Regulatory Management Option Analysis Conclusion Document

Substance Name: Asbestos

EC Number: -

CAS Number: Crocidolite (12001-28-4),
Amosite (12172-73-5),
Anthophyllite (77536-67-5),
Actinolite (77536-66-4),
Tremolite (77536-68-6),
Chrysotile (12001-29-5 and 132207-32-0)

Authority: The Netherlands (NL-CA)

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Foreword

The purpose of Regulatory Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: https://echa.europa.eu/documents/10162/1049086/svhc_roadmap_implementation_plan_en.pdf

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Asbestos is the commercial-industrial term for a group of silicate minerals that occur in polyfilamentous bundles of flexible, high aspect ratio fibres. The asbestoid forms of these minerals that follow the WHO 1997 specifications for fibres are considered hazardous. This refers to fibres with a minimum length of 5 µm, a diameter of less than 3 µm and an aspect ratio (length/diameter) greater than 3:1 (WHO 1997[2]).

Asbestos has a harmonised classification of Carc 1A and STOT RE 1. It is known to cause various forms of cancer, including mesothelioma, lung cancer and ovarian cancer (IARC 1977, 2012)[3,4]. It also causes asbestosis and non-malignant pleural diseases. Due to its Carc 1A classification, entry 28 of Annex XVII of REACH applies to the substance. This entry restricts the placing on the market of carcinogenic substances for supply to consumers. It is also restricted through its entry 6 listing on Annex XVII that prohibits the manufacture, placing on the market and use of these fibres and of articles and mixtures containing these fibres added intentionally in the EU.

Regulatory instruments that pertain to asbestos include legislation for the protection of workers (Directive 2009/148/EC[5], with additional provisions for pregnant and breastfeeding workers (Directive 92/85/EEC[6]) and protection of young people (Directive 94/33/EC[7])). Directive 2023/2668/EU[8] recently amended the asbestos at work directive. The changes include a lowering of the binding occupational exposure level (BOEL) from 0.1 f/cm^3 to 0.01 f/cm^3 (to be implemented in national legislations by 21 December 2025). From 21 December 2029, the BOEL will be lowered further to 0.002 f/cm^3 unless thin fibres (diameter < 0.2 µm) are considered as well (in that case, the BOEL remains 0.01 f/cm^3). The OEL applies to all exposures to asbestos. However, in cases of asbestos that was not intentionally added to products or naturally occurring asbestos, there is often a lack of awareness and therefore employers may not consider or assess the exposure to asbestos and take measures.

Other legislation concerning asbestos include rules governing its international transport (Directive 2008/68/EC[9]). The inadvertent recycling of asbestos is covered to a large extent by the legal EU framework governing the appropriate handling and disposal of hazardous waste (2008/98/EC)[10] and by the Asbestos Directive (2009/148/EC). Under the Cosmetics Regulation (EC 1233/2009[11]) a CMR such as asbestos is prohibited for use in cosmetic products (although under article 17 of this regulation, exemptions are made for trace amounts of natural impurities). The cosmetics industry has adopted guidelines to prevent the use of talc that contains asbestos[12]. These guidelines are generally effective. However, asbestos-containing talc has inadvertently been used in the production of cosmetic products.

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[2] Determination of airborne fibre number concentrations (who.int)
[3] IARC Publications Website - Asbestos
[4] IARC Publications Website - Arsenic, Metals, Fibres, and Dusts
[5] EUR-Lex - 02009L0148-20231220 - NL - EUR-Lex (europa.eu)
[6] Directive - 92/85 - EN - EUR-Lex (europa.eu)
[7] Directive - 94/33 - EN - EUR-Lex (europa.eu)
[8] Directive - EU - 2023/2668 - NL - EUR-Lex (europa.eu)
[9] Directive - 2008/68 - NL - EUR-Lex (europa.eu)
[10] https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:02008L0098-20180705&from=EN (accessed 10 October 2023)
[11] Regulation - 1223/2009 - EN - Cosmetic Products Regulation - EUR-Lex (europa.eu)
[12] Advice from the Netherlands Food and Consumer Product Safety Authority on the risk of asbestos in cosmetic products containing talc. https://www.nvwa.nl/documenten/consument/consumentenartikelen/non-food/cosmetica/advies-risicos-van-asbest-in-talkhoudende-cosmetische-producten

2. CONCLUSION OF RMOA

It is concluded that additional regulatory management measures are needed. This is due to the need to mitigate risk associated with the use and handling of articles and mixtures where asbestos has not been intentionally added, but is present. It is proposed to broaden the scope of the current restriction for asbestos (entry 6 of Annex XVII) to include asbestos that was not added intentionally to substances, mixtures or articles.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	[1]
Identification as SVHC (authorisation)	
Restriction under REACH	x
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

[1] Option to look into setting a specific concentration limit

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

The health effects of asbestos have been known for decades. The first restriction on asbestos (crocidolite) was introduced in 1983, after which the scope has been extended several times until its current wording (entry 6 of Annex XVII of REACH), prohibiting the manufacture, placing on the market and use of asbestos fibres and of articles and mixtures to which asbestos fibres were added intentionally. Therefore, exposure to asbestos in Europe is nowadays mostly related to past uses, e.g. during demolition of buildings where asbestos was used. Exposure due to use of products (mixtures or articles) that contain asbestos that has not been intentionally added or use of asbestos-containing mineral raw materials, is a less recognized source of exposure. However, a growing burden of evidence suggests that minerals that have widespread use (e.g. talc) or used for high exposure activities (e.g. olivine for blast cleaning) may pose a risk to workers and the general population due to their link with asbestos.

The current asbestos restriction does not apply to substances, mixtures or products in which asbestos is present that was not intentionally added. Sources of asbestos that was not intentionally added could be 1) asbestos that is naturally present in minerals that are geologically linked to asbestos (e.g. talc, feldspar, soapstone), 2) recycled (building) materials that were not completely cleared from asbestos before recycling or 3) asbestos as a (cross-)contamination in products. Notable cases have included the discovery of asbestos in cosmetic products (tremolite)[13, 14, 15], in coal slag blasting grit (chrysotile)[16], and in feldspar (tremolite)[17, 18] used for manufacturing ceramics. In these scenarios asbestos was not intentionally added and users were unaware of its presence. The risk of exposure is controllable in scenarios where asbestos is known to be present since adhering to the appropriate regulation should warrant sufficient protection. There are no such protections in the alternative scenarios.

It should be stressed that the health hazard is the same regardless of whether asbestos is known to be present or was not intentionally added to an article (e.g. contaminated blasting grit, talc in cosmetics). The carcinogenic effects of asbestos exposure are considered non-threshold effects, and therefore any exposure may form a risk for workers or the general population and should be eliminated.

The absence of an EU-wide proactive approach for avoidance of unacceptable exposure levels from unintentional use of and exposure to asbestos, undermines the Commission's new strategy for an asbestos-free Europe[19]. The continued use of asbestos would cause it to be even wider spread in the environment and would further complicate removal.

3.1 Harmonised classification and labelling

The six types of asbestos have a harmonised classification and labelling as Carc 1A and

[13] RIVM 2018 - Asbestos in cosmetic products
[14] US FDA 2019 FDA advises consumers to stop using certain cosmetic products
[15] Asbestos in talc powders (dguv.de)
[16] Safety Gate: the EU rapid alert system for dangerous non-food products (europa.eu)
[17] Cavariani et al. (2016) View of Asbestos contamination in feldspar extraction sites
[18] Gualtieri et al. (2018) Assessment of the potential hazard represented by natural raw materials containing mineral fibres—The case of the feldspar from Orani, Sardinia (Italy)
[19] https://ec.europa.eu/social/BlobServlet?docId=26080&langId=en

STOT RE 1. No other health effects have been identified in the RMOA. Therefore, additional harmonised classification and labelling is not considered necessary.

It may be worth to consider if a specific concentration limit could be set for asbestos, as incidents have shown that high exposure may occur from materials with an asbestos concentration below the generic concentration limit. This would improve communication about the presence of asbestos and therefore awareness, allowing users to take protective measures. However, the link between asbestos concentration in a material and exposure potential does not seem to be straightforward.

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

Although asbestos fulfils the criteria of article 57a, identification as a substance of very high concern followed by authorisation is not considered an appropriate RMO for asbestos, since there are no registrations of asbestos and intentional uses of asbestos are already prohibited by entry 6 of Annex XVII of REACH.

3.3 Restriction under REACH

Extending the scope of the current asbestos restriction is evidently an option to regulate the risks related to asbestos that was not intentionally added to substances, mixtures or articles. Two options for extending the current restriction under REACH can be considered:

1. Restrict the placing on the market and use of asbestos fibres, substances containing asbestos fibres and articles and mixtures containing fibres where the fibres are not a natural constituent of the substance.
2. Restrict the placing on the market and use of substances, articles and mixtures containing asbestos fibres regardless of whether they contain fibres that are a natural constituent of the substance or they contain fibres that are not naturally present in the material.

Both options should be worked out in more detail, thereby taking into account analytical methods and their detection limits, available alternatives and possible techniques to clear asbestos fibres from materials. Options such as a complete ban or a limit value would be considered, and it may be necessary to distinguish between naturally occurring asbestos and non-intentional asbestos contaminations. Under both options, the recycling of materials should be given careful consideration.

This first option is a relatively straightforward adjustment of the current restriction. This would improve enforceability in cases where products came into contact with asbestos during processing or transport (cross-contamination). The impact on public health would be limited since these cases are considered incidents and the risks related to asbestos that is naturally present in materials would continue to exist. Furthermore, the suite of regulations mentioned under chapter 1 should provide sufficient protections if stringently followed, although as mentioned there, there is often a lack of awareness of the presence of non-intentional asbestos. It might be necessary to set an upper limit for the presence of asbestos in recycled building materials and soil.

This second option would have greater public health impact. Similar to the first restriction

option, it will cater for cases where products became contaminated with asbestos. However, restriction option 2 would also limit the exposure of both workers and consumers to asbestos that is naturally present in minerals like talc. Several options could be considered: a ban on naturally occurring asbestos in certain high risk uses and/or a concentration limit for asbestos fibres in minerals. The availability of measurement techniques and their detection limits should be taken into account to select a limit value.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

The NL-CA intends to prepare an Annex XV restriction dossier for (not intentionally added) asbestos.

Follow-up action	Date for intention	Actor
Call for evidence	Q3 2024	
Restriction options: to be discussed	2025	Netherlands