

COMMENTS AND RESPONSE TO COMMENTS ON OEL: PROPOSAL AND JUSTIFICATION

All comments and attachments including confidential information received during the consultation have been provided in full to the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Last data extracted on 06.04.2021

Substance name: Asbestos

EC number: -

CAS number: -

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
30.03.2021	Sweden	The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals (NEG)	International NGO	1
Comment received				
See attachment				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment NEG comments on ECHA Asbestos 30 March 2021.pdf				
ECHA/RAC Response				
<p>It is noted that there were 4 generic comments and 50 more detailed comments.</p> <p>The generic comments dealt with terminology (fibre vs fiber, width vs breadth, f vs fiber and explicitly stating the study design of each epidemiological study cited). Fibre and width are now consistently used, except that breadth is used when directly quoting a piece of legislation using this term and fiber is sometimes used in the list of references which is automatically repeating the title of the original publication. As regards study designs, it was cross-checked that the study design of each study used in deriving the exposure risk relationship is explicitly mentioned.</p> <p>Many of the detailed comments were editorial and were implemented as such.</p> <p>More specifically:</p> <ul style="list-style-type: none">• The sections describing the exposure risk relationship were more thoroughly revised to improve the description of the epidemiological methodology and presentation of the results (including ease of comparison with national assessments) as well as to analyse, document and discuss the related uncertainties.• Regarding human mutagenicity the reference recommended has been added as well as a few other references. However, the human mutagenicity data was not considered critical for the main conclusions on asbestos non-threshold carcinogenicity.• Regarding the comments on current OELs, the amendments proposed were				

implemented.

- Regarding the comments on Monitoring exposure, the following has been implemented:
 - Typos and format corrections (including tables 5 and 6) and update of outdated methods
 - The BGI method has been removed as example of SEM method and the ISO 14966 has been included instead.
 - A new subsection of “challenges of measurement of asbestos” has been added
- As regards suggestions for structural changes, they were implemented when considered important for the critical conclusions.

Date	Country	Organisation	Type of Organisation	Comment number
29.03.2021	Pakistan	Dadex Eternit Limited Pakistan	Company Manufacturer	2

Comment received

Dadex Eternit Limited Pakistan

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Health Surveillance Data Analysis- Dadex Eternit Ltd Pakistan.pdf

ECHA/RAC Response

It is noted that the confidential data relates to manufacturing of asbestos cement products and includes cross-sectional health surveillance data for a limited number of workers as well as exposure measurement data from the plant. No cancer follow-up data was included that could have been used in the ECHA assessment. The exposure data referred to current manufacturing of asbestos products which is already banned in the EU and thus not representative of the exposure circumstances where the revised EU OEL will be applied.

Date	Country	Organisation	Type of Organisation	Comment number
27.03.2021	Belgium	European Trade Union Confederation (ETUC)	International NGO	3

Comment received

The European Trade Union Confederation (ETUC) thanks ECHA for the consultation on the update of the EU OEL for asbestos and would like to provide the following comments:

1. According to the latest scientific and peer-reviewed knowledge, The Lancet in Oct 2020 (Lancet 2020; 396: 1223–49) the number of annual (GBD 2019) deaths in EU28 was 90,730 deaths (this number includes mesothelioma, lung cancer, ovary cancer, larynx cancer and chronic respiratory diseases (asbestosis)).
2. ETUC understands that the Table (page 8 &9) in the ECHA scientific report linking exposure limit values to lifetime risk of asbestos may be based on relatively old data from 10 or more years ago.
3. ETUC is convinced that taken the latest knowledge of continuously growing asbestos death cases and Disability Adjusted Life Years in EU, and when adjusting for the extensive delays of such data, the updated OEL in the Asbestos at Work Directive should be 1000 f/m³, which is equal to 0.001 f/cm³. It is important for ECHA to provide a reliable Exposure risk relationship and in particular in the lower exposure levels. Therefore, all known cancer types caused by asbestos need to be considered. ETUC would like to remind that workers can easily inhale more than 1,000 fibres in less than an hour. HEPA and other similar filters

can be used to lower the exposure if no other higher hierarchy measures are not available.

4. The total mortality for the EU28 in 2019 was 90 730 deaths including asbestosis deaths (chronic respiratory.). Globally the difference between today (2019 data) and from 10 years ago in 2009 (when e.g. The Netherlands DECOS study was made) was 239,333 IHME/GBD / 108,000 (WHO). Furthermore, the IHME/GBD number of fatalities were coming from occupational injuries while WHO 108,000 covered both occupational and non-occupational deaths. Present risk levels are based on science 10+ years ago due to the usual slow process of science and meta-analysis. Individual studies, such as DECOS/The Netherlands are based on reported outcomes, including deaths caused by asbestos. If such data was not reported to WHO one cannot assume that these were reported better in each individual studies and meta-analysis. See full data from The Lancet (Lancet 2020; 396: 1223–49), best available at <https://vizhub.healthdata.org/gbd-compare/>
5. The OEL at 0.1 fibres/cm³ has been used in many countries from the 1990's, e.g. in USA and Finland in 1994. However, the biggest increases in total deaths over the last 10+ years have not come from reported EU mesothelioma cases that may have a latency delay of up to 50+ years, but from asbestos-related lung cancer not well identified as asbestos-related in the past. For lung cancer the exposure to outcome latency is much less than that of mesothelioma. Usually, lung cancer may develop 15 to 35 years after asbestos exposure. The concentration of 0.1 fibres/ cm³ has poorly protected those exposed.
6. Furthermore, the identification, recording and compensation of asbestos-related lung cancer has been and is today very poor everywhere in the EU. Only after the IARC study on the relationship between various asbestos fibres, in particular chrysotile, by McCormack, Peto, Straif et. al. on estimating the asbestos-related lung cancer burden from mesothelioma mortality in 2015 there has been more realistic estimates of the lung cancers. Clearly asbestos is not well identified because it has not been understood to be the immediate suspected and obvious cause of lung cancer, in particular, if the person smoked.
7. The European Union is the heaviest exposed region in the world and covers 38% of the global deaths. Latest studies (Chimed-Ochir, Takahashi et al.) of mesothelioma, pleural and peritoneal, are higher than those referred to in The Lancet Oct 2020 referred above. The method of estimating lung, ovary, and larynx cancers is based on mesothelioma as a proxy indicator of asbestos exposure, and as a result of such estimated exposure all other cancers are likely to grow in future reports of deaths for some time ahead.
8. The present estimates IHME/GBD 2019 in The Lancet are based on mesothelioma incidence and mortality as a proxy estimate of asbestos exposure. This exposure leads to much more common lung cancer, some 6-8 times more than mesothelioma.
9. In future IARC may reclassify colorectal, stomach and pharynx cancers as well – these are very common cancers - in the IARC List 1 increasing further the numbers (colon and rectum already noted by Nurminen, Karjalainen).
10. Mesothelioma itself is equally poorly diagnosed, recognised, reported and compensated in many EU Member States (reports from Bulgaria refer to reporting only some 10% of mesothelioma cases to WHO statistics (Katya Vangelova, Irina Dimitrova: Asbestos exposure and mesothelioma incidence and mortality in Bulgaria, 2016, DOI 10.1515/reveh-2016-0007). While IHME/GBD reports 10,304 deaths in EU28 in 2019, and J. Takala (in Eliminating occupational cancer in Europe and globally) 10,368 in 2015, overall global numbers based on the asbestos consumption in each country globally was estimated at 38,388 while the corresponding IHME/GBD number was 26,820 occupational deaths using GBD 2019. While the EU under-estimates may extensive, the best estimate today is around 20 % that are missing in EU27. In Finland some 80 mesothelioma deaths/year are recognised and compensated while IHME/GBD estimates 106 death cases in Finland.
11. Adding some 20% to the present exposures to lung cancer will further increase the lung cancer death cases.
12. ETUC thinks that the best measurement method is the transmission electronic microscopy (TEM), while understanding that phase contrast microscopy (PCM) can still be used with a practical conversion factor of 2.

13. The excess lifetime cancer risks calculated by ECHA for different air concentrations of asbestos are only based on mesothelioma and lung cancers. However, there is clear evidence from the literature that exposure to asbestos is also causing other types of cancer: larynx and ovary cancers as well as pharynx, stomach and colorectum cancers. These endpoints should also be considered to refine the exposure risk relationship. ECHA should provide an estimation of the contribution of these cancers to the excess lifetime cancer risks per 100 000 exposed. The fact that women are under-represented in the cohorts used in most of the available studies means that ovary cancers caused by asbestos are underestimated. This should also be discussed and taken into account by ECHA. A precautionary based safety factor could be proposed and used by ECHA to cover all types of cancers linked to asbestos exposure.

ECHA/RAC Response

The data sources describing current burden of disease, either by estimation methods or based on occupational disease registries, demonstrate that asbestos is currently the leading cause of fatal occupational diseases. This fact is now more clearly cited in the ECHA scientific report. However, such data sources are not suitable for quantitative risk assessment that aims at describing the life-time excess risk level as a function of the workplace air concentration of asbestos and to estimate risk at low exposure levels, often below present exposure. The reasons for this are now explained in the ECHA scientific report.

For the above data sources, the time trends and delays in reporting are indeed an important aspect. However, the description of cancer excess risk as a function of (cumulative) level of exposure is based on intrinsic hazardous properties of asbestos. For assessment of such intrinsic properties, the time of publication of a given suitable study is not important, provided that the quality of the exposure assessment and disease follow-up are of sufficient quality. Therefore, all studies suitable for quantifying the excess risk by level of exposure and of sufficient quality were used and combined in a meta(regression)analysis. However, it is to be noted that a spline function (instead of linear function) was used. This approach allows data points that represent lower exposures, many of them coming from more recent publications, to influence the risk function to a greater extent than in case of linear modelling.

For the thus derived exposure risk relationship, a more elaborated uncertainty analysis is added in the ECHA scientific report describing the potential effect of cancer sites included, type of asbestos fibre and quality of studies as well as assumptions made in extrapolating the risk for life-time. The documentation of that uncertainty analysis allows for considering any precautionary measures necessary. However, that is a policy consideration that takes place later in the OEL setting procedure under to Directive 2009/148/EC.

Further uncertainties are also linked to the choice of analytical monitoring methods. These are now more comprehensively described in the ECHA scientific report for further feasibility consideration that takes place later in the OEL setting process.

Date	Country	Organisation	Type of Organisation	Comment number
23.03.2021	Spain	<confidential>	Industry or Trade Association	4

Comment received

PAGE 19. 5.2.1 General population, 2nd and 3rd paragraphs

Current text: These paragraphs explain that the background ambient concentration of asbestos fibres may be high and close to the OEL, depending on the area where it is

measured.

Comment 1: There is no information about the ambient asbestos concentrations in Spain. It is important to realize this type of measurement to consider this value in addition to other controlled exposures, such as asbestos removal activities, in a concrete area.

Comment 2: We suggest adding a paragraph indicating that background ambient values cannot be corrected by the companies and must be taken into account when measuring the concentration of asbestos fibres in the workplace. This is particularly important because ambient concentrations occur due to ambient pollution and should be managed through environmental actions on the particular sites.

On the other hand, sometimes, Labour Inspectors do not understand the difference between ambient concentration and application of the OEL and sanctions have been applied to companies working in sites with high ambient concentration of asbestos fibres.

PAGE 19. 5.3.1 Principles for safe handling of asbestos, 2nd paragraph

Current text: National regulations and practices may go beyond these (...)

Comment: It is important to take into account regulations and practices that significantly differ from those developed at EU level. We suggest adding the case of Spain as the only Member Estate (to our knowledge) that limits the exposure of workers to asbestos to 4h/day when using PPE. In practice, asbestos removal implies most of the time the use of PPE, and thus the limitation to 4 hours is usually applied.

This situation should be explained in this chapter, but also will have consequences in other chapters, like in sampling and measuring air concentrations. We are including this comment in the other affected parts of the report.

PAGE 21. 5.3.2. General occupational exposure levels divided by industrial sectors and jobs. 3rd. paragraph

Current text: To be noted that earlier the measurements were mainly performed with phase-contrast optical microscopy (PCM) but nowadays electros microscopy (TEM or SEM) is considered more accurate (...)

Comment: Unless the text is correct, it must be added that "some Member Estates are using PCM as their official method (e.g. Spain)".

PAGE 22. 5.3.3 Exposures during handling of asbestos containing products. 1st. paragraph and following

Current text: The context of exposure in several Member Estates is provided.

Comment: There is no information regarding Spain. We are providing here the context for Spain, that should be added to give a more accurate picture of the situation in the EU, as Spain has been very active in the removal of asbestos from buildings and facilities.

Personal measures (PCM) made nowadays in Spain while working with asbestos-containing materials show ambient values under 0.1 f/cc.

On the other hand, it should be taken into account that exposure time in Spain is limited to 4h/day when using PPE; which is used in most of the tasks related to asbestos removal. See section V for further information.

PAGE 25. Table 5

Current text: The current table gives an overview of the techniques and methods for monitoring of asbestos fiber.

Comment: The Spanish official method is not included in this table. We suggest adding it, as it is being used by Spanish companies. See section V for further information.

PAGE 28 and following. 6.1.2 Electron microscopy

Current text: The current text explains the two methods applied (TEM and SEM), but does not discuss regarding sampling times.

Comment: As in Spain sampling times will not exceed 4h/day, it would be adequate to consider and discuss here how this legal provision will affect the application of EM to measure values below 0.01 fibers/cm³.

See Article 8 of Royal Decree 396/2006, of 31 March, on "personal protective equipment for the respiratory tract" which states the following:

"1. When the application of prevention and collective protection measures, of a technical or organizational nature, is insufficient to ensure that the limit value established in article 4.1 is not exceeded, personal protective equipment must be used for the protection of the respiratory tract, in accordance with the provisions of Royal Decree 773/1997, of 30 May, on minimum health and safety provisions relating to the use by workers of personal protective equipment. Notwithstanding the above, even if the aforementioned limit value is not exceeded, the employer shall make such equipment available to any worker who expressly requests it.

2. The use of personal respiratory protective equipment may not be permanent and its duration of use, for each worker, shall be limited to the strict minimum necessary and may in no case exceed 4 hours per day. During work with personal respiratory protective equipment, breaks must be provided for in accordance with the physical workload and climatic conditions".

As far as the exposure limit is concerned, our country is the only Member State that sets it at 4 hours per day, producing different effects on samplings and exposure.

PAGE 28 and following. 6.1.2 Electron microscopy

Current text: The current text explains the limits of detection and range of the available EM techniques. However, it is not discussed their applicability in the range of possible concentrations.

Comment: The document should include a discussion regarding the applicability of the sampling and analytical methods in regard of the ERR provided in table 9, chapter 9.1.2. It is of the outmost importance to identify clearly for which range of possible OELs there is a measurement method available.

PAGE 28 and following. 6.1.2 Electron microscopy

Current text: The current text explains the available methods, their basis and limitations. However, no considerations are made regarding the legal obligations on sampling and monitoring in the different Member Estates.

Comment: In Spain, sampling is mandatory for each work plan; it is not allowed to provide data related to activities (e.g. cutting fiber-cement plates). It implies that the costs for Spanish companies may be several times higher than the cost for companies working in other Member Estates. This fact, added to the higher costs of EM versus PCM (EM costs 2 or 3 times the cost of PCM), will increase considerably the costs for SMEs. This consideration should be explained in the document, even if the analysis of costs is not in the scope of the report.

PAGE 28 and following. 6.1.2 Electron microscopy

Current text: The current text explains the available methods, their basis and limitations. However, no considerations are made regarding the availability of laboratories in the Member Estates.

Comment: For those Member Estates that are currently applying PCM, there may not exist laboratories capable of offering the new techniques. This aspect should be discussed in the report.

PAGE 66. New chapter 8.4. Specific patterns of exposure

Comment: We suggest discussing specific patterns of exposure, with exposure times different from the current one of 8h/day and 40h/week. As previously explained, in Spain

the pattern of exposure is 4h/day if wearing PPE (which is the usual situation). Also, other patterns may be discussed, e.g. short exposure times in maintenance and similar situations.

PAGE 69. Germany

Current text: "In the German system the limit values for carcinogens are based on the acceptable risk (nominal risk of 4×10^{-3} and tolerable risk (4×10^{-4} , and the latest 2018, 4×10^{-5}) excess risk levels (AGS, 2014)

Comment: We understand that the tolerable is the higher level of risk and the acceptable the lower. It seems to be the contraire in the text. On the other hand, has the lower value been reduced since 2018? Please, check it.

SEVERAL PAGES. LACK OF INFORMATION REGARDING SPAIN

In general, this document presents several lacks of information regarding Spain. We are providing here the information that we consider should be added and the corresponding page of the document:

- Page 19. Guidelines published by the Instituto Nacional de Seguridad y Salud en el Trabajo.

The Spanish National Institute for Health and Safety at Work (INSST), as a technical scientific body of the General State Administration, is in charge of drawing up the Technical Guidelines for the interpretation of the regulations arising from the Law on Occupational Risk Prevention.

Article 8 of the OSH Spanish Law establishes as its functions, among others, the carrying out of information and dissemination activities in the field of occupational risk prevention.

Article 5.3 of the OSH Services Regulations provides for the possibility of using INSST guides (...): "when the assessment requires measurements, analyses or tests to be carried out and the regulations do not indicate or specify the methods to be used, or when the assessment criteria contemplated in said regulations need to be interpreted or specified in the light of other criteria of a technical nature".

In addition, the Royal Decree 396/2006, of 31 March, on Asbestos related to the "preparation and updating of the Technical Guide" expressly states that: "the INSST (...), will prepare and keep updated a non-binding Technical Guide for the assessment of risks related to exposure to asbestos at work. This Guide will establish, in particular, practical guidelines for the determination of sporadic and low-intensity exposure referred to in article 3.2 of this Royal Decree, as well as harmonized criteria for the approval of the work plans referred to in the article".

<https://www.insst.es/documents/94886/203536/Gu%C3%ADa+t%C3%A9cnica+para+la+evaluaci%C3%B3n+y+prevenci%C3%B3n+de+los+riesgos+relacionados+con+la+exposici%C3%B3n+al+amianto/0aecc8f0-d55c-4eee-becb-17db44e5768c>

- Page 20. Exposure data to asbestos in Spain.

It is difficult to determine the magnitude, identification and location of workers exposed to asbestos in Spain. This information is essential to be able to size the necessary health resources and to be able to implement health examinations.

The chronology would be as follows:

- In 1971 the number of exposed workers was estimated at 8,000, 70% of them in the asbestos cement sector.

- In 1991, the National Institute for Health and Safety at Work estimated the number of

exposed workers at 60,488.

- At the end of that decade, the CAREX project (CARcinogen EXposure, an international information system on occupational exposures to known carcinogens, which uses occupational exposure information mainly from the Nordic countries) estimated the number of people exposed at 56,600.

- In December 2016, the Integrated Health Surveillance Programme for Workers Exposed to Asbestos (PIVISTEA) included a total of 42.572 workers, from 17 Autonomous Communities (CCAA) and 2.526 companies, of which 26.388 are post-exposed workers. See file "PIVISTEA2016" in the ZIP-

- The Register of Companies at Risk of Asbestos (RERA), with 49%, but the deficient registration of exposed workers in the past, due to the voluntary nature of registration in the RERA by companies, and the current excess, due to the requirement that tenderers or, where appropriate, contracting companies be registered in the RERA, is also noted. See file "RERA2018" in the ZIP.

- Page 22. Data regarding registered asbestos companies, number of exposed workers number of work plans authorized, number of products containing asbestos registered in Spain. See file "PT20092019" in the ZIP.

- Page 25. Official Spanish sampling and analytical method. See in previous comments. See file "MA_051_A04" in the ZIP.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ECHA.zip

ECHA/RAC Response

A reference to the Spanish guidance on asbestos removal work, Spanish fibre measurement data and types of asbestos products used in the past were added to the ECHA scientific report.

It is noted that many of the comments address issues like feasibility of a reduced limit value, availability of laboratory capacity etc. Such considerations are subject to a separate assessment and not mandated to ECHA. However, aspects related directly to technical capabilities of the various available analytical methods are further elaborated in the ECHA scientific report.

It is further noted that some comments address guidance on how to measure asbestos, how to take into account concomitant environmental and occupational exposures, how to take into account periods without exposure potential etc. Such guidance to employers or other involved stakeholders as regards how to monitor compliance with the OEL are not part of the ECHA scientific report. Such guidance needs to be developed once a revised OEL has been defined according to the OEL setting procedure under to Directive 2009/148/EC. It is noteworthy that ECHA scientific report does not propose an OEL, but derives an exposure risk relationship, it also does not recommend a specific analytical method to be applied. Both of these aspects will be subject to discussion in the later stages of the above mentioned OEL setting procedure and take into account also feasibility and socio-economic aspects that are subject to a separate assessment.

Regarding the analytical methods, the document does not intend to detail every possible method or to recommend the adequate methods. It simply assesses whether a lower OEL can be adequately measured. However, the current Spanish method has been added to the table.

Regarding the EM methods, the sampling volumes are reflected (and those can be achieved within a work shift) because the flow rates can vary depending on the needs (e.g., for NIOSH 7401 recommended flow rate goes between:0.5 and 16 lpm). Moreover, a new

section on “challenges of measurement of asbestos” has been added where the challenges to achieve a lower limit of detection are reflected (among other limitations).

Finally, issues related to feasibility such as cost of monitoring or laboratory capacity are out of the scope of this report and can be flagged when the socio-economic analysis is performed at later stages of the OEL setting process.

Date	Country	Organisation	Type of Organisation	Comment number
01.04.2021	United States of America		Individual	5

Comment received

I am submitting a Relative Risk Model for Asbestos-Related Cancer.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment [IERF_Comment_ECHA_Asbestos_4_1_2021.pdf](#)

ECHA/RAC Response

The relative risk model submitted concerns mesothelioma only. For reasons further elaborated in the revised ECHA scientific report an absolute risk model for asbestos-related risk of mesothelioma has been postulated by US EPA and has acquired wide acceptance in the scientific community and among regulators. Furthermore, asbestos is an established risk factor for lung cancer for which a relative risk model is necessary. For both mesothelioma and lung cancer, indeed, fibre type related potency issues need attention. The ECHA scientific report has been further elaborated to (1) justify the use of absolute and relative risk models for mesothelioma and lung cancer, respectively, (2) justify choices made and discuss related uncertainties as regards fibre type, cancer sites and studies considered, and extrapolating combined individual study data to life-time risks in the entire (future) exposed population. Those considerations did not indicate a need for change of the scientific approach taken and the related residual uncertainties are documented for policy consideration during the later stages of the legislative process.

The reviews and meta-analyses cited in the comment were already described in the ECHA scientific report. The original articles cited in the comment were reviewed for potential inclusion in the new meta(regression)analyses performed by ECHA, but none of them provided the necessary information.

Date	Country	Organisation	Type of Organisation	Comment number
01.04.2021	Finland	Finnish Institute of Occupational Health (FIOH)	Academic Institution	6

Comment received

Although the different methods for asbestos exposure measurement, their performance and comparability are to some extent discussed in the ECHA report (Chapter 6 and 9, Appendix 5), the discussion could be elaborated on the following aspects:

As mentioned in the report, the size distribution and thickness of asbestos fibres in different work environments may vary widely. This weakens the assumption that larger (PCM equivalent) fibres could serve as an indicator for total asbestos exposure. As an example, thin (width below 0,2 µm) chrysotile fibres commonly occur in Finnish mines. Therefore, fibres with a width down to ca. 0,05 µm are counted and reported in the asbestos exposure measurements by FIOH. The analysis is carried out by SEM, using a magnification of 6000x to detect also the thinner fibres (in contrary to the current ISO standard 14966:2019). In

comparison to TEM, SEM provides an affordable and practicable option for asbestos measurements.

In the current standards for asbestos measurements, the ISO 14966:2019 standard for SEM and the NIOSH method 7402 for TEM do not include thinner fibres (width below 0,2 µm or 0,25 µm, respectively) in the reported measurement results. According to the HSE method MDHS 87, thinner fibres (width below 0,2 µm) are not reported when using SEM, while all detected fibres are reported upon TEM analysis. According to the AFNOR guidelines (NF X43-269) for TEM, fibres with width down to 0,01 µm can be detected and reported. In the ISO standards for direct and indirect analysis by TEM (ISO 13794:2019, ISO 10312:2019), all counted fibres and fibres with a width greater than 0,2 µm are reported separately (using a magnification of 10 000x). There is an evident need to harmonise the standards, and especially to enable reporting also thinner asbestos fibres with the SEM methods. The detection limit of the SEM method used by FIOH (using a magnification of 6000x to detect fibres with a width down to ca. 0,05 µm), with the air volumes currently in use, is 0,01 fibres/cm³ (as mentioned on page 22 of the ECHA report). Reaching a detection limit of 0,001 fibres/cm³ would require a tenfold increase in the analysed microscopic fields or, e.g., doubling the sampled air volume and counting fivefold microscopic fields. A lower detection limit (e.g., 0,0001 fibres/cm³) would not be practically achievable with the magnification needed to detect the thinner fibres. An additional aspect to consider is that in dusty work environments (e.g., underground mines) there often is a need to limit the sampled air volume to avoid blocking the filter, which further increases the detection limit. Achieving a detection limit below 0,01 fibres/cm³ in dusty work environments would require a significant development of the sample collection and/or sample treatment practices. To add on the discussion on exposure levels in Chapter 5.3.2, in the asbestos measurements carried out by FIOH in Finnish workplaces in 2016–2019 (personal sampling; N=187), the average level was 0,13 fibres/cm³, median 0,005 fibres/cm³, 95. percentile 0,57 fibres/cm³, and range below 0,01 to 7,6 fibres/cm³ (data extracted from the FIOH Register of Occupational Hygiene Measurements). A majority of the measurements, and all those exceeding the current limit value, were carried out in mining and processing of rock materials. The current limit value of 0,1 fibres/cm³ was exceeded in 13% (24/187) of the measurements. However, the sampling was carried out outside respirator, which was used in 15 of the 24 cases where the current limit value was exceeded.

ECHA/RAC Response

The issues related to fibre size and the analytical methods were further elaborated by adding the aspects raised by FIOH in the ECHA scientific report. A new section on “challenges of measurement of asbestos” has been added where the challenges to achieve a lower limit of detection are reflected (among other limitations). Furthermore, the need of EU harmonisation of analytical electron microscopy methods was underlined.

Date	Country	Organisation	Type of Organisation	Comment number
01.04.2021	United Kingdom	<confidential>	National NGO	7

Comment received

Executive Summary

- The Report contains omissions in the evidence base which may undermine the reliability of conclusions, some of these arise from scientific choices, but others are procedural defects which should be remedied before the report is acted upon.
- The epidemiological reliability of the report is questionable in relation to the transparency and/or rigour of some methods, the absence of justification for some analysis which might impact the risk analysis and skew results and some details in relation to the underlying literature and its use.
- The Report is technically flawed in its consideration of measurement methods, from the

consideration of scientific evidence, through to appreciation of practical considerations which will determine whether actual (rather than formal) compliance is achievable.

- The Panel considered the Report limited by the failure to properly explore the relationship between risk and limit values and the determination of whether different limit values are required for the different types of regulated asbestos; this was a clear requirement of the EU Commission's request to ECHA. It also identified issues with the transparency of data and analysis.

Additional recommendations for enhancing the transparency of the scientific method and working assumptions

- The basis of the selection for the "quantitative" cohorts for the exposure-risk relationship (ERR) should be set out in this report and the report should also tabulate how each cohort made the grade (e.g. numbers of actual measurement and over what period, and how many samples used to convert PCM to historic indices of exposures etc.)

- The lack of information on the number of asbestos removal and maintenance workers, their current compliance with the OEL, the effectiveness of the RPE and controls that are available to them would seem essential information to include in the science report for the RAC and the ongoing OEL procedure. It is recommended that this information is made available.

- The assumptions and limitations of the science should be summarised/listed in a separate section of the report, so it is easier to determine the limits of the evidence-base without re-reading the whole report.

Conclusion

The FAAM Panel was of the opinion that while the report was well-presented, there are appreciable defects in the scientific method through the exclusion of relevant considerations, the omission of evidence, defects in the transparency of the evidence base, missing elements in the scientific evidence base and a failure to appreciate the relationship between practice considerations and the realisation of the objective of limit values in the context of the Directive and European Law. It recommends that the Report is reviewed to address these defects prior to any further decisions being made on its basis, which may then be potentially subject to challenge and/or fail to realise the objective of appropriate worker health protection.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment FAAM BOHS ECHA Asbestos OEL response.pdf

ECHA/RAC Response

It is noted that several of the comments are related to feasibility of lowering the OEL or to compliance with current or future (lower) OEL. Such aspects are not subject of the ECHA scientific report. Instead they will be subject to a separate assessment (not mandated to ECHA) which together with the ECHA scientific report will be used in the policy process that takes place later in the OEL setting procedure under to Directive 2009/148/EC.

The description of the variety of analytical methods used nationally to monitor workplace asbestos concentrations has been elaborated. The relation between the traditional PCM method and electron microscopy are further discussed as an uncertainty linked to using the derived exposure risk relationship in revising the OEL. ECHA scientific report does not recommend a given new method but calls for harmonisation work at the EU level.

Uncertainty analysis addressing the aspects raised by the BOHS (e.g. fibre type, quality of studies included, exposure assessment in Olsson et al. (2017) study and parameter choices made by ECHA) has been added in ECHA scientific report in the context of the exposure risk relationship (ERR) derived. The reasoning for deriving a single ERR is elaborated further and the related uncertainties are assessed.

The sections describing the exposure risk relationship were revised to improve the description of the methodology and presentation of the results for points raised by BOHS. The effect of some of them was also assessed in the uncertainty analysis mentioned in the previous paragraph.

BOHS argues that the ECHA scientific report is based on assessment of a skewed literature data base, more specifically "The ECHA report is confined in scope to the updating of the risk assessments carried out by four EU member states that have already unilaterally lowered their OELs below that, in the directive 2009/148/EC." It is noted that all recent national scientific assessments by EU Member States were searched for and included. However, it turned out that there was no such recent national assessment which would not have recommended lowering the national OEL.

As regards the recent EPA (2020) assessment on chrysotile, it is noted that only drafts labelled as "not to be cited" were available at the time of the ECHA scientific report drafting. A final version was available only at the time when the ECHA scientific report was already in the process for open consultation. This and the scope and nature of the EPA assessment have now been added in the ECHA scientific report. Contrary to the US situation, all chrysotile use is already prohibited in the EU. Therefore, it is not likely that any European worker would experience long-term exposure (working life long) to chrysotile only. Rather it is likely that long-term exposure, from asbestos products still in place, represents the share of each asbestos type in the past use. Consequently, an ERR combining all asbestos types is a justified approach as further described in the ECHA scientific report together with related uncertainties.

The comment regarding publication of information submitted in the call for evidence is acknowledged. However, ECHA followed its established procedures, where such information is taken into account in compiling the ECHA scientific report, which is then available in the open consultation. The ECHA scientific report is based on both information submitted in the call for evidence and information identified from other sources, e.g. via literature searches.

The specific errors and unclear sentences pointed out were corrected/revised/removed.

Date	Country	Organisation	Type of Organisation	Comment number
01.04.2021	Belgium	FEDASBEST	Industry or Trade Association	8
Comment received				
comment on PCM and electronmicroscopy in regard of OEL asbestos				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment antwoord echa.docx				
ECHA/RAC Response				
The fact that national practices vary as regards if PCM, SEM, TEM or some combination of them are allowed, is now made clearer in the ECHA scientific report. The report also does not recommend a specific method as there seems to be an obvious need for harmonisation of nationally developed methods if imposing an EM method at EU level. This will be a policy consideration that takes place later in the OEL setting process under Directive 2009/148/EC.				
Indeed, SEM methods can detect much thinner fibres than 0.2 µm while many SEM standards are such that those thin fibres are not counted. This problem is now made clearer				

in Table 5 and in the text that describes SEM.

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2021	France	INRS (Institut National de Recherche et de Sécurité)	Academic Institution	9

Comment received

General Comments:
 This scientific report is very well constructed and clear, providing an exhaustive review of the most recent data, particularly in terms of metrology and toxicology. In particular, it includes the Afsset/INSERM recommendations published in 2009, which France has used to change the regulations on the risks of exposure to asbestos in order to better protect workers who carry out removal or encapsulation work on materials containing asbestos or who carry out work on materials that could cause the emission of asbestos fibres. One of these major developments was the adoption in 2012 of the ATEM (Analytical Transmission Electron Microscopy) technique for assessing asbestos fibre dust levels at work (Eypert-Blaison C., Romero-Hariot A., Clerc C., Vincent R. (2018), Assessment of occupational exposure to asbestos fibers: Contribution of analytical transmission electron microscopy analysis and comparison with phase-contrast microscopy. Journal of Occupational and Environmental Hygiene, 15:3, 263-274.). This technique, already used in France for the assessment of dust in ambient air, allows, in workplace area, to reach an analytical sensitivity of 1 f/L, corresponding to one tenth of the OEL_8h of 10 f/L, adopted in France since 2 July 2015. It will be explained in the comments below that it is technically possible to lower these detection thresholds in ATEM.

As asbestos is a non-threshold carcinogen, this scientific report rightly points out that it is impossible to identify a health-based OEL and recommends to rely on an exposure-risk relationship expressing the excess risk of lung cancer and mesothelioma mortality (combined) in function of the concentration of asbestos fibres in the air regardless of the type of asbestos fibres to which the working population has been exposed.

This scientific report also concludes and warns about fibres other than those covered by Directive 2009/148/EC. These recommendations were also formulated in France in two expert reports published by the ANSES. In these both reports of December 2015 ("Health Effects and the identification of cleavage fragments of amphiboles from quarried minerals") and June 2017 ("Elongated mineral particles - Identification of emission sources and proposed protocols for characterisation and measurement protocols"), ANSES considered, in a more general concept of "elongated mineral particle of interest (PMAi)", a certain number of particles meeting the WHO dimensional criteria for respirable fibres. These PMAi are: actinolite, anthophyllite, tremolite, amosite/grunerite, crocidolite/riebeckite, fluoro-edenite, winchite, richterite, erionite, chrysotile and antigorite. Some of these are already classified as carcinogens by IARC. In the absence of specific epidemiological or toxicological data, ANSES recommends the application of the recommendations of the asbestos regulation, in application of the precautionary principle.

On the basis of these recommendations, INRS participated in an ANSES research and development program in collaboration with BRGM (Geological and Mining Research Bureau) and LAFP (Laboratoire d'Etude des Fibres et Particules de la Ville de Paris) on "Analysis of elongated mineral particles (EMP) and crystalline silica emissions generated during attrition tests on natural materials in laboratory" (No public data). Following this work and the recommendations of the ANSES, the INRS is participating in a project led by the OPPBTP (Agency for risk prevention in the building industry), the main objectives of which are to objectivise the risk linked to the presence of PMAi in materials and in the air during work carried out in amphibole quarries (aggregates used by the construction industry) and on

natural terrain. These data will enable the concerned Ministries to adapt the regulations if necessary according to the risk linked to PMAi for workers and the general population. Additional information on this ECHA scientific report is provided in the join table (attached file).

It should also be noted that during the consultation period of this report, INRS was questioned by e-mail and by telephone by COWI in order to deepen its knowledge on:

- ATEM technique and its applicability to the objective of lowering the OEL
- Exposure data sets and the possibility to share them
- The number of TEMs and SEMs available in Europe and the cost of these analyses
- Data on the efficiency of risk management measures
- The existence of voluntary industry initiatives to reduce exposure in this area and of good practice documents to be recommended.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments_Report_OEL_ECHA_INRS_EN_03_2021.docx

ECHA/RAC Response

Reference to the various French national guidance documents and standards described in the attachment were added in the ECHA scientific report, in the section where national approaches to implement Directive 2009/148/EC are described. The occupational exposure related problems of naturally occurring asbestos were already mentioned in the ECHA scientific report but are now repeated in some additional sections. It is noted that the ANSES reports and the studies of Eypert-Blaison et al cited by INRS are already described in the ECHA scientific document along with their main conclusions. As regards the feasibility and socio-economic considerations of implementing a lower OEL, it is noted that such considerations are subject to a separate assessment and not mandated to ECHA. However, aspects related directly to technical capabilities of the various available analytical methods are further elaborated in the ECHA scientific report.

Date	Country	Organisation	Type of Organisation	Comment number
31.03.2021	Netherlands	The Health Council of the Netherlands	Academic Institution	10

Comment received

On behalf of the Dutch Expert Committee on Occupational Safety (DECOS) of the Health Council of the Netherlands, I would like to thank you for the opportunity to comment on ECHA’s public draft scientific report for evaluation of limit values for asbestos at the workplace, which was made available by the RAC for public consultation in February 2021. The DECOS published an advisory report on risks of environmental and occupational exposure of asbestos in 2010. We appreciate that this report has extensively been referenced in the ECHA report. The DECOS has discussed the ECHA report on asbestos, focusing on cancer risk assessment and OEL derivation.

The DECOS supports a risk-based approach, based on a meta-analysis of studies that include data on the relationship between asbestos exposure and excess risk of lung cancer and mesothelioma. ECHA applied an approach similar to the DECOS in 2010, but included several additional studies published since. The cancer risk associated with the risk values calculated by ECHA is slightly lower than the risk associated with the values proposed by the DECOS. This difference could partly be explained by a pragmatic conversion factor of 2, which was applied by the DECOS to account for differences between fibre counts, using transmission electron microscopy and phase contrast microscopy.

Notably, the DECOS also applied more strict criteria and subsequently used other studies for

the risk quantification. It has been argued that higher-quality asbestos exposure assessment yields higher meta-risk estimates, at least for lung cancer. ECHA has summarised the discussion on this issue on page 51/52, but does not draw a conclusion regarding the role of exposure assessment quality in its cancer risk assessment.

Also, the DECOS derived cancer risk values for both chrysotile, amphibole and mixed asbestos, whereas ECHA only provides estimates of excess cancer risk for exposure to mixed asbestos. The DECOS is of the opinion that the carcinogenic potency of amphibole asbestos is considerably higher than for chrysotile, which implicates that the cancer risk is underestimated when risk values derived by ECHA are used for exposure to amphibole asbestos.

Finally, on page 73 it is stated that "the data on species differences indicate that it is preferred to use human data for exposure-response analysis and risk assessment". The DECOS acknowledges the preference for human data, however, notes that this is regardless of any available data on species difference.

Kind regards, on behalf of the DECOS,

Scientific secretary

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Comments DECOS on ECHA report asbestos 2021.pdf

ECHA/RAC Response

An uncertainty analysis addressing the aspects raised by DECOS (fibre type, quality of studies included, cancer sites included, and parameter choices made by ECHA vs national bodies) has been added in the ECHA scientific report. The sentence on page 73 was removed as it was indeed not relevant as a preference for the use of human data is self-evident.

Date	Country	Organisation	Type of Organisation	Comment number
30.03.2021	Germany	Gesamtverband Schadstoffsanierung e.V. (GVSS, general association for remediation of contaminated buildings, Germany)	Industry or Trade Association	11

Comment received

The Gesamtverband Schadstoffsanierung e.V. (GVSS, general association for remediation of contaminated buildings, Germany) has read the ECHA scientific report for evaluation of limit values for asbestos at the workplace (2021-02-01) with great interest. The GVSS considers the set limit (0.1 fibres/cm³ OEL as 8 -hour TWA), originating from Directive 2009/148/EC, as insufficient for occupational safety.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment GVSS-Statement-ECHA-Consultation_30032021.pdf

ECHA/RAC Response

The support to the non-threshold approach of the ECHA scientific report and the need to lower the EU OEL is acknowledged. The actions taken at national level to tackle the asbestos problems in a holistic manner in Germany are summarised in the ECHA scientific report. Furthermore, the tolerable and acceptable risk level concepts and their application to

asbestos limit values are described. At the EU level, the OEL for non-threshold (carcinogenic) substances is set taking into account not only the RAC scientific opinion, but also socio-economic and feasibility aspects. That will take place in a later stage of the legislative process. As regards actions not directly related to EU OEL and ECHA's scientific mandate, the ECHA report has included some observations in section 9.4 for the Commission to consider. Those observations make reference to the national actions described.

Date	Country	Organisation	Type of Organisation	Comment number
30.03.2021	France	ANSES	National Authority	12

Comment received

General comments and specific comments are available in the zip file attached below.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ANSES Comments OEL asbestos.zip

ECHA/RAC Response

There were 3 general comments.

- A STEL was not proposed as there is no evidence of acute toxicity of asbestos. At EU level there is no similar default ratio between STEL and 8-hour TWA at EU level as there is at French national level that applies when no particular acute toxicity effects have been observed for the substance. Furthermore, the ECHA report does not propose an 8-hour TWA OEL, but derives an exposure risk relationship that will be used in the OEL setting procedure under to Directive 2009/148/EC. The French convention between STEL and 8-hr TWA is described in the ECHA scientific report and a reference is added that other Member States have similar conventions.
- The issue of cleavage fragments, short and thin fibres is now more extensively described in the ECHA scientific report and taken into account in the related conclusions made for the analytical methods.
- In the relevant section of the ECHA scientific report a reference was added indicating that unless otherwise specified the fibre concentration measurement results refer to those performed with the PCM method.

There were numerous detailed comments

- Many of the detailed comments were editorial and were implemented as such.
- The rationale for the approach combining different fibre types in the exposure risk relationship is further justified and sensitivity/uncertainty analyses were added
- The literature search follows a similar approach as in the most recent SCOEL documents and relies on reviews and international assessments when appropriate, instead of summarising individual studies. Nevertheless, despite of this general approach, recent relevant articles describing individual studies were referred to when pointed out by comments received during open consultation.
- As stated under the general comments, the fibre dimension and cleavage fragment issues and their impact on the analytical methods are further discussed.
- General population (non-occupational) exposure falls outside of the mandate and is not further described.
- Up to date description of the analytical methods was checked.
- As regards the non-asbestos fibres (e.g. erionite, fluoro-edenite and richterite), the related carcinogenicity conclusions by IARC/EPA were more clearly stated while acknowledging that these were not in the scope of the mandate of this assessment.
- More importantly, the sections describing the exposure risk relationship were more thoroughly revised to improve the description of the methodology and presentation of

the results (including ease of comparison with national assessments) as well as to document and discuss the related uncertainties.

- As regards suggestions for structural changes, they were implemented when considered important for the critical conclusions.
- Regarding the exposure monitoring and a comprehensive description of which method(s) is currently used by each MS, such comprehensive information was not collected during the scientific assessment and therefore it is not possible to include such a description in the report. It is noted that e.g. information on the use of electron microscopy in the EU Member States is part of the impact assessment, which is subject to a separate report not mandated to ECHA. However, the analytical monitoring section of the ECHA scientific report describes whether it is possible to measure a lower OEL with each of the main methods available. The proposed correction and additions of analytical methods have been implemented in the report.

Date	Country	Organisation	Type of Organisation	Comment number
29.03.2021	Germany	Department 4 - Hazardous Substances and Biological Agents - Federal Institute for Occupational Safety and Health	National Authority	13

Comment received

Since our comments also relate to information including characters that are forbidden in the text boxes, the comments will be sent in an attachment. The comments address the following:

- Chemical Agent and Scope
- Monitoring
- Health effects/tox data
- other related comments

ECHA note – An attachment was submitted with the comment above. Refer to public attachment [Asbestos_Report_Remarks_BAuA_FB4_20210329.docx](#)

ECHA/RAC Response

There were 4 comments under the title "General remarks".

Nr 1. Further details on genotoxicity have been added.

Nr 2. The reference cited was added in section 7.1.2. However, as it concerned nano materials and not directly asbestos and only peritoneal mesothelioma, it was considered not a sufficient basis to set a cut-off length of 5 µm for asbestos fibres with toxic properties.

Nr 3. No such studies were identified.

Nr 4. As regards the role of oral/inhalation exposure in extra-pulmonary cancer sites, we cite the IARC (2012) review that considered the data inconclusive. We could also not identify more specific studies and in any case the inhalation exposure results in oral exposure after mucociliary clearance as already explained. However, the uncertainties related to cancers other than mesothelioma and lung cancer are now more elaborated in Appendix 4 and summarised in section 9.1.2.

All the detailed comments under the title "Specific remarks" in the attachment were implemented in the ECHA scientific report.

PUBLIC ATTACHMENTS

1. IERF_Comment_ECHA_Asbestos_4_1_2021.pdf [Please refer to comment No. 5]
2. FAAM BOHS ECHA Asbestos OEL response.pdf [Please refer to comment No. 7]
3. antwoord echa.docx [Please refer to comment No. 8]
4. Comments_Report_OEL_ECHA_INRS_EN_03_2021.docx [Please refer to comment No. 9]
5. Comments DECOS on ECHA report asbestos 2021.pdf [Please refer to comment No. 10]
6. GVSS-Statement-ECHA-Consultation_30032021.pdf [Please refer to comment No. 11]
7. ANSES Comments OEL asbestos.zip [Please refer to comment No. 12]
8. NEG comments on ECHA Asbestos 30 March 2021.pdf [Please refer to comment No. 1]
9. ECHA.zip [Please refer to comment No. 4]
10. Asbestos_Report_Remarks_BAuA_FB4_20210329.docx [Please refer to comment No. 13]

CONFIDENTIAL ATTACHMENTS

1. Health Surveillance Data Analysis- Dadex Eternit Ltd Pakistan.pdf [Please refer to comment No. 2]