Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on

Chrysotile

ECHA/RAC/RES-O-0000005787-59-01/F

Adopted

25 November 2014

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Opinion of the Committee for Risk Assessment

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	Chrysotile
EC No.:	-
CAS No.:	12001-29-5, 132207-32-0

This document presents the opinion adopted by RAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

ECHA at the request of the Commission has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at **http://echa.europa.eu/web/guest/restrictions-under-consideration** on 19 March 2014. Interested parties were invited to submit comments and contributions by 19 September 2014.

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC:	**Marianne VAN DER HAGEN**
Co-rapporteur, appointed by RAC:	**Lina DUNAUSKIENĖ**

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on 26 November 2014.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted ***by consensus*** of all members having the right to vote.

OPINION

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on ***chrysotile*** is the most appropriate EU wide measure to address the identified risks in terms of the effectiveness in reducing the risks.

The proposed restriction is as follows:

6. Asbestos fibres (a) Crocidolite CAS No 12001-28-4 (b) Amosite CAS No 12172-73-5 (c) Anthophyllite CAS No 77536-67-5 (d) Actinolite CAS No 77536-66-4 (e) Tremolite CAS No 77536-68-6 (f) Chrysotile CAS No 12001-29-5 CAS No 132207-32-0	1. The manufacture, placing on the market and use of these fibres and of articles and mixtures containing these fibres added intentionally is prohibited.~~However, Member States may exempt the placing on the market and use of diaphragms containing chrysotile (point (f)) for existing electrolysis installations until they reach the end of their service life, or until suitable asbestos-free substitutes become available, whichever is the sooner.~~ ~~By 1 June 2011 Member States making use of this exemption shall provide a report to the Commission on the availability of asbestos free substitutes for electrolysis installations and the efforts undertaken to develop such alternatives, on the protection of the health of workers in the installations, on the source and quantities of chrysotile, on the source and quantities of diaphragms containing chrysotile, and the envisaged date of the end of the exemption. The Commission shall make this information publicly available.~~ ~~Following receipt of those reports, the Commission shall request the Agency to prepare a dossier in accordance with Article 69 with a view to prohibit the placing on the market and use of diaphragms containing chrysotile.~~ 2. By way of derogation, paragraph 1 shall not apply until 31 December 2025 regarding the placing on the market and use of diaphragms containing chrysotile (point (f)), and placing on the market and use of chrysotile fibres used exclusively for the purpose of including such fibres in diaphragms, to electrolysis installations in use on 17 January 2013, if placing on the market or use were exempted by a Member State in accordance with the restriction on asbestos fibres as initially codified by Regulation (EC) No 1907/2006 of 18 December 2006 (OJ L 396, 30.12.2006). Without prejudice to the application of other Union provisions on the protection of workers from asbestos, any manufacturer, importer or downstream user benefiting from the derogation shall: i) minimise exposure to asbestos fibres placed on the market or used in compliance with the derogation of this paragraph, ii) prepare an annual report per calendar year giving the amount of chrysotile placed on the market and used in diaphragms, in compliance with the derogation of this paragraph, iii) send the report specified in para 2(ii) to the relevant Member

	State (in which the aforementioned electrolysis installation is located) the European Commission, with a copy to the European Chemicals Agency, by 31 January of the following year. The relevant Member States may set a specific limit value for fibres in air or a monitoring regime for ensuring compliance with paragraph 2(i). If a Member State requires a monitoring regime, the results of the monitoring of exposures from the use of diaphragms and any fibres used should be included in the report specified in paragraph 2(ii). If a party granted an exemption concludes that the exemption needs to be extended because the relevant electrolysis installation has not reached the end of its service life and technically or economically viable asbestos-free substitutes are not yet available, they shall submit a report by 31 December 2020 to the Member State they are located in and the European Commission. The report shall include a risk assessment, including any relevant Exposure Scenarios describing the measures to minimise the risks, an Analysis of alternatives, and any information relevant for a socio-economic analysis related to the need for a further derogation.

JUSTIFICATION FOR THE OPINION OF RAC

This RAC opinion considers the evidence presented in the Background Document, and comments submitted both during the public consultation and RAC discussions.

IDENTIFIED HAZARD AND RISK

The proposed modification relates only to entry 6 Paragraph 1 of REACH Annex XVII, and to the need to assess whether to further restrict placing on the market and use of chrysotile i.e. whether it should be allowed to continue use of chrysotile in already existing electrolysis installations.

Currently, there are only two companies still making use of the exemptions granted by the Member States in accordance with the provisions of paragraph 1 of entry 6 of Annex XVII. These are AarhusKarlshamn Sweden AB (AAK) and Dow Deutschland Anlagengesellschaft mbH (Dow). These companies do not manufacture or export any chrysotile fibres or produce or export chrysotile containing articles.

AAK was given an exemption by Sweden to replace diaphragms containing chrysotile in electrolysis processes with the same type of diaphragms. The company produces hydrogen gas at high pressure. The installation has two electrolysis units. The diaphragms were replaced in 2006 in one of the other units and at the end of 2010/beginning of 2011 in the other one. (Swedish Chemicals Agency, 2011).

Germany, has granted a national (not a company specific) exemption allowing "the manufacture and use of diaphragms containing chrysotile" including the asbestos-bearing raw materials needed for their manufacture, in systems existing on 01.12.2010 until the end of their use" (Bundesgesetzblatt, 2010). Dow produces chlorine, hydrogen and caustic soda at this site and is the only company in Germany currently making use of this exemption on asbestos.

AAK has already decided to adopt a chrysotile-free production method for the production of hydrogen within the next 5-10 years. After that, it has no further need for diaphragms containing chrysotile and it would not need further exemption for the use or import of such diaphragms. In June 2014 Dow informed RAC and SEAC plenary meetings that it has made a commitment to the German Government not to import any chrysotile for its Stade production process after 2017. This suggests that the proposed derogation for importation (placing on the market) of chrysotile is needed only until 2018 and for use of chrysotile until 2025 as described in the proposal.

As requested by the European Commission, the main emphasis in the background document (BD) is on assessing risks to human health and the environment, on the availability of alternatives, and on the socio-economic impacts as a result of a prohibition. In practice, this means the focus is on the two electrolysis installations currently relying on the exemptions, i.e. AAK and Dow.

Description of the risk to be addressed by the proposed restriction

The health hazards related to chrysotile are well established. Therefore the dossier focuses on assessing the exposure and the risk. Chrysotile is carcinogenic and classified as Carc. 1A and STOT-RE 1 under the CLP-Regulation (EC) No 1272/2008. As stated by IARC, all forms of asbestos, including chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite are carcinogenic to humans (IARC Group 1).

In deriving the exposure-risk relationship, the assessment of unit risk for fatal asbestos-

induced lung cancer and mesothelioma as performed by the US EPA on the basis of epidemiological studies served as a starting point in the BD (EPA, 2013). According to the derived linear exposure-risk relationship for asbestos, a concentration of 10,000 fibres/m^3 corresponds to an excess lifetime cancer risk for workers of 4/10,000.

The European Commission has issued a binding European occupational exposure limit (OEL) of 100,000 fibres/m^3 (Art. 8 in Directive 2009/148/EC).

Information on emissions and exposures

AAK

AAK uses chrysotile in two high-pressure electrolysis units for hydrogen production. Chrysotile is used in the gaskets and in the diaphragms in these units. Chrysotile is located within the cells and thus, according to the DS, is not accessible to AAK employees. The cells are prepared by the chrysotile supplier (IHT, Switzerland) and only whole sealed cells have been imported to the AAK site. Therefore, although chrysotile is in continuous use in the electrolysis units, no chrysotile is handled at the site. As a result, there are no apparent points of exposure in the standard process activities at the site. Furthermore, the volume of chrysotile in the electrolysis units is relatively low totalling to about 7.5 tonnes.

Chrysotile containing cells within the blocks are replaced with cells with new chrysotile-containing diaphragms during refurbishment of the equipment every 10 to 15 years. There is no exposure to the chrysotile during these refurbishment activities, because only the sealed cells are handled at the site, not the chrysotile or the diaphragms themselves. No chrysotile is added or taken away between refurbishments.

No exposure data from AAK has been made available to RAC in the Background Document.

RAC agrees with the dossier submitter (DS) that there is no need to assess further in detail the exposure to chrysotile to workers in AAK.

Dow

At Dow the process consists of two subprocesses i.e., **use of diaphragms** containing chrysotile (exposure scenario entitled *Use in diaphragm cells*) and **use of chrysotile fibres** to maintain the diaphragms during their use in the process (Exposure scenario entitled *Use as reconditioning agent*).

The diaphragms containing chrysotile are embedded in cells such that both the diaphragms and the chrysotile in them are unaccessible to employees. Furthermore, inside the diaphragms, the chrysotile fibres are embedded into a plastic matrix and operated as a wet process, which prevents chrysotile fibre release. The waste water and potential fibre releases in it are treated separately. The potential points of exposure are managed by the process design and where needed (e.g. maintenance activities), by the use of personal protective equipment (PPE).

During the activities with a main potential for exposure e.g. cleaning and maintenance, the workers wear disposable protective clothing and a full face mask (in accordance with EN136:1998) with a powered air filtering unit with P3 filter cartridge (fulfilling EN 12941:1998/EN12942:1998). As general personal protective equipment all workers wear safety clothing and protective safety gloves, as well as helmet and safety shoes. For activities in the asbestos handling room, the shower room must be used and the employees wear disposable clothing.

Bulk chrysotile is brought to the site as dry fibres. For transportation Dow uses specially designed Dow System Containers (DSC) to ensure safe process (in the dossier see Annex 2.1.). As exposure to dry fibres is considered dangerous, all handling of the dry chrysotile fibres is fully automated. The dry fibres are mixed with brine in an automated process to

produce slurry, which is used to maintain diaphragms in cells while in operation. The process design i.e., automation and the use of robots, minimises the exposure. Furthermore, PPE is used where needed e.g. during any periodic cleaning or maintenance tasks.

When diaphragms are worn out and need to be replaced, the chrysotile is washed out from the cells and the waste is heat-treated in a special oven, such that the fibre structures are destroyed. Dow reports the resulting waste to be non-hazardous and usable as filler in construction.

The DS has submitted detailed exposure scenarios developed in close cooperation with Dow for both Use in diaphragms cells and Use as reconditioning agent.

No environmental assessment has been conducted for either of the two exposure scenarios, as there is no release of asbestos to environmental compartments. Release to air is prevented by the use of ventilation and negative pressure as well as the use of HEPA filters before emission. This is confirmed by measurements at the stacks were the air is released in 2010, 2011 and 2013 which all were below the detection limit (<100 fibres/m3). The background level of asbestos in outdoor air in Germany is in the range of 100 – 150 fibres/m3. Used HEPA filters are collected and destroyed at the site. All waste water possibly containing asbestos enters a closed waste water treatment system. The fibres in the waste water are destroyed on-site.

RAC therefore considers that no environmental assessment beyond this is needed.

Dow has provided ECHA with monitoring information. All measurements are from stationary monitoring. Details of the exposure data are given in annex 1 to the opinion. At Dow there are many short-term tasks in which a single task takes only 1-2 hours each. The same worker may carry out many such tasks during a single work day, and could potentially be exposed to asbestos in several consecutive tasks.

The program for occupational exposure estimation of asbestos at Dow was developed in cooperation with the local authorities, the employer's liability insurance, industrial hygiene experts at Dow, the analysis institute and the Dow workers council. The monitoring is carried out by external experts.

The asbestos fibre concentrations in the working atmosphere are generally below the level of detection (which is approximately 100 f/m3), and always far below the German legal limit of 1000 fibres per m^3. In comparison the EU OEL is 100,000 fibres/m^3.

Maximum fibre equivalents from six annual sampling points:

Year	Maximum fibre equivalents, fibres/m3
2008	-
2009	100
2010	-
2011	100
2012	290

Exposure scenario 1 for workers: Use as reconditioning agent (closed systems)

This scenario consists of one Environmental contributing scenario (ECS) and 8 Worker

contributing scenarios:

ECS1: No title
WCS1: Receival and storage of fibre packages (PROC1)
WCS2: Dumping of fibres in mixing vessel (PROC1)
WCS3: Formulation of slurry (PROC1)
WCS4: Filling of feeding containers (PROC1)
WCS5: Feeding slurry to electrolysis cells (PROC1)
WCS6: Flushing of feeding lines and (de)coupling of hoses (PROC3)
WCS7: Maintenance and cleaning (PROC8b)
WCS8: Waste handling (PROC8b)

Exposure data is only available for WCS 2, 6 and 8, where there is a possibility of exposure. In WCS2 all 6 measurements were below the level of detection (approximately 100 fibres/m^3). In WCS 6 the measurements (n=2) were below the level of detection. In WCS 8 all 6 measurements were below the limit of detection. For calculation of the statistics the level of detection as such was used as the result of the measurement. Details of the exposure data are given in annex 1 to the opinion.

For the other WCSs minimal (or no) exposure is expected: The asbestos is fully sealed for WCS1. In WCS3 workers are controlling the process from a remote position (control room). Also WCS4 and 5 are fully closed processes. The workers control this from a remote position. For WCS7 the concentration in the room is very low due to local exhaust ventilation and a high level of hygiene. Also the workers are protected by personal protective equipment (PPE) including powered respirator with efficiency of 97.5 %.

Exposure scenario 2 for workers: Use in diaphragm cells (closed systems)

This scenario consists of one Environmental contributing scenario (ECS) and 7 Worker contributing scenarios:

ECS1: No title
WCS1: Receival and storage of electrolysis cells (PROC1)
WCS2: Assembly of electrolysis cells (PROC3)
WCS3: Installation of electrolysis cells (PROC3)
WCS4: Service life of electrolysis cells (PROC1)
WCS5: Disconnection of electrolysis cells from production line and intermediate storage in water pit (PROC3)
WCS6: Dismantling and cleaning of dismantled parts (PROC8b)
WCS7: Waste handling (PROC8b)

Exposure data is only available for WCS 2, 6 and 7. In WCS2, 4 out of 6 measurements were below the level of detection (approximately 100 fibres/m^3). In WCS 6, 4 of 9 measurements for dismantling were below the level of detection. For cleaning of anode/cathode one result was below the level of detection, the other two were at the level of detection. In WCS 7 all 6 measurements were below the level of detection. For calculation of the statistics the level of detection as such was used as the result of the measurement. Details of the exposure data are given in annex 1 to the opinion.

For the other WCSs minimal (or no) exposure is expected: The asbestos is fully sealed for WCS1. In WCS3 the asbestos is bound in matrix, and the diaphragm itself is not handled so the probability of exposure is very low. WCS4 is a fully closed process as the cells are fully closed during its service life, and no exposure is foreseen. Also in WCS5 the cells are fully closed, and during storage submerged in water, preventing release of fibres.

There is a need for continuation of the restriction and the associated risk management measures already in place in order to minimise risk of possible exposure to chrysotile

asbestos for workers in the two companies. Also, a continuation of the restriction will prevent other companies from initiating import and use of chrysotile asbestos, a substance that is known to be carcinogenic to humans.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

Asbestos-related diseases are still a major public health concern and actions to minimize potential exposure need to be taken on an EU wide basis. Thus paragraph 1 of entry 6 of REACH Annex XVII covers six types of asbestos fibres and prohibits the manufacture, placing on the market and use of the fibres, and of articles and mixtures containing these fibres added intentionally

Paragraph 1 of the existing entry 6 of REACH Annex XVII applies across the EU. There is no information available suggesting reconsidering the EU wide basis of entry 6. Thus, any modification to the entry clearly needs to be made on an EU wide basis.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

There is no information available to suggest that the EU-wide basis of entry 6 should be reconsidered in its entirety; the necessary focus is on the elements relating to chrysotile. The amendment to entry 6 on chrysotile is a special case of restriction affecting only two member states. Currently, chrysotile is used by two producers, AAK and Dow. There are no other installations which are using chrysotile in electrolysis operations in the EU, and entry 6 prevents any plant from starting new use of chrysotile.

In the case of **AAK**, there is no exposure with chrysotile during the use of electrolysis units and thus potential risks from chrysotile use, renovation and disposal are negligible. AAK has already decided to move away from chrysotile in the next 5-10 years. Thus no further renovations will take place at the AAK site prior to the final dismantling and removal of the equipment as part of the switch to a chrysotile-free alternative technology. The potential risks would not be affected by earlier removal of chrysotile from the production system. On the other hand, the earlier removal would be costly as transfer to chrysotile-free technology requires several years.

In the case of **Dow**, exposures from chrysotile are minimized due to the currently implemented risk management measures. Supporting air monitoring data shows that implemented risk management measures are effective and potential risks from the use of chrysotile are controlled. Dow is currently testing an alternative substance for possible use instead of chrysotile in its operation. The decision about adopting the substitute in the best case scenario can be made in 2015. If this alternative proves to be technically and economically feasible, change to chrysotile free operation could be completed by 2025. In June 2014. Dow informed RAC and SEAC plenary meetings that it has made a commitment to the DE Government not to import any Chrysotile (neither as fibres nor contained in diaphragms) for its Stade production process after 2017. Until 2017, Dow will need to ensure the quality of the fibres they have available to make sure that they have the right type of long fibres.

The existing entry 6 appears to be valid as such, and thus, one option is not to amend the entry at all. This would have the advantage of having limited implications in terms of administrative and legislative burden. The main motivation for proposing options to change the current entry was to improve clarity and transparency of the existing derogation e.g. by adding reporting requirements and the time limit.

Five RMOs to change the current regulation of crysotile have been discussed in sections E.1.2 and E.1.3. of the BD (four modifications of current restriction and authorisation):

RMO 1 proposes to continue the current derogation, but sets a time limit to the national exemptions granted by the Member States. 10 years seems a reasonable time limit for an exemption to continue before (if necessary and justified) being renewed, as this would enable both AAK and Dow to undertake planned switch over to alternative non-asbestos technologies (in the case that they are available). The first RMO would be administered by a Member State, as is the case at the moment.

RMO 2 includes explicit derogation in the entry with a time limit of 2025. Thus, any use after 2025 would require another review of the need to prolong the restriction and amendment of the entry via an Annex XV restriction report.

RMO 3 utilises a volume constraint as the basis for the exemption instead of the time limit. Under this RMO, it would be ECHA – not the Member State Competent Authority – that would administer the exemption.

RMO 4 would end the current derogation immediately (after the necessary legislative changes have been made, probably 3 - 4 years), and ban all existing uses of chrysotile in diaphragms. (The risks of continued chrysotile use at AAK and Dow are already significantly controlled and effectively negligible. Thus, the benefits of any immediate closure of the two plants would also be negligible, and certainly orders of magnitude lower than the costs of closure. Due to reasons mentioned above it was concluded that this RMO is not justified and this RMO was not further considered in BD.)

RMO 5 maintain current entry but require companies to apply for an authorisation for continued use under the assumption that chrysotile would be added to Annex XIV. The advantage of the authorisation requirement is that it would modify the regulatory approach assigning clear burden of proof to the company applying for authorisation. The main disadvantage of this RMO is that the importation of diaphragms containing chrysotile would not be regulated, as the authorisation requirement does not apply to imported articles. Addressing this issue would still require a revision to the existing restriction entry. Thus it was concluded that the disadvantage mentioned above is sufficient for this RMO to be given no further consideration.

The 'shut-down' (Option 4) and authorisation RMOs were discarded from further assessment for the reasons stated above. The three remaining RMOs (1 to 3) were assessed and compared. Given the phase out of chrysotile in AAK, the assessment therefore focused mostly on impacts related to Dow.

Given the overall objective of phasing out the use of chrysotile in the EU, and the uncertainties related to the viability and timing of alternatives to chrysotile, **RMO 2** is proposed. The main motivation for proposing options to change the current entry was to improve clarity and transparency of the existing derogation and include the addition of a reporting requirement which would permit better monitoring, enforcement and revision as appropriate. The proposed RMO 2 gives a clear end date for the derogation, based on the best current knowledge about the substitutes. By assigning an explicit end date, the proposal improves clarity (see E.2.3.1.1) compared to the current entry, which only refers to the end of the service life of the existing electrolysis installations. As a result, the proposed time limit on the derogation and the annual reporting requirement provide stronger incentives for finding an alternative and switching to chrysotile-free technology. Based on the foregoing analysis, the new proposal is preferred to the current situation as incentives for substitution are strengthened and the finite duration of the derogation will provide administrative savings in the future. The most recent information from Dow supports the view that substitutes may be available sooner (the decision about adopting the substitute can be made 2015). Based on all the reasons mentioned above the proposal (Option/RMO 2) for the amendment of entry 6 is considered to be the most appropriate

Union-wide measure.

The majority of comments received during the public consultation were split in two with one big block (mainly consisting of Dow and affected customers/downstream users of chemicals distributed by Dow, local authorities and communities) supporting the proposed restriction (option 2), and another big block (mainly consisting of NGOs) supporting an immediate ban of chrysotile asbestos (option 4).

In light of comments received during the public consultation, RAC considered the option of banning without delay the import of chrysotile fibres for reconditioning of the remaining installed diaphragms. The alternative option to uphold the import derogation was also discussed. However, RAC was unable to decide between these two options as the health risks at Dow and AAK were already very low, even without an outright import ban. SEAC was better placed to consider the relative impacts of these RMOs."

Effectiveness in reducing the identified risks

AAK has already decided to adopt an alternative hydrogen production methodology (not involving chrysotile), due to ageing of the current machinery and other increases in maintenance costs. AAK has reviewed alternative production techniques to replace its current technology. These techniques include low pressure electrolyser, steam reforming or methanol cracking, and most likely the technology would be chosen from these three methods. In sum, AAK plans to be ready to replace its current chrysotile-based technology with chrysotile-free in about 5-10 years, i.e. by 2025 at the latest. As long as it is chrysotile-free, and complies with EU legislations, the specific choice of the future technology by AAK does not have relevance for RAC. Only a short description of these alternative techniques is available, and no estimated exposure data. So RAC cannot assess the risk from these alternatives. However the RAC notes that all alternative methods are chrysotile free.

Dow has designed and further developed its electrolysis machinery by itself, and has been doing R&D over the last forty years in order to find suitable alternatives to replace chrysotile in the process. However, no alternative substance or material has been found for the very special case of low current density technology used by and for the cells typical for Dow. Dow is currently doing a production level testing on a promising alternative to chrysotile diaphragms. The testing should provide final results during the year 2015. Dow has previously studied other alternative production methodologies. There is no information available on the identity, hazards and risk from the alternative substances. None of the alternative methodologies studied (membrane technology, replacing electrolysis cells with commercial cells, switching from low to high-current-density) are described as promising. The only solution seems to be switching to chrysotile-free diaphragm, but the time-frame for this seems to be very long. With the current rate of substituting chrysotile at Dow all of the electrolysis series would be asbestos free in 2025.

Membrane electrolysis cells provide the state-of-the-art technology for chlor-alkali production, and all other European companies use other processes than the chrysotile based.

Practicality, incl. enforceability

RMO 2 would require the relevant Member States (limited to DE and SE) to consider if exemptions to Entry 6 in REACH Annex XVII should be granted, and if a specific limit value and or a monitoring regime should be set. This RMO would also require the relevant Member States to check the annual reports from the manufacturer, importer or downstream user, and to check that the exposure is minimised and below the specific limit value for fibres in air if such values have been set by the Member State. Also the member state must check if the monitoring regime is in accordance with the conditions in the given

exemption(s). With RMO2 the manufacturer, importer or downstream user would also have to send the annual report to the European Commission, with a copy to ECHA. No immediate action would be taken upon receival of the reports in the European Commission (and ECHA).

RAC notes that there is a binding occupational exposure limit (equals 100.000 fibres/m^3) in the directive on the protection of workers from the risks related to exposure to asbestos at work (2009/148/EU). RAC recommends that the relevant member states should set a specific limit not exceeding this exposure limit. RAC also recommends that the affected member states should set a monitoring regime and a requirement for both to be reported annually by the importer or downstream user making a use of the derogation.

RMO1: Continue the current derogation with time-limited exemptions

RMO2: Derogation with a fixed end date

RMO3: Limiting the amount of chrysotile used

RMO4: Shut-down (immediately end the current derogation)

RMO5: Authorisation (add chrysotile to annex XIV and maintain current entry)

RMO2 is considered to be implementable (as graded +++) and enforceable (+++) and to increase the enforceability compared to the situation today. The implementability and enforceability of all the RMOs in the BD is summarised in the table:

RMO	Implementability	Enforceability	Comment
1	+++	++	Add time limit to exemptions
2	+++	+++	The RMO proposed by the DS
3	++	+	Administered by ECHA who will set the permitted use amount
4	+	+++	Immediate ban
5	++	++	Authorisation (would not cover imported diaphragms, regarded as articles).

RAC notes that Forum consider the proposed restriction (RMO2) to be enforceable.

Monitorability

RAC notes that a time limit and reporting requirement are simple to monitor. Standardized methods for sampling and analysis are available.

RAC notes that the Forum considers the proposed restriction to be monitorable.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

Basis for the opinion of RAC

There are no changes introduced by RAC in this opinion to the restriction proposed in the Annex XV restriction dossier submitted by ECHA at the request of the Commission. RAC considered deleting the final paragraph of the proposed restriction, which would prevent any additional review for an extension after 2025. However, being at least in part a policy issue, this seemed outside the mandate of RAC.

Chrysotile, like other forms of asbestos, is carcinogenic to humans. This has been assessed in detail and described by IARC and many other internationally reputable scientific and regulatory organisations. There has been an EU-wide restriction on asbestos since 1977 and the consumption of asbestos worldwide peaked in 1980, but due to the long latency period between the onset of exposure and the incidence of cancer caused by asbestos, the peak of cancer cases in many countries has yet to be realised (Stayner etal, 2013).

In RAC's view, the exposure (due to continued use of asbestos in the two companies) is controlled to a risk level of low concern for all the uses described in the exposure scenarios received from Dow. Comments from some stakeholders have indicated that there may be higher risks associated with other stages of the life cycle of the chrysotile being used, for example in the non-EU mining and milling of fibres, and the manufacturing, packaging and transportation of fibres and diaphragms containing fibres. Although these steps in the life cycle of chrysotile have not been the subject of RAC's assessment they do perhaps serve as a reminder that it is not possible for the EU to ensure all workers and other people at risk are adequately protected from chrysotile. In principle, it would therefore seem appropriate from RAC's perspective not to prolong the derogation after the proposed end-date in 2025.

This would also be in line with the request from the COM to ECHA to prepare an Annex XV restriction report with a view of prohibiting the placing on the market and use of diaphragms containing chrysotile.

References:

Stayner L, Welch LS, Lemen R: The Worldwide Pandemic of Asbestos-Related Diseases, Annu Rev Public Health. 2013;34:205-16. doi: 10.1146/annurev-publhealth-031811-124704. Epub 2013 Jan 4. Review.

WCS	Title	Number of measurements or model applied	90th percentile fibres/m3	Geometric Mean fibres/m3	Geometric standard deviation	Duration	Frequency	Persons/shift	Number of samples below level of detection (LoD) (approximately 100 f/m3) versus all samples in WCS	
1-2	Dumping of fibres in mixing vessel	6	108	102	1.04	1 hour per day	2 times per week	1 technician in remote control room	6/6	
1-6	Flushing of feeding lines and (de)coupling of hoses	2	n/a	100	1.00	0.5 hour per day	2 times per week	1 technician	2/2	
1-8	Waste handling	6	112	103	1.05	8 hours per day	75 days per year	1 technician	6/6	
2-2	Assembly of electrolysis cells	6	253	122	1.56	8 hours per day for 20 days	2 times per year	4 technicians	4/6	
2-6	Dismantling and cleaning of dismantled parts					8 hours per day	75 days per year	3 technicians		
	Disassembly	9	235	123	1.48				4/9	
	Cleaning	3	n/a	100	1.0				1/3 (2/3 at LoD)	
2-7	Waste handling	6	112	103	1.05	8 hours per day	75 days per year	1 technician	6/6	

n/a: cannot be calculated as the results are identical