The Director General

Maisons-Alfort, 4 December 2015

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

on "Health Effects and the identification of cleavage fragments of amphiboles from quarried minerals"[1]

ANSES undertakes independent and pluralistic scientific expert assessments.
ANSES primarily ensures 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.
This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 4 December 2015 shall prevail.

On 28 August 2014, ANSES was requested by the Directorate General for Labour (DGT), the Directorate General for Risk Prevention (DGPR) and the Directorate General for Health (DGS) to undertake the following expert appraisal: Health Effects and identification of cleavage fragments of amphiboles from quarried minerals.

1. BACKGROUND AND PURPOSE OF THE REQUEST

ANSES received a formal request from the DGT, the DGPR and the DGS following alerts by the State's decentralised departments to the possible presence of actinolite asbestos in coated aggregate (asphalt) for road use, as well as "cleavage fragments". In the context of changes to the regulations following the AFSSET Opinions of 2009 (AFSSET 2009a and 2009b) and the ANSES Opinion of 2010 (ANSES, 2010), the Decree of 4 May 2012 on the risks of exposure to asbestos recalled the scope of the obligation for prior assessment of risks incumbent on the contracting authority (principal), on the basis of Articles L.4121-3 and L.4531-1 of the French Labour Code. With regard to asbestos, this implies surveying sites before starting work, to enable the principal to decide whether or not the work should be governed by the asbestos regulations, and the contractor to perform its own risk assessment. In this regulatory context, the Circular of 15 May 2013 issued by the Directorate General for Infrastructure, Transport and the Sea (DGITM) of the Ministry of Ecology, Sustainable Development and Energy (MEDDE) lays down instructions on the management of health risks related to asbestos in the case of work on surfacing materials containing asbestos on the publicly-managed national road network. This operational instruction

[1] Cancels and replaces the Opinion dated 30 October 2015. See Annex 1.

focuses in particular on the surveying of areas containing asbestos, operating methods, the management of waste, and information for staff, and applies to the national road network. Many analyses of asbestos have accordingly been performed at the sites of different road works, to detect the possible presence of chrysotile asbestos. Chrysotile was used intentionally in road surfaces in the years 1975-1995 at rates of up to 1% by mass, for its resistance properties. During these procedures, actinolite was detected in aggregates when core samples were taken. Unlike chrysotile, the actinolite found in aggregates was not added intentionally, but occurs naturally in rocks extracted from quarries in recent decades for the manufacture of road surfacing materials.

Under the European regulations, the term asbestos refers to six minerals naturally present in several types of rock: one serpentine (chrysotile) and five amphiboles (actinolite-asbestos, anthophyllite-asbestos, tremolite-asbestos, amosite and crocidolite). These minerals have been exploited commercially for their physical and chemical properties, such as their low electrical and thermal conductivity, their chemical stability, their resistance to wear, their high resistance to traction, their flexibility, etc.

In the environment, naturally occurring actinolite (as well as other amphiboles) is found in different morphologies, described as either asbestiform or non-asbestiform. Only the asbestiform types of the five aforementioned amphiboles and chrysotile are regulated as asbestos. However, when a mechanical stress is applied to rocks containing non-asbestiform actinolite or a non-asbestiform amphibole with the same chemical composition as regulated asbestos, these minerals are likely to split, creating particles of different lengths known as "cleavage fragments", which, as a result of their dimensional characteristics, can sometimes be counted as asbestos.

While the effects on health of the asbestiform types of the five regulated amphiboles are well documented, there remains uncertainty on the toxicity of cleavage fragments. In addition, current analytical methods cannot easily distinguish between cleavage fragments and asbestiform fibres, irrespective of the nature of the sample (in the air and materials).

Against this background, the Request included the following points:

1/ To review the toxicological and epidemiological evidence relating to cleavage fragments of minerals with non-asbestiform profiles: actinolite, anthophyllite, tremolite, grunerite and riebeckite. What conclusions can be reached about their effects on health?

2/ What current data are available regarding the specific exposures to cleavage fragments of the minerals cited above?

3/ Are there routine analytical methods, i.e. methods that can be implemented by laboratories accredited by the COFRAC[2], capable of distinguishing the fibres of actinolite-asbestos, anthophyllite-asbestos, tremolite-asbestos, amosite and crocidolite on the one hand, from cleavage fragments from five (non-asbestiform) amphiboles, actinolite, tremolite, anthophyllite, grunerite and riebeckite on the other?

If not, what complementary techniques could be used to make this distinction? In particular, have additional criteria been studied, other than the morphological criteria used today to characterise asbestos (length (L), diameter (D) and aspect ratio (L:D))?

On the conclusion of the expert appraisal, recommendations may be proposed concerning the protection and the prevention of risks to the health of persons exposed to these cleavage fragments.

Following preliminary discussions between ANSES, the DGT, the DGS and the DGPR, it was agreed that Question 2 would focus on the occupational exposures only, and that Question 3 would focus on sampling and analysis of fibres in bulk materials and the air. The expert appraisal contract was signed between ANSES and the three Ministerial Directorates on 30 September 2014.

[2] French Accreditation Committee

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with the French standard NF X 50-110 "Quality in Expertise – General Requirements of Competence for Expert Appraisals (May 2003)".

These issues fall within the area of expertise of the Expert Committee (CES) on "Assessment of the risks related to air environments". ANSES entrusted the appraisal to the "Cleavage fragments" Working Group (WG). The methodological and scientific aspects of the Group's work were submitted to the CES between February and October 2015. They were adopted by the CES at its meeting on 15 October 2015.

ANSES analyses interests declared by experts before they are appointed and throughout their work in order to prevent risks of conflicts of interest in relation to the points addressed in expert appraisals.
The declarations of interest by experts are made public via the ANSES website (www.anses.fr).

The work was undertaken on the basis of a synthesis and a critical analysis of the data in the published literature (scientific articles, institutional reports, analytical standards) and on the previous work of ANSES relating to mineral fibres:

- Report of the expert collective appraisal "Short and thin asbestos fibres. Taking dimensional criteria into account for the characterisation of health risks associated with the inhalation of asbestos. Reassessment of the toxicological, metrological and epidemiological data with a view to an assessment of health risks to the general and working population" (AFSSET, 2009a);
- Report of the study on "Natural outcrops of asbestos" (ANSES, 2010);
- Report of the collective expert appraisal on the "Assessment of risks related to talc alone and talc contaminated by asbestiform and non-asbestiform fibres" (ANSES, 2012);
- Report of the collective expert appraisal on the "Assessment of the toxicity of antigorite" (ANSES, 2014);

The collection of information necessary for conducting this appraisal was also supported by interviews with representatives of:

- the French Federation of Public Works (FNTP);
- the Federation of Trade Unions of the French Road Industry (USIRF);
- the French Union of the Quarrying and Construction Materials Industries (UNICEM);
- the Union of Independent Quarries of Greater West France (CIGO).

Hearings were also held for experts and external individuals likely to contribute information and additional data relating, in particular, to the analytical determination of mineral fibres in bulk materials and in the air.

Finally, international agencies and national authorities in the fields of occupational health and/or safety (in Europe, North America, Australia and South Africa) were consulted to learn about the practices implemented abroad for the analysis of cleavage fragments, and the applicable regulations, and to identify ongoing studies on mineral particles (metrology, exposure, toxicology or epidemiology).

3. ANALYSIS AND CONCLUSIONS OF THE WG AND CES

Summary of the results of the appraisal

The current definitions relating to mineral particles vary considerably. In the framework of this expertise, **the term "cleavage fragment" refers to the mineral particles resulting from the fragmentation of non-asbestiform amphiboles, and having the dimensions of a fibre**:

- In air, the fibres taken into account for the measurement of asbestos levels are those with a minimum length of 5 µm, a maximum diameter of 3 µm, and an aspect ratio greater than 3:1 (L > 5 µm; D < 3 µm and L:D > 3:1). These dimensions are those used by the World Health Organization (WHO) to define a fibre capable of being inhaled.
- In materials, no document sets the dimensional criteria to take into account for qualifying the presence of asbestos. The NF X 43-050 Standard specifies, for analyses carried out by Transmission Electron Microscopy (TEM), that a fibre must have an aspect ratio greater than 3:1.

The term "elongated mineral particle" (EMP) applies to any mineral particle with an aspect ratio (L:D) greater than 3:1, irrespective of whether its origin is asbestiform or non-asbestiform. For the purpose of this expert appraisal, EMPs of interest are those capable of being inhaled (D < 3 µm).

Figure 1 shows the breakdown of mineral particles as a function of their morphology (asbestiform or non-asbestiform) and their dimensions.

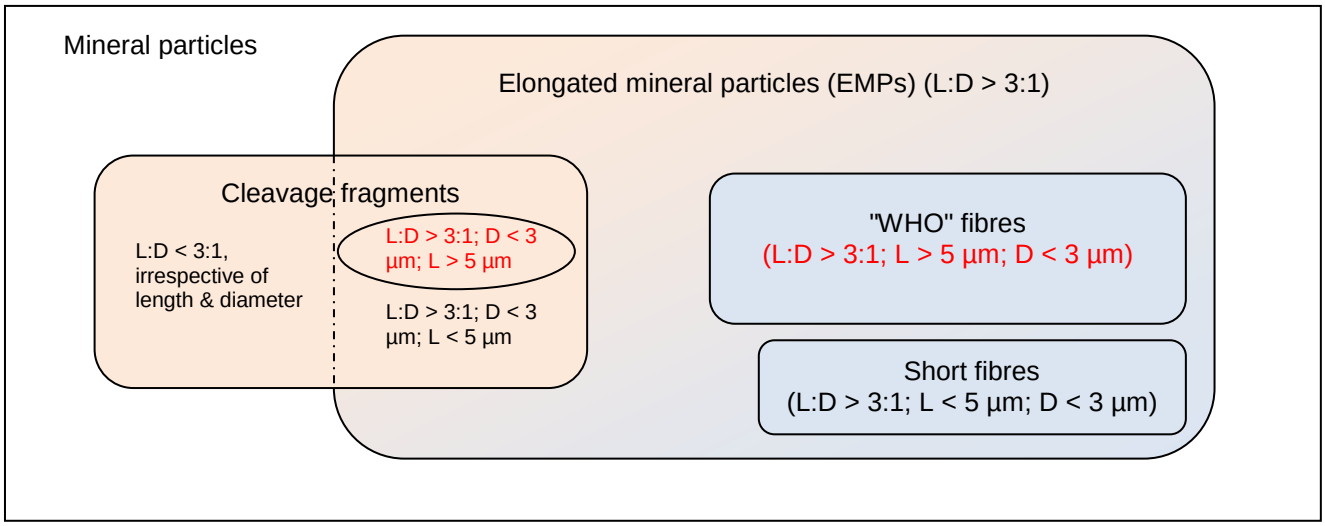

Figure1: Representation of the different mineral particles as a function of their morphology and their dimensions

The amphiboles included in the scope of this expert appraisal are the non-asbestiform varieties of the five regulated amphiboles (i.e. actinolite, anthophyllite, tremolite, grunerite and riebeckite). Because of the existence of data of concern with respect to the toxicity of other mineral species belonging to the same sub-groups as some of these amphiboles, in particular winchite, richterite and fluoro-edenite, and their close proximity in terms of chemical composition, data on all the calcic and sodic-calcic amphiboles were reviewed by the WG.

- <u>Health effects of cleavage fragments</u>

Epidemiological studies on the general population and on workers in extraction industries (e.g. workers in mines of taconite, or vermiculite in the USA) exposed to amphiboles EMPs highlight excessive incidence and/or mortality by mesothelioma and/or by lung cancer and/or by other respiratory pathologies, and/or excessive pleural and parenchymal anomalies. However, these studies are unable to attribute the health effects observed to cleavage fragments alone, as the

populations studied are exposed to complex mixtures of particles, including asbestiform particles or crystalline silica. In the light of the data analysed, ANSES concludes that it is not possible to rule out a risk to health linked to exposure to cleavage fragments of actinolite, anthophyllite, tremolite, grunerite and riebeckite.
The most informative studies are those concerning workers in the taconite mines, who, in the current state of the available data, are exposed to a complex mixture of mineral particles, including EMPs (of amphiboles and other mineral species), almost exclusively non-asbestiform and very predominantly short (L < 5 µm) (University of Minnesota, 2014). However, it is possible that asbestiform EMPs, even in very small proportions, could be responsible for the excessive mesotheliomas and pleural anomalies observed. In addition, there may be a confusion bias related to exposure to commercial asbestos, despite the adjustments made by the authors. These studies will not be completed until 2017.
Studies highlighting excessive mesotheliomas among workers in vermiculite mines and mills in the USA exposed to Libby amphibole asbestos (LAA), which is composed mainly of winchite and richterite, or subject to environmental exposure to fluoro-edenite, have recently been reviewed by the US EPA and the International Agency for Research on Cancer (IARC), which have respectively confirmed the carcinogenicity of amphiboles from vermiculite mines (Libby, USA) ("Libby amphibole asbestos is 'carcinogenic to humans'") and of fluoro-edenite (classified as carcinogenic to humans by the IARC) (Group 1)) (US EPA, 2014; IARC, 2014).

From a toxicological perspective, several reviews have concluded that ‘cleavage fragments’ are less toxic than asbestiform fibres, but an analysis of the articles cited in these reviews, apart from the three articles cited below, indicates that the cleavage fragments studied did not have the dimensions of a "WHO" fibre and are in fact non-elongated mineral particles. These reviews confirm that non-elongated mineral particles are not toxic or are less toxic than asbestiform fibres, but provide no information on the toxicity of cleavage fragments as defined in the framework of this expert appraisal, i.e. with the dimensions of a "WHO" fibre (L > 5 µm; D < 3 µm; L:D > 3:1) (Ilgren, 2004; Addison and McConnell, 2008; Mossman, 2008; Williams *et al*., 2013).
Only three studies *in vitro* or *in vivo* that focused on the toxicological effects of cleavage fragments of tremolite and ferro-actinolite corresponding to the definition of a WHO fibre were identified by the WG (Davis *et al.*, 1991; Cyphert *et al*., 2012; Kodavanti *et al.*, 2014). The results of these studies show that samples composed "mostly of cleavage fragments" induce mesotheliomas in rats by intra-peritoneal injection and can induce an inflammatory reaction in rats by intra-tracheal injection. Studies on LAA (corresponding to a mixture of cleavage fragments and asbestiform fibres, according to the metrological analyses) tend to demonstrate that these amphiboles are less toxic than asbestos but, when adjusted on the number of particles injected or to the dimensions of those particles, the differences in toxicity are not significant. The other studies identified do not provide sufficient information for a granulometric characterisation of the mineral particles studied (dimensions and/or microscope images). The WG highlights the fact that other parameters modulating the toxicity (biopersistence, contaminants, surface reactivity, etc.) are not discussed in these studies.

- <u>Exposure to cleavage fragments</u>

No exposure data specifically on the cleavage fragments of the amphiboles within the scope of this expert appraisal were identified in the literature. In France, measurements of exposure on road construction sites and in quarries have been carried out or are in the process of validation. These analyses are carried out in compliance with the standards in force, which do not enable a formal distinction between cleavage fragments and their asbestiform counterparts. Besides quarries and road construction, other professional sectors may be concerned by the problem of cleavage fragments, whenever workers come into contact with materials containing amphiboles (e.g. tunnelling). It should also be stressed that workers in these industrial sectors can be exposed to

other risk factors, such as crystalline silica, classified as carcinogenic to humans by the IARC. Workers involved in road works can also be exposed to chrysotile on certain sites.

- Sampling and analysis of cleavage fragments

In France, there is currently no reference document on sampling strategy in quarries. General recommendations on the identification of asbestos-bearing areas (targeted or non-targeted sampling) in the ANSES's 2010 report on naturally occurring asbestos can be implemented. For road-construction materials, the guide to the characterisation of bituminous asphalts prepared by the National Steering Committee on road works and occupational risks proposes broad guidelines for the sampling strategy for road-work operations (USIRF, DGT, CNAMTS, FNTP, INRS, OPPBTP, GNMSTBTP, 2013).
From a metrological perspective, it should be noted that sampling and analysis of bulk materials are a lot more complex than manufactured materials. As bulk materials are likely to contain many elongated mineral particles, their analysis requires time and specific skills. The existing procedures on asbestos-containing manufactured materials analysis can be applied to bulk materials but they are currently not sufficiently standardised and lead to disparities in the results they produce. For example, laboratories are currently not required to define their limit of detection or their limit of quantification, nor to mention them in their test reports, which can lead to differences of interpretation of results between laboratories.
There is currently no method for the routine analysis of air or materials capable of distinguishing clearly between cleavage fragments and their asbestiform counterparts, on the basis of the current criteria to define a fibre. The most accurate method of routine analysis is TEM, which can simultaneously characterise the objects analysed in morphological, chemical and crystallographic terms. However, this method has limitations, including a vision in two dimensions that precludes the observation of the different sides of the object. This technique, as described in the NF X 43-050 Standard[3], is not always capable of distinguishing between asbestiform fibres and cleavage fragments. In air, the other routine methods, i.e. polarised light microscopy (PLM) and conventional Scanning Electron Microscopy (SEM), do not provide sufficient spatial resolution to observe and take into account thin fibres, and cannot clearly distinguish between cleavage fragments and asbestiform fibres. For materials, TEM has the same limitations as mentioned above. PLM, currently more or less abandoned by a large number of laboratories for air analysis and replaced by TEM, may constitute a first level for identifying the presence of suspicious fibrous occurrences. It can distinguish the cleavage fragments of asbestiform fibres by the criterion of their extinction angle, but this distinction remains limited to objects whose diameter is greater than 1 µm. SEM can also be used to search for asbestos in materials, but has the same limitations as those mentioned for air samples. Some authors investigated the use of additional criteria, mainly dimensional, in order to refine the analysis using TEM and exclude the majority of cleavage fragments. It is indeed the case that, for a given length, cleavage fragments generally have a greater diameter than asbestiform fibres and a lower aspect ratio. As a result, the probability that the objects analysed are asbestiform fibres increases with the aspect ratio. However, there is still an overlap in the dimensions of the two populations of objects. Other criteria (twinning, sharpness of the diffraction at the edge of the object, etc.), enable further refinement of the distinction but are difficult to apply routinely and no assessment has been made of the uncertainty related to their implementation. Other methods of analysis can be used in combination to refine the analysis, but these techniques are difficult to use routinely because they require special skills and equipment and a considerable time for analysis.

Conclusions of the CES

[3] NF X 43-050 (January 1996) Air Quality - Determination of the concentration of asbestos fibres by transmission electron microscopy - Indirect method

The CES emphasises that, for the amphiboles included in the scope of this expert appraisal, i.e. the non-asbestiform varieties of the five regulated amphiboles (actinolite, anthophyllite, tremolite, grunerite and riebeckite) and all the calcic and sodic-calcic amphiboles:

- In the light of the epidemiological studies, it is not possible to rule out a risk to health linked to exposure to cleavage fragments from the non-asbestiform species of the five regulated amphiboles;
- A relationship between the occurrence of cancers and the exposure of populations to some calcic or sodic-calcic amphiboles present in the form of a mixture of different facies, such as fluoro-edenite, winchite or richterite, has been established in recent assessments;
- There are currently no validated scientific toxicological data to confirm that cleavage fragments with the dimensional criteria laid down by the WHO for "fibre" (L > 5 µm; D < 3 µm and L:D > 3:1) are less toxic than their asbestiform counterparts.

Furthermore, the CES points out that:

- for EMPs in general, there is a hazard gradient depending on the length and the diameter[4], without an identifiable dimensional threshold;
- There are other parameters besides the dimensional criteria capable of affecting the toxicity, such as biopersistence, contaminants, surface reactivity, etc.;
- In the case of taconite mines, where excessive mesotheliomas are reported, workers are exposed to complex mixtures of particles, including EMPs of amphiboles and other mineral species. There are currently insufficient data available to distinguish between the effects of specific minerals. Studies are under way but will not be completed until 2017 (University of Minnesota, 2014);
- Routine analytical methods do not make a clear distinction between cleavage fragments and asbestos fibres.

To sum up, the CES concludes that:

- **In the current state of knowledge concerning their health effects, cleavage fragments from non-asbestiform amphiboles of actinolite, anthophyllite, tremolite, grunerite and riebeckite meeting the WHO's dimensional criteria for fibres (L > 5 µm; D < 3 µm and L:D > 3:1) should not be distinguished from their asbestiform counterparts (actinolite-asbestos, anthophyllite-asbestos, tremolite-asbestos, amosite and crocidolite);**
- **Health effects similar to those of asbestos are demonstrated for other calcic and sodic-calcic EMPs, present in the form of a mix of asbestiform and non-asbestiform particles: fluoro-edenite, classified as carcinogenic for humans by the IARC in November 2014 (Group 1) and winchite and richterite, which are the major components of Libby amphiboles, classified as carcinogenic to humans by the US EPA in December 2014;**
- **There are currently no specific data on the health effects of the other calcic and sodic-calcic EMPs;**
- **There is no reason to make a distinction between the cleavage fragments meeting the "WHO" dimensional criteria for fibres (L > 5 µm; D < 3 µm and L:D > 3:1) and asbestiform fibres of calcic and sodic-calcic EMPs, in particular due to the uncertainties and difficulties related to their characterisation and to their differentiation by routine analytical methods.**

[4] The longer and narrower the EMPs, the more dangerous they are.

Recommendations of the CES

- Concerning the terminology used, the CES recommends

o adopting harmonised definitions for the terminology associated with mineral particles, based on objective and acceptable criteria to the different disciplines working on mineral particles and to the regulatory agencies in France and in Europe. Definitions on which a consensus emerged within the CES are proposed in Section 2 of the Report.

o using the term "elongated mineral particle" (EMP) to describe any mineral particle with an aspect ratio (L:D) greater than 3:1, irrespective of whether its origin is asbestiform or non-asbestiform. The term EMP therefore includes asbestiform fibres and non-asbestiform mineral particles, including cleavage fragments, meeting these dimensional criteria. For the purpose of this expert appraisal, EMPs of interest are those capable of being inhaled (D < 3 µm).

- In terms of the assessment and prevention of occupational risk, the CES recommends

o considering EMPs from the five regulated amphiboles with an asbestiform facies in the same way as their five non-asbestiform counterparts.

o Enforcing regulation on asbestos to take into account the following EMPs with a minimum length of 5 µm, a maximum diameter of 3 µm, and an aspect ratio greater than 3:1 (L > 5 µm; D < 3 µm and L:D > 3:1):

- the five regulated asbestiform amphiboles and their non-asbestiform counterparts, i.e. the following species: actinolite and actinolite-asbestos, anthophyllite and anthophyllite-asbestos, tremolite and tremolite-asbestos, grunerite and amosite, riebeckite and crocidolite;
- winchite, richterite and fluoro-edenite, considering the health effects similar to those of asbestos observed for these mineral species;
- erionite, which is classified as carcinogenic for humans by the IARC (Group 1).

o in the absence of evidence to support a lower toxicity of other EMPs of the family of calcic and sodic-calcic amphiboles longer than 5 µm and with a diameter of less than 3 µm (L > 5 µm, < 3 µm and L:D >3:1), implementing provisions at least to allow the monitoring and surveillance of sites, as well as the traceability and reduction of exposure to these EMPs to the lowest possible level for workers. Nevertheless, the CES draws attention to the fact that stricter prevention measures are justified for EMPs with a high aspect ratio because of the hazard gradient depending on the length and the diameter, without an identifiable dimensional threshold. For example, the US EPA uses an aspect ratio of 20 (L:D > 20:1) to distinguish between asbestiform and non-asbestiform particles.

o continuing epidemiological surveillance of mesothelioma, the main tracer of pleural pathologies due to exposures to carcinogenic EMPs.

Regarding the characterisation of EMPs in materials

The CES draws attention to the management practices implemented in several countries (e.g. Germany, USA, Canada) to fix a threshold, in the form of mass percentage, for declaring a material to be "asbestos-containing". However, it is not easy to establish the relationship between the asbestos content of a material and its ability to release asbestos fibres into the air, that is to say its emissivity. The emissivity of an asbestos-containing material depends on several factors, some related to the typology in which it occurs, others to its conditions of use and the mechanical stresses applied to it. In this regard, the PIMAC study currently being conducted by the French

Geological Survey (BRGM), in partnership with the DGPR and the French Union of the Quarrying and Construction Materials Industries (UNICEM), will provide clarification on the ability of some materials containing amphiboles to release elongated mineral particles capable of being inhaled, by artificially simulating the effects of friction and wear undergone by the material during the extraction, treatment and erosion processes.
This approach, designed to determine the emissivity of a material, is also being studied by the US EPA.
If a threshold should be established to declare a material as "EMP-containing material", the CES recommends that it should preferentially be a threshold of emissivity into the air. Pending the establishment of this threshold, a pragmatic threshold in the form of mass percentage in the materials could be proposed.
The CES draws attention to the fact that the higher the aspect ratio of EMPs released into the air or present in the materials, the lower the threshold proposed (mass percentage or threshold of emissivity) will need to be.

Regarding operations likely to cause exposure to EMPs of calcic and sodic-calcic amphiboles (quarrying, road-work activities, etc.)
The CES recommends that, before the start of operations, sites be mapped and measures for detecting EMPs be implemented: preparing thin sections, petrographic studies, chemical characterisation of the species found, with reference to the INRS guide on work in asbestos-bearing areas (INRS, 2013).
If EMPs are found to be present in the materials, all of the above recommendations must be applied.
In view of the uncertainty concerning emissivity, if EMPs are identified, the CES insists on the need to measure exposure to EMPs in the air.

Furthermore, the CES points out that

- Other workers in the construction sector in the natural environment (e.g. road-building or tunnelling) or employing materials manufactured from naturally occurring EMPs, can also be exposed to EMPs;
- These workers, in addition to exposure to EMPs, may be exposed to other risk factors involving proven carcinogenic particles and/or chemicals, including crystalline silica or polycyclic aromatic hydrocarbons (PAHs). The CES emphasises that the implementation of measures to prevent exposure to EMPs also reduces exposure to crystalline silica.

- Concerning the sampling and analysis of EMPs of calcic and sodic-calcic amphiboles in materials and the air, the CES recommends:

  - measuring EMPs without distinction as to whether or not they are asbestiform;
  - defining a sampling protocol for quarries or construction sites in order to monitor levels of EMPs. The sampling protocol must be developed together with geologists, metrologists and contracting authorities.
  - using TEM for the characterisation of EMPs in the air.
  - using TEM to supplement the analysis of materials and for the observation of fine EMPs.
  - creating a database of the different species of amphiboles potentially present in France, specifying the intervals of chemical composition analysed by TEM. Based on the BRGM'ssamples bank, this would provide more complete references than the standards

currently used, which only present an average chemical composition per species of amphibole.

- considering only EMPs with a minimum length of 5 µm and a maximum diameter of 3 µm (L > 5 µm; D < 3 µm) to characterise bulk materials.
- reporting the presence of EMPs with a length of less than 5 µm, and a diameter of less than 3 µm (L ≤ 5 µm and D < 3 µm) so that they can be monitored in the air and materials.

Considering the particular nature of bulk materials, whose analysis requires specific skills compared to samples of manufactured products, the CES recommends:

- drafting a document (by the COFRAC) of specific requirements for the accreditation of organisations performing the analysis of bulk materials.
- standardising the methods for preparing and analysing samples of bulk materials (test portions, treatment of the sample, number of trials for a conclusive result), to enable a harmonisation of the limits of detection between different laboratories.
- harmonising the way results are reported between laboratories. The limits of detection and quantification should at the very least be mentioned in the test report of each laboratory.
- encouraging laboratories to participate in interlaboratory tests for the analysis of natural materials, in order to assess and maintain their skills, and to better take into account the uncertainties related to chemical identification.
- validating analyses, in case of doubt, by a consensus between several analysts in the same laboratory or, if the laboratory has only one analyst, between the latter and one or more competent referees identified in this area.
- providing specific training for analysts responsible for the analysis of bulk materials, including in mineralogy and microscopy.

All the recommendations concerning metrology must apply to manufactured materials likely to contain naturally occurring EMPs.

- <u>In terms of scientific watch and research, the CES recommends</u>

  - undertaking toxicology studies in order to identify new characteristics potentially responsible for toxicity, using samples of elongated particles, whether from bulk minerals or from nanotechnology manufactured products, rigorously characterised as regards their dimensions, composition, structure, biopersistence, etc. Multidisciplinary networks should be supported to determine the relationship between the characteristics of particles and their biological effects, and to model the biological response depending on its nature and the characteristics of the particles.
  - closely following the results of ongoing studies, in particular those relating to taconite.
  - identifying the other amphiboles and other mineral species likely to generate EMPs, and assessing their toxicity.
  - continuing to encourage epidemiological research to analyse the health impacts related to exposure to EMPs, in particular for the occurrence of mesothelioma where no exposure to asbestos has been observed.
  - applying measurement protocols to acquire knowledge and data on exposure in situations likely to release EMPs both longer and shorter than 5 µm.

- creating databases to make available the information acquired in the fields of chemical composition, emissivity, metrology and exposure, as well as in biological effects.

4. CONCLUSIONS AND RECOMMENDATIONS OF THE AGENCY

The French Agency for Food, Environmental and Occupational Health & Safety adopts the conclusions of the Expert Committee on "Assessment of the risks related to air environments" presented above.

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KEYWORDS

Cleavage fragments, actinolite, amphiboles, elongated mineral particles, mineral fibres, asbestos, asbestiform, non-asbestiform

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ANNEX 1: TRACKING CHANGES TO THE OPINION

Date	Version	Page	Description of the change
October 2015	01		First signed version of the ANSES Opinion
November 2015	02	1	Following discussions with the DGT held during the feedback meeting of 9 November 2015, the regulatory context that led to the discovery of actinolite in the coated aggregates for road surfaces was clarified. The following paragraph was added: *In the context of changes to the regulations following the AFSSET Opinions of 2009 (AFSSET 2009a and 2009b) and the ANSES Opinion of 2010 (ANSES, 2010), the Decree of 4 May 2012 on the risks of exposure to asbestos recalled the scope of the obligation for prior assessment of risks incumbent on the contracting authority (principal), on the basis of Articles L.4121-3 and L.4531-1 of the French Labour Code. With regard to asbestos, this implies surveying sites before starting work, to enable the principal to decide whether or not the work should be governed by the asbestos regulations, and the contractor to perform its own risk assessment. In this regulatory context, the Circular of 15 May 2013 issued by the Directorate General for Infrastructure, Transport and the Sea (DGITM) of the Ministry of Ecology, Sustainable Development and Energy (MEDDE) lays down instructions on the management of health risks related to asbestos in the case of work on surfacing materials containing asbestos on the publicly-managed national road network. This operational instruction focuses in particular on the surveying of areas containing asbestos, operating methods, the management of waste, and information for staff, and applies to the national road network. Many analyses of asbestos have accordingly been performed at the sites of different road works, to detect the possible presence of chrysotile asbestos. Chrysotile was used intentionally in road surfaces in the years 1975-1995 at rates of up to 1% by mass, for its resistance properties. During these procedures, actinolite was detected in aggregates when core samples were taken.*