The Director General

Maisons-Alfort, 23 February 2012

OPINION
of the French Agency for Food, Environmental and Occupational Health & Safety

on the assessment of the risks related to talc alone and talc contaminated by asbestiform[1] and non-asbestiform fibres

ANSES undertakes independent and pluralistic scientific expert assessments.
ANSES's public health mission involves ensuring environmental, occupational and food safety as well as assessing the potential health risks they may entail.
It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its Opinions are made public.

On 24 March 2009 the Agency received a formal request from the French Directorate General for Health (DGS), the Directorate General for Risk Prevention (DGPR) and the Directorate General for Labour (DGT) to conduct an assessment of the risks related to talc containing cleavage fragments, or asbestiform and non-asbestiform fibres.

An expertise contract between the Agency and the three Ministerial Directorates was signed on 12 February 2010. Two amendments to this contract were signed, on 18 May 2010 and 19 April 2011 respectively.

These amendments changed the scope and objectives of the request. They became necessary after the first interim report on the expert appraisal work, in view of the available scientific data. They also changed the deadline for submitting the findings, which was justified by the subject's complexity and the difficulties encountered in collecting data.

1. BACKGROUND AND PURPOSE OF THE REQUEST

The request followed a report by the French Railways (SNCF) to the National Research and Safety Institute (INRS) at the end of 2005, about the use of an epoxy coating that may contain mineral fibres suspected of being asbestos. The DGT stated that other reports have been made by at least three departmental labour authorities (DDTEFP).

In October 2005, two accredited French laboratories[2] identified asbestos fibres, according to the regulatory definition, in an epoxy coating used by the SNCF. This coating is made with talc from a deposit in New York State in the United States. Identification was made using the transmission electron microscopy (TEM) method of analysis (NF X 43-050). Talc from this

[1] The term "asbestiform" means having the form or appearance of asbestos. For more details, please refer to the annex of this document.

New York State deposit is commonly called "tremolitic talc" because it contains a high proportion (40 to 60% depending on the source) of tremolite fibres.

The request sought a review of the following points:

- ✓ What is known about the formation of cleavage fragments?
  - Concerning exposure assessment, toxicology and health effects, are the fibres formed different from asbestos fibres or should they be treated in the same way as asbestos fibres? In particular, do tremolite cleavage fragments have the same hazard properties as asbestiform tremolite fibres?
  - Are the cleavage fragments transformed into inhalable fibres as defined by WHO?
- ✓ What are the most suitable methods for characterising and measuring these fibres in substances/products and in ambient air?

2. ORGANISATION OF THE EXPERT APPRAISAL

The Agency entrusted examination of this request to the Expert Committee (CES) on assessment of the risks related to air environments. A working group (WG) dedicated to this expert appraisal and reporting to the CES was set up in April 2010 following a public call for candidates.
The group's expert appraisal work was regularly submitted to the CES. The report produced by the working group takes account of the observations and additional information provided by the CES members. The report entitled "Assessment of the risks relating to talc alone and talc contaminated by asbestiform and non-asbestiform fibres" was validated by the CES on 26 January 2012.

This work was therefore conducted by a group of experts with complementary skills. It was carried out in accordance with the French Standard NF X 50-110 "Quality in Expertise Activities" to ensure compliance with the following points: competence, independence and transparency, while at the same time ensuring traceability.

Work methodology:

- ✓ A Research and Development Agreement (CRD) was signed between the Agency and the Occupational Health and Safety Research Institute Robert-Sauvé (IRSST) of Quebec (Canada) on 29 April 2010. In particular, the IRSST agreed to produce a summary of the epidemiological data on the health effects of different forms of talc. The findings of this CRD are documented in a report that was given to the Agency in December 2010.
- ✓ To supplement these data and gather information about the use of talc and its health effects, the Agency issued requests to:
  - certain organisations, including AFSSAPS, INERIS, the INRS, etc.;
  - government administrative departments, including the Directorate General of Customs;
  - economic operators trading in talc, including the talc production company in Luzenac, Ariège, France (Rio Tinto), and the European Talc Association (IMA-Europe).

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[2] The Laboratory for the study of inhaled particles (LEPI) and the Health, Environment & Hygiene Laboratory in Lyon (CARSO/LSEHL).

- ✓ The WG also interviewed external experts and other figures likely to provide additional information and data, particularly concerning the analytical techniques for mineral particles and the health effects of talc. The list of persons interviewed and the minutes from these interviews are included as annexes in the WG's report.

3. ANALYSIS AND CONCLUSIONS OF THE CES

The main points of this expert appraisal are as follows:

- ✓ **Characterisation and analysis of talc and its mineral contaminants**

Talc particles generally occur in the form of platelets. More rarely, they may be found as long, thin fibres, thus forming fibrous or asbestiform (asbestos-like) talc. However, it is important not to confuse asbestiform talc with talc containing asbestos.

Depending on the different production deposits from which it originates, raw talc may contain other fibrous or non-fibrous minerals. In particular, it may contain mineral fibres with chemical structures comparable to those of the six mineral fibres classified as asbestos fibres according to the regulatory definition. These six asbestos fibres are chrysotile from the serpentine class, and five fibres from the amphibole class: actinolite, anthophyllite, tremolite, amosite and crocidolite. Talc is known as tremolitic when it is particularly rich in tremolite fibres. This is the case with the talc from Gouverneur in a New York State County, which is at the origin of the request.

The six asbestos fibres[3], also known as asbestiform (asbestos-like), result from specific linear geological growth that gives them a particularly high aspect ratio (length-to-diameter ratio). Fibres do exist that are similar to these asbestos fibres, with the same empirical chemical formula but without the linear geological growth. They are called non-asbestiform fibres.

Therefore, talc that is formed from magnesium carbonate may contain quartz and few or no amphiboles. Conversely, in talc deposits from rocks rich in siliceous dolomite or magnesium, amphiboles can be very abundant (30 to 70%). This is the case with the talc mined in Gouverneur in a New York State County. It is unclear whether other talc deposits worldwide may be significantly contaminated by tremolite. However, in 1987 the International Agency for Research on Cancer (IARC) reported the presence of tremolite in talc from Italy, and the presence of tremolite and anthophyllite in talc from Norway.

Overall, knowledge about the mineral nature and composition of the different talc deposits in the world is limited. Only some European and North American talc, including that of the State of New York, have been studied to varying degrees. The composition of the talc of other regions of the world is unclear, meaning that this talc is imported and processed in France and Europe without its traceability being fully assured.

[3] See the annex to this document for the definitions and terminology relating to fibres, asbestos and cleavage fragments.

The presence of asbestos fibres cannot therefore be ruled out, particularly fibres of actinolite, tremolite and anthophyllite (also named ATA fibres), which are most often found in certain talc deposits.

Cleavage fragments, which are found in milled and ground talc, result when the different blocks of minerals are cut along the favoured growth axes. They may equally be fragments of fibrous talc or asbestos fibres (asbestiform), or non-asbestos amphibole fibres (non-asbestiform). When these cleavage fragments are viewed in the samples analysed in the laboratory, routine analytical techniques fail to differentiate them.

Indeed, the different analytical methods recommended by the regulations[4] for counting fibres cannot differentiate an asbestiform type from its non-asbestiform counterpart. They are therefore unable to reliably differentiate asbestos fibres from fragments of other minerals.

Several publications have proposed additional criteria for counting fibres, which can distinguish between asbestiform amphiboles and non-asbestiform amphiboles. However, these criteria have not been validated in routine measurement conditions and are still under study within the scientific community.

- ✓ **Occupational exposure to talc dust**

Talc is used in many areas of industrial activity. Different grades of talc with physical characteristics more or less specific to certain industrial applications are available on the market.

Occupational exposure to talc dust occurs during mining, milling, bagging and loading of talc. It also occurs during operations to use and process talc. This is particularly true in the rubber industry, and in the manufacture of ceramics, paints, enamels and various other products.

Occupational exposure to talc usually involves a mixture of talc and mineral dust of various compositions. In particular, quartz and mineral fibres (asbestiform or non-asbestiform) are common contaminants.

Occupational exposure to talc dust has been measured at several mines and mills. In most cases, the characterisation of exposure is often limited and imprecise, with no description of the analytical methods used. Thus, the available data rarely mention the mineralogical nature of the talc studied. In particular, there is no available information on the potential presence of tremolite in the talc deposits, whether asbestiform or non-asbestiform.

Data on exposure values in other activities (excluding mining and milling plants) are very limited, with the values for the rubber industry being the only ones available. The only values obtained for France come from the INRS's Colchic database and are very fragmentary. They cannot be used for assessing exposure or estimating the health risks.

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[4] To apply the regulations in force in different countries, routine surveillance of occupational environments can choose from among a number of PCM reference methods, such as: XP X43-269 (2002), ISO 8672 (1993), WHO (1997) or WHO (1998); NIOSH 7400 criteria A (1994a); HSE – MDHS 39/4 (1995); IRSST 243 (1995), etc. The XP X43-269 (2002) method is applied in France.

- ✓ **Health risks**

In most cases the available epidemiological studies do not give any indications of possible contamination of the studied talc, by asbestiform or non-asbestiform fibres.

These studies, on the risk of mesothelioma related to exposure to talc in the workplace, present difficulties with diagnosis and causal interpretation. Establishing a possible causal link is made difficult by the presence of confounding factors, exposure from previous jobs, and the short latency period between the start of exposure and the time of the study. Mesothelioma's low incidence rate and particularly long latency period (estimated to be 30 to 40 years depending on the study) explain why often the studies cannot confirm the relationship between exposure to talc not containing asbestiform fibres and mesothelioma.

Studies on the risks of other cancers linked to exposure to talc show that there is a significantly increased risk of lung cancer in some miners. However, the data are unable to confirm the existence of a relationship with this disease due to simultaneous exposure to other carcinogens such as radon, quartz, or asbestos. In the user industries, the situation is even more confusing because of the presence of a variety of other carcinogens, and the inadequate exposure data. Moreover, most published studies and evaluations have major limitations, including low numbers of subjects in the cohorts, or a low number of cases. Therefore, the available epidemiological studies cannot be used to confirm the existence of a possible link between exposure to talc which does not contain asbestiform fibres and the risk of lung cancer.

Data on the experimental toxicity of talc containing other non-asbestiform mineral fibres (including actinolite, tremolite or anthophyllite fibres), or cleavage fragments from other sources, are very limited. These data cannot be used to conclude on the risk of lung cancer or mesothelioma that may result from exposure to this talc, nor can they completely exclude this risk.
Finally, the biological reactivity of non-fibrous talc particles has been confirmed in experimental models and in humans exposed by inhalation or intravenous injection. However, because of the lack of available data in the literature, it is difficult to characterise pneumoconiosis due to inhalation of pure non-fibrous talc (no described dose-effect relationship) and to distinguish the clinical forms related to different mineral components associated with non-fibrous talc (mainly silica and different types of fibres formed on talc or amphiboles).

4. Conclusions and recommendations of the Agency

The Agency endorses the conclusions and recommendations of the CES, which were adopted at its meeting on 26 January 2011.

It recalls that talc containing asbestos fibres is regarded as a proven carcinogen in humans by the IARC (2010).

The expert appraisal was unable to conclude on the carcinogenicity of talc contaminated with non-asbestiform amphibole fibres (including ATA fibres), or with cleavage fragments from other minerals, mainly due to the lack of data.

In addition, there is currently no simple, reliable and reproducible method that can differentiate non-asbestiform fibres and cleavage fragments from asbestiform fibres, regardless of the nature of the sample studied.

Knowledge of the geological origin of the talc deposits may help to predict the presence or absence of other mineral fibres in these deposits, and to characterise them. However, this information is not available for many deposits. In addition, there are currently no regulatory requirements stipulating the obligation to trace the origin of talc marketed or found in products placed on the market.

Consequently the Agency recommends:

- Making an accurate map of the different talc deposits in the world with identification of the other mineral fibres they are likely to contain, and ensuring the traceability of the talc, from its extraction to its sale in France.

- That in the absence of any reliable and validated information on the origin of the talc, which would confirm the absence of contamination, screening should be conducted for elongated ATA amphibole particles, asbestiform or non-asbestiform, in talc or in products containing talc that are marketed in France, in accordance with the regulatory methods concerning screening materials for asbestos.

- For products containing talc, marketed or already in use, applying the asbestos regulations if ATA amphibole fibres are found.

- In the workplace, if ATA amphibole fibres are found in the air inhaled by workers exposed to talc, or to products containing it, applying the asbestos regulations.

- Developing analytical methods and studies on the health effects, both to differentiate asbestiform fibres from non-asbestiform fibres and to improve knowledge of the health effects of the different non-asbestiform fibres.

The Director General

Marc Mortureux

ANNEX - DEFINITIONS AND TERMINOLOGY

Fibre

The WHO defines a fibre as an elongated particle with an aspect ratio greater than 3, and whose length and diameter respectively must be greater than 5 microns and less than 3 microns. These dimensions must be determined by phase contrast optical microscopy (WHO 1998). The term "fibre" therefore covers all elongated mineral particles, both asbestiform and non-asbestiform (including cleavage fragments), as well as elongated non-mineral particles that meet the WHO's dimensional criteria.

Asbestos

Asbestos is a commercial term describing six naturally-occurring minerals, hydrated silicates, divided into two groups: serpentines and amphiboles. Its commercial value comes from various specific properties, including low electrical and thermal conductivity, good chemical stability, durability, high tensile strength, flexibility, etc.

There is some confusion associated with asbestos terminology, which is not used consistently by mineralogists, hygienists and occupational physicians, epidemiologists, chemists or analysts, and regulatory organisations. This confusion is perpetuated by the difficulties in identifying different fibres. Indeed, several silicates can occur in two forms: non-asbestiform and asbestiform. The table below lists the six asbestos silicate minerals (asbestiform) and their non-asbestos counterparts (non-asbestiform), with their chemical compositions and CAS numbers[5]. In the amphibole group, the asbestiform and non-asbestiform forms of tremolite, actinolite and anthophyllite do not have different names, which is why, in certain texts, the term asbestos or asbestiform is added to the mineral's name. The asbestiform mineral and its non-asbestiform equivalent have the same chemical composition but differ in their crystal growth.

Asbestiform

The term "asbestiform" refers to a morphology resulting from the natural, one-dimensional crystallisation of a mineral, producing fibres with the appearance of hair. This morphology gives the mineral particular characteristics including a high aspect ratio (length/diameter ratio) and increased mechanical properties (including strength, flexibility and durability).

In this asbestiform morphology, the growth of the crystals has led to long and threadlike fibres being produced. These fibres gather in agglomerates that can easily be separated into smaller fibres (fibrils). They retain their surface and activity properties during the different processing methods. Their asbestiform nature does not depend on the structure of the fibre, but rather on the way in which the crystal grows.

When pressure is applied to an asbestos fibre it will bend rather than break. The fibres may be separated into fibrils of a smaller diameter, often less than 0.5 µm. This effect is the basis of the term "polyfilamentous" corresponding to asbestos's most important feature. The term asbestiform has not been defined for regulatory purposes.

In 1993 the US Environmental Protection Agency (US EPA) recommended a definition of the morphology of an asbestiform mineral:

[5] The CAS number of a chemical is its unique registration number from the Chemical Abstracts Service (CAS) database

"Said of a mineral that is like asbestos, i.e. crystallized with the habit of asbestos. Some asbestiform minerals may lack the properties which make asbestos commercially valuable, such as long fiber length and high tensile strength. With the light microscope, the asbestiform habit is generally recognized by the following characteristics:

- ✓ *Mean aspect ratios ranging from 20:1 to 100:1 or higher for fibers longer than 5 µm; Aspect ratios should be determined for fibers, not bundles;*
- ✓ *Very thin fibrils, usually less than 0.5 micrometers in width;*
- ✓ *Two or more of the following:*
  - *Parallel fibers occurring in bundles;*
  - *Fiber bundles displaying splayed ends;*
  - *Matted masses of individual fibers;*
  - *Fibers showing curvature."*

Non-asbestiform

Most non-asbestiform mineral varieties have had little commercial significance. They are weaker and less resilient than their asbestiform counterparts. They do not grow one-dimensionally into long fibres, but rather in two or three dimensions, resulting in a more extensive morphology. When subjected to pressure, the non-asbestiform minerals fracture easily into prismatic particles. Some particles are acicular (needle-shaped), and stair-step cleavage along the edges of some particles is common. Particles with this morphology may, however, meet the definition of respirable fibres given by the WHO, when viewed under a microscope. The difference between asbestiform and non-asbestiform fibres therefore clearly results from their crystallisation process.

Cleavage fragments

Cleavage fragments come from the mining and milling of the different minerals, including non-fibrous amphibole minerals. Specifically, they result from when the blocks of minerals are cut, generally along the favoured mineral growth axes.

The cleavage fragments from non-asbestiform amphibole fibres have the same chemical composition as the corresponding asbestos fibres without having their other features:

- ✓ dimensions (length, diameter and aspect ratio),
- ✓ chemical and physical properties,
- ✓ mechanical performance.

Thus, within a population of cleavage fragments, a fraction of the particles may meet the definition of an asbestos fibre as adopted by the various regulations.

Asbestos fibres and their non-asbestiform counterparts

Asbestiform types (CAS no.)	Chemical composition	Non-asbestiform types (CAS no.)
	Serpentine group	

Chrysotile (12001-29-5)	$3MgO.2SiO_2.2H_2O$	**Antigorite** (12135-86-3) **Lizardite** (12161-84-1)
	Amphibole group	
Actinolite asbestos (77536-66-4)	$2CaO.4MgO.FeO.8SiO_2.H_2O$	**Actinolite** (13768-00-8)
Anthophyllite asbestos (77536-67-5)	$7MgO.8SiO_2.H_2O$	**Anthophyllite** (17068-78-9)
Tremolite asbestos (77536-68-6)	$2CaO.5MgO.FeO.8SiO_2.H_2O$	**Tremolite** (14567-73-8)
Amosite (grunerite) (12172-73-5)	$11FeO.3MgO.8SiO_2.\ H_2O$	**Grunerite** (14567-61-4)
Crocidolite (12001-28-4)	Na2O.Fe2O3.FeO.8SiO2.H2O	**Riebeckite** (17787-87-0)