Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

Federal Institute for Occupational Safety and Health

Regulatory Management Option Analysis (RMOA)

Conclusion Document

Authority: DE CA

Date: 26.05.2023

Group Name / substance name: Substances in fibre form

Revision history

Version	*Date*	*Description*
1	26.05.2023	Final version for publication

Contents

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is voluntary, i.e., it is not part of the processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[1].

[1] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

AGS	German Committee on Hazardous Substances
BAuA	German Federal Institute for Occupational Safety and Health
BOELV	Binding Occupational Exposure Limit Value
BP	Brief Profile
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
CNT	Carbon nanotubes
CSR	Chemical Safety Report
DEv	Dossier evaluation
ED	Endocrine disruptor
ES	Exposure scenario
GD	Guidance document
I.P.-testing	Intraperitoneal testing
ILSI	International Life Sciences Institute
LWGMD	Length Weighted Geometric Mean Diameter
MMVF	Man-Made Vitreous (silicate) Fibres
MWCNT	Multi Walled Carbon Nanotubes
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PAN	polyacrylonitrile
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
PE	Polyethylene
PP	Polypropylene
PMT	Persistent, mobile in water and toxic
PET	Polyethylene-terephthalate
PROC	Process catergories

RCF	Refractory Ceramic Fibres
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
TG	Test Guideline
tpa	Tonnes per annum
TWA	Time-weighted average
WHO	World Health Organization

1 Overview of the substances and concern

1.1 The general concern regarding substances in fibre form

The European market knows many so-called fibre materials. They have been and continue to be scientifically and technologically developed by experts in the field of material science and are subject to European and Member State research funding, e.g. the EU framework “Horizon Europe” or “From materials to innovation” by the German Federal Ministry of Education and Research. Fibre materials can be made of various substances and mixtures, their appearance and area of use are broad and diverse. This includes but is not limited to fibres with a woollen form, individual fibres, fibre bundles and woven or non-woven fabrics. Their use is determined by their properties in terms of mechanical strength, electrical or thermal conductivity, specific weight or (non-)resistance against physical or chemical influences. The advances in science and technology lead to innovations including what is commonly called advanced materials, which fibres are a part of. In the past, asbestos once was also seen as an advanced material but it is banned from production and use today on account of its toxicological properties.

Asbestos represents a well-known example of fibre toxicity and the hazard that arises from fibre dusts. The adverse health effects of fibre dusts originate from their critical morphology and biopersistence beyond their specific chemical composition. Fibrous dusts with critical morphologies are dusts containing elongated particles with a length greater than 5 µm, a diameter smaller than 3 µm and a length-to-diameter ratio larger than 3:1 (WHO fibre criterion[2]). Fulfilling these dimensional specifications, they are able to reach the deep lung (alveoli and bronchioles) after inhalation. This also applies to thicker fibres (> 3 µm), if they have a fracture behaviour that leads to fibre dust (splinter fracture) (Kehren, et al, 2019). Current test results also indicate that at very thin fibre diameters, a change in the flexural rigidity of the fibres occurs, resulting in a loss of pathogenicity of fibres (Fortini et al, 2020). Hence flexural rigidity is related to the substance and the diameter of a fibre. The change in rigidity most likely affects only substances that fall under the definition for the nanoform of a substance for which registration obligations already exist under REACH. Therefore, it could be considered to limit the planned regulatory measure to fibre materials that do not belong to the group of "substances in nanoform".

It is well established that airborne respirable fibres can induce fibrosis and lung cancer as well as mesothelioma (Schinwald et al, 2012). Substances (as such or contained in mixtures or articles) with the above mentioned characteristics are considered in this RMOA independent from their chemical composition.

[2] Reference Method for Measuring Airborne Man-made Mineral Fibres (MMVF). Environmental Health Report No.4. Copenhagen, Denmark: World Health Organization, Regional Office for Europe; 1985.

1.2 The current legal situation and the resulting issues

The hazard concern of fibre materials, for which the before mentioned WHO fibre criteria apply, does not depend on the chemical composition, but on the morphology/shape of the substance, which is commonly known and generally accepted as the "fibre pathogenicity paradigm" (Pott and Friedrichs, 1972; Stanton and Wrench, 1972). This complicates the regulation of fibres in the context of a regulatory framework that focuses on chemical substances, based on their chemical composition.

The term material is not legally defined in the European chemicals regulations REACH[3] and CLP[4]. The regulatory framework of REACH covers substances, mixtures and articles. A material could belong to any of those three categories, i.e. be a substances (in fibre form), or be part of mixtures or articles. In addition, substances, mixtures and articles - even if not fulfilling the WHO fibre criteria themselves - might release hazardous fibre fragments with critical dimensions according to the WHO definition.

Currently, REACH requires information on substances and their properties (compiled in a registration dossier), if they are manufactured or imported into the EU above 1 tpa (as a substance as such or in mixtures). REACH has recently been amended by adding specific information requirements for nanoforms of substances, stressing information on physico-chemical properties in addition to the chemical composition. The morphology, including diameter, length and aspect ratio, of the nanoform has to be given inter alia. However, similar requirements for non-nano fibre materials are still lacking. Furthermore, as registration duties under the REACH Regulation apply to intentionally manufactured substances, the composition, characteristic properties and release of *biopersistent* fibre dusts are not addressed.

Therefore, health hazards resulting from inhaled biopersistent fibre dusts of chemical substances, mixtures or originating from articles will most likely not be identified during the chemical safety assessment under REACH, even if a substance is registered. Only few commercial fibre types on the European market have been registered under REACH, e.g. man-made vitreous (silicate) fibres (MMVF), refractory ceramic fibres (RCF), or more recently multi walled carbon nanotubes (MWCNT).

Without requirements to provide information on the morphology and/or shape of the substance, there is also no basis for both the appropriate (harmonised) classification of such forms of substances under the CLP Regulation and for hazard communication in the supply chain via the safety data sheet (SDS).

Following the fibre pathogenicity paradigm, only a small number of substances have a harmonised classification as carcinogenic in Annex VI of

[3] Regulation (EC) 1907/2006 - Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
[4] Regulation (EC) 1272/2008 - Classification, Labelling and Packaging of substances and mixtures (CLP)

the CLP Regulation, e.g. fibre mineral erionite (650-012-00-0), mineral wool (650-016-00-2), RCF (650-017-00-8) as well as microglass fibres (014-046-00-4, 014-047-00-X).[5] Lack of knowledge and missing information in the SDS about the potential presence or the release of substances in fibre form and the related hazard makes it difficult or even impossible for employers to consider these in their workplace risk assessment.

Additionally, for articles, REACH and CLP regulations are only applicable to a limited extent, e.g. REACH only contains notification obligations if substances of very high concern (SVHC) are present in articles. Furthermore, articles neither require safety data sheets nor can they be classified under the CLP regulation.

Besides REACH and CLP, also other relevant EU regulations do not yet specifically consider health risks by fibres and even if they do, they have been implemented differently at national level, such as the OSH Framework Directive[6].

The omission to adequately address substances in fibre form in the EU chemicals legislation has direct consequences, in particular for the protection of workers. In addition, if fibre forms of substances are placed on the market either as such, in mixtures or in articles (or if they can be released from other substances, mixtures or articles placed on the market), the aspect of consumer exposure during its use has to be considered as well.

In conclusion, there is currently no EU-wide legislation in place to adequately address the hazards and risks from substances in fibre form and/or mixtures and articles containing (and/or releasing) fibres, respectively. However, coherent regulation of these forms of substances is urgently needed in order to mitigate risks arising from the manufacture and use of these forms of substances, in particular when taking into account that a variety of advanced materials in fibre form can be anticipated. This could be achieved either by introducing new regulations, by amendments of the legal text of existing regulations or via specific regulatory risk management measures focussing on these forms of substances. Therefore, different options to address the concern identified are discussed in this RMOA, including the introduction of additional risk management options under REACH and OSH.

[5] For Mineral Wool, Note Q[5] and R[5] in Annex VI of the CLP Regulation describe exemptions from the classification as a carcinogen. Note Q describes possibilities for exempting a mineral wool from classification as a carcinogen by experimental testing. By Note R, non-critical substance morphologies for wools (mineral wool, RCF) can be exempted. One example is the Mineral Wool mentioned here (650-016-00-2) which is classified according to C&L Inventory as Carc. 2 and which can be exempted from this classification if the respective proof has been brought by the registrant.

[6] Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work

1.3 Overview of the human health hazard and the related concern

The key factors for the fibre pathogenicity paradigm are dose, dimensions (length and diameter) and biopersistence. It is generally accepted that respirable high aspect ratio particles (fibres) pose an additional hazard beyond that produced by conventional more spherical non-fibrous compact particles (Donaldson, 2009). The note Q criteria[7] in the CLP Regulation are considered to be insufficient to address fibres with the critical morphology, as they focus only on fibres with a length > 20 µm, so that the assessment of relevant fibres between 5 µm and 20 µm is not covered. The fibre length is important for the induction of lung tumours in rat inhalation studies. It is questionable whether results from studies with high doses of fibres with a length > 20 µm are representative for workplace exposure scenarios (Wardenbach et al, 2005).

The aerodynamic diameter of a fibre is an important parameter, which is relevant for the pulmonary deposition. Small aerodynamic diameters enable the deposition beyond the ciliated airways. Fibre length has been shown to be important for the pathogenicity of a fibre. Numerous experimental toxicological studies showed a substantial response on inflammatory processes, fibrosis and proliferative effects for long fibres compared to shorter ones.

There is an interaction between length and biopersistence regarding the clearance of long fibres following inhalation. Non-biopersistent fibres are cleared efficiently from the lungs by dissolution or breakage to shorter fragments, which can then be enclosed and cleared by macrophages. Biopersistent fibres retain their shape and accumulate. Part of the underlying aspects of fibre toxicity is the incomplete phagocytosis of rigid fibres, which exceed a certain length threshold, by alveolar macrophages. Macrophages that are unable to completely engulf long fibres foster pro-inflammatory conditions that lead to a chronic functional tissue damage (fibrosis) or even cancer in the lung and pleura.

A challenge in the assessment of the carcinogenicity of fibres is the fact that the standard test method (long-term inhalation animal studies) for this endpoint is not always informative to demonstrate the carcinogenic potential and also to determine the potency of fibres because of the long lung tumour latency, in particular with regard to mesothelioma formation as well as the considerable low concentration of critical fibres in the pleura. Moreover, carcinogenicity studies under REACH are required in very few cases, i.e. only for very high tonnages (> 1000 t/a, REACH regulation Annex X). The German Committee on Hazardous Substances (AGS) questions the

[7] Note Q: The classification as a carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions: 1) a short term biopersistence test by inhalation has shown that the fibres longer than 20 µm have a weighted half-life less than 10 days; or 2) a short term biopersistence test by intratracheal instillation has shown that the fibres longer than 20 µm have a weighted half-life less than 40 days; or 3) an appropriate intra-peritoneal test has shown no evidence of excess carcinogenicity; or 4) absence of relevant pathogenicity or neoplastic changes in a suitable long term inhalation test.

suitability of rat inhalation tests for the study of the carcinogenicity of fibre dusts because of the following reasons:

- Rat inhalation tests with known human carcinogenic amphibole asbestos resulted in inconsistent carcinogenicity findings at high fibre concentrations.

- Comparing epidemiological data with results from inhalation studies in rats shows that the aerosol fibre concentrations resulting in statistically significant increased lung tumour incidences in rats have to be about two orders of magnitude higher than those inducing significantly increased tumour risks in humans. This also applies if the specific organ doses are compared.

Therefore, lacking tumour findings after long-term inhalation cannot be assessed as an absence of carcinogenicity (AGS, 2010).

Alternatively, more straightforward methods, such as intratracheal instillation or intraperitoneal injection, should be considered. Recently, the induction of both, lung carcinoma and mesothelioma, by MWNT-7 has been demonstrated by long-term intermittent instillation exposure of rats, whereas a preceding 2-year inhalation study was positive for lung carcinogenicity only (Hojo, 2022; Horibata, 2022). Likewise, intraperitoneal injection, which sets a local bolus at sites of mesothelial tissue in the test animal, could reliably inform on the carcinogenic potential of fibres with sufficient biopersistence. Accordingly, Note Q already allows the latter method as an alternative to inhalation exposure, whereas intratracheal exposure currently is to be applied only to demonstrate the absence of biopersistence in a short-term assay. Lung tumours or mesothelioma develop independently from the used species (rat, mouse, hamster). Incidental development of mesothelioma can be excluded because the spontaneous incidence is low. Direct injection of fibres into the peritoneum of rats does not represent a physiological exposure scenario of workers, however, the resulting mesotheliomas are considered predictive, as the induced mesothelioma in the peritoneum are observed after inhalation in humans. Asbestos workers did suffer not only from pleural mesothelioma but also from mesothelioma of the peritoneum (AGS, 2010).
The scope of this RMOA includes substances in fibre form with a diameter below 3 µm (respirable fibres), as well as mixtures containing these substances. Also articles that can release respirable fibres during their life cycle because of mechanical stress (breaking/splicing), chemical processes (oxidation/ageing) or physical conditions (heat) are included.

2 Overview: uses of substances in fibre form

Some substances in fibre form are already registered under REACH. The total tonnage bands differ widely from substance to substance, from just a few tons per year (e.g.: EC no. 266-046-0) to 1 million to 10 million t/a (e.g.: List no. 926-099-9). Others, such as List no. 926-722-4 or List no. 607-870-6 for example, have only pre-registration status.

Substances in fibre form are used widely. Common registered uses are for applications in thermal-, high temperature- and/or acoustic insulation (e.g.: List no. 926-099-9, List no. 604-314-4, List no 931-219-8 or List no. 610-130-5). There are also registered uses in fire prevention materials, the automotive industry, in engine brakes, in agriculture and in food production, in paper products manufacturing, in bricks, ceiling tiles, ceramic panels, construction articles and in plastic manufacturing (e.g.: List no. 926-099-9). Other fields of application are the uses in tires (e.g.: List no. 936-414-1), in rubbers, plastics, composites, adhesives and sealants (e.g.: List no. 951-407-3), as well as the use in research and development and in laboratories.

Some substances in fibre form are used in filtration non-wovens (e.g.: List no. 926-099-9), in filtration media (e.g.: List no. 926-099-9 and EC no. 266-046-0), in batteries as separators or as components, in electrical appliances (e.g.: List no. 926-099-9, List no. 936-414-1 and List no. 951-407-3) or in functional or process fluids (e.g.: List no. 926-099-9, List no. 604-314-4 and List no. 931-219-8). Registered uses also include mixtures with water or other solvents (e.g.: List no. 936-414-1), mixtures and/or articles with thermosets, thermoplastics or elastomers and with inorganic materials or with metals (e.g.: List no. 936-414-1 and List no. 701-160-0). Furthermore, substances in fibre form are used in coatings, paints and inks (e.g. List no. 936-414-1 and List no. 951-407-3) as well as for chemical functionalisation and as intermediates (e.g.: List no. 936-414-1).

For more detailed information see Annex 3: Overview of uses based on information available in registration dossiers, where an overview of uses based on the available information in registration dossiers for a group of exemplary chosen substances in fibre form has been gathered.

For these examples, professional and/or consumer uses (which are expected to be widespread (at many sites and by many users)) and/or uses in article service life are registered for all of the applications mentioned above, except for the use in chemical functionalisation and as intermediates.

There are at least some registered applications (PROCs) for most of the uses mentioned above (except for the uses in fire prevention materials, in the automotive industry, in engine brakes, in agriculture and food production, in plastic- and paper products manufacturing and for chemical functionalisation) that lead to a potential for human exposure (see Annex 3).

3 Justification for the need for a regulatory risk management action at EU

Current scientific knowledge establishes that fibre dusts, irrespective of their chemical properties, are harmful to human health, if the fibres are sufficiently long, thin and biopersistent. Requirements for the placing on the market of chemical substances, mixtures and articles in the European Union

need to take this into account. Fibre forms of different substances have a similar mode of carcinogenic action that require fibre-specific risk assessments largely independent of substance identity.

3.1 Already existing regulation

3.1.1 EU chemicals regulation

Several substances in fibre form are already classified according to the EU **CLP Regulation:**

The harmonised classification for mineral wools in Annex VI of the CLP Regulation (EC No 1272/2008) specifies in Note R the determination of the length-weighted mean geometric diameter of fibres (Method A. 22 according to Regulation (EC) No 761/2009 amending Regulation (EC) No 440/2008 laying down test methods) in terms of exemption.

Furthermore, Note Q specifies four different in vivo toxicological test methods for exempting fibres from the classification as hazardous for humans. These criteria were developed in 1999 by the Joint Research Centre, Ispra (Italy) on behalf of the European Commission. Meanwhile, the determination of biopersistence by intratracheal instillation (ECB/TM/27 rev. 7) and the carcinogenicity test by intraperitoneal injection (ECB/TM/18(97) rev. 1) have also proven to be particularly reliable for the assessment of adverse health effects of fibre dusts for substances in fibre form.[8] However, the chronic toxicity test (B. 30 according to Regulation (EC) No. 440/2008 laying down test methods under the REACH Regulation, (EC) 1907/2006) does not adequately reflect the extent of the health effects of fibre dusts in humans. This also applies to other inhalation test methods provided for the registration requirements in the REACH Regulation.

A number of substances in fibre form are already registered under **REACH**. However, no requirements currently exist to provide explicit information on possible release of biopersistent fibre dusts in the registration.

3.1.2 Other EU legislation

Under the **OSH legislation,** Directive 2009/148/EC: risk management measures for the protection of workers from the risks related to exposure to asbestos at work, apply. As part of the directive, a BOELV of 0.1 f/cm^3 is valid for asbestos (2009/148/EC)[9]. However, lower values of 0.01 – 0.001 f/cm^3 are currently under discussion and could possibly be indicative for other substances in fibre form with critical dimensions. For example, in Germany occupational exposure limits (risk-based acceptance and tolerance thresholds) currently exist only for asbestos and refractory

[8] Ausschuss für Gefahrstoffe - Begründungen zur TRGS 905: Anorganische Faserstäube (außer Asbest), https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/905/905-anorganische-fasern.pdf

[9] 0.1 f/cm^3 means fibres per cubic centimetre of air as an eight-hour time-weighted average

ceramic fibres. The asbestos acceptance threshold is also recommended as an assessment standard for rigid nanofibre materials (TRGS 527[10]).

3.2 Regulatory option analysis

3.2.1 EU chemicals regulation

As outlined above in section 3.1.1, harmonised classification as carcinogenic under certain conditions is already in place for mineral wools. The pragmatic approach taken there is also transferable to other fibre types that may have a potential to contain and/or release respirable fibre dust. This would require preparations for a proposal for harmonised classification and labelling for the whole group of fibrous and fibre-releasing substances fulfilling the hazard criteria. Such a proposal is not considered a prerequisite but could support a potential restriction proposal. On the other hand, such a CLH process takes time and might delay further regulatory action. In addition, CLH is not applicable to articles. Therefore, this is not the preferred option.

Another option that has been considered is the implementation of the fibre pathogenicity paradigm in the **CLP Regulation.** For this, it would be necessary to expand the classification criteria so that the hazards from substances and mixtures that release alveolar and biopersistent fibre dusts, can be adequately covered in the classification system. A harmonised classification as a health hazard in a new hazard class “biopersistent fibres” is an option for consideration that could be based on the morphology and biopersistence of substances in fibre form and would only concern the inhalation route. Currently neither the UN GHS nor the CLP regulation are addressing the hazards from substances in fibre form and/or mixtures containing (and/or releasing) fibres. The implementation of the fibre pathogenicity paradigm as a new hazard class under the CLP Regulation would prompt the need to adopt the UN-GHS guideline to ensure that there is global consistency in the classification and labelling of chemicals. The aMSCA acknowledges that the implementation and further development of the “Globally Harmonised System for classification and labelling” implemented in the CLP regulation in the EU is a key instrument for the effectiveness of a global chemicals management. The aMSCA welcomes future initiatives to address potential hazards at a global and EU scale. However, we would like to note that the scope addressing the hazards of certain forms of substances and mixtures may/should not be limited to fibres. Therefore the scope would be much broader than the scope of this RMOA and thus would need a thorough EU-wide/international discussion. Consequentially, this is not the preferred option.

An amendment of Note Q is not considered effective as this would only affect substances in fibre form that have a harmonised classification.

[10] Technical Rule for hazardous substances 527: Activities with nanomaterials https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/TRGS-527.html

Articles are not covered by the CLP regulation and to achieve a harmonised regulation, which considers the fibre toxicology paradigm also for articles of concern, amending the CLP regulation is not sufficient.

As a regulatory option under **REACH,** the **authorisation** process was considered. The main aim of the authorisation procedure is the substitution of SVHC-substances. Because of the expected widespread uses of substances in fibre form in the future, a step-wise substance-driven substitution would not be a viable option to regulate hazardous fibres. In addition, it might not be possible to include all substances in fibre form in Annex XIV to Regulation (EC) No 1907/2006 and regrettable substitution could occur. A more pragmatic, i.e. generic or tailored approach is required. Furthermore, the socioeconomic benefits of fibre-based advanced materials to realise resource and energy savings and thus supporting the Green Deal are considered to be significant. Therefore, the authorisation process is not considered proportionate. Furthermore, the use of substances as intermediates as well as their presence in imported articles are not covered, causing a further problem for a coherent regulation of fibre materials.

As an example, the DE CA intended to include all RCF in Annex XIV for authorisation as the most effective measure. Certain aluminium silicate RCF (Al-RCF) and zirconia-aluminosilicate RCF (Zr-RCF) meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore meet the criteria for inclusion in Annex XIV to Regulation (EC) No 1907/2006 set out in Article 57(a) of that Regulation.[11] Al-RCF and Zr-RCF are used in very high volumes in the scope of authorisation. The use of articles made from these substances is expected to take place at a high number of sites, and can potentially lead to significant worker exposure. Therefore, it was proposed to prioritise Al-RCF for authorisation.[12] However, the use of articles consisting of fibres is not subject to authorisation under Regulation (EC) No 1907/2006. In order to decide on the most appropriate regulatory approach, the Commission considers it appropriate to postpone the decision on the inclusion of Al-RCF and Zr-RCF in Annex XIV to Regulation (EC) No 1907/2006 for the time being. Those fibres are manufactured at a very limited number of industrial sites and are in general directly transformed within the same manufacturing process into articles that are subsequently used in a broad range of industrial equipment for high-temperature insulation potentially leading to a significant worker exposure.

As another option, **supplementary information requirements for the REACH registration** of the fibre forms of substances could be introduced. This would require a revision of the REACH Regulation. However, **supplementary information requirements** for REACH registration would not cover articles. Additionally, there is a gap in data regarding the fibre pathology paradigm; manufacturers and importers might not know that

[11] Al-RCF: https://echa.europa.eu/de/candidate-list-table/-/dislist/details/0b0236e1807db749
Zr-RCF: https://echa.europa.eu/de/candidate-list-table/-/dislist/details/0b0236e1807db873
[12] Al-RCF: https://echa.europa.eu/de/recommendations-for-inclusion-in-the-authorisation-list/-/dislist/details/0b0236e1807dfc79
Zr-RCF: https://echa.europa.eu/de/recommendations-for-inclusion-in-the-authorisation-list/-/dislist/details/0b0236e1807e1c07

their substance or mixture contains or is made of fibres with a critical morphology, and in workplaces activities at risk are often not recognised because of a lack of information. Therefore, employers do not have sufficient information to implement a workplace risk assessment that protects employees from fibres with a critical morphology adequately.

A **REACH restriction** has, therefore, been considered, as it could also cover articles and allows to regulate substances in fibre form and mixtures containing these substances before they are placed on the market. A restriction may not only cover substances, mixtures and articles, but could also cover substances, mixtures and articles that release other substances, which would encompass both cases of potential release of fibre dusts (WHO fibres) described above. Furthermore, a restriction could address entire groups of substances at once, providing an advantage over authorisation, where individual substances would have to be assessed case by case. Also, the conditions under which the restriction applies could be defined precisely. Moreover, the restriction is a very flexible instrument that can define all possible types of risk reduction measures. Exceptions to the restriction and a wide variety of transition periods for a step-by-step restriction could also be defined. Finally, a restriction encourages the industry to consider safer innovation and safety-by-design approaches even before an (innovative) material will enter the market.

The aMSCA, hence, proposes an entry in Annex XVII (Restriction) of the REACH regulation covering the use and the placing on the market of substances in fibre form as well as mixtures and articles containing these substances or releasing fibre dust, if the fibres themselves or the released fibre dust contain or consist of particles with a length greater than 5 µm, a diameter smaller than 3 µm and a length-to-diameter ratio larger than 3:1 (WHO fibre criterion[13]) and are biopersistent. Exemptions from the restriction could be formulated in a way, so that it would be possible to demonstrate via a tiered testing strategy that a substance, mixture or article, even if fulfilling the WHO fibre criterion, does not pose a risk to human health.

The following five-tiered testing strategy is only a rough outline and would be further specified in the restriction proposal. It could encompass the following steps:

At tier 1, the solubility should be assessed, for which standard methods according to the Test Method Regulation[14] can be applied. Additionally, within OECD WNT Project 1.5, a new Guidance document (GD) on the solubility of nanomaterials is currently being developed.[15] The extension to substances in fibre form would have to be evaluated.

[13] Reference Method for Measuring Airborne Man-made Mineral Fibres (MMVF). Environmental Health Report No.4. Copenhagen, Denmark: World Health Organization, Regional Office for Europe; 1985.
[14] Council Regulation (EC) No. 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
[15] WNT Project 1.5: Determination of solubility and dissolution rate of nanomaterials in water and relevant synthetic biologically mediums – anticipated finalisation 2023

At tier 2, a dustiness test to assess the release potential of relevant particles should be applied, using the methods laid down in ISO/TS 12025:2021(en) or EN 17199:2019, between those two, the more appropriate one should be selected. Moreover, OECD WNT Project 1.8 adds the fibre specific method of vibro-fluidisation to a new OECD Test Guideline (TG), which will also comprise the methods of EN 17199:2019.[16]

Tier 3 would evaluate the morphology of the fibres, if they fulfil the WHO-criteria or release fibres with critical morphology, for which OECD TG 110 and TG 125 can be used for bulk material and nanomaterial, respectively.[17] Additionally, information on the rigidity of the fibres are important; to obtain the data, the application of ISO TS 11888 could be one approach.

At tier 4, the fibres should be tested on their biopersistence or their carcinogenicity, for which the methods laid out in Note Q of Annex VI, CLP regulation, are a reference. However, the four methods described aim at MMVF, and further method development is necessary.

As a final step (tier 5), the exposure and the life-cycle of the fibres should be assessed, for which EN 15051:2014 can be used as a reference, yet it is not specific for fibre forms. Additionally, OECD WNT Project 1.8 also develops an OECD GD for using dustiness data for the exposure assessment[18] and an OECD WPMN project develops guidance on release tests[19]. If no safe production and use can be achieved, there is a fibre-related concern, with the need for additional risk management measures. When applying this tiered strategy, advancing to the next tier is necessary if the prior tier results in a concerning test outcome.

3.2.2 OSH legislation

The expected increase of uses of advanced materials, which could possibly release biopersistent fibres and fibre dusts with critical morphology, poses an increased risk for workers. The negative experience with asbestos clearly shows that the manufacture, use and disposal of fibres and materials containing fibres can be associated with significant risks to human health if their safety is not proven by the results of appropriate testing and assessment methods. It needs to be checked whether these risks could be addressed by OSH legislation. Therefore, supplementing Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work with specific protective measures against alveolar and biopersistent fibre dusts released during the life cycle from substances, mixtures or articles was considered. In addition, specific protective measures, up to a ban on exposure (cf. Directive 2009/148/EC on the protection of workers from the risks related to

[16] WNT Project 1.8 Aim #1: New TG on Determination of the Dustiness of Manufactured Nanomaterials – anticipated finalisation 2024
[17] OECD TG 110: Particle Size Distribution/Fibre Length and Diameter Distributions
OECD TG 125: Testing of Chemicals Particle Size and Particle Size Distribution of Nanomaterials
[18] WNT Project 1.8 Aim #2: Guidance on using dustiness data for nanomaterials exposure assessment modelling
[19] WPMN Project: Guidance on Release Tests for Manufactured Nanomaterials

exposure to asbestos at work), could be established for specific hazardous activities.

The main disadvantage would be that sufficient and informative data from a defined testing and evaluation strategy for substances in fibre form, and for fibre materials and articles are needed for risk assessment at the workplace, but are not available (yet) and hence a regulation via OSH would not be effective. An adequate selection of effective occupational health and safety measures is not possible within the framework of the risk assessment according to Directive 98/24/EC, if the employer obliged to provide protection is not informed by the supplier about hazards and necessary measures. However, this would be of particular importance for the definition of adequate occupational health and safety measures, in particular when developing new and high-performance fibre materials. Furthermore, OSH legislation under Art. 153 TFEU requires implementation in the legal systems of the Member States, which could lead to distortions of competition in the EU internal market.

3.2.3 Conclusion on the most appropriate (combination of) risk management options

To protect citizens and workers from hazardous fibre dusts, the integration of the fibre pathogenicity paradigm into the EU regulatory framework is important. The aMSCA proposes a restriction of biopersistent (Fibre) materials (as substances as such, in mixtures or articles) with the potential to release fibre dusts fulfilling the WHO criteria in combination with a mandatory tiered approach to assess critical parameters such as the solubility, biopersistence and the dust behaviour of solids within the framework of a restriction under REACH with the possibility to make use of derogations if sufficient data can exclude a fibre-related health concern.

In particular, also mixtures and articles that release fibre dusts would be covered by a restriction, whereas it is not possible to reach the same goal with registration obligations.

Additional actions in CLP, which are connected with UN GHS adaptions, are not considered further because of the considerable amount of time needed. Specific complementary OSH regulations may be needed/advantageous to avoid regulatory gaps, but the difficulties to generate a harmonised approach under OSH across the EU have to be taken into account. Additionally, establishing effective risk management under OSH requires communication of adequate information on hazard, exposure potential and corresponding control strategies /to employers via the supply chain.

4 Conclusions and actions

Table 1: Conclusions and proposed actions for regulatory risk management options

EC /List/CAS number	Human Health Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
926-099-9	Known or potential hazard Dermal irritation Eye and respiratory irritation Possible critical morphology → fibre pathology to be considered	Widespread uses	Need for EU RRM: Restriction Justification: Restriction preferred over authorisation as it is considered more efficient to regulate the placing on the market. The proposed assessment strategy for the "fibre pathogenicity paradigm" would be possible with a restriction	**Next steps (if hazard confirmed):** Restriction
604-314-4 142844-00-6	Known or potential hazard acute mechanical irritation of the skin and eyes Possible critical morphology → fibre pathology to be considered	Widespread uses		
931-219-8	Possible critical morphology → fibre pathology to be considered	Widespread uses		
266-046-0 65997-17-3	Possible critical morphology → fibre pathology to be considered	No high potential for human exposure		
610-130-5 436083-99-7	Possible critical morphology → fibre pathology to be considered	Widespread uses		
308076-74-6	Carcinogenic	Unclear		
926-722-4 926-722-4	Possible critical morphology → fibre pathology to be considered	Not enough information available		
936-414-1 701-160-0 951-407-3	Possible critical morphology → fibre pathology to be considered	Widespread uses		
607-870-6 26125-61-1	Possible critical morphology → fibre pathology to be considered	Not enough information available		
Other	Possible critical morphology → fibre pathology to be considered	Not enough information available		

5 References

Committee for risk assessment (2020) Opinion proposing harmonised classification and labelling at EU level of Multi-Walled Carbon Tubes (synthetic graphite in tubular shape) with a geometric tube diameter range ≥ 30 nm to < 3 µm and a length ≥ 5 µm and aspect ratio ≥ 3:1, including Multi-Walled Carbon Nanotubes, MWC(N)T; CLH-O-0000007108-75-01/F

Committee on Hazardous Substances (AGS) (2010). ERR (exposure-risk relationship) for aluminium silicate fibres, https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/pdf/910/910-aluminium-silicate-fibres.pdf

Cullen, R.T., Searl, A., Buchanan, D., Davis, J.M.G., Miller, B.G., Jones, A.D.; (2000) *Pathogenicity of a special-purpose glass microfiber (e glass) relative to another glass microfiber and amosite asbestos*, Inhalation Toxicology, 12:10, 959-977, DOI: 10.1080/08958370050138012

ECHA Dissemination site; https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15024/7/2/2/?documentUUID=b64b96f8-dd7d-4b00-9ba9-5b264adb6760

Fortini, R., Meyer-Plath A., Kehren, D.,Gernert, U., Agudo Jácome, L., Sturm, H; (2020) *Measurement of Flexural Rigidity of Multi-Walled Carbon Nanotubes by Dynamic Scanning Electron Microscopy,* fibres, 8:5, 31, DOI: 10.3390/fib8050031

Donaldson, K.; (2009) *The inhalation toxicology of p-aramid fibrils*, Critical Reviews in Toxicology, 39:6, 487–500, DOI: 10.1080/10408440902911861

Bäger, D., Simonow, B., Kehren, D., Dziurowitz, N., Wenzlaff, D., Thim, C., Meyer-Plath, A., Plitzko, S.; (2019) *Pechbasierte Carbonfasern als Quelle alveolengängiger Fasern bei mechanischer Bearbeitung von carbonfaser-verstärkten Kunststoffen (CFK)* (German) Gefahrstoffe – Reinhaltung der Luft, 79:1-2, 13-16

Bäger, D., Plitzko, S., Broßell, D., Dziurowitz, N., Thim, C., Wenzlaff, D., Hutsch, T., Weißgärber, T., Rießelmann, J.; (2020) *Anwendungssichere nanokohlenstoffbasierte Fasermaterialien* (German) Gefahrstoffe – Reinhaltung der Luft, 80:7-8, 257-265

Hartwig, A., MAK Commission (2020) Siliciumcarbid (Faserstaub) (einschließlich Whisker). MAK-Begründung, Nachtrag. (German) The MAK Collection for Occupational Health and Safety, 5:4 Doc076, DOI: 10.34865/mb40921d5_4ad

Hojo, M., Maeno, A., Sakamoto, Y., Ohnuki, A., Tada, Y., Yamamoto, Y., Ikushima, K., Inabata, R., Suzuki, J., Tquahashi, Y., Yokota, S., Kobayashi, N., Ohnishi, M., Goto, Y., Numano, T., Tsuda, H., Alexander, D., Kanno, J.,

Hirose, A., Inomata, A., Nakae, D.; (2022) *Two-year intermittent exposure of a multiwalled carbon nanotube by intratracheal instillation induces lung tumors and pleural mesotheliomas in F344 rats*, Particle and Fibre Toxicology,19, 38, doi: 10.1186/s12989-022-00478-7

Horibata, K., Takasawa, H., Hojo, M., Taquahashi, Y., Shigano, M., Yokota, S., Kobayashi, N., Sugiyama, K-I., Honma, M., Hamada, S. (2022*) In vivo genotoxicity assessment of a multiwalled carbon nanotube in a mouse ex vivo culture*, Genes and Environment, 44, 24, doi: 10.1186/s41021-022-00253-2

Kehren, D., Simonow, B., Bäger, D., Dziurowitz, N., Wenzlaff, D., Thim, C., Neuhoff, J., Meyer-Plath, A., Plitzko, S.; (2019) *Release of Respirable Fibrous Dust from Carbon Fibers Due to Splitting along the Fiber Axis,* Aerosol and Air Quality, 19, 2185-2195, DOI: 10.4209/aaqr.2019.03.0149

Mattenklott, M., van Gelder, R.; (2019) *Carbonfasern und carbonfaserverstärkte Kunststoffe (CFK) Teil 1: Charakterisierung, Exposition, Bewertung und Schutzmaßnahmen.* (German). Gefahrstoffe - Reinhaltung der Luft, 79:9, 317-322

Oberdörster, G., Maynard, A., Donaldson, K., Castranova, V., Fitzpatrick, J., Ausman, K., Carter, J., Karn, B. Kreyling, W., Lai, D., Olin, S., Monteiro-Riviere, N., Warheit, D., Yang, H.; (2005) *A report from the ILSI Research Foundation/Risk Science Institute Nanomaterial Toxicity Screening Working Grou*p, Particle and Fibre Toxicology,2, 1-35

Pott, F., Friedrichs K. H.; (1972) *Tumoren der Ratte nach i.p.-Injektion faserförmiger Stäube* (German), Naturwissenschaften, 59: 7, 318

Searl, A., Buchanan, D., Cullen, R.T., Jones, A.D., Miller, B.G., Soutar, C.A.; (1999) *Biopersistence and durability of nine mineral fibre types in rat lungs over 12 months*, The Annals of Occupational Hygiene, 43:3, 143–153, DOI: 10.1093/annhyg/43.3.143

Schinwald, A., Murphy, F.A., Prina-Mello, A., Poland, C., Byrne, F., Movia, D., Glass, J. Dickerson, J., Schultz,D., Jeffree, C.; (2012) *The threshold length of fiber-induced acute pleural inflammation: Shedding light on the early events in asbestos-induced mesothelioma*, Toxicological Sciences, 128:2, 461-470, DOI: 10.1093/annhyg/43.3.143

Stanton, M.F. Wrench, C.; (1972) *Mechanisms of mesothelioma induction with asbestos and fibrous glass*, Journal of the National Cancer Institute, 48:3 797-821

Steinhausen, M., van Gelder, R., Gabriel, S.; (2012) *Arbeitsbedingte Expositionen gegenüber krebserzeugenden, erbgutverändernden oder Fortpflanzungsgefährdenden Substanzen in Deutschland* (German), Gefahrstoffe - Reinhaltung der Luft 72:9, 347-358

Wardenbach P., Rödelsperger K., Roller M., Muhle H.; (2005) *Classification of man-made vitreous fibers: Comments on the revaluation by an IARC working group.* Regulatory Toxicology and Pharmacology 43:2, 181-193 DOI: 10.1016/j.yrtph.2005.06.011. PMID: 16099571.

Westphal, G., Monsé, C., Walter, D.; Brüning, T., Bünger, J.; (2019) *Gefährdungsanalyse für Carbonfaser-verstärkte Kunststoffe* (German) IPA-Journal 01, 10-13