The Advisory Committee on Safety and Health at Work



Opinion on an EU Binding Occupational Exposure Limit Value (BOEL) for Asbestos under the Asbestos at Work Directive 2009/148/EC.

Doc. 008-21

Adopted on 24/11/2021

Asbestos

This Opinion is one of a series of chemical specific Opinions adopted by the ACSH in support of the forthcoming Commission proposals on amending the Chemical Agents Directive (CAD) 98/24/EC and the Asbestos at Work Directive (AWD) 2009/148/EC.

In the meetings of the Working Party of Chemicals on $5^{th} - 6^{th}$ October 2021 and 3^{rd} November 2021 and the technical exchange meeting on 8^{th} November 2021, the adopted RAC Opinion (ECHA/RAC/A77-O-0000006981-66-01/F¹) of June 2021 was discussed.

The three Interests Groups agreed the following points concerning limit values for asbestos:

There is consensus agreement on the need to substantially revise downwards the existing binding occupational exposure limit (OEL) to better protect workers' health and safety, taking into account scientific and technical developments since the current OEL of 0.1 fibres/cm³ was adopted in 2003.

It is agreed that the phase contrast microscopy (PCM) which is currently the most widely used methodology for measurement of asbestos fibres in the air at the workplace (as mentioned in article 7 of the Asbestos Directive) must be replaced by a more modern and sensitive methodology based on electron microscopy (EM).

Due to the differences between the way EM techniques are used across the Member States, more EU level harmonization is needed, including conversion factors between different EM methodologies and differences in the size of fibres counted given the fact that all fibres are considered carcinogenic.

The three IGs also agree that guidance shall be developed under the responsibility of the Commission in consultation with the ACSH to help companies complying with the new BOEL as well as the improved risk management measures linked to the exposure to asbestos fibres. This guidance should be developed considering the needs of different sectors and companies of different sizes.

Specific comments of the Government Interest Group (GIG):

The most important asbestos-related diseases are mesothelioma and lung cancer. The latency period of these diseases is on the average 30-40 years. This means that the incidence of diseases we see today reflects the exposure, which occurred before the current BOELV of 0.1 fibres/cm³ (8h TWA) came into force on 2003. To further increase the protection of the workers, the current BOELV should be revised.

The GIG considers that a first step will be the adoption of a new binding OEL for asbestos of 0.01 fibres/cm³ (8h TWA) no later than 4 years after the entry into force of the amending Directive. According to RAC the excess life-time cancer risk for this level of exposure is 1.2 cases per 10 000 workers exposed for 40 years (or 3 per million per year exposed). This is generally considered an

¹ <u>https://echa.europa.eu/documents/10162/7937606/OEL_asbestos_Final_Opinion_en.pdf/cc917e63-e0e6-e9cd-86d2-f75c81514277?t=1626256168788</u>

acceptable protective value in those member states that have defined risk levels for occupational exposure to carcinogenic substances.

Measuring asbestos fibres in the air at the workplace using analytical methods based on electron microscopy (EM) will be a real upgrade for the monitoring of asbestos as it allow the counting a thinner and shorter fibres resulting in counting 2-4 times the numbers of fibres that can be identified with phase contrast microscopy (PCM). As many member states still use PCM, GIG acknowledges there is need for a transition period to allow the laboratories to acquire new equipment, to train the technicians and to organise interlaboratory comparison. Based on the experience of the member states using EM, laboratories will need 2-3 years to be ready.

After the new BOEL enters into force in the Member States' national legislations, member states and employers will need time to gain experience with the fibre counting carried out by EM, implement improved preventative measures and collect new exposure data, before a second revision of the OEL start.

3-4 years after the entry into force of the BOEL, GIG recommends the European Commission to evaluate the feasibility of further reduction of limit value for asbestos based on the experience collected. For the building of the revised OEL, the Commission should take into account the differences of the analytical methods used by member states. To facilitate the analysis of the exposure data, the GIG advises the Commission to promote the development of harmonised assigned protection factor for respiratory protection.

Considering that also thinner fibres ($<0.2~\mu m$) are carcinogenic, RAC is of the opinion that these fibres should be considered when measuring exposure in the workplace. Therefore, the review should also consider the possible need to revise the dimensional definition of fibres to be counted and the way this relates to the numerical value of the OEL, that is now based on PCM measurements.

The entry in the Directive at Article 8 should be:

'Employers shall ensure that no worker is exposed to an airborne concentration of asbestos in excess of 0.01 fibres per cm³ as an 8-hour time-weighted average (TWA)'.

This topic of the GIG Opinion is on the EU BOEL for asbestos, because the discussions in the Working Party on Chemicals were exclusively on the OEL and aspects, which are clearly related to the OEL, like measurement methodologies and the need for guidance. There was no discussion asked, or brought up by any of the parties, on the other parts of the directive.

| IG | EC No | CAS No | NAME OF THE CHEMICAL AGENT | OEL LIMIT VALUES 8 hours | Transitional measures |
|-----|----------|--|--|--------------------------------|---|
| GIG | | 77536-66-4 12172-73-5 77536-67-5 12001-29-5 | Asbestos: (a) asbestos actinolite, (b) asbestos grunerite (amosite), | 0.01 f/cm ³ | 4 years after the entry into force of the amending Directive. |

| | 12001-28-4 77536-68-6 | (c) asbestos anthophyllite, |
|--|--------------------------|-----------------------------|
| | 77330-08-0 | (d) chrysotile; |
| | | (e) crocidolite; |
| | | (f) asbestos |
| | | tremolite, |

Specific comments of the Employers Interest Group (EIG):

EIG supports the following OEL for asbestos fibers, as well as transitional measures:

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| EIG | | 77536-66-4 12172-73-5 77536-67-5 12001-29-5 12001-28-4 77536-68-6 | Asbestos: (a) asbestos actinolite, (b) asbestos grunerite (amosite), (c) asbestos anthophyllite, (d) chrysotile; (e) crocidolite; (f) asbestos tremolite, | 0.01 f/cm ³ | dd.mm.yy (To be adopted 4-5 years after the entry into force of the directive amending the AWD.) |

According to RAC scientific assessment, asbestos fibres are a non-threshold carcinogen. Thus, based on a risk-based approach, ECHA provided an ERR relating the level of risk associated to a range of fibres concentrations, as the basis for the adoption of a BOEL. According to this ERR, the level of risk associated to 0.01 fibres/cm³ is 10 times lower than the existing OEL at 0.1 fibres/cm³. This is generally considered as an acceptably protective value in Member States that have adopted the risk-based approach for non-threshold carcinogens. This risk level is adopted for many other non-threshold carcinogens, where adopting a health-based OEL is not possible.

Adoption of ECHA's ERR for asbestos fibres. The EIG considers that the work performed by ECHA deriving the ERR is the most updated for the time being. It has been adopted in the RAC opinion after a process that has included two public consultations as well as the participation of stakeholders as observers. It has been developed, thus, with the appropriate guarantees for every interested party and scientific body to have the opportunity to provide information and comments. EIG therefore supports it.

The value of the OEL is influenced by the measurement methodology of fibres. The concentration of fibres is useless if the methodology of fibre counting is not determined. For the time being, all data used to derive the ERR comes from measurements carried out with the Phase Contrast Microscopy (PCM) methodology. This means that the values that are considered for a new OEL are extrapolated from such measurements.

When measured with other techniques based on Electron Microscopy (EM), the number of fibres detected is higher. Thus, adopting as new OEL 0.01 fibres/cm³ is equivalent to adopting a lower value, when measured with EM (a conversion factor of 2 may apply, depending on the type of fibres).

Furthermore, there is a need to **adopt a more sensitive methodology** to measure concentration of fibres. The reference method of fibre counting for the current OEL by phase-contrast microscope (PCM) (in accordance with the method recommended in 1997 by the World Health Organization (WHO)) is not sensitive enough to allow proper measurements of lower concentrations of fibres. Thus, a new methodology based on EM is needed, as agreed in this opinion.

The Member States that currently refer their national OELs to EM are applying different methodologies based on different EM techniques (SEM or TEM). In consequence, concentrations measured applying different national methodologies are not comparable, nor with the new EU OEL.

To solve this problem, either an EU harmonized methodology or the determination of conversion factors between different methodologies applied in the Member States (with a validation at international level) are needed, in order to provide comparable data across the EU. Developing this activity will take some years², which is why EIG considers that a transitional period of 4-5 years is needed before a new OEL of 0.01 f/cm³ is in force across all the EU.

EIG stresses that legislation must be applicable and implementable. Otherwise, the governments, companies and individuals that are obliged to enforce and respect it are in a situation of legal insecurity. The new OEL should be measurable in all circumstances that may occur at workplaces. The absence of proper measurement methods makes the legislation inapplicable until this issue is tackled.

For 0.01 f/cm³, difficulties in measurement are not foreseen. For lower values, measurements may not be feasible.

In addition, the preventive measures to adopt in workplaces must be feasible, allowing SMEs to adopt them. As stated in the RPA report, lower values may impact negatively the smaller companies, not allowing them to continue in the market.

New advances in the future. EIG considers that a new reduction of the OEL must be supported, among other issues, by the experience collected in the application of an OEL of 0.01 f/cm³, as derived in the ERR. Some time to collect data is thus needed. The application of the guidance mentioned in the opinion will be of assistance to ensure that appropriate preventive measures are applied across sectors and different sizes of companies.

It is of utmost importance that a possible new reduction of the OEL is supported by a clear and objective assessment carried out by the Commission, describing in detail its merits as regards worker health protection and technical compliance challenges together with the associated benefits and costs.

² Considering the activity at scientific and technical level, the approval of certification bodies for the methodologies, the certification of laboratories to assure the validity of measurements.

Impact on the asbestos removal plans. The adoption of the proposed OEL, while increasing the cost of asbestos related activity, can be absorbed and likely will not impact too negatively on the removal of asbestos, permitting also national plans to complete the removal of asbestos at private and public level. However, lower values will increase very significantly the total cost of operations and this may discourage small operators, like private buildings or microcompanies, to carry out proper removal, thus jeopardizing the current plans.

The discussions in the Working Party on Chemicals were exclusively on the OEL and aspects, such as measurement methodologies and need for guidance, which are clearly related to the OEL. There was no discussion on the other parts of the directive

Specific comments of the Workers Interest Group (WIG):

Asbestos kills at least 47 000 people from lung cancers and mesothelioma every year in the EU³. The medical community is aware of the adverse health effects of this deadly substance since the early 20th century when the first cases of asbestos-related mortalities were diagnosed and documented. Despite this knowledge, the use of asbestos continued, due inter alia to the industry's denigration of the risks associated with asbestos exposure and its efforts over the decades to keep vital information out of the scientific literature and the popular press⁴.

The use of asbestos reached its heyday after World War Two, when it was used in ever greater amounts in a continuously growing number of products in industry and building construction. Since then, it is estimated that **between 2 and 4 million people** have died in the EU as a result of exposure to asbestos, the vast majority being asbestos workers⁵.

The costs of occupational cancer in the EU accounts for between €270 and €610 billion per year, or 1.8 % to 4.1 % of the EU GDP⁶. The most common occupational cancers are lung cancers and mesothelioma caused by asbestos and thus an important share of these costs is linked to this carcinogen.

While manufacturing asbestos, placing it on the market and using it have been banned in the EU since 2005, asbestos is still present in many European buildings (administrative centers, schools, housing, infrastructure and public transport facilities, etc.), bedrock in mines and water supply networks.

With the adoption of the European Green Deal and the Renovation Wave for Europe, it is expected that 35 million buildings will be maintained, renovated, or demolished by 2030. Therefore, millions of workers in the construction and renovation sector, the waste management sector and firefighters will be at increased risk of exposure to asbestos fibres in the next decade. Since the harmful health effects of inhaled asbestos fibres and asbestos-related diseases can take up 10-40 years to manifest, a new

³ Eliminating occupational cancer in Europe and globally, Jukka Takala, ETUI, 2015

⁴ Doubt is their product. How Industry's Assault on Science Threatens your health, David Michaels, Oxford University Press, 2008

⁵ ETUI own estimations

⁶ https://www.etui.org/publications/reports/the-cost-of-occupational-cancer-in-the-eu-28

wave of asbestos victims is to be expected if strict preventive measures are not put in place and if the legal text is not transparent about the residual cancer risk associated with the OEL.

The EU BOEL of 0.1 fibres/cm³ (or 100 000 fibres/m³) defined in the Asbestos at Work Directive (AWD) does not provide a satisfactory level of protection for the ~ 6 million workers currently exposed to asbestos in the EU. This limit value adopted in 2003 allows 100,000 fibres to be inhaled at work in an hour or so – and millions of fibres in a short period of time - depending on the energy intensity of the work task.

In view of the latest development in scientific knowledge and research, France, Germany, and the Netherlands have already updated their national OEL on asbestos. France and Germany have a national BOEL of 0.01 fibres/cm³ and the Netherlands a national BOEL of 0,002 fibres/cm³ as compared to the current outdated 0,1 fibres/cm³ in the AWD.

Experts of the International Commission of Occupational Health (ICOH) and medical research propose a limit value of **0.001 fibres/cm³** to adequately protect workers against cancer in asbestos removal works⁷ and recently the **European Parliament** in the resolution overwhelmingly adopted on 20 October 2021 (675 votes in favour to two votes against and 23 abstentions)⁸ calls on the European Commission to set the updated BOEL on asbestos **at 0.001 fibres/cm³** (measured by Analytical Transmission Electron Microscopy or similarly advance methods for fibre counting).

Asbestos is a **non-threshold carcinogen**, which means that every level of exposure, however low, brings a risk of developing cancer and no health-based OEL can be identified. In its opinion adopted on 10 June 2021⁹, RAC/ECHA proposes an exposure-risk relationship (ERR), expressing the excess risk for lung cancer and mesothelioma mortality (combined) as a function of the fibre concentration in the air.

The WIG is critical with the ERR derived by RAC/ECHA because it does not fit with the reality when asbestos victims are counted.

At the RAC-56 meeting in March 2021, the ICOH expert accompanying the regular ETUC observer commented the ERR in the light of the estimated current asbestos disease burden¹⁰. According to him, there is an important discrepancy between RAC/ECHA ERR and the estimation of annual cancer deaths due to asbestos according to the Global Burden of Diseases. At the exposure level of 0,1 fibres/cm³ (the current OEL adopted at EU level in 2003 but already in force in different Member States for more than 25 years), RAC/ECHA's modelling applied to ~6 million exposed workers would lead to around 7500 deaths/year in the EU while the ETUC expert estimates that the actual number is more than 10 times higher.

The reasons for RAC/ECHA's underestimation are many: errors in statistical estimations, model assumptions, poor quality of exposure estimates in epidemiological studies, the fact that only 2 cancers (lung cancers and mesothelioma) are taken into account in the ERR. In the WIG views, other cancers proven to be associated with asbestos exposure (larynx, ovary cancers) or suspected by IARC of being associated with asbestos exposure (colorectum, nasopharynx and stomach cancers) should have been given more consideration.

⁷ Furuya, Sugio; Chimed-Ochir, Odgerel; Takahashi, Ken; David, Annette; Takala, Jukka. 2018. "Global Asbestos Disaster" Int. J. Environ. Res. Public Health 15, no. 5:1000. https://doi.org/10.3390/ijerph15051000

European Parliament resolution of 20 October 2021 with recommendations to the Commission on protecting workers from asbestos. P9 TA(2021)0427

⁹ https://echa.europa.eu/documents/10162/d6decc44-5e30-70b0-784b-053cec318776

¹⁰ https://echa.europa.eu/meetings-of-the-rac/2021

The WIG acknowledges that these reasons are transparently mentioned as "uncertainties in the risk estimates" in the RAC/ECHA's opinion but regrets that they have not been used to correct the proposed ERR in light of the current asbestos disease burden.

In the Commission' external study which compares the costs and benefits linked to 4 possible options for the new EU OEL on asbestos (0.1 fibres/cm³, 0.01 fibres/cm³, 0.002 fibres/cm³ and 0.001 fibres/cm³), the consultants have based their estimations on the ERR proposed by RAC/ECHA.

For each of the 4 OEL options assessed, the WIG is therefore convinced that **the estimations of the Study Team** on the current burden of disease, the future burden of disease, the benefits (*i.e.* the future cancer cases and deaths avoided) and consequently the cost-benefit analysis **are biased and cannot be relied on**.

As an example, the Study Team estimates that the incidence for lung cancer and mesothelioma together due to past exposure is 336 new cases per year at EU level¹¹ while the incidence for mesothelioma alone is 1160 new cases/ year in France¹².

However, the Commission' external study is useful as it reports about the experience from different Member States on the measurement of asbestos fibres at the workplace. It is worth noting that in the Netherlands, the national OEL for asbestos in place since 2016 is 0.002 fibres/cm³ (measured with Scanning Electron Microscopy-SEM/EDXA). This binding limit value is based on the report of the Health Council of the Netherlands published in 2010¹³ which is one of the key source used by ECHA to derive its ERR.

Based on the Dutch experience measuring down to 0.0002 fibres/cm³ (10% of the OEL) is possible and the SEM/EDXA measurement methodology would be applicable for testing compliance with all the OELs assessed in the Commission' external study¹⁴.

The WIG recalls the fundamental legal principle that, in the context of health and safety at work, state-of-the-art technology must always be applied to achieve the highest possible level of protection. For example remote-controlled robots and other advanced technologies are already used for automated removal of asbestos contamination¹⁵.

The WIG is of the opinion that what is feasible in the Netherlands is also feasible in the other Member States. Since the Dutch OEL is already 7 years old and continuous efforts must be made to curve the peak of deaths due to asbestos as quickly as possible in Europe, it is high time for the EU to adopt an ambitious BOEL.

Based on all the reasons mentioned above, the WIG strongly supports ICOH and European Parliament demands and is therefore of the opinion that the new BOEL on asbestos should be set at 0.001 fibres/m³ (measured by Electron Microscopy) as soon as possible after the entry into force of the updated AWD.

¹¹ Study on collecting information on substances with the view to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 98/24/EC (Chemical Agents) and Directive 2009/148/EC(Asbestos). Final report for asbestos, Sept 2021: Table 4.60, page 186.

https://www.santepubliquefrance.fr/maladies-et-traumatismes/cancers/mesotheliomes (please note that asbestos is banned in France as of 1 January 1997 which is 25 years ago)

¹³ Asbestos: Risks of environmental and occupational exposure. The Hague: Health Council of the Netherlands, 2010; publication no. 2010/10.

¹⁴ ibid ref 9, pages 157-158

¹⁵ https://robotnik.eu/bots2rec-robotic-system-used-for-the-automated-removal-of-asbestos-contamination/#

The discussions in the Working Party on Chemicals were on the OEL and aspects such as measurement methodologies and need for guidance, which are clearly related to the OEL. However, in addition to an updated OEL, to prevent a new wave of asbestos victims through the removal of asbestos and in the mining industry, the WIG is of the opinion that other changes are needed in the revised Asbestos at Work Directive. The WIG fully supports the concrete amendments to the legal text of Dir 2009/148/EC listed in the Annex II to the European Parliament resolution "Protecting workers from Asbestos" adopted on 20 October 2021¹⁶

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