Written evidence from the British Occupational Hygiene Society (ASB0025)

About the British Occupational Hygiene Society and the Faculty of Asbestos Assessment and Management

1.1 The British Occupational Hygiene Society (BOHS) is a scientific charity and the Chartered Society for Worker Health Protection in the United Kingdom. The Faculty of Asbestos Assessment and Management (FAAM), which it hosts is the UK's pre-eminent body in the science and practice of asbestos assessment. BOHS has had a longstanding role in advising upon occupational exposure limits in asbestos and was responsible for recommending the first Phase Contrast Microscopy (PCM) limit based on personal sampling, which remains the basis of the current OEL for asbestos in the EU.

1.2 BOHS (FAAM) continues to be the leading independent technical and scientific voice for asbestos assessment and management in the UK. For example, it recently provided detailed technical and scientific comment on the ECHA Scientific Report for evaluation of limit values for asbestos at the workplace, bringing together the leading UK and international voices from science and practice in the area. (see Appendix 1).

1.3 FAAM recognises that at the present time, peak levels of asbestos-related cancers from past industrial manufacture and use are occurring in the EU member states, reflecting the outcomes of regulatory approaches and the limits of scientific knowledge in the past. Asbestos is also the subject of widespread litigation. This has a distorting effect on the current approach to regulation, which has to reflect the current concern for past shortcomings. BOHS (FAAM) continue to be concerned for the impact of current regulation on the future, but also on the quality of the industry that supports the control of asbestos.

What are the current risks posed by asbestos in the workplace? Which groups of workers are most at risk?

2.1 HSE has been a key reference point for collating statistics on asbestos diseases (https://www.hse.gov.uk/statistics/causdis/). Given the latency of diseases and the changes in employment sectors, practices impacting the exposure levels of different occupational groups, it would be imprudent to take these data as anything other than broad indicators of occupational risk categories.

2.2 The list of work categories for those who are likely to disturb or remove asbestos remains valid. (See tables in https://www.hse.gov.uk/statistics/pdf/occ8000.pdf)

2.3 Individuals working in occupations where undetected or disturbed asbestos may pose a hidden risk may include those working in hospitals and schools. That the education professionals and teacher's PMR has risen from 95% 2001-2010 to 143% in 2011 -2019 will not doubt attract much attention. These figures may reflect exposures dating back several decades, but the possibility of continued exposure should not be discounted because of the nature of older estate in educational and healthcare establishment.

2.4 HSE data is driven by the well-established association between asbestos exposure and mesothelioma. Other illness caused by asbestos exposure have less clear links, but may not be statistically insignificant.

2.5 Construction and allied trades will continue to face a risk of exposure to asbestos, especially as more commercial buildings are converted for residential use, with the upgrading of older stock in relation to enhanced electrical wiring and energy efficiency standards. The prevalence of SMEs and the absence of systematic education on asbestos (and other health protection) risks may lead to this becoming a particular occupational risk group.

2.6 Waste management will continue to be an area where inadvertent asbestos handling is likely to take place. The absence of comprehensive and affordable asbestos disposal services may lead to mixing of asbestos into general waste. Manual separation of recycling materials by waste management workers may lead to inadvertent exposure. In these roles, where it may not be easy to discriminate between different forms of asbestos, additional precautionary measures may be relevant, such as adopting the European recommendation

2.7 Reliable data and monitoring in both the SME construction sector workers, energy/insulation installers and of a single limit for exposure among waste management manual workers does not appear to be available. Given current trends, a focus on credible monitoring of these at-risk sectors is a necessary underpinning for an effective regulatory regime. Visible monitoring of at-risk groups not only gives early warning on trends, but can engender a better compliance focus and awareness in the affected industries.

2.8 The EU's modifications to the Directive earlier this century aimed to reflect the changing patterns of exposure in the workplace. As asbestos is no longer installed and used, the workers most affected are those involved in plant and building maintenance and development, as well as analysis, removal and disposal. Consideration needs to be given to future trends, particularly the development of the Green Economy and the likely impact on workplace exposure.

How effective is the current legislative and regulatory framework for the management of asbestos?

3.1 The current legislative and regulatory framework represents an approach developed by the UK and modified to comply with the requirements of European Law. For this reason, the legislative and regulatory approach may not, in principle, be aligned with the policy priorities of the UK post-Brexit. In practice, however, implementation of any Directives enables States to determine the most appropriate means of achieving the common standards set out for Europe. Thus, the effectiveness of the means of implementation will be determined to a large extent by the UK's own regulatory approach.

3.2 The current regulatory policy set with an eye to balancing a range of priorities, including social need, economics and health. The UK has a unique opportunity to recognise that health protection in the workplace and in buildings can have a disproportionately positive effect on future health, social opportunity and the future economic burdens of care. Prioritising preventative health protection at a time when building stock is undergoing radical transformation to environmental goals provides a once-in-a-lifetime opportunity to focus on the removal of this pervasive toxin from the environment.

3.2 This will not, however, be achievable by regulatory and enforcement means alone. Our current regulatory approach balances the immediate costs and practicability of removal (as opposed to management in situ) with the long-term risk of maintaining a toxin that pervades the fabric of our constructed environment.

3.3 However, the longer the maintenance in situ approach is taken, the greater the risk of accidental exposure, defaults in duty-holder management and long-term costs of maintenance. Fiscal and financial incentives to undertake safe removals, the integration of asbestos surveying and removal into any programme of building upgrading for environmental purposes and a programme of education are necessary complements to a more effective regulatory regime.

3.4 Without these, the current pragmatic policy of trying to prioritise the immediate health and safety of workers to gradually enable the dilution of the presence of asbestos in our environment is probably the only regulatory policy that is sustainable.

3.5 Essential to effective regulation is the setting of Workplace Exposure Levels. In terms of the standards set as exposure levels, Europe is currently consulting on new standards for asbestos exposure and had we not left the European Union, HSE would need to consider the implications of those changes. BOHS provided feedback from the Faculty of Asbestos Assessment and Management on those proposed exposure limits. HSE is currently in the process of determining a new methodology for setting Workplace Exposure Levels now that we no longer can draw upon the resources or are required to follow the European ECHA process.

3.6 At present there is not a clear process for WEL setting for asbestos (or any other substance). The importance of clarity in process for standard setting is the impact that the process has on compliance. Prior to the European responsibility for WEL setting the UK had an excellently resourced system to draw upon scientific expertise and then to engage with worker representation and employer representation.

3.7 Current HSE proposals for WEL setting, which would include standard setting would rely upon advice from a) WHEC Workplace Health Expert Committee (WHEC) (hse.gov.uk) a small handpicked group of experts who are not representative of scientific bodies per se, but appointed in the personal capacities; and b) the Board of HSE, which will not have intrinsic knowledge of the complex issues that need detailed consideration when setting WELs for specific substances. This will be supported by the excellent, but heavily reduced, scientific capabilities of HSE's science division.

3.8 This is a very slim resource to address every current and future substance that workers may be exposed to. Even with industry consultation, this capability may fundamentally undermine the credibility of future regulations because of the potential for scientific oversights, insufficient structured consultation and engagement and public law challenge. The future capability of HSE to originate essential tools for the regulation of asbestos will be undermined by the weaknesses in this infrastructure. The capability to evolve and develop appropriate regulatory responses will be impeded by a lack of available resource as highlighted by the years that it has taken to update the HSE Asbestos Analysts Guide and the fact that the Regulations have not been materially updated in years.

3.9 This is not to say that HSE has done its job badly – far from it. HSE's own Post-Implementation Review of the last changes to the Asbestos Regulations highlights the societal impact of restricting exposure to asbestos. It is, in many ways, an exemplar of the hidden opportunity to rescue the UK from thousands of stories of personal tragedy and billions wasted in preventable additional health and social care costs. Asbestos represents a large proportion of the know occupational diseases which account for an estimated 1.6m people's health problems. Occupational disease arises from exposures that occur in the workplace. The workplace is an environment which is invariably wholly controllable by humans. In this sense, all occupational diseases are preventable.

3.10 Asbestos is a perfect example of the health and social care cost of failure to adequately prevent harmful exposures through integrated legislative and fiscal policy in the workplace and the importance of effective regulation. The peak of asbestos illness witnessed this century came after much of the medical evidence related to exposure was known. The risk threshold that we tolerated for asbestos exposure was determined by the perceived challenge for industry, rather than the cost to society and the individual. The research highlighted that implementation of a better regulatory regime will lead to 25,700 fewer deaths this century.

3.11 The projected savings in financial terms were estimated at £20.9 bn largely through the enforcement efforts of HSE and the associated responsible bodies. However, given exposure to asbestos could be almost entirely prevented, this impact could be scaled ten-fold. This could be achieved by a more direct drive to remove asbestos, clearer tools for the management of the asbestos duty and a more aggressive enforcement campaign, backed by more resources for HSE and Local Authorities.

3.12 In common with other occupational diseases, the costs of ineffective regulation are the costs of health and social care, of benefits for those who become ill and those they support, declining revenue from tax and national insurance from shortened working lives, as well an indirect costs to productivity. These dwarf the costs of enforcement and the burden on business.

3.13 The cost to British industry of poor regulation is significant as well, and there is a hidden asbestos premium in the additional funds being raised through national insurance for health and social care which is to support those in need of treatment and care as a result of occupational disease. In addition, the cost of litigation, averaging £100k per claim, is a burden on British business.

3.14 However, the direct regulatory cost on industry for duty-holders and employers is marginal to bear the cost of compliance with avoiding exposing people and the environment to this toxic substance. As the PIR report states:

> "Additionally, the research on costs to society of work-related cancer described in paragraph 45 shows that it is the individuals affected by work-related cancer who bear the overwhelming majority of the costs of that condition (98% of the total). By comparison, employers bear a disproportionately small share of the overall costs. The latency of work-related cancer, which is often decades, means that by the time most individuals are diagnosed with cancer, they are beyond retirement age, and many of those who are still working will be with a different employer or even in a different industry. This limits the financial incentives for employers to reduce those exposures based on concern for 'the bottom line' alone. The finding provides an economic rationale for government to continue to intervene in this area, and for HSE to support, incentivise and regulate businesses to address cancer risks."

3.15 The capacity of HSE, Local Authorities (LAs) and the Office of Rail and Road (ORR) to enforce asbestos regulations is limited by funds. The capacity to comply is limited by the availability of affordable disposal options, the "leave it alone" option and the absence of systematic regulation tools such a searchable register of asbestos for purchasers of buildings, developers, small constructors etc.

3.16 The relatively low priority of asbestos and the way in which the insurance market has "accepted" the risk has another economic effect. There is no great driver for high quality and wide-ranging asbestos surveys and analysis. Survey standards are not uniformly good and there are variable standards in the quality and nature of reports. Asbestos surveys and reports may be seen as a tick-box exercise and/or leave clients not fully approved of the risks or opportunities that they have as duty-holders. Again, the resource to assure this is limited and there are few drivers for professionalisation in the industry. A British Standard for reports and a better-defined standard for asbestos surveys would assist the duty-holder, the asbestos removal industry and the regulator.

3.18 The Faculty of Asbestos Assessment and Management is an attempt to link professional standards and practice to the industry and is supported by the HSE. New arrangements in Appendix 9 of the Analysts Guide highlight the need for better professional standards. However, a statutory professional register for those qualified to work with this toxic substance (and indeed other occupational exposures) would provide the public and business with more assurance that they are being properly protected.

3.19 In the absence of a national sense of priority over asbestos and adequate resources in the policy, scientific and enforcement divisions of HSE, its risk-based approach to enforcement seeks to use limited funds to prioritise the engagements they have with duty holders and those undertaking work. Consequentially, the market takes a risk-based approach to compliance. Asbestos analysts report to the Faculty decreasing levels of funding and time available for asbestos surveys to detect the extent of asbestos and lower levels of expertise being deployed consequently by asbestos surveying companies.

3.20 The quality challenges and need to improve the levels of compliance are reflected by the fact that HSE's recently reviewed guidance on asbestos analysis and management (which was several years in the making) is the longest of all HSE's guides.

3.21 The absence of regulatory resource, the desire to ensure minimum interference with business, resulting in different regulatory systems for different levels of risk and the complex guidance are clear indicators of a regulatory system which may been inefficient. Clarity and consistency are not features of the asbestos regulatory regime, creating challenges for the regulators, those involved in delivering services and for business. In civil law claims on asbestos, the simplification of rules of evidence in relation to causation, exposure limits and process provide a sharp contrast.

3.22 Further, consideration of a civil law statutory remedy to challenge the decision to of duty holders to leave asbestos in situ should be contemplated.

3.22 If the regulatory bodies are not to be more adequately resourced to deal with the complex and nuanced area of asbestos, then a simpler and clearer regulatory system may be desirable. This may include the codification and simplification of the civil claims process which has evolved in the common law. Enabling claimants to have an expedited process of claim, the moment they are diagnosed with mesothelioma may lighten the burden on the courts and the personal toll on victims and sharpen the attention of businesses.

3.23 Given asbestos is such a cost to society, from a purely regulatory perspective, a clearer policy in relation to: a) the goal of total eradication of the risk; b) the requirement of duty-holders and surveyors to register details of asbestos; c) a systematic and resourced removal programme; a review of the relationship between civil and regulatory law may be desirable.

3.34 This is broader than consideration of HSE's role in the process. Drivers for exposure risk include the absence of a comprehensive, affordable and accessible programme of waste disposal for asbestos containing materials. A United Kingdom postcode lottery exists which sees asbestos disposal free in one county, prohibitive in another and non-existent in another. It is an invidious task for the regulator to enforce standards where there is inconsistency in the ability of duty-holders to comply through no fault of their own.

3.35 A national register of asbestos which is accessible and free is a means by which workers can risk assess the probability of encountering asbestos and to ensure that purchasers are aware of asbestos. However, this also provides a useful basis to potentially contribute to the risk-based approach to enforcement and enables more compliance through knowledge.

3.36 Consideration of the fiscal and financial implications of asbestos is needed at a strategic and policy level, reviewing the experience of contaminated land remediation. Investigation and enforcement move the burden of responsibility, but a re not in themselves sufficient to systematically address the presence of a once commonplace material.

3,37 Education about asbestos (and other occupational hazards) needs to be mainstream part of the curriculum. Awareness of the risks of asbestos, as well as other key occupational exposures such as silica, heat, noise and stress should be systematic parts of school, apprenticeship, STEM and health education. Without this background awareness, the regulator needs to both educate and enforce.

How does HSE's approach to managing asbestos compare to the approach taken in other countries? Are there lessons that the UK could learn from best practice elsewhere?

4.1 The UK is a world leader in the management of asbestos. HSE from a technical, scientific and enforcement perspective are rightly regarded as providing reference points for good practice and effectiveness in their purpose.

4.2 Minimum exposure levels are higher in other EU countries, but their role in regulation varies, as does the degree to which there is compliance and the technological capability of monitoring workplace exposure levels. There is a temptation to view lower exposure levels as better, but it is an important consideration that they are practically achievable, otherwise they may be counter-productive (as highlighted in Appendix 1).

4.3 Other jurisdictions import the experience of improvement of environmental standards. An example is Israel's use of the polluter pays principle in the 2011 Prevention of Asbestos Hazards and Hazardous Dust Law. The Supreme Court of Israel's determination of the effect of section 74 in requiring those who profited from asbestos to contribute to the cost of removal highlights to opportunity to ensure that the economic burden of the hazard is distributed. At the very least, a polluter pays principle in relation to those duty-holders who elect to leave asbestos in situ before transferring the risk to new owners would have the effect of encouraging removal, rather than getting a hidden tax benefit through the writing down of sale value based on the presence of asbestos and therefore reducing tax liability on asset transfer.

How does HSE measure and report its progress in mitigating the risks of asbestos?

5.1 Accurate recording of the impact of HSE's regulatory role in risk management is problematic. The duty-holder must keep an asbestos register, but this does not feed into a centralised database. Integrating the mapping of RIDDOR reporting, but modifying RIDDOR standards to provide less latitude in when an exposure might be reported would give a clearer identification of whether leaving asbestos in situ is actually well managed.

5.2 Without real-time data about location and disturbance, the effectiveness of regulation will be subject to latency which might be up to 40 years. This would not provide a credible basis to judge the effectiveness of interventions.

Does HSE keep adequate records of asbestos in public buildings?

6.1 This is not a current public law duty on HSE. The IT infrastructure required to do this would require substantial investment and careful design and probably sits outside HSE's current data methodologies. However, the potential benefits of having a national register, tied in with RIDDOR, enforcement, civil claims and Employer Liability Tracing Office data, may well justify the investment.

Is HSE making best use of available technology and systems to monitor the safety of asbestos which remains in buildings?

7.1 Aside from an approach as outlined in 6.1, HSE has limited opportunity to deploy technology to monitor asbestos. The duty-holder and the surveyors/analysts have access to the information which will help identify asbestos risk. Much of the risk of in situ exposure relates to ergonomics and human factors. Building maintenance and development processes are key points of risk. Integrating asbestos risk assessment directly into building standards and planning restrictions for change of use, combined with asbestos registers, may enable better monitoring and control. There is a huge missed opportunity to integrate regulatory systems for better asbestos control. This does not lie with HSE, but its new role as a building regulator may enable this to be realised.

Does HSE commit adequate resources to asbestos management in line with the level of risk?

8.1 HSE has inadequate resources to perform its function in preventing health exposures. This was true even before Brexit, where the scientific and regulatory resources and authority of the EU could be leant upon. The country loses billions of pounds and thousands of lives because of avoidable health exposures. For every one worker who dies from a safety incident 99 will die from a workplace health exposure. The cost to the economy through health and social care and lost years of tax revenue is probably beyond calculation. Within the HSE's budget, it is being asked to do more with less.

8.2 Prioritising asbestos regulation without a national fiscal, legal and education policy is likely to have limited effectiveness and would be perhaps at the cost of other areas of health prevention where regulatory intervention can be targeted and effective. Other exposures like silica have continuing devastating consequences, but do not have the infrastructure, awareness or industry to enable compliance and present a growing risk for the UK workforce.

8.3 HSE needs more resources in health protection. It is likely that a pound spend on regulation will save ten or a hundred-fold in health costs in the medium to long term. However, asbestos requires a national cross-departmental strategy. Aside from naturally occurring asbestos, it is a hazard that can be removed from our environment and which can be done in tandem with the improvement of the energy sustainability and fire safety of our building stock. Expecting the regulator alone to enable this change is like expecting the police to eradicate domestic violence. Asbestos is a social, economic, behavioural and cultural legacy. It needs to be addressed and resourced as such.

How robust is the available data about the risks and impact of asbestos in the workplace? What gaps in evidence need to be filled?

8.4 The epidemiology of asbestos is reliable and stable and represents one of the better case studies in how occupational health exposures link to disease. However, data and the mining of qualitative information about asbestos risk is limited and does not make use of the information which is gathered by each and every asbestos survey. There is a tremendous opportunity that stems from the way in which asbestos is regulated in the UK to bring together duty-holder qualitative and quantitative data, as well as that which can be derived from surveys and laboratory assessment to better inform our understanding or patterns of risk. Our regulatory requirements provide structured data sets which could be of national and international significance in the fight against asbestos exposures. However, this requires a national research strategy around prevention and detection.

Is HSE drawing on a wide body of international and national regulatory and industry expertise to inform its approach to the management of asbestos safety in buildings?

9.1 BOHS has a number of members who work for HSE's science and enforcement branches. They are characterised by scientific curiosity and exemplify a science-base ethos which knows no jurisdictional boundaries. However, the level of resource and the stretch on individuals means that the opportunities for those experts to engage internationally are limited by their available time. Our continued engagement with PEROSH exemplifies this attitude.

How effectively does HSE engage with external stakeholders and experts about its approach to the regulation of asbestos?

10.1 Whether through strategic necessity or persona choice, the asbestos team in HSE have been outward-facing, receptive and engaged. HSE have been actively involved in BOHS and FAAM and are invaluable contributors of scientific and practical knowledge.

10.2 The industries for whom asbestos is a major concern are fragmented, competitive and have very varying levels of quality and standards. HSE's engagement is strategic and welcomed by some and seen as a lobbying opportunity for others.

10.3 Given the scope of the problem, HSE's stakeholder engagement is exemplary and would make other regulatory agencies seem disconnected. As ever, the issue is the very thin resource available to HSE to address this and other fatal health exposures.

September 2021

Appendix 1

Faculty of Asbestos Assessment and Management (British Occupational Hygiene Society) Response to European Chemical Agency (ECHA) *Occupational Exposure limits for Asbestos – Consultations on OEL Recommendation*

About the British Occupational Hygiene Society and the Faculty of Asbestos Assessment and Management Review Process

The British Occupational Hygiene Society (BOHS) is a scientific charity and the Chartered Society for Worker Health Protection in the United Kingdom. The Faculty of Asbestos Assessment and Management (FAAM), which it hosts is the UK's pre-eminent body in the science and practice of asbestos assessment. BOHS has had a longstanding role in advising upon occupational exposure limits in asbestos and was responsible for recommending the first Phase Contrast Microscopy (PCM) limit based on personal sampling , which remains the basis of the current OEL for asbestos in the EU.

BOHS brought together an expert panel to consider the ECHA Scientific Report for evaluation of limit values for asbestos at the workplace (i.e. Report) on the 10th of March with the intention of bringing together the leading UK voices from science and practice in the area, informed additionally by international expertise. The responses are a summary of the deliberations of the seminar and in some instances, information previously submitted by BOHS/FAAM in the call for evidence. Further technical detail is available upon request.

It is recognised that at the present time, peak levels of asbestos-related cancers from past industrial manufacture and use are occurring in the EU member states. Asbestos is also the subject of widespread litigation and a wide number of interests are required to be developed, making even a science report a difficult undertaking. Our conclusions relate to the scientific method and evidence base of the report and, to the extent that the scientific objectives can be realised in practice as well as in theoretical terms. The observations are not meant to undermine the invaluable work in this important field, but to provide helpful scientific critique to enable this work to be more robust and objective.

Faculty of Asbestos Assessment and Management Panel Findings

Executive Summary

- The Report contains omissions in the evidence base which may undermine the reliability of conclusions, some of these arise from scientific choices, but others are procedural defects which should be remedied before the report is acted upon.
- The epidemiological reliability of the report is questionable in relation to the transparency and/or rigour of some methods, the absence of justification for some analysis which might impact the risk analysis and skew results and some details in relation to the underlying literature and its use.
- The Report is technically flawed in its consideration of measurement methods, from the consideration of scientific evidence, through to appreciation of practical considerations which will determine whether actual (rather than formal) compliance is achievable.
- The Panel considered the Report limited by the failure to properly explore the relationship between risk and limit values and the determination of whether different limit values are required for the different types of regulated asbestos; this was a clear requirement of the EU Commission's request to ECHA. It also identified issues with the transparency of data and analysis.

Additional recommendations for enhancing the transparency of the scientific method and working assumptions

- The basis of the selection for the "quantitative" cohorts for the exposure-risk relationship (ERR) should be set out in this report and the report should also tabulate how each cohort made the grade (e.g. numbers of actual measurement and over what period, and how many samples used to convert PCM to historic indices of exposures etc.)

- The lack of information on the number of asbestos removal and maintenance workers, their current compliance with the OEL, the effectiveness of the RPE and controls that are available to them would seem essential information to include in the science report for the RAC and the ongoing OEL procedure. It is recommended that this information is made available.

- The assumptions and limitations of the science should be summarised/listed in a separate section of the report, so it is easier to determine the limits of the evidence-base without re-reading the whole report.

Conclusion

The FAAM Panel was of the opinion that while the report was well-presented, there are appreciable defects in the scientific method through the exclusion of relevant considerations, the omission of evidence, defects in the transparency of the evidence base, missing elements in the scientific evidence base and a failure to appreciate the relationship between practice considerations and the realisation of the objective of limit values in the context of the Directive and European Law. It recommends that the Report is reviewed to address these defects prior to any further decisions being made on its basis, which may then be potentially subject to challenge and/or fail to realise the objective of appropriate worker health protection.

1. Observations on the Approach to the General Scientific Evidence Base

The FAAM panel observed that there were three types of limitations to the scientific evidence base of the report. These arose from Report's own terms of reference, the chosen methodology for compiling the Report and from procedural defects in following the selected methodology.

These issues with the evidence base may undermine the effectiveness of the scientific method reached and represent limitations on the value of the conclusions drawn and the degree to which the report can be relied upon for the determination of the next stage of the process.

a) Limitations in the scope of evidence included, arising from the terms of reference

The ECHA science report is constrained by the service level agreement, the standard format used by ECHA and the RAC's involvement being just one part of a multi-stage procedure for re-assessing the OEL. As a consequence, the report has based its assessment on updating recent European evaluations of risk:

"International assessments such as, NFA (2019), IARC (2012), DECOS (2010), Afsset (2009a,b) and AGS (2008)". This has been complemented by a literature search of published papers from the last ten years". The only international report listed is the IARC (2012) review of human carcinogens for hazard classification.

The ECHA report is confined in scope to the updating of the risk assessments carried out by four EU member states that have already unilaterally lowered their OELs below that, in the directive 2009/148/EC.

b) Limitations in the scope of evidence arising from problematic methodological approaches

The limited scope has the effect of leaving existing procedures and assumptions used in the DECOS (2010) review and its follow-up publications unchallenged.

The literature review of recent publications (Appendix 3) uses a complex trail of not very transparent selection requirements (see Paragraph 2 of Appendix 3) and does not make best use of the recent literature because of the further application of the evidence-quality requirements arising from the DECOS (2010) review. A key point in the BOHS/FAAM submission of evidence to ECHA (June 2020) was that the parameters used by an "expert panel" for the Health Council of the Netherlands report were not properly applied. This meant in particular the DECOS (2010) review and further on-going reviews based on it, had ongoing limitations, particularly for the consideration of the risks from amphibole asbestos.

c) Limitations in the scope of evidence arising from procedural omission.

The science report appears to take no account of the recent USEPA (2020a) update of chrysotile and the many detailed publicly available comments made on this report.

Further comment is limited because of the failure to make available literature provided as a result of the call for information (April 2020) by ECHA. The provision of this literature is a procedural requirement in relation to enabling proper consultation.

2. Observations on Epidemiological Reliability

The panel observed three types of limitation to the reliability of the epidemiology. These arose from the lack of transparency in the exposition of the analysis undertaken, the lack of justification for the methodological approaches taken in some instances and errors in the methodology apparent from the report itself.

These issues may call into question the scientific justification for conclusions drawn in the report and may lead to erroneous conclusions, undermining the next stage of the limit-setting process.

a) *Limitations because of lack of transparency in the epidemiological analysis.*

More detailed reporting of the epidemiological analyses is required, particularly those relating to lung cancer. In particular more detail is required of:

- analyses for lung cancer analagous to those shown for mesothelioma in tables 13 and 14. This is needed to clarify how model fit and heterogeneity might vary by fibre type grouping. Other covariates than fibre type would be of interest (for example, by study type, i.e. cohort or case-control; effect measure. i.e. SMR vs OR/RR; and industry i.e. mines, textiles, cement, insulation etc). The absence of this detail calls into question whether the epidemiological methodology has sufficient underpinning rigour to justify the conclusions.
- sensitivity to the position and number of knots. The extrapolation to risk at 4 and 0.4 f/ml.yrs might plausibly be quite sensitive to the placement of the lower boundary knot and therefore may call into question the validity of epidemiological conclusions.
- graphical reporting of the exposure response curve over the whole cumulative exposure range. Using a log scale for exposure would probably produce something readable across the exposure range.
- The lifetime risks shown in Table 15 should be shown separately for lung cancer and mesothelioma.

b) *Limitations because of the absence of justification of epidemiological methodology*

The panel observed two related issues in the justification of epidemiological analysis of data. These are substantive matters which are not acknowledged or discussed in the report, which calls into question whether they have been properly considered. The impact of them would be to amount to underestimation of the true risk level and to create distortions in the data which could undermine epidemiological conclusions.

- The process for "adjusting the exposure response relation for the elevated risk at zero exposure" briefly mentioned on page 123/4 needs fuller explanation and justification. If it is essentially the adjustment described on page 3 of van der Bij et al., (2013), its effect is to set aside the intercept and base risk estimates only on the internal slopes of the individual studies. To the extent that the intercept results from a flattened dose response curve due to exposure estimate inaccuracies, the adjustment adopted will underestimate the true risk level. This will undermine the validity of further conclusions that are drawn in the report and subsequent decision-making.

- The use of a single average intercept applied across studies may distort comparisons between, for example fibre type groups, if the observed intercepts vary systematically between the groups.

c) *Limitations because of methodological error*

The panel observed two methodological issues relating to the underlying literature and its use:

- The exposures assigned to participants in the Olsson pooled case-control study were based on the geometric means of their job categories. This will underestimate the derived cumulative exposures which should be based on arithmetic means. Peters et al (2016) (page 809) suggest this could be by a factor of 1.47.
- In Table 11 the Berry and Newhouse study is misclassified as a nested case-control study. In respect of lung cancer this was a cohort study and measured risk by SMR. It was the analysis of mesotheliomas in this cohort that used a case -controlled approach.

d) As noted that in the previous submission of evidence from BOHS/FAAM most measurements which define the slope of the dose-response relationships (i.e. at the higher exposure levels) were taken using other measurement indices and static sampling methods. These conversions to PCM fibre counts were for many of the amphibole cohorts highly problematic and failure to understand the limitations of the exposure measurements underlying the epidemiological assessment of the risk, means that the ERR derived and the mathematical modelling used is often built on limited evidence and unstable assumptions for the conversion of historic indices of exposure. Even in more recent epidemiological studies (e.g. from China and Russia), the conversions from historic indices of total dust to PCM are based on a few tens of parallel samples and do not adequately account for the considerable difference between static dust sampling and personal exposure monitoring for fibres by PCM.

3. Observations on the Reliability of the Measurement Approach Outlined in the Report

The Panel felt that the measurement section of the Report to be the most technically problematic. It observed eight significant areas where the Report had limitations, ranging from issues with the evidence base, failure to take into account relevant scientific considerations, failure to take into account relevant practical considerations which would impact on the ability of workers to derive rights and actual protection from the OEL through to inconsistency between practical and theoretical measurement methods.

a) *Limitations arising from limited use of scientific evidence to support the Report's conclusions in relation to sample measurement*

The Report relies on one data set from France (INRS, 2019) to assess the level of compliance (i.e. 8-hour personal samples taken to assess the OEL) with the current directive. Since such measurements have been collected over the last 30 years this would seem to be essential / critical knowledge for this report to have gathered, to inform both the RAC and the following procedures. It is hard to see how any evidence-based decisions on the new OEL can be made without this data. INRS, (2019) is cited as reporting results from 76,681 "regulatory" measurements between 2012 -2018, coming mostly from worksites with removal of ACMs or the disposal and handling of asbestos waste. However, the actual IRNS report referenced showed that only some 10% of the measurement were taken to assess the 8-hour OEL. The TEM measurements gave a mean of 0.4 fibres/cm^3 and median of 0.025 fibres/cm^3 with results ranging from <0.00001 to 200 fibres/cm^3. It is not normally possible for an 8-hour personal samples to be collected and analysed to give results to <0.00001 f/ml, nor would an average sampling period of 151 minutes suggest that the current 8-hour OEL is a readily measurable time period: therefore this summary must be treated with some caution. Even so, the average is well above the current OEL and the 75th percentile of the measurements was also above the current OEL for asbestos fibres in workplace air.

Numbers are important. The only published epidemiological review on asbestos removal workers (Frost et al., 2008) showed that 52 387 asbestos removal workers took part in the (UK Asbestos worker) survey between 1971 and 2005. These figures only capture the workers who were removing the most friable forms of ACMs requiring the removal contractor to be licenced by the UK HSE. Although this study had many limitations it did show that less than half of the workers were in the asbestos removal industry for <2 years, which raises considerable challenges for their training, experience and exposure monitoring. In many ways the monitoring of maintenance workers (who may only infrequently work with asbestos) is an even bigger challenge.

The Report (section 5.3.3) gives estimates for work on a wider range of ACMs (*including smaller maintenance work*) cites the number of currently registered enterprises involved in working tasks with ACMs in Germany in 2017, as 20 455. However, this is acknowledged to be an underestimate and some 750,000 workers are thought to actively disturb asbestos during renovation activities (BAuA, 2020b). Similar numbers are assumed to apply in other EU member states. Again a better understanding of the numbers and types of workers across the EU who are likely to be impacted would appear to be essential information.

b) *Limitations arising from the Report's approach to practical measurement considerations.*

The problems with deciding which size of fibre and which types of fibres to count are reviewed on page 75 of the Report. Section B subpart d of the Panel's response raises the importance of the historic indices of measurement and their conversion to PCM fibre counts. That this section of the report seems oblivious to historical measurement indices and assumes the measurements were all made by PCM is simply astonishing! That it then goes on to discuss what is a suitable conversion of a conversion for the new OEL shows little understanding of the reality. Fibre-counting considerations must also be determined by what is practically achievable by Member States, given the current state of technology and practice-based considerations, as well as the scientific and health objectives.

Setting standards for measurement determined solely by epidemiological limits, but which cannot be practicably measured, may undermine the effectiveness of any rights derived from the Directive and implies an impossible obligation on Member States. Although the Directive may set the OEL at a level where precautionary control measures may be appropriate to the epidemiological risk, this may result in a limit value for workers at which reliable measurement of actual exposure may not be routinely achievable.

To ensure the equal applicability and enforceability of rights under the Directive, the limit must be consistent, assessable, reliable and enforceable. Practical measurement issues are therefore of importance. The main purpose of measuring the OEL (including when and how often it is measured), must be to assess whether the various work practices are either suitable to use and are being applied effectively in the many workplace scenarios.

As air measurements do not take account of any personal respiratory protective equipment, worker compliance with the OEL may often only be achieved by the use of RPE. Again the practical effect of a lower OEL is to increase the use and complexity of the RPE. However, the Report does not attempt to describe or assess the RPE methods available and their in-use protection factors and the many other risks associated with their use (e.g. limited visibility, weight, ergonomics, heat stress, falls from height, trip hazards etc.). This is particularly important as ALARA would normally apply to a non-threshold carcinogen.

c) *Limitations arising from the failure to consider the practical issues arising from measurement as a means of preventing exposure.*

It is vital to determine whether controls being applied are actually sufficient to suppress the emissions of fibres to air when the asbestos-containing materials are being actively disturbed during removal or maintenance work. The term "actively" is critical in the context of asbestos removal in particular, since most measurements of fibres in air are not personal samples taken in removal enclosures or enclosed areas where active maintenance work is carried out. Also, due to the precautionary principle, no sampling personnel are usually present in the enclosure during active removal or maintenance work.

The report acknowledges that the protection of workers and a reduction of risk, is only achieved by first knowing you are going to disturb ACMs and then applying sufficient at -source controls, to ensure that release of airborne fibres in the breathing zone of the worker is reduced to <OEL. To achieve this, incidents of any peak emissions (e.g. due to failure of the controls) must also be minimized (see section 5.3).

As it is rarely possible to control asbestos fibre releases, while not controlling the other non-asbestos particles: the use of a simple dust particle counter would in most removal and maintenance circumstances, alert the worker and supervisors to the fact that the current controls were inadequate or failing in real-time. It is not effective protection to find this out retrospectively, or in most cases, not at all - if the OEL is not measured or measured when the peak emissions are unlikely to occur. Also it is important that the regulatory 8-hour TWA OEL measurement should not be confused with the many other types of asbestos in air measurement data (e.g background, clearance and leak- testing etc.)

d) *Limitations arising from the inconsistency of current Member State's approaches to sample analysis*

The current Directive simply requires an assessment of the OEL based on personal sampling over 8-hours with the filter analysed for the number of fibres in a specific size range (>5 µm long, <3 µm width and an aspect ratio >3:1) using the WHO (1997) light microscope method of fibre counting. However, in practice member states assess images based on several different types of microscopy (using transmitted light, backscattered, secondary and transmitted electrons) covering a range of illumination intensities, view images on a range of devices (oculars, phosphor screens, LCD screens etc.) which range in physical dimensions from a few mm^2 diameter for a Walton-Becket graticule (as used in the current WHO method) to large LCD display screens nearly a metre in width. The magnification used for sizing the fibres may vary from ~ x500 to x20,000+ and a range of analytical techniques can be used to discriminate between asbestos and non-asbestos fibres (e.g. polarised light microscopy, energy dispersive x-ray analysis and selective area electron diffraction) even though the WHO method in AWPD required all visible fibres of a required dimension to be counted for the OEL.

The fibres being counted for near source removal and maintenance work can be part of complex bundles, clusters and matrices: either embedded in or attached to particles of the non-fibrous matrix of the asbestos product. The rules used for counting these complex objects and assigning fibre number differ between analytical methods. Electron microscopy uses different counting rules to the WHO method, required by theDirective. In some EU Member States, the use of preparation methods, such as selective ashing of the surface of the sample or even ashing the whole filter and deposit with redispersal in a liquid before re-filtering for analysis (i.e. indirect analysis), can produce large differences in the fibres counted (Chesson et al., 1990, USEPA, 1989). This issue was further demonstrated by the results from Eypert-Blaison et al. (2018a, 2018b) in Appendix 5 of the science report, " *When restricting the counting to WHO fibres, the arithmetic mean TEM/PCM ratio was 4.6 when combining all asbestos fibre types, but it ranged from 0.1 to 19 depending on the type of asbestos material removed*."

It is presumed that the Commission has considered that a standardised procedure across the EU was required. The previous European Reference Method for fibre counting was published with the original directive, and the current directive was updated to specify a world-wide reference method (WHO, 1997). The Report should consider whether the WHO method based on PCM analysis must always be carried out first and reported before additional electron microscopy analysis is applied.

Limitations arising from the difference between actual measurement of limit values and referenced/theoretical measurement limit values

OELs require personal sampling at a flow rate of 0.5 - 2 l/min. and the pressure drop across the filter and battery life of currently available personal sampling pumps has a practical upper limit of ~4 l/min. Reference to flow rates above 4 l/min in ECHA to achieve greater sensitivity in an OEL is misleading (e.g. table 6 page 28). The theoretical calculated lower limit of measurement for PCM is 0.0025 f/cm^3 sampling 480 l of air over 8 hours and counting 200 Walton-Becket graticule areas. This is similar to the current Dutch OEL for amphiboles measured by SEM.

e) *Limitations arising from the Report's failure to address inconsistency in the effectiveness of different analytical techniques across Europe*

Four types of analytical techniques are noted in the report, namely PCM, SEM, TEM and fluorescence microscopy. Amongst practitioners in the discussion group as in Europe, there is a division in preferences for using PCM or SEM and TEM.

PCM fibre counting has been used for over 50 years as an index of exposure for asbestos workplaces. It assumes that the fibres are asbestos and the visibility of the >5 µm long fibres is limited to fibres of ~ 0.2 µm width (depending on fibre type, the numerical aperture and the magnification used x400 – x500). Other airborne particles, including other fibres, will usually limit its use to concentrations above 0.005 f/ml. but it is available to use on-site, if required. SEM requires sampling on a different type of filter, which simplifies sample preparation but normally requires off-site evaluation. Several EU member states use the SEM method according to ISO 14966 especially when lower OELs are applied (e.g. NL, Germany). The TEM requires more complex sample preparation but can use part of the unused PCM filter (if available) for direct analysis (ISO 10312).

Both SEM and TEM can count and discriminate between asbestos and other types of fibres to give a concentration based on the PCM index. If using direct preparation methods the improved resolution and visibility at the search magnifications used (e.g. x1000 – x5000), usually results in higher fibre counts, unless a measured minimum width is applied. Both EM methods have the potential to count shorter and thinner fibres but if higher magnifications are used, more microscope time is required to achieve the same limit of quantification. If an indirect sample preparation is used (see page 75 of the ECHA report and EPA, 1990) the results may have no equivalence with PCM results. The cost of sampling for all three methods is essentially the same but for both: the time to obtain results and the cost of analysis is PCM<SEM<TEM.

f) *Limitations arising from failure to determine key relevant scientific questions.*

Systematic discussion and conclusions on sampling and measurement can only be made based on determinations which have not been made by the report of the following issues:

- Whether a single ERR applies for all types of asbestos;
- The exact description on the ERR/s and what the intercept on the response (ordinate) means in reality, rather than in the context of mathematical modelling;
- How far it is reasonable to extrapolate from the lowest reliable exposure;
- Which of the many levels of risk (4×10^{-3} – 1×10^{-5}) described in the science report and those applied in different EU member states, will be adopted to set the OEL..
- Whether individual EU member states may continue to apply their own national risk guidelines, as at presently allowed.

4. Observations on the Report's Approach to Risk-Assessment

The Panel observed limitations in the rationale of the relationship between risk and the derived limit values, as well as a lack of transparency in the data underpinning the risk section.

a) *Limitations based upon a lack of clarity in how and whether risk had been used as the basis for determining limit values.*

While the argument (page 132) that since current and future exposures will be to an unpredictable mix of fibre types, the risk assessment should be based on evidence drawn from all fibre types is reasonable, this does not obviate the need to do a separate risk assessment and a limit for the amphiboles , if only to test the adequacy of a single limit.

Use of a single ERR may mean that, in relation to mesothelioma, it is the ERR is too high for chrysotile and unduly low for crocidolite. It would be appropriate to consider establishing different risk factors between chrysotile and amphiboles, even if insufficient high quality studies for individual types of amphibole asbestos was available. It was accepted that that the asbestos risk could be modelled as linear by cumulative exposure.

Consideration and discussion of the relationship between risk and the limit value should be analysed, since it has a significant bearing on the determination of limit values. It is noted that EU member states apply use different terms and values (e.g. acceptable, tolerable, excess risk) and some have different risks for chrysotile and amphibole (see Table 8 in the Report). It is necessary to determine whether there is a need for differential limit values, e.g. for amphiboles and other similar fibres and one for chrysotile or to reporting separate risk factors without separate exposure limits.

b) *Limitations arising from the lack of transparency in the evidence and the analysis of evidence*

While this report includes some additional cohorts compared to the DECOS (2010) report, there is no explanation or listing of the expert assessments that have been carried out to include or exclude cohorts. The quality, types and periods that measurement data were available and how older indices of measurement have been converted are key to the quantitative modelling of risk. The USEPA review of chrysotile (USEPA, 2020b) provided an example of how this could have been done and the assessments should have been published as an annex with the report. If the main purpose of the report was to model the risk (ERR), there is a singular lack of clarity and transparency on what factors were considered and weighted and what data was input into the SAS computer modelling.

5. Discussion

The question remains whether the science report has addressed the requirements set out in of the service level agreement. This is quoted in the preamble on page 2,"*the scientific evaluation shall include, where appropriate, review of/or proposals for OEL(s), biological limit value(s) and/or appropriate notations. It shall include an evaluation of different types of asbestos fibres (as defined in Art 2, Dir 2009/148/EC) and take into account the nature of the health effects due to these differences. It shall include an assessment of whether a differentiated limit value may be appropriate for the different types of asbestos fibres.*". Clearly the risk analysis (e.g. Tables 11 &13) has divided up the cohorts selected as suitable by asbestos type (chrysotile, mixed (mainly chrysotile with some use of crocidolite or amosite), amosite, crocidolite and tremolite). While the degree by which the "chrysotile" cohorts are free of tremolite and crocidolite is an area of significant debate, however, as this differentiation has been made for modelling, it seems odd that only a single ERR for all the cohorts combined was presented in the report.

The reason given for this approach was that workers who remove asbestos will be exposed to a range of asbestos types. While this approach can perhaps be justified if the range of responses between asbestos types is around a factor of three (as for the modelling of lung cancer), this is much harder to understand when the dose-response (K_M values) differ by some three orders of magnitude, as for mesothelioma (see Table 13).

This "homogenised" analysis approach used in the Report gives the RAC no option but to adopt a single and lower OEL. The OEL adopted defines what work practices are acceptable (i.e. the level of dust suppression and the type of personal protection). This in practice means a similar degree of dust suppression for removing a chrysotile asbestos cement roof, as a sprayed crocidolite coating – often for the simple reason that the filter will become too-overloaded to measure an 8-hour OEL. While this can be passed-off as the status-quo, a lower OEL, requires the development and deployment of new approaches and technologies. The only measurement data available in the report (INRS, 2019) suggests that even the current status-quo is not being routinely achieved after a decade since it was last reduced. Due regard has to be given to what is currently achievable and a considered staged approach will be required for the development, availability and deployment of cost-effective efficient methods and technologies for removal and construction work.

The seminar also highlighted a number of key ramifications that were not mentioned in the Report but cannot be ignored going forward, especially if the OEL is lowered:

- **The amount of waste generated**: other than the asbestos materials themselves, large amounts of potentially "contaminated" materials from building contents, building materials, made-ground and surrounding soil are generated.
- **The waste cycle:** transport, treatment, recycling and/or storage of asbestos waste.
- **Decarbonisation and impact on the global warming targets adopted by the EU**: many square kilometres of single use polythene are already used. Some EU member states are using high energy thermal destruction technologies or other CO_2 producing technologies to treat asbestos wastes.
- **Abandoning the WHO method:** The EU wide adoption of a different analytical method and counting rules from the WHO method, will require considerable time and cost for some member states to adopt and deploy.

- **Worker protection**: The ability to measure the OEL and to comply with it, will determine the levels of cumulative exposure to workers, occupants and bystanders. Adopting a too difficult or stringent an approach will increase the amount of unacknowledged work, illegal removal or avoidance of representative measurements.
- **Subsidiarity**: It was already noted that a range of acceptable risk levels are quoted by member states as suitable for use in the report. As the AWPD allows EU member states to adopt their own more conservative OELs and several have already chosen to do so, it should be remembered that no such derogation to increase the OEL exists.

6. Conclusion

The Panel was of the opinion that while the report was well-presented, there are appreciable defects in the scientific method through the exclusion of relevant considerations, the omission of evidence, defects in the transparency of the evidence base, missing elements in the scientific evidence base and a failure to appreciate the relationship between practice considerations and the realisation of the objective of limit values in the context of the Directive and European Law. It recommends that the Report is reviewed to address these defects prior to any further decisions being made on its basis, which may then be potentially subject to challenge and/or fail to realise the objective of appropriate worker health protection.

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Final Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos Systematic Review Supplemental File: Data Quality Evaluation of Environmental Releases and Occupational Exposure Data (epa.gov)

Appendix 1

The following short paragraph from page 10 of the Report is given as an example of the need for further scientific editing of the report.

"Amphiboles typically have a more glassy structure, making them less-flexible, more brittle and more rough-textured than chrysotile. The diameter of the amphibole fibrils is never less than 0.1 µm, with the exception of crocidolite (thinnest ones approximately 0.05 µm). "

With reference to each highlight in turn:

- Amphiboles are crystalline minerals. The term "glassy" is incorrect: it applies to non-crystalline structures without a three-dimensional repeat structure as in glass.

- Chrysotile slip fibre is less-flexible than commercial crocidolite, as also was one form of commercial amosite (Montasite).

- No asbestos is "brittle". If this is meant to refer to tensile strength, it is still incorrect as the tensile strength of chrysotile varies considerably. Commercial crocidolite has on average the highest tensile strength, followed by (in decreasing order) the average chrysotile, amosite, anthophyllite and tremolie-actinolite.

- All clean asbestos fibres are smooth surfaced. Chrysotile, having a more chemically reactive surface than the amphiboles, is more likely to be rough-surfaced when it has been mixed with other silicates during commercial use. Amphibole mineral fragments which are not asbestos can have a "stepped" appearance at high magnification where crystal defects are revealed as cleavage.

- Amphiboles are not circular in cross-section and the term width is normally used.

- The statement, " The diameter of the amphibole fibrils is never less than 0.1 µm, with the exception of crocidolite (thinnest ones approximately 0.05 µm)" shows little understanding of mineralogy and airborne fibre measurements by electron microscopy. This width observation applies only in general terms to commercial raw fibres. The fineness of the fibres is dependent on conditions at formation (e.g. crocidolite mined in Western Australia is finer than that from Cape Provence, South Africa which in turn is finer than Malipsdrift fibre from Transvaal (the source of mined amosite) where some of the crocidolite seams have amosite tips (continuous fibres) and the fibre size distribution is more akin to that of amosite. All amphiboles have the possibility of similar variations, especially in the contaminant minerals such as tremolite-actinolite. Tremolite in talc and chrysotile are prime examples of this size variation.