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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2009/148/EC on the protection of workers from the risks related to exposure to asbestos at work

In accordance with the guidance on Impact Assessment (doc. 16024/14), delegations will find attached the compilation and summary of the replies to the Impact Assessment questionnaire on the abovementioned proposal.

PCY Questionnaire

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of workers from the risks related to exposure to asbestos at work **Impact Assessment** **2022/028 (COD)**	
Delegation	**AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IT, IE, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK**
Lead DG	**DG LIFE.4**

1. Are the policy context and the legal basis of the initiative explained clearly?

☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (27): AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (0):

No response (0):

Comments:

MT: The legal basis of the Proposal is clearly explained. Furthermore, the Proposal is coherent with existing policies

2. Problem definition

a) Are the problems and the underlying drivers clearly demonstrated and underpinned by evidence including comments and studies submitted by Member States or stakeholders during consultations carried out by the Commission?

b) Is any gap in evidence acknowledged?

a) ☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (24): AT, BE, BG, CY, CZ, DE, DK, EE, FR, FI, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (3): EL, ES, MT,

No response (0):

Comments:

EL: There are only a few studies, some of which are rather old, to provide strong evidence

ES: In the opinion of the ACSH, all interest groups agree 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).

MT: The legal basis of the Proposal is clearly explained. Furthermore, the Proposal is coherent with existing policies

b) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (6): AT, BE, CZ, FR, IE, SE

No (16): BG, CY, DE, EL, HR, HU, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK

To some extent/partly (5): DK, EE, ES, FI, MT,

No response (0):

Comments:

ES: EM will detect more fibres due to its greater sensitivity in detecting shorter and thinner fibres. Therefore, the review should also have considered the possible need to revise the definition of fibres to be counted. 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 OEL is useless if the methodology of

fibre counting is not the same in all countries

FI: There is a clear need to replace phase contrast microscopy with more modern electron microscopy methods. All of the three interest groups of the ACSH agreed on this need. It is not properly explained why the Commission concluded that this change could not be included in the directive proposal and/or what the Commission possibly intends to do in order to address this issue later on. The measurement technology used is directly linked to the limit value (e.g. what kind of fibres can be measured) and therefore leaving this aspect for a very superficial level in the IA is not justified. Sticking to PCM methods has impacts to the worker protection level.

MT: Given that research and analysis are ongoing any potential gap in evidence will be acknowledged at a later stage

3. Policy objectives

a) Coherence of the intervention logic: Do the objectives correspond to the problems?

b) Are the objectives consistent with the broad policy strategies and other relevant policy initiatives?

c) Does the IA set out clear policy objectives, including general aims and more specific/operational objectives?

d) Are objectives linked to measurable monitoring indicators?

a) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (24): AT, BE, BG, CY, CZ, DE, DK, EE, EL, FI, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, SE, SI, SK

No (0):

To some extent/partly (3): ES, FR, RO

No response (0):

Comments:

ES: Not entirely, because although a new OEL has been set lower than the previous one, the measurement method has not been harmonised and each country may use different methods, so the results are not comparable.

FR: The French authorities consider that it is not possible to dissociate the lowering of the European occupational exposure limit value (OEL) for asbestos from the analytical technique used for counting airborne asbestos fibers in the workplace.

While the impact study presented by the European Commission takes into account the economic impact of switching from the current analytical technique (phase contrast optical microscopy or PCM) to an electronic analytical technique when assessing the different options for lowering the OEL (see paragraph 6. 1 of the IA), it does not decide on the need to impose such a technological change in the European legislation, ultimately leaving this initiative to the Member States.

However, the available technical and scientific data highlight that PCM has several intrinsic limitations, such as:

- the inability to identify so-called "fine" asbestos fibers with a diameter of less than 0.2 µm
- the impossibility of differentiating, among the fibers actually counted, those containing asbestos from other fibers with similar dimensional characteristics);

- a limit of quantification technically incompatible with the level of the OEL proposed by the Commission (0.01 f/cm3 or 10 f/L over 8 hours) – to support this argument, please refer to the indications given on pages 14 and 153 of the report entitled "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) which is available clicking on the following link: here.

It is therefore to be feared, for the Member States which would remain at the PCM, as allowed by the proposal formulated by the Commission, that the measurements carried out would not make it possible to control effectively the respect of the new OEL of 0,01 f/cm3 (10 f/L).

Consequently, to allow full effectiveness of this new OEL and a correct assessment of the level of exposure of workers to asbestos, and as recommended by the GIG (government interest group) in the opinion of the ACSH (Advisory Committee on Health and Safety at Work at European level) of November 2021, French authorities believe it is essential to accompany the lowering of the OEL with an obligation to use the electronic analytical technique. In turn, this requirement would be accompanied by an adequate transitional period of at least 4 years to allow the various Member States to adapt to this technological change and the various laboratories to acquire the appropriate analytical equipment and, if necessary, to train their laboratory workers for its use.

In this regard, the absence of positions in this impact study on the need to switch to an electronic analysis method and to put in place measures to support the Member States for this technological evolution constitutes, according to the French authorities, a shortcoming in the impact study.

MT: Yes, the main objective is to ensure and maintain a high level of protection of worker's health and safety in the EU

RO: Limited scope of the initiative, given that the occupational exposure limit is only one aspect of the protection required to reduce workers' exposure to asbestos.

b) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (26): AT, BE, BG, CY, CZ, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (1): ES,

No response (0):

Comments:

ES: One of the objectives is to achieve a more uniform and better protection of workers across the UE from the risks caused by asbestos exposure. But as different techniques are used to analyse the concentration of asbestos fibres in air, the level of protection of workers will not be the same in all Member States.

c) ☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (26): AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (1): FR,

No response (0):

Comments:

FR: Section 4.2 of the Impact Assessment states as specific objectives associated with the Commission proposal:

- To improve the effectiveness of the OEL provided for by Directive 2009/148/EC by updating it on the basis of available scientific expertise.

- To ensure a more harmonized and a better protection of workers throughout the European Union against the risks related to exposure to asbestos.

While it is understood that these specific objectives can be achieved by lowering the European OEL for asbestos, and that the option chosen (0,01 f/cm3 or 10 f/L) is in itself a satisfactory response in this respect, the French authorities consider however, as detailed in the response given in point (a) of this paragraph, that an effective response to the aforementioned objectives also requires, by necessity, the introduction into European legislation of an obligation to use an electronic analysis method for counting airborne asbestos fibers in workplaces.

Indeed, as explained in the report of the impact study of the European Commission's consultant, the PCM is restricted by a quantification limit technically incompatible with the OEL level proposed by the European Commission. Moreover, this analytical technique does not allow to identify the so-called "fine" asbestos fibers (diameter lower than 0.2 µm) among the asbestos fibers counted, whereas it is admitted that all asbestos fibers with a length higher than 5 µm (so-called "WHO" fibers as well as so-called "fine" fibers) are carcinogenic and must thus be taken into account when establishing an OEL for asbestos.

Consequently, according to the French authorities, maintaining PCM as the principle analytical technique is not compatible with the specific objectives underlying the Commission's proposal to lower the European asbestos OEL to 0.01 f/cm3 (10 f/L). Indeed, in the Member States maintaining the use of the PCM method, this would lead to an underestimation of the level of exposure of workers to asbestos fibres and, consequently, to the maintenance of a two-speed Europe in terms of protection against this occupational risk (between the Member States already implementing or which voluntarily implemented the electronic analysis technique following this proposal and the others).

These aspects do not appear to be sufficiently addressed in the impact study, since it does not address the question of switching to an electronic analysis method and leaves this initiative to the Member States alone in the context of transposing the Commission's proposal into their national law.

d) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (24): AT, BG, CY, CZ, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (3): BE, DE, ES,

No response (0):

Comments:

BE: See point 9.1 of the IA, 'collection of reliable data in this area is complex', and 'the Commission and EU-OSHA are actively working on improving data quality and availability so that the actual impacts of the proposed initiative could be measured in a more accurate way and additional indicators could be developed in the future'.

DE: See IA 9.1

ES: Indicators could be measured but not compared between countries that used different equipment to measure asbestos fibres in air.

LV: As regards data comparison the data will not be compared between countries that used different equipment to measure asbestos fibres in air

4. Subsidiarity & Proportionality

a) Is the Union's competence clearly established, and the legal basis?

b) Does the IA analyse whether acting is consistent with the principle of subsidiarity? Are necessity and added value of EU action clearly demonstrated?

c) Does the IA analyse whether acting is consistent with the principle of proportionality?

d) Does the IA contain consideration of action already taken or planned by EU and Member States, if relevant?

a) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (27): AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (0):

No response (0):

Comments:

b) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (27): AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (0):

No response (0):

Comments:

ES: It is necessary to review the OEL of asbestos

c) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (27): AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (0):

No response (0):

Comments:

MT: Yes, this proposed Directive is in accordance with the principle of proportionality and does not go beyond to what is necessary in order to achieve its objectives

d) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (27): AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (0):

No response (0):

Comments:

5. Policy Options

a) Does the IA identify all feasible policy options (regulatory and, where appropriate in accordance with the 2003 IIA, non-regulatory) to meet the objectives, including the "no EU action" option, alternatives to regulation and further harmonisation?

b) Are the most affected subjects/stakeholders identified?

c) Has the information on how the inputs from end-users and stakeholders informed the policy options been provided?

d) If options favoured by stakeholders in open consultations are discarded, is thorough examination provided?

a) ☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (26): AT, BE, BG, CY, CZ, DE, DK, EE, EL, FI, FR, HR, HU, IT, IE, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (1): ES,

No response (0):

Comments:

ES: there is no harmonisation related to the measurement methods and the size of fibres to be measured

b) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (27): AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (0):

No response (0):

Comments:

c) ☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (27): AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (0):

No response (0):

Comments:

d) ☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (18): AT, BE, BG, CY, DE, EL, FI, HR, HU, IE, IT, LT, LV, PL, PT, SE, SI, SK

No (1): LU,

To some extent/partly (8): CZ, DK, EE, ES, FR, MT, NL, RO

Comments:

DK: Electron Microscopy (EM) is a more modern method for sensitive measurement of asbestos in low amounts in the air than PCM. Making the EM method the standard for measuring asbestos fibres in the air will ensure that analysis of exposure levels are carried out with more advanced methodologies across the EU.

We recognize the need for a transition period to acquire new EM equipment and train staff. The IA notes that, following recommendations from GIG and EIG, it is expected that a change of the preferred method could occur in a period of 4-5 years. A description of the steps needed to achieve harmonisation in measurement methodology would give a better understanding of how long a transition period should be and what it takes to achieve harmonization.

The move towards the use of EM also allows for a lower and safer OEL in the future

ES: In the opinion of the ACSH, all interest groups agree 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). This has not been taken into account in the directive nor has it been justified why it has not been included.

FR: In its opinion, the ACSH had insisted on the need to switch to an electronic method for counting airborne asbestos fibres in the workplace. The government and employer interest groups proposed a transitional period of at least 4 years for this technological development to allow Member States to adapt to it. The switch to electronic analysis technology was also supported by the workers' unions and by the European Parliament in its resolution of 20 October 2021.

However, the impact study on which the Commission's proposal is based, while taking into consideration the economic impact of adopting an electronic analysis method, does not decide on whether to impose such a technological change in European legislation, preferring to leave this initiative to the Member States when transposing the Directive.

However, as explained in the answers to points a) and c) of paragraph 3, the intrinsic limits of the PCM make it crucial to change the analytical technique in order to make the lowering of the

asbestos OEL to 0.01 f/cm3 actually effective. In addition, electron macroscopy allows the consideration, for its control, of all the so-called "long" asbestos fibers presenting carcinogenic properties, i.e. the so-called "WHO" fibers as well as the "fine" fibers.

In this sense, it does not appear to the French authorities that there is sufficient justification for not following the opinion of the ACSH, the resolution of the European Parliament and the position of the workers' unions on this point, and:

- not to include in the European legislation the obligation to use an electronic analysis technique for the counting of airborne asbestos fibres in the workplace, as a replacement for the PCM ;

not to propose an initiative allowing a progressive implementation of the electronic analysis technique.

LU: RAC says single exposure can lead to cancer, Two worker groups propose to take out sporadic exposure, but this has not been taken into consideration in the amendments and there is no examination why.

NL: Elekro Microscopy (EM) is a more modern and sensitive measurement method that can detect lower amounts of asbestos in the air than PCM. It is clear that harmonization of the methodologies is needed. The IA notes that, following recommendations from GIG and EIG, it is expected that a change of the preferred method could occur in a time frame of 4-5 years. Yet the proposal does not contain any steps that are needed in order to achieve harmonisation in methodology.

We recognize that a transition period is needed to acquire new EM equipment and train staff. Concrete action is needed to facilitate a structural move to EM in the future

The move towards the use of EM also allows for a lower and safer OEL in the future. This contributes to a further reduction of cancer cases and death in the EU.

6. Analysis of impacts

a) Are the positive and negative impacts of each policy option and for the 'no EU action' option, including the direct and indirect environmental, economic, and social impacts, clearly considered?

b) Are impacts of different policy options expressed in a comparable format and compared against a clear set of criteria?

c) Are impacts on the main groups of affected subjects/stakeholders clearly analysed, for each policy option, especially for the preferred option?

a) ☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (25): AT, BE, BG, CY, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (2): CZ, ES,

No response (0):

Comments:

ES: The setting of a lower OEL implies that companies might need to invest in better preventive measures, such as vacuum cleaning and dust suppression techniques and/or individual protective equipment (e.g. masks with different filtering levels) in order to comply with the lower level. But for example, in Spain we still use PCM and if we want to have better quality of results we need to acquire new equipment (electronic measurement techniques), we need time to train the technicians and to organise interlaboratory comparison for that technique.

b) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (27): AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (0):

No response (0):

Comments:

c) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (23): AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, HR, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (4): BG, FR, HU, LV,

No response (0):

Comments:

BG: Lower OEL implies further investments in better preventive measures to comply with the lower level at the part of the employers. Price for the monitoring the levels of asbestos fibres accordingly to the new OELs will be also paid by the stakeholders. For countries like Bulgaria, that use PCM there will be additional expenses to acquire new equipment (electronic measurement techniques) if the goal is to have better quality and comparability of results, plus, we will meet additional administrative and financial burden to train the technicians and to introduce all the applicable accreditation procedures of the laboratories for the EM technique

FR: It is to some extent, considering the consequences of not using an electronic analytical technique to count the asbestos fibers (and thereby actually make it possible to respect the new OEL set by the proposed Directive) has not been sufficiently taken into account. Workers would be exposed to carcinogenic asbestos fibers which were not taken into consideration when assessing the risk of exposure, given the intrinsic limitations of the PCM analytical method already explained above.

HU: The Commission's working documents manage the economic effects of the reduction of the OEL of asbestos in a imprecisely and optimistic way with regard to the most affected construction industry sector (maintenance, demolition, removal of asbestos)

LV: There is a need for detailed information regarding measurements (impact on laboratory work, the costs of new electronic microscope and the costs for laboratories, and approximate costs of the measurements for undertakings).

In Latvia we use PCM. The new electronic microscope for measurements costs a lot and there is a need for additional time, financial resources, adaptation, training and awareness raising activities

7. Where relevant, are specific impacts[1] clearly presented, both in qualitative and quantified terms, for each option in a comparable manner and assessed on the basis of appropriate data and evidence?

☐ **a) <u>Economic impacts</u>**

☐ **aa) Impacts on competition**

☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (22): AT, BE, CY, DE, DK, EE, EL, FI, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK

[1] For a detailed list of possible impacts see section 8 of the Commission's Impact Assessment Guidelines (footnote 2), see http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_en.pdf

No (0):

To some extent/partly (5): BG, CZ, ES, FR, LV,

No response (0):

Comments:

BE: The link in footnote 1 refers to an archived document that is no longer in use

ES: Countries still using PCM technology (such as Spain) will have to adapt to switch to electronic technologies. This is a much bigger investment than for those countries that already have them in place. It takes not only money but also time to become familiar with the new technology.

FR: As indicated in point c) of paragraph 3, the fact that the impact study does not decide on the need to impose on the Member States the use of an electronic analytical technique for counting airborne asbestos fibres, and leaves it to the Member States to decide whether to retain the use of PCM or to change analytical technology, is likely to maintain a two-speed Europe in terms of protection of workers against the risk of exposure to asbestos (between the Member States already implementing or having voluntarily recourse, following this proposal, to an electronic analysis technique and the others retaining the PCM).

This situation is likely to lead to a distortion of competition between companies in the Member States carrying out asbestos-related work (the cost of electronic analytical techniques being effectively higher than that of PCM), which is not sufficiently studied in this impact study.

LV: There is a difference between Member states as regards the used methodology and necessary investments to transpose the directive with the aim of better prevention of workers by using more precise measurement

☐ **ab) Impacts on consumers**

☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (20): AT, BE, CY, CZ, DE, DK, EE, EL, FI, FR, IE, LT, LU, MT, NL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (6): BG, ES, HU, IT, LV, PL,

No response (1): HR,

Comments:

BG: See 7c above

ES: Consumers are likely to bear part of the cost of the investment in new equipment

HU: It is likely that any additional costs incurred by businesses will be passed on to the costumers of asbestos removal. The transition to more modern measurement methods (e.g.

electron microscopy) can be a significant burden for laboratories measuring the asbestos content of workplace air

LV: Possible costs of measurements in the case of decision to change the fibre counting method to better

☐ **ac) Impacts on competitiveness**

☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (20): AT, BE, CY, DK, EL, FI, FR, HR, HU, IE, IT, LT, LU, MT, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (5): CZ, DE, EE, ES, LV

No response (2): BG, NL

Comments:

BG: See 7c above

DE: With regard to competitiveness, the lowering of the limit value has positive effects. However, other aspects, for example different qualification requirements for companies in Member States are a key factor in competitiveness. As a result, the positive effects of lowering of the limit value can be relativised.

ES: We cannot compare our measures and the level of our workers protection with countries that have already implemented electronic technology.

LV: There is a difference between Member states now (status quo) if we look at future and are going to use EM

☐ **ad) Impacts on Small and Medium Enterprises including micro-enterprises**[2]

☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (17): AT, BE, CY, DK, FI, FR, HR, IE, IT, LU, MT, NL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (10): BG, CZ, DE, EE, EL, ES, HU, LT, LV, PL

No response (0):

Comments:

[2] Impact assessments should assess SME impacts, and should also analyse the case for allowing (a) exemptions for micro-enterprises with <10 employees and <€2 mio turnover or balance sheet, and (b) lighter regimes for SMEs. See http://ec.europa.eu/governance/impact/key_docs/docs/meg_guidelines.pdf.

BE: The link in footnote 2 is invalid

BG: See 7c above

DE: With regard to competitiveness, the lowering of the limit value has positive effects. However, other aspects, for example different qualification requirements for companies in Member States are a key factor in competitiveness. As a result, the positive effects of lowering of the limit value can be relativised

EL: Only limited evidence for SME and no info for micro-enterprises

ES: Our companies will have to bear part of the cost of the new equipment

HU: The majority of SMEs are probably neither professionally nor technically prepared to comply with regulations that are even stricter than the current ones. Regarding the planned preparatory period, the transposition deadline, and the application of transition periods as needed, further negotiations would be necessary - both at the EU and Member State level

LT: See Summary, point 2.

PL: The rules of cost calculation for option 2 (Additional MRRs – p. 26 IA) need to be clarified

☐ **b) Social impacts**[3]

(for example impacts on employment and labour markets, social inclusion and protection of particular groups, public health and safety, etc.)

☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (23): AT, BE, BG, CY, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LV, MT, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (3): CZ, ES, NL

No answer (1): LU,

Comments:

BE: The link in footnote 3 is invalid

ES: Risk of an increase in unauthorised work (due to the increase in prices for consumers) with a consequent increase in the level of fibres, exposure of the general population and more people could get sick.

NL: Table 8 shows the number of avoided cancer cases per OELV. An OELV of 0,002 f/cm3 is technically and practically possible and reduces the number of cancer cases to 53 over the next 40 years.

[3] See also Guidance for assessing Social Impacts within the Commission Impact Assessment system (http://ec.europa.eu/governance/impact/commission_guidelines/commission_guidelines_en.htm)

☐ **c) <u>Environmental impacts</u>**

(for example impacts on climate, air and water quality, use of the renewable or non-renewable resources, the likelihood or scale of environmental risks, use of energy etc.)

☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (24): AT, BE, BG, CY, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI

No (0)

To some extent/partly (2): ES, SK

No response (1): CZ

Comments:

CZ: Not relevant

ES: Risk of an increase in unauthorised work (due to the increase in prices for consumers) with a resulting increase in uncontrolled asbestos waste.

☐ **d) Regulatory costs (including administrative burdens and compliance costs, especially for businesses or business operators)**

☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (22): AT, BE, CY, DE, DK, ES, EL, FI, FR, HR, HU, IE, IT, LU, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (5): BG, CZ, EE, LT, LV

No response (0):

Comments:

BG: See 7c above.
The preferable EM method for countries still using PCM technology means the switch to electronic technologies implies bigger investment than for those countries that already have them in place and also bigger administrative burden in terms of training the laboratories and the controlling bodies' personnel, etc.

The ultimate goal of the directive is to eliminate all residual risks from asbestos, after banning its use, and the expectations are that for most countries the asbestos from the old buildings will be gradually removed (supposedly safely) in some short future period. In this regard, we want some clarification about cost/effectiveness of the investments in new technologies for measuring fibers, like EM, and new OEL, compared to investments in other preventing measures like technical solutions for lowering dust generation or PPE?

LT: See Summary, point 2.

LV: The information is very general

☐ **e) Impacts on individual Member States / regional or local authorities**

☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (17): AT, BE, CY, DE, DK, EL, FI, FR, HU, IE, LU, MT, NL, PT, RO, SE, SK

No (0):

To some extent/partly (10): BG, CZ, EE, ES, HR, IT, LT, LV, PL, SI

No response (0):

Comments:

BG: See 7d

ES: No account has been taken of the fact that countries still using PCM technology (such as Spain) is advisable to adapt to switch to electronic technologies. This is a much bigger investment than for those countries that already have them in place. It takes not only money but also time to become familiar with the new technology.

LT: See Summary, point 1.

LV: No information as regards the individual differences, therefore no information about the individual impacts. But of course, this proposal doesn't set the mandatory replacement by a more modern and sensitive methodology based on electron microscopy (EM)

☐ **f) Impacts on third countries/ international aspects**

☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary)

Yes (20): AT, BG, CY, DE, DK, EE, FI, FR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SK

No (1): CZ

To some extent/partly (4): BE, EL, HR, SI

No response (2): ES, LV

Comments:

PT: Not relevant

☐ **g) Impacts on fundamental rights**

☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (27): AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK

No (0):

To some extent/partly (0):

No response (0):

Comments:

MT: Yes, the impacts on fundamental rights are considered positive as it will further improve the protection of workers from the health risks posed by asbestos exposure

8. Opinion of the Impact Assessment Board[4] (IAB) of the Commission **a) Are all comments and recommendations of the IAB (as presented in its latest opinion) considered in the Impact Assessment report?**	
a) ☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary) **Yes (19): AT, BE, BG, CY, CZ, DE, DK, EE, EL, FR, HU, IE, IT, LT, MT, NL, PL, SE, SI** **No (1): LU** **To some extent/partly (4): ES, HR, LV, RO** **No response (3): FI, PT, SK** **Comments:** **BE:** In the table in annex 1 of the IA, adaptations following the RSB opinion are described **ES:** The recommendation to use modern and sensitive methodology based on electron microscopy (EM)is not included **LU:** IAB is not mentioned in the document	
9. Monitoring, transposition, compliance **a) Will the proposed indicators enable the intended effects to be measured? Are those responsible for monitoring (and compliance) identified?** **b) Are operational monitoring and evaluation arrangements proposed?** **c) Does the IA contain information on the impact of the transposition deadline proposed in the context of MS legislative processes?**	
a) ☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary) **Yes (22): AT, BG, CY, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK** **No (0):** **To some extent/partly (5): BE, CZ, DE, ES, LV,** **No response (0):**	

[4] Available by searching by Commission DG and date of publication at the following website http://ec.europa.eu/governance/impact/ia_carried_out/cia_2012_en.htm

Comments:

BE: See comment concerning point 3.d**.**

DE: see IA 9.1

ES: The potential problems or limitations of using PCMs to measure are not identified

b) ☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (26): AT, BE, BG, CY, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK

No (1): CZ

To some extent/partly: LV,

No response (0):

Comments:

c) ☐ **Yes** ☐ **No** ☐ **To some extent/partly** (please comment, if necessary)

Yes (16): AT, CY, DE, DK, EE, EL, FR, HR, IE, IT, NL, PL, PT, RO, SE, SK

No (2): CZ, LU

To some extent/partly (9): BE, BG, ES, FI, HU, LT, LV, MT, SI

No response (0):

Comments:

ES: No comment is made on how long it would take for those countries still using PCM technology to adapt to new technologies

FI: It is challenging to measure the limit value proposed, i.e. 0,01 fibres/cm3, in dusty workplaces like mines (the filters of the air samplers get clogged by general dust). Technological changes need to be made to the methods used to collect samples in the mines and development of such technologies will take time. Hopefully, the needed technological advances can be made before the end of the transposition time. This has not been discussed in the IA.

HU: Only basic information given. Does not go into a lot of detail

MT: In this regard, MT would have preferred if the IA contains detailed information on the impact of the transposition deadline proposed in the context of MS legislative processes

10. Methodology **a) Is an appropriate methodology applied? Are the methodological choices, limitations and uncertainties made clear?**
a) ☐ **Yes** ☐ **No** ☐ **To some extent/partly (**please comment, if necessary) **Yes (24): AT, BE, CY, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK** **No (0):** **To some extent/partly (2): BG, CZ** **No response (1): ES** **Comments:**

Main issues regarding the Commission IA proposed to be discussed during the WP meeting when examining the Commission's IA:

Summary (BE)

As became clear during the first meeting of the WP, the measurement method is a main discussion point for this proposal. In this respect, the following statements in the IA are of interest:

Page 24: '*In addition, the monitoring costs for options 2 (i.e. the selected option) to 4 include the incremental costs of replacing phase-contrast microscopy (PCM) by electron microscopy (EM) analysis*.'

Page 36: '*Option 2 is possible using either PCM or EM*.'.

Page 115: '*The findings from the external study highlight that likely more than half of the asbestos analysis for compliance control today is undertaken by EM methods*'.

In addition, it is very important that the entry into force of the reduced limit value is not delayed, as exposures increase: Page 13: '*it is assumed that the number of exposed workers* ***will increase by 4% every year for the next 10 years***.'.

Summary (BG)

- The measurement methodology
- The transition period

Summary (DE)

- With regard to competitiveness, the lowering of the limit value has positive effects. However, other aspects, for example different qualification requirements for companies in Member States are a key factor in competitiveness. As a result, the positive effects of lowering of the limit value can be relativised.

- The impacts on SME that process natural mineral raw materials with an asbestos content of less than 0.1% (e.g. stonemasons) were not taken into account. Even with such activities, workers can be exposed to more than 0.01 fibres/cm^3.

Summary (DK)

- Description of concrete steps that could facilitate a move towards the use of EM.

Summary (ES)

- Methodology based on electron microscopy (EM)

Summary (FI)

- The directive does not include a requirement to replace PCM methods with the EM methods. The impacts of sticking to the PCM methods instead of moving to more modern EM technologies are not assessed.

Summary (FR)

- The lack of justification for maintaining an intrinsically limited method of analysis with regard to the specific objectives presented by the Commission associated with the lowering of the OEL for asbestos (protection of EU workers; reduction of the distortion of competition between companies in the Member States).

- Consideration of the implications of the shortcoming mentioned in point 1 in terms of effective protection of all workers in the European Union and the risk of distortion of competition between companies established in the various Member States.

Summary (HR)

- Croatian delegation would like to know additional information regarding protection of workers who are exposed to asbestos in construction work, such as renovation and demolition, especially regarding their personal protective equipment (PPE). Is this equipment effective? Will the investment in the new PPE make a difference?

Summary (HU)

- Practical implementation. Impact on technological processes, working methods and costs for enterprises

Summary (IT)

- The field of application must be defined more precisely, i.e. whether this rule impacts exclusively on workers engaged in maintenance, renewal, demolition, remediation, asbestos waste management, or even on those who carry out their work in workplace where asbestos containing materials presence is ascertained, while not intervening directly on them (e.g. workers employed in building containing asbestos materials).

- In case of activities of maintenance, renewal, demolition, remediation, asbestos waste management on asbestos or asbestos containing materials, providing for the use of PPE for each case of processing that may involve exposure of workers to asbestos to protect workers even at exposures below 0.01 f / cm3.

- Before beginning demolition or maintenance work, define in more detail who has the task of collecting data on asbestos presence in the building and the methodology to apply.

- Implementation of electron microscopy technique for the measurement of asbestos fibres in all EU countries: it is considered correct to insert EM while maintaining optical microscopy, considering an excessive impact on some economic analytical sectors using only EM. In the latter case a more deep impact analysis of the increase in the cost should be done.

- Setting a transitional period for the implementation of the new BOELV for asbestos

Summary (LT)

- In our view IA lacks information on implementation of electron microscopy for the measurement of asbestos fibres in Member States: what is the situation in different MS and what would be the costs of switching to electron microscopy. We spot the attention that not only the costs of purchasing new equipment but also the payback of it should be considered. Also, it is a question if EM is suitable while different EM techniques exist between MS (and even between laboratories) and what would be the costs of harmonisation.

- We miss more detailed information on the personal protection equipment currently used in EU and what would be the need and the costs for employers to apply new PPE after the new limit value of asbestos is established.

Summary (LV)

- Detailed information on guidance for enterprises, best practise examples, better protection of workers.

Summary (MT)

- Malta does not have particular issues that wishes to put forward during the upcoming WP meeting when examining the Commission's IA.

Summary (NL)

- Inclusion of concrete steps that facilitate a move towards the use of EM.
- More ambition on the OELV. This contributes to less cancer cases and a level playing field.

Summary (PL)

- Impact of changes in the reduced BOELV for asbestos on occupational risk management, especially in micro and small enterprises removing asbestos
- Impact of the increase in the cost of asbestos removal on customers, which will be connected to the increase in the cost of occupational risk management borne by the employers
- Implementation of electron microscopy technique for the measurement of asbestos fibres in all EU countries
- Setting a transitional period for the implementation of the new BOELV for asbestos

Summary (SI)

- Practical guidelines for work with asbestos
- Practical guidelines for sporadic and low intensity exposure
- Measurement methods

Summary

Main issues regarding the Commission IA proposed to be discussed during the WP meeting when examining the Commission's IA:

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-

-

etc.

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of workers from the risks related to exposure to asbestos at work

Summary of the replies to the Impact Assessment questionnaire

All the delegations considered **the policy context and the legal basis of the initiative** to be clearly explained in the IA.

While almost all delegations agreed that the **problems and underlying drivers** had been demonstrated and underpinned by evidence, many delegations considered that a gap in evidence has not been acknowledged, notably regarding a possibe change in methodology.

The coherence of the intervention logic and consistency **with broad policy strategies** - the protection of workers' health and safety – were fully or at least partially acknowledged by all the delegations. Delegations also broadly agreed that the Impact Assessment sets out clear policy objectives. As to the **link with measurable monitoring indicators**, delegations were fully or partially satisfied. However, some delegations pointed to the complexity of data collection and the difficulties in comparing indicators across countries.

The **Union's competence and the legal basis** were considered by all to be clearly established. In addition, delegations were satisfied with the IA analysis on **compliance with the principle of subsidiarity and proportionality.** They also agreed on the IA containing consideration of action already taken or planned by EU.

Delegations agreed that the IA has identified all feasible **policy options** and most affected **stakeholders**. The delegations were fully satisfied with information regarding how stakeholders inputs fed into the policy options. The discarded options that were favoured by stakeholders in open consultations were considered thoroughly or partially examined.

Overall, delegations considered that the **impacts** of each policy option had been clearly considered and they recognized that impacts were clearly expressed in a **comparable format and compared against a clear set of criteria**.

The **impacts on the main groups of affected stakeholders**, the **economic impacts, including impacts on, consumers and SMEs including microenterprises**, the **social and environmental impacts**, the **regulatory costs**, the **impacts on individual Member States** and the **impacts on third countries and fundamental rights** were widely considered to have been at least partially clearly presented and assessed. However, some Member States pointed out that investments are likely to be needed to update the required equipment whose costs are likely to fall on businesses and final consumers. Taking this into account, some Member States ask for the harmonisation of tools and methodologies across the EU to ensure comparability across countries and avoid a two-speed Union. Some others also noted the need for a transition period to allow, if an equipment replacement is requested, businesses to comply with it.

All but one delegation thought that **comments and recommendations of the Impact Assessment Board (IAB)** have been considered, or partly considered.

As for the **monitoring**, most delegations thought that the indicators were clearly or to some extent clearly able to measure the intended effects. Delegations were also fully, or to some extent, positive regarding the presentation of the **operational monitoring and evaluation arrangements.** Comments on the **transposition deadline** have been made concerning the timeframe needed by Member States to modernize the equipment and the lack of detail and guidance on this aspect.

Finally, most delegations recognised that **the methodological choices, the limitations and uncertainties** were made clear.