcinogenicity of non-asbestiform talc in male and female rats based on increased incidences of benign or malignant pheochromocytoma of the adrenal gland and evidence for*

carcinogenicity of non-asbestiform talc in female rats based on an increased incidence of alveolar or bronchiolar adenoma and carcinoma of the lung (NTP 1993).

Response:-There is evidence from the original report on this inhalation study that the talc used actually contained significant amounts of tremolite (as reported to the study authors by McCrone Research, Chicago). If so then there could well have been asbestos present and the study could not inform as to the carcinogenicity of 'non-asbestiform talc'. Furthermore, the exposure regimes were such that the value of the study in informing about the possible carcinogenicity of talc is seriously undermined.

13 Statement:- ***4.2 Asbestiform talc***

The IARC reviewed the carcinogenic potential of asbestiform substances via various routes in various species up to 1987. The studies reviewed used Italian talc and commercial talc (IARC 1987a). The IARC also reviewed studies in which asbestiform fibers or different forms of asbestos (amosite, anthophyllite, crocidolite, chrysotile), without regard to mineralogy, were used (IARC 1977, 1987b). For evaluation of the carcinogenicity of asbestiform talc, asbestos is considered a reasonable surrogate, in part, because asbestos is the generic term for all naturally occurring fibers of mineral silicates of the serpentine and amphibole series (IARC 1977)

Response:- For the reasons discussed earlier in reference to the use of the term asbestiform it is clear that asbestos is not a reasonable surrogate in the evaluation of carcinogenicity for 'asbestiform talc'. Asbestos is emphatically not the generic term for all naturally occurring fibres of mineral silicates of the serpentine and amphibole series.

14 Statement:- ***4.3 Summary.*** *Inhaled non-asbestiform talc was associated with increased incidences of benign or malignant pheochromocytoma of the adrenal gland in male and female rats and with an increased incidence of alveolar or bronchiolar adenoma and carcinoma of the lung in female rats.*

Response:-For reasons given above this study might not be used to inform as to the carcinogenicity of 'non-asbestiform talc'.

15 Statement:- *Italian and commercial talc (both presumably containing asbestiform fibers) did not significantly increase the incidences of tumors in rats when given orally or via intrapleural*

injection; a leiomyosarcoma was found in one study after oral exposure of rats to Italian talc.

Response:-There is absolutely no reason why the Italian and commercial talcs should be presumed to contain asbestiform fibres. The outcome of the experiment is no substitute for a proper mineral analysis.

16 Statement:- *However, asbestiform dusts (chrysotile, crocidolite, amosite, anthophyllite), as toxicological surrogates for asbestiform talc, caused tumors of the lungs (mostly mesotheliomas) following inhalation, intrapleural, intrathoracic, intratracheal, or intraperitoneal exposure.*

Response:-Asbestiform dusts (chrysotile, crocidolite, amosite, anthophyllite) are not toxicological surrogates for 'asbestiform talc'. None of the results from these experiments can inform about anything other than talc containing asbestos.

17 Statement:- *6.2.3 Fiber dimensions and mineralogy... Furthermore, carcinogenicity studies in laboratory animals suggest that asbestiform tremolite causes tumors, but non-asbestiform tremolite does not (Reger and Morgan 1990). However, Wylie et al. (1997) suggested that mineralogical composition, rather than fiber size, plays an important role in the toxicity of mineral fibers. They compared the cytotoxic and proliferative effects of fibrous talc and asbestos on hamster tracheal epithelial and rat pleural mesothelial cells. Three talc samples, containing varying amounts of talc fibers and asbestos, were used in the study. Talc fibers accounted for 62% to 99% of the total fibers in the sample that were greater than 5 μm in length. Both cell types were less sensitive to talc than to asbestos, even though the talc samples contained fibers that were similar to the asbestos fibers in size and shape.*

Response:-Studies in laboratory animals did indeed show that asbestiform tremolite and non-asbestiform tremolite had very different potential to cause mesothelioma (Davies et al 1991), indeed that study was extensively cited by OSHA in their review of the Occupational Standards. The study also stated quite clearly that fibre shape and size were not the only factors influencing the carcinogenicity of minerals. The work of Wylie et al does not contradict that study, rather it emphasises that in addition to shape and size, fibre composition is a very important factor in determining toxicological reactions.

18 Statement:- *6.2.6 Asbestiform fibers as cancer promoters*

Response: This section is entirely based on the effects of asbestos minerals and does not inform as to the effects of asbestiform fibres.

19 Statement:- *6.3 Summary The current data indicate that inhaled talc containing asbestiform fibers induces effects in the lungs that are essentially identical to those associated with asbestosis. Asbestiform minerals may induce cancer by directly or indirectly interacting with DNA or may act as a tumor promoter*

Response:- In both of these statements the correct terms should be asbestos rather than asbestiform.

Concluding Comments

The report is mineralogically superficial and uninformed and cannot be used to gauge the value of the studies or their conclusions. It contains numerous errors and omissions. Too many of the references are listed as 'cited in' a second reference, giving the strong impression that the authors did not read and evaluate the original. Too often has a mineralogical statement been referenced to a physician (e.g. Morgan 1990) or a committee with no mineralogical expertise. The net result is that the report as it exists today should be withdrawn. The NTP is strongly advised to rely on the current listing for the asbestos minerals to provide protection against any commercial or industrial material containing asbestos, and to consider talc as a mineral alone. It may be difficult to find positive carcinogenicity studies for talc alone but that may only mean that talc per se is not carcinogenic to humans and should not be listed as such by the NTP.

Appendix

A number of other errors that may be of lesser significance to the substance of the Draft Report are included here because they further demonstrate that the report represents a very weak basis for the proposed listing of talc in the Report on Carcinogens

A1 Statement:- *Talc ($Mg_3Si_4O_{10}[OH]_2$, mol. wt 379.26, CASRN 14807-96-6) is a white to grayish-white, very fine crystalline powder (unctuous) consisting of natural hydrous magnesium silicate.*

Response:- The description given is oversimplified. Talc is not just a white to greyish-white,

very fine crystalline powder, it is a translucent platy crystal that forms a white powder when finely ground. It may appear discoloured or off-white if the talc contains iron or other elements in the crystal lattice, or if it is accompanied by other minerals in the powder.

A2 Statement:- *Talc is formed by geological metamorphosis and is therefore associated with many types of minerals. Table 1-1 lists some minerals commonly found in talcs.*

Response:- This statement is a gross oversimplification. The geological processes involved in talc formation are complex. It is facile to suggest that when talc is formed it is always associated with many other mineral types. While it is the nature of rocks that they are usually mixtures of minerals, they are also occasionally mono-mineralic as it may be with talc rocks. In the United States the talcs of Beaverhead and Yellowstone, Montana are good examples of 'pure' talcs.

The list of minerals presented as those commonly found in talcs should be presented as the list of minerals that may be associated with talc deposits. They are not minerals universally found in talcs.

A3 Statement:- *Talc may contain asbestiform fibers (tremolite, anthophyllite, and chrysotile) in total concentrations greater than the concentration of the talc mineral itself (Kleinfeld et al. 1973, 1974, Rohl & Langer 1974, both cited in IARC 1987a).*

Response:- Some commercial talc deposits might contain asbestos but most do not. Some commercial talc products contain high concentrations of tremolite and/or anthophyllite but none contain asbestos in concentrations higher than the talc. The tremolite in these products is almost invariably massive non-asbestiform, they are used in specific industrial applications and are no longer used in cosmetic materials. The analyses for amphibole content described in the Draft Report were carried out by X-ray diffractometry before the 1980s. This method can not differentiate between the asbestos and normal analogues of the amphibole minerals. In fact Dement and Zumwalde (1979) state that most of the tremolite detected by XRD in their analyses was of a non-fibrous habit.

Analytical techniques such as electron microscopy can make the proper distinctions between asbestos and normal amphiboles, and are used as a matter of course to confirm the absence of asbestos from commercial talc products.

A4 Statement:- *Some minerals have different names depending on whether they are asbestiform or non-asbestiform (e.g., the non-asbestiform of chrysotile is antigorite) (Morgan 1990).*

Response:- It is true that some minerals have been given different names for their asbestiform or normal crystal habits, (crocidolite and riebeckite, amosite and grunerite) but antigorite is not the non-asbestiform of chrysotile: chrysotile, lizardite and antigorite are different minerals within the serpentine mineral group, each with different crystal structures. Antigorite has a fibrous analogue called picrolite that fractures to produce crude columnar cleavage fragment fibres; these fibres are not asbestos.

A5 *Statement:- "Asbestiform habit" refers to the unusual crystallization habit of a mineral in which the crystals are thin, hair-like fibers. Historically, the definition of the asbestiform habit was based primarily on appearance, and the properties were only implied. At present, the definition of asbestiform habit often is augmented to include a statement on the properties of asbestiform fibers: shape; enhanced strength, flexibility, and durability; diameter-dependent strength; and unique surfaces. The fibers of asbestos are good examples of the asbestiform habit.*

Response:- These and many of the following statements were taken, word for word, from the 1984 National Research Council document Asbestiform Fibers Nonoccupational Health Risks pp28-30. This report was somewhat erratic in its use of the terms asbestiform and asbestos. Interestingly the NRC document is not included in the list of references of the Draft Report which is unusual given the extent to which it is copied.

The better definition of the term asbestiform (HEI) carries no implications of enhanced strength, durability etc. and there has been no general historical implication of these properties. The properties of enhanced strength, flexibility, durability, diameter-dependent strength and unique surfaces are uniquely displayed by the true asbestos minerals. Asbestiform brucite or gypsum do not possess these properties but they are still correctly referred to as asbestiform: they are never to be referred to as asbestos.

A6 Statement:- *"Acicular crystals" are crystals that are extremely long and thin and have a small diameter (an acicular crystal is a special type of prismatic crystal). However, small-diameter crystals with a high aspect ratio may be asbestiform if they are strong and flexible.*

Larger-diameter crystals, even if stronger and more flexible than the parent mineral, usually are described as "filiform" or hairlike.

Response:- Acicular crystals are needle-like crystals. Acicular is a descriptive term derived from the Latin word for needle. Acicular crystals are not "extremely long and thin and have a small diameter"(sic). They may be short and thin, or long and thin, or long and fairly thick. They may or may not have high strength and flexibility but that is irrelevant to the use of the term acicular, and possession of these properties does not make them asbestiform. Larger diameter crystals are not described as filiform or hairlike. These terms are applied to crystals that are longer and thinner than acicular crystals, as in the difference between a needle and a hair.

A7 Statement:- *The limiting upper diameter of "whiskers" (synthetic crystals that share the properties of asbestiform fibers) usually is considered to be 15 μm; the same diameter may be used for the definition of asbestiform fibers.*

Response:- The 15 μm limiting upper diameter of "whiskers" is irrelevant to the definition of asbestiform fibres. Whiskers share some of the properties of asbestos fibres but in the crucial property of longitudinal splitting they differ fundamentally. Whiskers are single crystals whereas asbestiform fibres are polyfilamentous bundles. The 15μm diameter upper limit may not be used for the definition of an asbestiform fibre. A commonly cited maximum diameter for asbestos fibres is about 0.5 μm.

A8 Statement:- *"Fibrous" refers to (l) single crystals that resemble organic fibers such as hair or cotton and (2) large crystals or crystalline aggregates that look like they are composed of fibers (i.e., long, thin, needlelike elements) (Dana and Ford 1932). The apparent fibers do not need to be separable. If the fibers are separable and are strong and flexible, they are asbestiform. If they have the normal strength and brittleness of the mineral, they are acicular. If the apparent fibers are not separable, the specimen may be a single crystal or a multiple (polycrystalline) aggregate displaying a fibrous pattern (resulting, for example, from striation or pseudomorphic replacement of an initially fibrous mineral).*

Response:- The first part of the statement is accurate. "Fibrous" is a broad term that covers both separable and other masses that have the appearance of fibres in a composite structure. Silicified

amosite or crocidolite (the tiger-eye of lapidarists) is a good example of a mineral with a fibrous appearance but with inseparable fibres. However, the strength and flexibility of a fibre is not the determinant of whether it is described as asbestiform or acicular. Fibrous brucite can be accurately described as asbestiform even though it does not exhibit high tensile strength.

A9 Statement:- *Talc is derived by alteration of mineral rocks after exposure to specific temperatures, pressures, and circulating liquid solutions or by the thermal metamorphism of silicon dolomites.*

Response:-This statement is both mineralogically and petrologically incorrect. All rocks and minerals are formed under more or less specific conditions of temperature, pressure and circulating fluids. The geological nomenclature is incorrect. Perhaps the authors mean that some talc deposits are formed from the thermal metamorphism of siliceous dolomite. Most talc deposits are formed during the retrograde metamorphism of ultrabasic rocks in the course of orogenesis.

A10 Statement:- ***2.3 Analysis***

Response:- The whole of this section shows again that the authors have little understanding of the analytical methods used in occupational hygiene monitoring or in analytical testing. It is superficial, confused and oversimplified, consisting mostly of a list of NIOSH standards with snippets of information reproduced to confer a dubious authority.

A11 Statement:- ***Table 2-3. Occupational airborne concentrations of talc dust***

Response:- The table is incorrect. Concentrations in the header are expressed as $\mu g/m^3$ while the actual concentrations are mg/m^3.

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