COLLECTIVE EXPERT APPRAISAL:
SUMMARY AND CONCLUSIONS

Regarding the expert appraisal for recommending occupational exposure limits for chemical agents

Recommendation of occupational exposure limits for "dust without specific effects" (DWSE) based on existing scientific recommendations

This document summarises the work of the Expert Committees on Health Reference Values (HRV Committee) and on Expert appraisal for recommending occupational exposure limits for chemical agents (OEL Committee)

Presentation of the issue

On 18 November 2015, ANSES received a formal request from the Directorate General for Labour (DGT) to conduct the expert appraisal work required for revising occupational exposure limits (OELs) for so-called dust without specific effects (DWSE), i.e. "that is not capable alone of causing any effect on the lungs or any other organ or system of the human body other than an overload effect" (DGT Circular of 9 May 1985).

France currently has binding regulatory values for DWSE (Article R.4222-10 of the Labour Code): an 8-hour time-weighted average (TWA) exposure value for total dust of 10 $mg \cdot m^{-3}$ and an 8-hour TWA exposure value for respirable dust of 5 $mg \cdot m^{-3}$.

The DGT asked ANSES to re-assess these values as a matter of priority, following publication of ANSES's opinion on “Chemical air pollution in underground railway areas and the associated health risks for workers”.

The request to prioritise the revision of these values led to a proposal to organise the expert appraisal work in two stages:

- initially, to recommend new 8h-OELs based on a critical analysis of existing international scientific reports and expert appraisals;
- subsequently, to conduct an analysis of all the existing scientific literature in order to recommend values according to the OEL establishment methodology generally used at ANSES.

This document is a response to the first stage of the expert appraisal work.

Scientific background

The French system for establishing OEL values has three clearly distinct phases:

- independent scientific expert appraisal (the only phase entrusted to the Agency);
- proposal by the Ministry of Labour of a draft regulation for the establishment of limit values, which may be binding or indicative;
- stakeholder consultation during the presentation of the draft regulation to the French Steering Committee on Working Conditions (COCT). The aim of this phase is to discuss the effectiveness of the limit values and if necessary to determine a possible implementation timetable, depending on any technical and economic feasibility problems.

The organisation of the scientific expertise phase required for the establishment of Occupational Exposure Limits (OELs) was entrusted to AFSSET in the framework of the 2005-2009 Occupational Health Plan (PST) and then to ANSES after AFSSET and AFSSA merged in 2010.

Occupational exposure limits, as proposed by the Committee , according to its derivation methodology, are concentration levels of pollutants in workplace atmospheres that should not be exceeded over a determined reference period and below which the risk of impaired health is negligible. Although reversible physiological changes are sometimes tolerated, no organic or functional damage of an irreversible or prolonged nature is accepted at this level of exposure for the large majority of workers. These concentration levels are determined by considering that the exposed population (workers) is one that excludes both children and the elderly.

These concentration levels are determined by the Committee experts based on information available from epidemiological, clinical, animal toxicology studies, etc. Identifying concentrations that are safe for human health generally requires adjustment factors to be applied to the values identified directly by the studies. These factors take into account a number of uncertainties inherent in the extrapolation process conducted as part of an assessment of the health effects of chemicals on humans.

The Committee recommends the use of three types of values:

- 8-hour occupational exposure limit (8h-OEL): this corresponds to the limit of the time-weighted average (TWA) of the concentration of a chemical in the air of a worker's breathing zone over the course of an 8-hour shift. In the current state of scientific knowledge (in toxicology, medicine, epidemiology, etc.), the 8h-OEL is designed to protect workers exposed regularly and for the duration of their working lives from the medium- and long-term health effects of the chemical in question;
- short-term exposure limit (STEL): this corresponds to the limit of the time-weighted average (TWA) of the atmospheric concentration of a chemical in the workers' breathing zone over a 15-minute reference period during the peak of exposure, irrespective of its duration. It aims to protect workers from adverse health effects (immediate or short-term toxic effects such as irritation phenomena) due to peaks of exposure;
- ceiling value: this is the limit of the atmospheric concentration of a chemical in the worker's breathing zone that should not be exceeded at any time during the working period. This value is recommended for substances known to be highly irritating or corrosive or likely to cause serious potentially irreversible effects after a very short period of exposure.

These three types of values are expressed:

- either in $mg \cdot m^{-3}$, i.e. in milligrams of chemical per cubic metre of air and in ppm (parts per million), i.e. in cubic centimetres of chemical per cubic metre of air, for gases and vapours;

- or in $mg \cdot m^{-3}$ only, for liquid and solid aerosols;
- or in $f \cdot cm^{-3}$, i.e. in fibres per cubic centimetre for fibrous materials.

The 8h-OEL may be exceeded for short periods during the working day provided that:

- the weighted average of values over the entire working day is not exceeded;
- the value of the STEL, when it exists, is not exceeded.

In addition to the OELs, the Committee assesses the need to assign a "skin" notation, when significant penetration through the skin has been identified (ANSES, 2014). This notation indicates the need to consider the dermal route of exposure in the exposure assessment and, where necessary, to implement appropriate preventive measures (such as wearing protective gloves). Skin penetration of substances is not taken into account when determining the atmospheric limit levels, yet can potentially cause health effects even when the atmospheric levels are respected.

The Committee also assesses whether or not it is necessary to assign a "noise" notation, indicating a risk of hearing impairment in the event of co-exposure to noise and the substance below the recommended exposure limits, to enable preventionists to implement appropriate measures (collective, individual and medical).

The Committee also evaluates the applicable reference methods for measuring exposure levels in workplace atmospheres. The quality of these methods and their applicability to the measurement of exposure levels for comparison with an OEL are assessed, particularly with regards to their compliance with the performance requirements in the NF-EN 482 Standard and their level of validation.

Organisation of the expert appraisal

ANSES entrusted examination of this request to the Expert Committee on Expert appraisal for recommending occupational exposure limits for chemical agents (OEL Committee) and then to the Expert Committee on Health Reference Values (HRV Committee).

The methodological and scientific aspects of the expert appraisal work were regularly submitted to the OEL Committee.

The report produced takes into account the comments and additional information provided by the members of the Committees.

This expert appraisal was therefore conducted by a group of experts with complementary skills. It was carried out in accordance with the French Standard NF X 50-110 “Quality in Expertise Activities”.

Prevention of risks of conflicts of interest

ANSES analyses the links of interest declared by the experts prior to their appointment and throughout the work, in order to avoid potential conflicts of interest with regard to the matters dealt with as part of the expert appraisal.

The experts’ declarations of interests are made public *via* the ANSES website (www.anses.fr).

Description of the method

<u>For the part relating to the recommendation of values:</u>

A summary report was prepared by one of the experts and submitted to the Expert Committees, which made comments and further additions. Several ANSES employees also contributed to this work and were responsible for scientific coordination of the different expert groups.

This document is a response to the first phase of the expert appraisal work. It is based on an inventory of the scientific reports and collective expert appraisals available as of April 2017, with the aim of selecting OELs that can be put forward on the basis of existing scientific recommendations without a complete literature search being carried out; the publications cited in this report to enable the issues to be understood were also referenced in the expert documents analysed.

The collective expert appraisal work and its conclusions and recommendations for the health effects part were adopted on 22/03/2019 by the HRV Committee.

This collective expert appraisal work and the summary report were submitted to public consultation from 13/05/2019 to 13/07/2019. The people or organizations who contributed to the public consultation are listed in appendix 4 of the report (only available in French). The comments received were reviewed by the Committee on Health Reference Values (term of office 2017-2020) who finally adopted this version on the 17/10/2019.

Result of the collective expert appraisal on the recommendation for OELs based on existing scientific recommendations

Definition and physico-chemical data

Dust without specific effects (DWSE) is defined as dust with no effects other than those resulting from the consequences of lung overload, where no other specific effect could be demonstrated. Other dust and, more generally, other substances excluded from the criteria for defining DWSE are then subject to specific OELs.

The particles covered by the DWSE definition have the following characteristics:

- Insolubility or very low solubility. By convention, a compound is considered "practically insoluble" or insoluble if its solubility is proportionately less than 1/10,000 (CRC, 2016);
- Surface property: DWSE does not have surface activity (e.g. oxidoreductive or catalytic properties such as the generation of reactive oxygen species, ROS);
- In particular, it is neither cytotoxic, genotoxic, radioactive, immunogenic or chemically reactive in lung tissue, but may cause indirect genotoxicity via an inflammatory process (ILSI, 2000);
- Form: particulate and not fibrous;
- Size: excludes ultrafine particles, aggregates and agglomerates of nanometric particles, even if they have the same chemical composition as the DWSE.

It should be stressed that this dust is considered to be DWSE if it has not been possible to demonstrate that it has a specific effect: for a given substance, it is therefore a provisional classification that may be revised if specific effects are demonstrated. This classification does not exclude the possibility that a given substance may have more pronounced effects than another one (e.g. respiratory effects occurring at lower levels of exposure).

Definition of the conventional inhalable, thoracic and respiratory fractions

When in the vicinity of the respiratory tract, aerosol[1] particles can be inhaled. They then settle along the airways (from the nasal cavities and mouth to the pulmonary alveoli). They can then have either a local (irritation) or systemic action depending on their overall physico-chemical characteristics (shape, chemical species, solubility, surface properties, etc.). The NF EN 481 Standard defines several particle-size fractions for airborne particles in relation to their penetration in the respiratory tract, as well as the sampling conventions for these fractions. The three main conventional fractions are the inhalable, thoracic and respirable fractions.

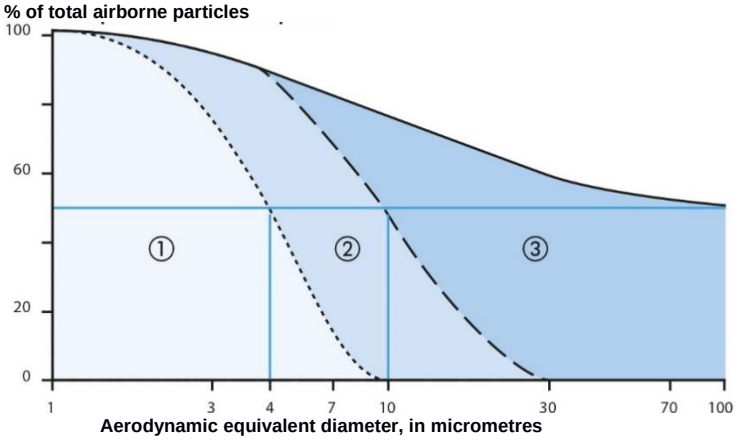

Figure 1: The conventional fractions are represented by the areas delineated by the curves

①: respirable; ① + ②: thoracic; ① + ② + ③: inhalable (INRS, 2016).

The inhalable fraction (①+②+③) is the mass fraction of total airborne particles inhaled through the nose and mouth. To sample this fraction, the percentage (I) of airborne particles with aerodynamic equivalent diameter (AED) to be collected is conventionally defined by the following relationship:

$$I = 50\,[1 + \exp(-0.06 \cdot AED)] \text{ where } AED \leq 100\ \mu m$$

The thoracic fraction (①+②) is the mass fraction of inhaled particles penetrating beyond the larynx. Sampling of this fraction must comply with the following convention: the percentage of the inhalable convention to be collected is given by a cumulative log-normal distribution with a median AED of 11.64 µm and a geometric standard deviation of 1.5. The cut-off diameter[2] with respect to the ambient aerosol is 10 µm.

The respirable fraction (①) is the mass fraction of inhaled particles that penetrates the unciliated airways. By convention, sampling of this fraction must be such that the percentage of the inhalable fraction to be collected is defined by a cumulative log-normal distribution with a median AED of 4.25 µm and a geometric standard deviation of 1.5. The cut-off diameter with respect to the ambient aerosol is 4 µm.

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[1] *The term "aerosol" refers to any group of solid or liquid particles suspended in a gaseous medium. Particles are conventionally considered to be suspended if their maximum settling velocity does not exceed 0.25m/s (see INRS ED 984, 2016)*

[2] *Cut-off diameter = AED value such that 50% of the particles have a smaller AED*

Two other fractions and conventions can be deduced from the previous ones:

- The extrathoracic fraction (③) is the mass fraction of total airborne particles in inhaled air that cannot penetrate beyond the larynx. The conventional extrathoracic fraction is deduced from the difference between the inhalable and thoracic conventions.
- The tracheobronchial fraction (②) is the mass fraction of total airborne particles in inhaled air that penetrate beyond the larynx but cannot enter the unciliated airways. The conventional tracheobronchial fraction is deduced from the difference between the thoracic and respirable conventions.

Only the inhalable and respirable fractions have been considered in this work, since the scientific expert appraisals already available only recommend OELs for these two conventional fractions.

Toxicokinetics

The kinetics of DWSE in the respiratory tract only depend on deposition and clearance.

Deposition

Deposition is dependent on particle concentration, material density, particle size and shape, agglomeration/aggregation tendency and aerosol particle size. The location of aerosol deposition in the respiratory tract is, in addition to physico-chemical characteristics, strongly influenced by inter-individual and inter-species anatomical differences (branching of the bronchial system), breathing via the nose or mouth in humans (physical activity), respiratory rate and pathophysiological changes (e.g. chronic obstructive disease) (MAK and BAT, 2016, Chap Vc).

Particles are therefore distributed differently in humans and animals (MAK 2012; Hofmann and Bergmann, 1998).

Rats breathe through the nose only. Their nasal filter is very effective for AED particles > 5 µm or < 0.1 µm. In humans, nasal filtration is much less effective and oral breathing comes into play from a breathing rate of 35 L/min.

Differences in deposition site and density also depend on the type of bronchial bifurcations in rats and humans. Anatomical differences between species were described in the paper by Miller (1993). In humans, for instance, regardless of particle size, DWSE is deposited massively in the carina and in areas close to the bronchial bifurcations. In rats and dogs, more intense and more uniform deposition is observed in the lung periphery, terminal bronchioles and immediately adjacent alveolar areas (MAK 2012).

Clearance

Pulmonary clearance, whose function is to purify the lungs, takes place according to different mechanisms: particles are purified from alveolar and tracheobronchial regions according to different half-lives. In humans (healthy non-smokers), pulmonary clearance of practically insoluble dust occurs in two phases: the first is based on mucociliary clearance; the half-life of the particles ranges from a few hours to a few days. The second phase is based essentially on alveolar clearance, and the half-life of the particles is about 400 days (MAK, 2012). Some of the particles deposited in the bronchi and bronchioles therefore have elimination half-lives of more than one working day (MAK, 1997).

When there is a higher particle load, an influx of monocytes is observed and elimination half-lives are prolonged because the macrophages, loaded with particles, can no longer function optimally and

their migration to the mucociliary escalator is reduced. The particles then migrate increasingly through type I alveolar cells (or between these cells) and reach the interstitium; they can also migrate into the lymphatic system.

The decrease in alveolar clearance, a distinctive feature of lung particle overload, was first correlated with the volume of internalised particles in the alveolar macrophage pool (Morrow, 1988). The scientific community is currently still debating which parameter is most likely to be relevant in terms of risk assessment: surface area or volume (Borm *et al.*, 2015).

According to Pauluhn (2011), the alveolar elimination half-life is dependent on the exposure concentration (expressed in volume per m^3). For example, for a cumulative exposure increasing from 1 µL/m^3 to 10 µL/m^3, the elimination $T_{1/2}$ would increase from 60 days to more than one year in rats.

Transfer to interstitial tissue

Morphometric analyses of histological sections from humans and monkeys have confirmed that particles are predominantly retained in interstitial tissue and that the retention percentage increases with higher doses, which may lead to fibrosis. In rats, however, particles are found mainly in the alveolar region, and primarily in macrophages (MAK, 2012).

General toxicity

Subchronic and chronic toxicity

Particulate matter in general can cause various respiratory system diseases resulting from lung overload, or carcinogenic, fibrogenic, allergenic or irritant effects. These effects mainly depend on the physico-chemical and dimensional characteristics and the location of particle deposition.

So-called alveolar aerosols, including droplets containing fine, poorly soluble particles also known as fibrogenic dust, can cause chronic diseases, with the formation of connective tissue. As the development of fibrosis is determined by the deposition of aerosols in the alveolar space, the atmospheric dust concentration relative to the respirable fraction should therefore be used to assess the impact of fibrogenic aerosols (MAK and BAT, 2016).

The lung overload hypothesis is defined in terms of consequences related to the accumulation of alveolar dust. Signs of overload appear when macrophages, type II epithelial cells or bronchial epithelial cells secrete signals (cytokines and chemokines), resulting in a distinct and persistent accumulation of phagocytes. After the multiplication and activation of alveolar macrophages, lymphocytes and neutrophil granulocytes also become carriers of lung inflammation. Their number increases considerably. The physiological mechanisms are overwhelmed and various elements appear that signal particle overload (MAK, 2012):

- increase in the number of free particles in the alveoli that have not been phagocytised by type I cells (very little assimilation by type II);
- damaged macrophages can enter apoptosis and release particles taken up previously;
- epithelial cells and macrophages release pro-inflammatory mediators (e.g. interleukins, chemokines and mitogens);
- alveolar epithelial cells are damaged, which leads to a compensatory proliferation of type II cells. Mediators secreted by macrophages and alveolar epithelial cells have a mitogenic effect on the epithelium. These two effects, compensatory proliferation and direct mitogenicity, are likely to promote tumourigenicity;
- particles that cross the epithelial barrier, penetrate the pulmonary interstitium and indirectly stimulate fibrosis via fibrogenic mediators secreted by particle-containing macrophages;

- particles reach the lymphatic nuclei to an increased extent.

It has been suggested that for low-solubility low-toxicity particles, an inflammatory response in rats may occur when the surface lung load exceeds 1 cm^2 of particles/cm^2 of proximal alveolar region (region closest to the terminal bronchioles) (Donaldson, 2008).

The accumulation of inhalable dust in the lungs is likely to lead to progressive disorders including chronic obstructive pulmonary disease (COPD). COPD is a lung disease characterised by a persistent decrease in the flow of inhaled gases that develops over years or decades. Symptoms gradually worsen, with shortness of breath on exertion eventually also occurring at rest. It tends to be under-diagnosed and can be life-threatening.

Green (2000) compared tissue reactions to biopersistent granular dust in humans and rats: comparable reactions have been described for dust accumulation, encapsulation, diffuse interstitial fibrosis, lipoproteinosis and alveolar/bronchilolar hyperplasia. Increased morbidity and mortality caused by non-neoplastic respiratory disorders (pneumoconiosis and COPD) have been observed in humans after massive exposure to biopersistent granular dust. Biopersistent granular dust is usually less fibrogenic than asbestos and crystalline silica but has a higher potential to cause COPD. As with rats, exposure to high concentrations leads to overload, causing a collapse in alveolar clearance, although acute inflammation and proliferative reactions appear to be less pronounced in humans.

Carcinogenicity

Poorly soluble particles cause tumours in rats when deposition overwhelms the lung clearance mechanisms, characterising the condition termed "overload". Since the responsiveness of the rat model at lung overload is dependent on both chronic inflammation and cell proliferation, no risk of lung cancer is anticipated at lower lung doses unlikely to induce chronic inflammation or cell proliferation (ILSI, 2000).

In conclusion regarding the carcinogenic risk, it seems that it is not currently transposable to humans, at least not as a proven risk. However, while mice and hamsters do not develop cancer from DWSE, it should be noted that the rat is the most sensitive species in this case. Most expert groups (MAK, ILSI, NIOSH, IARC) consider that while the carcinogenic risk has not been demonstrated in humans, it cannot be rejected as a possible consequence of chronic inflammation.

Available scientific expert appraisals

The following scientific expert appraisals were identified:

- Maximale Arbeitsplatz-Konzentration (MAK) (respirable fraction: 2011, inhalable fraction: 1997).
- National Institute for Occupational Safety and Health (NIOSH) (2011): report on occupational exposure to titanium dioxide and recommending OELs;
- Health & Safety Executive (HSE) Research Report 141 (2003);
- American Conference of Governmental Industrial Hygienists (ACGIH): the monograph was last published in 2001 (has since been deleted from references) and only provides recommendations.

In all the available documents, the critical effects selected for the OEL recommendation are all based on the consequences of lung overload.

The summary table below shows the consistency of the different OELs proposed, particularly for the respirable fraction, regardless of the model used to transpose animal data to humans:

Table 1: Summary of available scientific expert appraisals

Author	Critical effect	Key study	Critical concentration	Extrapolation from animals to humans	Recommended 8h-OEL for humans
MAK Inhalable 1997	Increase of about 5% in the incidence of chronic bronchitis	DFG study in humans (1983) reanalysed	3.8 mg·m^{-3}	none	4.0 mg·m^{-3}
MAK Respirable A 2011	Proliferative pulmonary inflammatory response	Muhle et al. (1991) Study in rats exposed to toner or TiO_2 powders	NOAEC = 1 mg·m^{-3}	MPPD model	0.3 mg·m^{-3} (d=1)*: average of the three values (0.11, 0.25 and 0.50 mg·m^{-3})
MAK Respirable B 2011	Displacement of the volume of distribution of alveolar macrophages < 6%	Several studies in rats, with 6 different particles	$NO(A)EC = \frac{1\mu L}{0.29m^3} \times \frac{\rho}{\int vi} \times \frac{100}{PM_{resp}} \left[\frac{mg}{m^3}\right]$	MPPD model	
NIOSH Respirable	Inflammation and cancer	Several studies in rats	Dose-response modelling with calculation of a benchmark dose	Conversion with the ratio of rat/human lung surface areas	2.4 mg·m^{-3}
HSE, Research Report 141 (2003) prepared by Institute of Occupational Medicine	Inflammation (<2% of neutrophil granulocytes in broncho-alveolar lavage fluid for 95% of the population)	Not applicable	NOAEC = 4.0 mg·m^{-3} (obtained by modeling)	PBPK model (Tran et al, 1999)	1.3 mg·m^{-3}

* For the 8h-OEL for respirable fraction, the MAK Commission recommended the average of the 3 values obtained with the two calculations A and B:

- A: 0.11 mg.m^{-3} for toner powder
- A: 0.25 mg.m^{-3} for titanium dioxide powder
- B: 0.5 mg.m^{-3} based on a study with 6 different particles

Choice of OEL

8h-OEL for the inhalable fraction

The MAK Commission value of 4 mg·m^{-3} is the only one with a documented scientific basis currently available. The MAK Commission determined a threshold value, based on data from a human study for impaired lung function, corresponding to an increase of around 5% in the baseline incidence of chronic bronchitis. In 1966-1970, the DFG study on chronic bronchitis was performed as a transversal epidemiological study. Data collection was continued in the years 1972-1977 in the form of a longitudinal study on foundry workers. This value appears protective insofar as the exposure also included dust with identified specific effects.

In view of the scientific expert appraisals currently available, the HRV Committee proposes retaining a value of 4 mg·m^{-3} for the 8h-OEL for the inhalable fraction of DWSE.

8h-OEL for the respirable fraction

The HSE approach is different from NIOSH and the MAK Commission, as it uses a PBPK model (Tran *et al.,* 1999). This model makes it possible to calculate mass fractions of particles at different times in different lung compartments, mainly the alveolar surface, interstitial tissue and lymph nodes (themselves divided into subcompartments). However, the disadvantage of this approach is that the model's predictive capacity of the PBPK model in humans has not been established, even if the model did use the well-established physiological parameters of the human body.

This approach was therefore not retained.

The main differences between the two approaches of the MAK Commission (A and B) are the choice of critical effect, the number of key studies selected, the number of substances studied and the critical concentration used. Both approaches are based on the use of MPPD software to extrapolate from animals to humans.

The MAK A approach is based on the proliferative pulmonary inflammatory response i.e., the NOAEC retained should not induced a significant increase in inflammatory cells, inflammation-specific cytokines, enzymes specific for cytotoxicity or pulmonary epithelial hyperplasia, and was based on a study on rats exposed to TiO_2 or toner powder. In comparison, the MAK B approach, based on the study by Pauluhn *et al.*, 2011, has the advantage of proposing a value based on six types of particles of different densities. It is also based on a better documented mechanism of action.

The MAK Commission recommended the average of the 3 values derived with the two approaches as the 8h-OEL. On the opposite, the MAK Commission's B approach, leading to an 8h-OEL of 0.5 mg.m^{-3} (d=1), was preferred to the A approach by the HRV committee for the reasons mentioned above.

The main differences between the MAK and NIOSH approaches also lie in the choice of critical effect, the number of key studies selected, the number and nature of substances studied and the critical concentration used.

A major advantage of the MAK Commission's B approach is that the value is based on six different particles, unlike that of NIOSH, which is based on studies conducted only on TiO_2. The HRV Committee considers the two approaches to be highly comparable in terms of quality, and that the fact that the MAK Commission uses six particles of different densities is a key element in favour of this approach. However, the HRV Committee also believes it is important to correct this value by density, as the MAK Commission did not do so in order to leave users the option of using the density of the particle of interest.

In the absence of field data or studies providing data on density for dust without specific effect at the workplace, the Committee chose to remain consistent with the data of the experimental study used

to derive the value in the MAK B approach and to be conservative by correcting with the lowest density value of the six particles used excluding nanometric particles (Pauluhn *et al.,* 2011). Based on the study by Pauluhn *et al.* (2011), the lowest density of the particles used in the calculation excluding nanometric particles is that of carbon black with 1.8 $g.cm^{-3}$. Considering the strengths of this approach described above, the HRV Committee therefore chose to retain the value of the MAK Commission's B approach, corrected by the density of 1.8, for deriving the 8h-OEL for the respirable fraction.

The value used to recommend an 8h-OEL for the respirable fraction for DWSE is therefore 0.5 x 1.8 = 0.9 $mg \cdot m^{-3}$. This value is used regardless of the density of the particles found in the working atmosphere.

Results of the collective expert appraisal

8h-OEL recommended for the inhalable fraction based on existing scientific expert appraisals: 4 $mg \cdot m^{-3}$

8h-OEL recommended for the respirable fraction based on existing scientific expert appraisals: 0.9 $mg \cdot m^{-3}$ (to be used regardless of the density of the particles found in the working atmosphere)

The HRV Committee would like to stress that these values may be reviewed more precisely at the end of the second phase of the work to be carried out, but they nevertheless constitute a basis for an initial revision of the regulatory values for DWSE currently in force.

Given the particle-size continuum encountered in workplaces, and although this OEL specifically concerns particles larger than 100 nm, the Committee suggests that this OEL should be applied to any exposure to inhalable or respirable dust without a suspected specific effect, regardless of the particle-size distribution.

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