COMMENTS AND RESPONSE TO COMMENTS ON OEL: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website.

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Last data extracted on 15.01.2020

Substance name: lead and its compounds
EC number: -
CAS number: -

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Poland	Economic Chamber of Non-Ferrous Metals and Recycling	Industry or Trade Association	1

Comment received

GENERAL NOTES

The report summarises the assessment of the influence of lead on human health.
Although it contains more than 200 pages, many issues were not analysed in depth. Many aspects were presented selectively and without regard for the current state of affairs.
We assess the review of literature on the influence of lead on health as superficial. The report does not systematically and critically assess, correct, and synthesise the source literature. As a result, all presented information on the influence of lead on health is not fully synthesised and there is much uncertainty in this regard.
The literature review was limited to summarising major health effects as presented in original literature. The correctness of conclusions made in literature was not assessed.
No independent opinion regarding the OEL values in the workplace was formulated. The report repeats and reinforces opinions from other sources. For this reason, a critical assessment of the evidence for the dose-response relationship being related with health effects resulting from exposure to lead in the workplace is virtually impossible.
There is no reference to and critical assessment of the research methodology and conclusions presented in literature. More importantly, there is also no critical assessment of uncertainty as regards the assumptions made and the models used. Model uncertainties
were not properly presented. The assumptions and estimates do not take into account the existing uncertainty level for this type of data. We also noticed the tendency to ignore mistakes (such as errors in exposure estimates and other accompanying variables). How much the Jack of critical analysis of the data and methodology can be misleading is illustrated by the example of the influence of lead in blood on neurobehavioral effects.
It turns out that based on available historical information on blood lead level, it is usually

assumed that exposure to high-intensity lead causes long-term cognitive impairment. In other words, the effects observed can be attributed to recent measurements indicating relatively low blood lead levels, which in reality reflect high exposures occurring in the past.
Model uncertainties are not properly described in the presented tables and discussion. As a result, uncertain estimates, models and assumptions are treated as if they were the observations which are flawless and known to be correct. With respect to nonmeasurement
models of exposure assessment, according to Gromiec et al. (2014), there
are no reliable non-measurement models for assessment of exposure to chemicals in Poland, but there are countries where such models are used. Several models of nonmeasurement
assessment of exposure and risk estimation tested by the above mentioned
authors were assessed as a good tier-one tool for screening exposure assessment. In the EU, the research on the usefulness of such models, their validation and the preparation of tier-two models as a substitute of tier-one models is still ongoing. Moreover, according to the Polish Labour Code, the employer is obliged to carry out research on factors in the work environment in Poland. Such models can be used by the employer for substances which have no values relating to hygiene standards (PEL) to be used by the employer to determine the level of occupational risk.
In some parts, the report refers to research results achieved 20 years ago. These results do
not reflect the current situation in the workplaces with regard to health and safety at work
and the technological processes used, and do not show the actual, real conditions in which people work.
The number of annual deaths due to lead blood level, which is 412,000 cases, is highly questionable.
ECHA's level of occupational exposure to inorganic lead in ambient air should not result from extrapolation or mathematical proportion. Instead, it should be established based on a thorough scientific analysis of a limit for lead in the air leading to a blood lead level no higher than the range defined by the dose-response relationship for the influence of lead on health.

SPECIFIC COMMENTS

Section 3.2: REACH Registrations
Page 17, Table 10: The numbers of registrants are different, according to the lists shown on
the ECHA website. For example, for orange lead (EC/list number 215-235-6), the table indicates 11 registrants while the ECHA website - 9. The same applies to Table 44 on pages
156-157.

Section 4: Existing Occupational Exposure Limits
Page 21, Table 13: In order to achieve a complete overview of the Member States' biological
limit values (BLY), all Member States' biological limit values have to be taken into account.
Otherwise, it may be not clear why the data is provided. BL V-PbB in Poland is 500 µg/L (50 µg/dl) and is higher than in the table below where the highest value is 400 µg/L.
Incomplete data resulting in a maximum BL V-PbB value amounting to 400 µg/L may distort
the current status of the acceptable levels of exposure to lead. This data should be

supplemented. These are described in the Study to collect recent information relevant to modernising EU Occupational Safety and Health chemicals legislation with a particular emphasis on reprotoxic chemicals with the view to analyse the health, socio-economic and
environmental impacts in connection with possible amendments of Directive 2004137/EC and
Directive 98/24/EC, prepared for DG Employment, Social Affairs and Inclusion on 18 March
2019, p. 365 XI0.1.3 Existing OELs and BLVs. For Poland, it is 50 µg/100 ml. In addition, the OEL 8-hr TWA was spec,ified: 0.05 mg/m3•
In the guidelines of the Interdepartmental Commission for Maximum Admissible Concentrations and Intensities for Agents Harmful to Health in the Working Environment of
the Central Institute for Labour Protection - National Research Institute, entitled Harmful factors in the work environment, the limit values, published in Poland in 2018, the following
PEL (Permissible Exposure Limit) and STEL (short-term exposure limit) values were proposed for lead tetraethyl: 0.05 mg/m3 and 0.1 mg/m3 respectively. Note that skin absorption can be equally as important as inhalation exposure with respect to this substance.
In Poland, there are no biological limit values (BL V) for both lead tetraethyl and lead tetramethyl. For lead tetramethyl, no PEL is also defined.

Section 5.2: Production and Use Information
This section fails to identify occupational exposure to lead and lead compounds which are used in a way other than described in REACH registration, e.g. glass recycling, paint removal,
building demolition and shipbuilding/repair/breaking. These uses result in occupational exposure to lead, but are not included as the uses of lead or lead compounds within the meaning of REACH. It seems that these occupations/activities should also be mentioned in
the report for a more complete view.
Page 31: Lead steels and lead copper alloys are not included, although they are listed in the
REACH documentation. There are also no lead aluminium alloys. Many lead alloys are of key
importance in sectors such as aerospace, automotive, etc.
Page 31 : Lead sheet can also be produced by sand and machine casting.

Section 5.3: Occupational Exposure
Pages 32-33: Similarly as above, this section should contain information on exposure from
other industries or work areas (e.g. paint removal, demolition industry, etc.) which are not
covered in scope of REACH.
Page 33, Table 20: This table references reports cited by IARC in 2006 and that are now over
20 years old. Exposures are therefore not reflective of conditions encountered in 2019 and it is
misleading to include this very outdated information. For example, the level of lead in the air
(PbA) for Italian primary production plants in 1977-1978 or for British cadmium production
plants in 1970-1979 is provided. The term "conditions observed in 2019" means not only

the
progress in occupational health protection or technological progress, but also an incomparable
increase in the level of awareness of both workers and managers.
Page 37, Table 22: This table also contains very outdated measurements of blood lead level
(PbB) (IARC 2006) which no longer reflect the overall population/background levels currently observed in the EU. We recommend removing this.
Page 40, Table 24: The same as above. The table contains outdated measurements of blood
lead level (PbB) which no longer reflect the blood lead levels currently observed in EU workers.

Section 7.1: Toxicokinetics (absorption, distribution, metabolism and excretion - ADME)
Page 43 (Inorganic compounds/Excretion): "As the various tissues and compartments provide
different characteristics of lead storage and exchange, the lead blood level displays multiphasic elimination kinetics. After cessation of lead exposure the blood concentration decreases in the first phase with a half-life of 29 to 36 days. Due to counterbalancing from
soft tissues and the different bone compartments, further compartment elimination processes
have to be considered with half-life values of 1.2 years for a second compartment and 13 years for a third compartment."
Comment: The fact that lead in blood is a marker of a current exposure to this element is true. After the exposure is terminated, the blood lead level may inter alia indicate the release
of lead from bones. However, it is not possible to separate the lead released from bones from
that resulting from environmental exposure. The release of lead from bones is a limiting factor
in the rate of whole-body lead loss after long-term workplace exposure. In practice, this means that measurements of lead in human blood cannot be directly related to measured levels of lead in the air as they reflect both past exposure (and release from bones) and current
exposure with regard to air and swallowing. This is a clear indication of the need for a broadbased
scientific programme. To the best of our knowledge, such research has not been conducted in Poland so far. In Poland, biological monitoring of occupational exposure to lead
is obligatory, but to carry out such monitoring after work to check the kinetics of lead excretion is an unusual practice.

Section 7.3: Specific Target Organ Toxicity/Repeated Dose Toxicity
Page 48: "Adverse health effects of Pb have been observed in every organ system."
Comment: Lead has a multiple organ effect. There are many research papers to support this
thesis, covering the issues from nervous system, through vascular disorders, to cognitive disorders. However, it should be stressed that not every impact of lead on organs is clinically
relevant. One should therefore agree with the opinion that the ongoing research and discussions on harmful effects of lead and its impact on health do not allow for an authoritarian/arbitrary statement on all organs and organ systems.

Section 7.3.1.1: Neurological Effects
Page 48: "SCOEL (2002) summarised that studies of the peripheral nerve toxicity, based upon
measurement of nerve conduction velocity (NCV) provide evidence of a causal relationship
between a reduction in NCV and PbB greater than 700 µg/L, with effects possible at PbB levels as low as 300 µg/L."
Comment: This extremely important problem has not been widely analysed in Poland. Only
studies on exposure to arsenic with the accompanying exposure to lead have been performed.
However, on the basis of the available literature, it should be emphasised, as an addition to the
quotation above, that the peripheral nerve toxicity effects observed in the blood lead level range 300-400 µg/L fall within the clinical standards. Moreover, these effects appear to mitigate if the exposure is removed. Such reversibility with no functional changes and no long-term clinical consequences shows that peripheral nervous system effects with blood lead
levels between 300-400 µg/L should not be considered adverse effects. Clinical and electrophysiological evaluation of peripheral nervous system in workers chronically exposed
to inorganic lead compounds was performed by Bilinska et al. (2003). The study was carried
out in 41 workers and 35 healthy subjects. Nerve conduction study (NCS) in relation to motor
conduction (in radial nerve and fibular nerve) and sensory conduction (in radial nerve and sural
nerve), electromyography recording of musculus extensor digitorum and sympathetic sudomotor
skin response (SSR) examination were performed. The limit blood lead level (dividing workers
into two groups) was assumed to be 400 µg/L. The authors did not show any clinical symptoms of
neuropathy in patients with chronic exposure to lead. The symptoms of peripheral nervous system
damage in the form of neurogenic changes in EMG and abnormal sympathetic sudomotor skin
response were revealed.

Section 7.3.1.2: Renal Effects
Page 58: ''BMDL10 253 µg/L for changes in NAG was calculated (Lin and Tai-Yi, 2007). These are sub-clinical changes and their long-term prognostic value is unclear and therefore they cannot be considered as adverse."
Comment: We agree with ECHA's opimion stating that the NAG enzyme changes "are subclinical lesions and their long-term predictive value is unclear, and for these reasons, they cannot be considered negative". However, in the summary section on kidney effects (p. 115),
ECHA stated: "The data subjected to analysis indicates that the lowest BMDL10 value amounting to 253 µg/L for subclinical lesions revealed by the impaired kidney function marker (NAG enzyme) can be considered no-adverse-effect level." We are afraid that this statement may imply a threshold value that is not supported by other studies reported in the literature. In Poland, no renal threshold and low molecular weight protein filtration studies has been performed. However, Evans and Elinder (2011) found that current levels

of exposure to lead and the work environment do not adversely affect renal function and do not increase the prevalence of kidney diseases. In addition to cadmium, lead is a well-known nephrotoxic agent. It causes damage to both renal tubules and glomeruli. Sensitive indicators of proximal tubule failure caused by lead, cadmium and metallic mercury compounds include serum proteins CP2-microglobulin, al-microglobulin), RBP (retinal-binding protein) and NAG (lysosomal enzyme of the proximal convoluted tubule cells). In Poland, there are very few papers on kidney failure due to exposure to lead. In 2001, Skoczynska et al. described the evaluation of the usefulness of trehalase as an indicator of kidney failure in steelworkers occupationally exposed to lead. The authors believe that trehalase activity in urine is a sensitive indicator of lead-induced dysfunction of brush border in the proximal renal tubules and may be a biomarker of early effects. Wronska-Nofer et al. (2015) conducted such studies in 53 workers exposed to lead by analysing suggested biomarkers and performing renal scintigraphy. The blood lead level ranged from 121.3 to 175.3 µg/L. The authors did not observe any differences in RBP, P2-microglobulin and NAG concentrations in exposed workers and control group. Significant correlations between 99m Tc-DTP A clearance and blood lead level as well as between urinary albumin excretion and blood lead level were found. The authors conclude that the use of renal scintigraphy may indicate increased glomerular filtration and may be an early indicator of kidney failure in workers occupationally exposed to lead.

Section 7.3.1.3: Cardiovascular Effects
Page 63: "A small effect on blood pressure within the normotensive range of blood pressure is not a health outcome per se but a risk factor for cardiovascular and cerebrovascular disease. Considering increases of the order of 1 mmHg of systolic or diastolic blood pressure the risk is small for many individuals; however, in a population, it may be important since it could shift a population's distribution to increase the percentage of individuals considered hypertensive. There are no studies having assessed in a working population the long-term predictive value of s'uch small blood pressure increases for cardiovascular morbidity of mortality."
Comment: IGMNIR agrees with ECHA's conclusions on blood pressure stating that this cannot be a predictor of cardiovascular morbidity and mortality.

Section 7.3.4: Summary
Page 70 (Cardiovascular effects/Increased blood pressure/Cardiovascular mortality): "Based on those results, the LOAEL for small increases in blood pressure (order of 1 mm Hg) that have been observed in working populations is around 300 µg/L. In the general population, similar effects have been observed at even lower PbB levels. However, a small effect on blood pressure within the normotensive range of blood pressure is not a health outcome per se but a risk factor for cardiovascular and cerebrovascular disease. Considering increases of 1 to mmHg of systolic or diastolic blood pressure the risk is small at the individual level and there are no studies which have assessed in a working population the long-term predictive value of such small blood pressure increases for cardiovascular morbidity of mortality. and
"Some of the recent studies, especially in their internal comparisons by exposure level (Steenland et al 2017, Bertke et al 2016, Kim et al 2015, McElvenny et al 2015, Chowdhury et al 2014), provide some indication of an association between past exposure to lead and cardiovascular mortality. In the studies reporting PbB as an exposure metric, the effect was typically seen at levels above 200-400 µg/L. However the studies did not adjust for potential confounding effects of non-occupational risk factors."
Comment: In a small number of studies on excessive risk of cardiovascular disease, it was reported that there are no relationships between blood lead level and blood pressure, or no such reports were made. The absence of a specific causal relationship between blood lead level and blood pressure, combined with study reports on excessive risk of cardiovascular disease with lead not being an indicator of blood pressure, precludes the

calculation of the excessive risk of cardiovascular disease based on the assumption that the effects are caused by blood pressure effects. The search for evidence for cardiovascular diseases associated with exposure to lead can only be based on multi-annual epidemiological studies focused on the examination of health criteria on the basis of dose-response and dose-effect relationships. Few existing studies without clear results cannot be treated as evidence that such effects are interrelated because the issue of significance of exposure to lead in the pathogenesis of hypertension and other cardiovascular diseases remains unresolved. Some studies on the impact of exposure to lead on the occurrence of cardiovascular diseases were carried out, also in Poland. However, these are not epidemiological studies. Poryba et al. (2010) assessed the impact of chronic exposure to lead, cadmium and manganese, and the occurrence of hypertension. The study covered 171 men occupational exposed to metals (workers of the Glog6w and Legnica copper smelters) and 19 members of the control group. The authors concluded that chronic exposure to lead increases the risk of hypertension by about 13 times compared to healthy subjects. Zawadzki et al. (2006) presented views on the mechanisms and effects of toxic activity of lead in the cardiovascular system. They concluded that lead affects all components of the cardiovascular system. It causes morphological and physiological changes in the heart. They also pointed out that not all aspects of the influence of lead on the cardiovascular system are known. The study of Beck (2005) with the use of Doppler echocardiography showed statistically significant differences in left ventricular diastolic function indicators between the group of subjects exposed to lead and the control group. According to the authors, the results indicate a negative influence of lead on left ventricular diastolic function. In the study conducted by Gajek et al. (2004), the influence of lead on daily heart rate variability (HRV) was excluded. No differences were found between the group of copper smelter workers occupationally exposed to lead, with whole blood lead level not exceeding 500 µg/L, and the control group. Hypertension is currently considered to be more dependent on lead deposited in bones than on current exposure, but there is insufficient reliable data to support this hypothesis. As suggested by Prof. Skoczynska (2008), genetic factors and the occurrence of gene polymorphisms involved in the toxic effects of lead should also be taken into account. This means that also research works carried out in Poland confirm that the presence or absence of causal relationship between cardiovascular diseases, including hypertension, and the lead exposure, is not fully known.

Section 8.2.1: Occupational Exposure Limits (OELs)
Page 113 (Inorganic compounds): "ECHA notes that the current values set in the Annexes of
CAD are 150 µg/m3 (8 hours TWA) and 700 µg/L. Using this correlation, the recommended
BL V of 150 µg/L would correspond to an 8-hour TWA of 30 µg/m3 (150 µg/L/700 µg/L * 150 µg/m3 = 32 µg/m3
). ECHA notes that this correlation between air and blood limit is close
to the ones used by ANSES and Safe Work Australia.
It should be noted that the BL V as the primary tool for protecting workers from lead toxicity
has to be complied with. In order to help to achieve PbB below 150 µg/L, ECHA also recommends setting an 8-hour TWA to 30 µg/m 3 ."
Comment: We are pleased to see the conclusion that the BL V should be the primary tool for protecting workers from lead toxicity as this is supported by our extensive experience in minimising exposure to lead. However, we cannot support ECHA's approach of using a simple proportion to derive an air limit from an existing and target BL V as it ignores the complexities and uncertainties associated with the relationship between lead in air and lead in blood. Direct relationship between the level of lead in the air, juxtaposed with PEL, and blood lead level (BL V) in workers is subject to a high level of uncertainty as it

does not take account the following:
1. Long-term exposure of workers to lead - at the time of taking a blood sample, the level lead (PbB) is the sum of the current exposure and lead released from parenchymatous tissues and bones. The direct correlation could only occur in the case of new workers.
2. The influence of many different factors on the lead level in the air, which is then juxtaposed with PEL, including:
the atmospheric conditions on the day of measurement (pressure, temperature, precipitation, etc.),
- intensity of technological processes on the day of measurement (it may vary depending on the day),
types of technological processes on the day of measurement (e.g. different alloying additives, production of different alloys),
- human factor (e.g. on the day of measurement, a worker deliberately stays in the place of an increased exposure to lead for an extended period of time or performs activities not performed under "normal" conditions (i.e. on a daily basis),
- the use and technical functionality of the collective protection measures (air sprinklers, workplace extraction systems, mechanical ventilation, etc.) on the day of measurement,
- other factors that have a direct impact on the final result juxtaposed with PEL.
Nowhere in the ANSES document (ANSES 2017) is there a derivation of an air limit for lead.
ANS ES does reference (on p. 5 of their expert appraisal) the French Labour Code describing
that enhanced health surveillance of workers is triggered when: (I) exposure to a lead concentration in the air is greater than 0.05 mg/m3 (50 ug/m3
), calculated as a time-weighted
average on an eight-hour basis; or (2) a blood lead level higher than 200 µg/L of blood for
men or 100 µg/L of blood for women is measured in a worker. No mathematic proportion like
the one used by ECHA was adopted by ANSES and no air limit as low as ECHA's was proposed by ANSES.
Likewise, ECHA' s assessment that Safe Work Australia used a correlation between air and blood limit values similar to theirs to derive an 8-hour TWA of 30 µg/m 3 is not entirely accurate. Safe Work Australia in fact proposed an air limit of 50 µg/m 3 that was designed to
keep the majority of male workers below a blood lead removal level (BLRL) of 300 µg/L.
Prediction of the blood lead air lead relationship in the workplace is complicated by the ingestion route of exposure. Exposure to lead in the workplace occurs via ingestion and inhalation, both of which can yield systemic exposure as evidenced by elevations in blood lead. Lead ingestion, generally of lead-containing dusts, will vary as a function of the personal
hygiene practices of the individual worker and the overall cleanliness of the work environment. Personal habits such as frequent hand-to-mouth activity, smoking, and eating in
the workplace provide opportunities for lead ingestion. The intensity of exposure resulting from such habits varies as a function of personal hygiene (e.g. hand washing frequency) and
the levels of lead contamination on work surfaces. The extent of lead contamination in the work environment in turn varies as a process-specific function of the industrial setting. Industrial processes generating particulate lead products (e.g. lead oxide) can directly contaminate the work environment, with the level of workplace contamination being dependent upon the adequacy of production process controls and procedures used to handle

and package product material. Contamination of the work environment will also occur as a function of aerosol generation and dust deposition from processes producing or using lead.
Ultimately, levels of lead ingestion in the workplace will be dependent upon lead loading on
work surfaces, as modified by the behavioral patterns of the individual worker. Quantities of
lead loading will in turn be dependent upon the rate at which lead deposition occurs and the
rigor and frequency with which measures are employed to clean work surfaces and the general work environment. The German Federal Ministry for Labour and Social Affairs (UAill) is of the same opinion and considers the uncertainties in the conversion of blood lead
level to air lead concentration to be so relevant that a scientifically satisfactory quality of the
corresponding air lead concentration (OEL) is not deemed guaranteed."
This statement accurately depicts the problem in establishing a quantitative health-based OEL
by extrapolating from a set blood lead measurement.
Referring to the report's recommendation to adopt BLV-PbB below 150 µg/L (p. 113), we present the opinion of Prof. Slawomir Kasperczyk who is scientifically involved in the impact
of chronic occupational exposure to lead and other metals on workers' health and, as an occupational medicine doctor, carries out preventive examinations (pre-employment, periodic
and control) for workers exposed to lead dust in the workplace. For several years, he has been
involved in prophylaxis measures. He performs about one thousand examinations a year for
people occupationally exposed to lead. His scientific achievements include over 40 original publications on lead toxicity, released mainly in foreign journals: "The report's recommendation to adopt BLV-PbB below 150 µg/L (...)may be acceptable from the health
point of view, but with current production technologies in mind, it may prevent the operation
of any lead processing plants. As an occupational medicine physician who is actively engaged
in anti-lead prophylaxis programmes, I can state that achieving a lead concentration below
150 µg/L in blood would entail the necessity to close almost all lead processing plants. Workers with PbB above 150 µg/L would not be allowed to work.
Based on the example of prophylactic examinations carried out in Huta Cynku Miasteczko Slllskie, the average PbB concentrations among production workers are 300 µg/L, while in the
case of companies working on its premises and performing maintenance and repair works -
400 µg/L on average. Sometimes PbB is above 500 µg/L, which is caused by exposure to lead
due to a breakdown in the technological process. Among new workers, the average PbB values increase to 200-350 µg/L within 3 months after starting work. Adopting a PbB standard below 150 µg/L would result in approximately 80-90% of workers being put out of
work, and consequently the need to close the plant. In other plants, the situation is likely to be

similar.
It seems that BL V-Pb should be progressively reduced, but on a gradual basis, over a period
of several years so that current technologies can adapt to the reduction of exposure to lead
with regard to the workers affected. In the first place, BL V-Pb should be reduced to 450 µg/L,
and then to 400 µg/L".

Section 8.2.3: Biological Limit Value (BLV)
Pages 115-116 (Inorganic compounds/Cardiovascular effects): "Some recent studies (Steenland et al. 2017, Bertke et al. 2016, Kim et al. 2015, McElvenny et al. 2015, Chowdhury et al. 2014), provide some indication of an association between past exposure to
lead and cardiovascular mortality. In the studies reporting PbB as an exposure metric, the effect was typically seen at levels above 200-400 µg/L. However, the studies did not adjust
for potential confounding effects of non-occupational risk factors."
Comment: We support ECHA's conclusion that misleading effects make it difficult to associate blood lead levels with cardiovascular effects.
Page 116 (Inorganic compounds/Male fertility): "SCOEL (2002) concluded that adverse effects on male reproduction appear consistently at PbB levels above 400 µg/L. More recent
studies investigating the fertility of lead-exposed workers support this conclusion."
Comment: We support the conclusion on male fertility.
Page 116 (Inorganic compounds/Female fertility): "The data with regard to female fertility is
very limited. One recent studies on female lead-exposed (Paredes Alpaca et al., 2013) indicates an increased risk of miscarriages at a PbB level >50 µg/L."
Comment: We support the conclusion on female fertility.

Section 8.2.3.2: Organic Compounds
Pages 118-119: "However, since the higher acute (neuro) toxicity of tetraethyl and tetramethyl lead compared to the inorganic lead compounds is accounted for by the OEL, the
body burden resulting from any exposure to a lead compounds is addressed by measuring systemic lead exposure as blood lead. Therefore, it is proposed to apply the BL V for inorganic lead compounds also for the organic lead compounds.
Comment: ECHA may consider re-adopting the same BL V for organic lead compounds as for inorganic lead compounds, given ECHA's conclusion on acute (neurological) toxicity of lead compounds higher compared to inorganic lead compounds and differences in toxicokinetics, especially with regard to absorption and excretion through respiratory system
and skin as mentioned earlier. The evidence in respect of organic compounds is insufficient.
Further research, analysis and evidence are needed.

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ECHA/RAC response

General comments:
The Annex is based on a critical review of a vast amount of published papers of the last ten years and the international reviews and evaluations as listed in the section Literature. Your comment to systematically and critically assess, correct, and synthesize the literature to give an accurate synthesis of knowledge and uncertainty of health effects observed is taken into account, as far as possible, during the opinion development process and the alignment of the Annex. Furthermore, additional relevant literature and reviews, based on comments received during the Consultation are included in the Annex.

Comment on REACH registrations: The numbers of REACH registrations are corrected.

<u>Comments on Existing Occupational Exposure Limits</u>
Detailed list of BLVs including the BLV in Poland has been included. The OELs for inorganic lead and lead tetraethyl were already included in the document.

Comments regarding challenges of reducing BLVs to the proposed level

- A table is is added from OEHHA illustrating the effect of the bone release of past Pb burden and the challenge in terms of time needed that this poses to reducing PbB levels to desired level.
- Consideration of this information is part of the socio-economic and feasibility aspects that follow at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC.
- The problem of lead release from bones representing higher past environmental and/or occupational exposures which causes uncertainty associating current healh outcomes to recent blood lead measurements. There indeed, the health outcomes might be linked to higher past exposures not correctly reflected by current measurements. This uncertainty is now more expliciely explained in Chapters 7.1.5 and 8.2.3.

Comments concerning neurotoxic effects, more specifically peripheral nerve conductivity

- More detailed description is included using recent meta-analyses and reviews in order to concisely summarise the data base.

Comments on human data on renal and cardiovascular effects

- The support for the conclusions is appreciated and the references to individual Polish studies supporting these conclusions are noted.

Comments on exposure assessment and model uncertainties

- See replies to comment 30

Further comments

- More details have been added to the Annex.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Czech Republic	Federation of European Explosives Manufacturers (F.E.E.M.)	Industry or Trade Association	2

Comment received

Please the attached document

ECHA note – An attachment was submitted with the comment above. Refer to public attachment FEEM_STATEMENT_Public consultation Pb.pdf

ECHA/RAC response

Some of the uses of lead compounds are not described in detail as they account for a relatively small tonnage of the substance, e.g. for lead monoxide less than 1% of the tonnage is used for explosive manufacture, catalyst production and the other uses combined. A note on this has been included in the Annex.
Your support to lower the BLV, and for your considerations about challenges related to the air value and to women in fertile age is noted.
The RAC opinion and its Annex assesses the scientific information available and makes a proposal based on that information. The socio-economic aspects are considered at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Czech Republic	Austin Detonator s.r.o.	Company-Downstream User	3

Comment received

See the attached document ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Austin Detonator_ STATEMENT_ Call for evidance Pb.pdf
ECHA/RAC response
Your information on your uses and blood lead levels is noted. The RAC opinion and its Annex assesses the scientific information available and makes a proposal based on that information. The socio-economic aspects are considered at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Belgium	Ceemet - European Tech and Industry Employers	Industry or Trade Association	4
Comment received				
ECHA SCIENTIFIC REPORT ON LEAD AND ITS COMPOUNDS page 11 ECHA note – An attachment was submitted with the comment above. Refer to public attachment Ceemet response_ECHA consultation on Lead and its inorganic compounds.pdf				
ECHA/RAC response				
Your information on your experience on blood lead levels and RMM, and your considerations related to the proposed values is noted. The RAC opinion and its Annex assesses the scientific information available and makes a proposal based on that information. The socio-economic aspects are considered at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Germany		Individual	5
Comment received				
see attched document: 8.2.1.1 Inorganic compounds and 8.2.3.1 Inorganic compounds ECHA note – An attachment was submitted with the comment above. Refer to public attachment 191216_Comments_on_the_OEL_report_PIC.pdf				
ECHA/RAC response				
• Your considerations on challenges related to air values, measurement and lack of correlation between air and blood concentrations are noted. The Annex includes in Chapter 6 examples of analytical methods that have the potential to fulfil the requirements of the sampling standards for the proposed OEL. For instance, the first method in table 20 has an LOQ of 0.13 mg/m3 (for a sample of 2 hours duration). • The RAC opinion and its Annex assesses the scientific information available and makes a proposal based on that information. The socio-economic aspects are considered at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC.				

Date	Country	Organisation	Type of Organisation	Comment number

16.12.2019	France	Fédération Française Bâtiment	Industry or Trade Association	6
Comment received				
La Fédération Française du Bâtiment est attentive aux travaux actuellement menés par l'Agence européenne des produits chimiques relatifs à l'évaluation des valeurs limites du plomb et de ses composés sur le lieu du travail. A ce titre, la FFB souhaiterait apporter des commentaires sur le cadre règlementaire existant et les propositions énoncées (cf pièce jointe) ECHA note – An attachment was submitted with the comment above. Refer to public attachment Réponse FFB consultation européenne abaissement VLB plomb.pdf				
ECHA/RAC response				
• Your comments on BLV, women in childbearing age, and consequences of lowered limit values, please note that the RAC opinion and its Annex assesses the scientific information available and makes a proposal based on that information are noted. The socio-economic aspects are considered at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC. • The current values for the BLV in France have been included in the Annex. Intermediate thresholds are not identified in Directive 98/24/EC or ECHA guidance https://echa.europa.eu/documents/10162/23036412/ircsa_r8_appendix_oels_en.pdf/f1d45aca-193b-a7f5-55ce-032b3a13f9d8				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Germany	Ecobat Technologies	Company Manufacturer	7
Comment received				
Ecobat Technologies welcomes the revsion of the workplace directive 98/24 and appreciates the opportunity to present these comments to ECHA. Our companies have a long term experience in production and recycling of Lead and Lead compounds and had installed several Management measures and tranings for the reduction of blood-lead values of employees. Overall we think from our experience from the last decades that the BLV should be used as the primary tool for protecting workers from lead exposure and not the air lead limits as there is no clear coherence between BLV and lead in air. Members of ECHA are very welcome to visit our primary- or secondary smelters to get an overview about our sucessfull blood-lead reduction programs. Detailed comments on the ECHA proposal were provided in the pdf attachment from ILA- International Lead Association. ECHA note – An attachment was submitted with the comment above. Refer to public attachment 19.35.ECHA OEL report ILA Comments-Final Draft 4_12_19-clean (003).pdf				
ECHA/RAC response				
For responses to your comments, please see Comment number 30.				

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Austria	Wirtschaftskammer Österreich	Industry or Trade Association	8
Comment received				
@ p. 11 ECHA recommendation: The proposed Occupational Exposure Limit (OEL) (8-hour TWA) of 30 µg/m3 for inorganic				

compounds and organic lead compounds is too low to be practicable for many industries. The Biological Limit Value (BLV) of 150 µg Pb/L in blood for inorganic and for organic lead compounds is also too low.
Despite protective measures taken in the past the suggested OELs and BLVs cannot be achieved in the metal industry. The introduction of such a low OEL and BLV may lead to a relocation of metal production to other parts of the world.
Many forms and compounds of waste contain lead. Lead measurement of blood helps to motivate employees to wear personal protective equipment. The values measured in waste disposal are between 50 and 200µg/l, whereby persons with values above 150µg/l are smokers.
The limit value proposed by ECHA is much too low, as it reduces the current BLV from 700µg/l to 150µg/l. Also in the waste disposal and resource management sector serious doubts are raised that the limit value as proposed in the consultation document can be successfully implemented.
Before deciding on a new BLV/OEL an analysis of the economic consequences is needed. The benefits in health of a lower BLV/OEL must be in proportion to the costs.

ECHA/RAC response

The RAC opinion and its Annex assesses the scientific information available on health effects and exposure response relations and makes a proposal based on that information. The socio-economic aspects are considered at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Poland	Economic Chamber of Non-Ferrous Metals and Recycling	Industry or Trade Association	9

Comment received

The report summarises the assessment of the influence of lead on human health. Although it contains more than 200 pages, many issues were not analysed in depth. Many aspects were presented selectively and without regard for the current state of affairs.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2019 12 16 Stanowisko IGMNiR-skonwertowany(1).pdf

ECHA/RAC response

Please see responses to Comment 1.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Sweden		MemberState	10

Comment received

Page 118,
The Swedish Chemicals Agency agrees with Option 2: ”The blood-lead level for women of childbearing age should not be higher than the reference values of the respective general populations not occupationally exposed to lead”.
However, the reference value (90-95th percentile?) must not be higher than 50 µg/L, otherwise Option 1 would be a better choice. In Sweden, blood lead levels in pregnant women are currently around 10 µg/L, and they rarely appear to be above 20 µg/L.

Setting a reference level for women of childbearing age in the EU should not be driven by possible high levels in certain regions of Europe.

In our opinion, a BLV in blood is a good exposure metric as it takes into account all exposure to lead and in our view, an OEL provides no added value in this case. Given the situation when there are two different BLVs to relate to (one for women of childbearing age and one for others), the OEL will be a complicating factor to consider. This, combined with the uncertainties in the methodology for deriving the OEL (as illustrated in figure 1), we propose to derive only BLVs for lead, and exclude the OEL.

ECHA/RAC response

Your preference in relation to a separate BLV for women of childbearing age, as well as your preference to exclude the OEL and set only a BLV is noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Germany	CeramTec GmbH	Company Manufacturer	11

Comment received

The attached report shows that literature data as well as the workplace measures show that for lead titanium zirconium oxide the current OEL of 0.1 mg/m³ from TRGS 900 Germany results in blood lead levels below 150 µg/L. Thus, the OEL the correlation should not be used to generalise an OEL for lead compounds. Especially for lead titanium zirconium oxide the correlation results in 8- hour TWA which is much lower than needed to reach blood lead levels below 150 µg/L. In addition, this is supported by the variations in solubility and thus bioavailability as well as toxicity of lead compounds support. Therefore, lead titanium zirconium oxide (PZT) should be excluded from the suggested generalised OEL and an adjusted OEL of e.g. of 0.1 mg/m³ should be considered for lead titanium zirconium oxide (PZT).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Report CeramTec GmbH_DLAC GmbH_01_20191216_fin.pdf
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Worker Exposure to Lead Titanate_Roy.pdf

ECHA/RAC response

This aspect, related to poorly soluble lead compounds, has been included in the Annex to the opinion.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Czech Republic	Association of Chemical Industry of the Czech Republic	Industry or Trade Association	12

Comment received

Association of Chemical Industry of the Czech Republic fully supports the comments of its member- Austin Detonator (member of FEEM) on the ECHA Scientific report for evaluation of limit values for lead and its compounds at the workplace.

ECHA/RAC response

Your comment is noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Belgium	AFEMS - Association of European Manufacturers of Sporting Ammunition	Industry or Trade Association	13

Comment received

General Comments

AFEMS (Association of European Manufacturers of Sporting Ammunition) supports and shares the comments on the 17 October “ECHA scientific report for evaluation of limit values for lead and its compounds at the workplaces”, as submitted by ILA (international Lead Association, Inc.)/Pb REACH Consortium on December, 6th.

Specific comments

Page 32) ECHA provides a review of the ‘production and uses information’ related to Pb and Pb compounds in section 5.2, and addresses the use of Lead (5.2.2) in the production of ammunition in point 5.2.2.6. In the mentioned section, at the end of the paragraph, the report states:

“On 17 August 2018, ECHA sent the opinion of its scientific committees supporting a restriction on the use of lead for shooting in terrestrial areas, ammunition and fishing tackle, in addition to action on lead shot in wetlands.”

This section reports incorrect and particularly misleading information.
First, the content of the mentioned section conflicts with the content of Section 3.4, which correctly enunciates that “ECHA […] has been requested by the European Commission to investigate the need for a restriction to address the risk” related to be same uses of lead ammunition and gunshot.

Second, the formal discussions at RAC and SEAC pertaining to the proposal of a terrestrial restriction of the use of lead ammunition and gunshot have not started yet. Moreover, there is no Annex XV report recommending a restriction at this stage, but only the ECHA Investigation Report. De facto, this means that the ECHA Investigation Report, which was published in September 2018, was not subject to stakeholder scrutiny via an ECHA public consultation so far.

AFEMS wants to stress the shortcoming of such assertion and the deceptive meaning it holds, for the sake of the veracity of the present ECHA scientific report and of a possible future Annex XV report recommending such restriction on the use of lead for shooting in terrestrial areas.

ECHA/RAC response

The text has been rephrased to clarify that ECHA’s Committees RAC and SEAC adopted its opinion on an Annex XV dossier proposing restrictions on the use of lead in gunshot in wetlands.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Italy	Stitra SrL	Company-Downstream User	14

Comment received
We will be forced to close our business if lead is banned from ammunition for big game hunting and target shooting, and all of that for no benefit from an environmental perspective as 99% of lead diffusion in the environment is due to car batteries. There is no other material possible to produce bullets in sufficient quantities to meet current demand at current prices. Non lead alternatives for bullets for big game hunting are not effective and result in many lost and wounded animals.
ECHA/RAC response
The RAC opinion and its Annex do not concern a proposed restriction under REACH (Annex XV dossier), but concern a scientific evaluation of limit values for lead and its compounds at the workplace (CAD).

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Germany		MemberState	15
Comment received				
ECHA describes that the correlation between lead air concentration and blood concentration is influenced by various factors and not constant over various occupational settings. Thus, there are uncertainties in establishing an airborne lead concentration limit departing from the blood lead level, i.e. the biological limit value. Consequentially, ECHA chooses a pragmatic approach in relating the BLV proposed to an OEL by using the same quantitative relationship from the current binding limit values for lead in the CAD ('Using this correlation, the recommended BLV of 150 µg/L would correspond to a 8 hour TWA of 30 µg/m3 (150 µg/L / 700 µg/L * 150 µg/m3 = 32 µg/m3).') However, there is a recent scientific approach by the Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency (OEHHA 2013) to correlate lead air levels to lead blood levels. This approach does not and cannot overcome or rule out the uncertainties described above. Nevertheless, it is considered the best and most recent approach and has developed the pharmacokinetic model of Leggett (1993) further. OEHHA is referred to in the OEL/BLV proposal by ECHA but is not described in detail and does not seem to have been analyzed with scrutiny. ECHA quotes the German AGS which referred to OEHHA (2013) that based on these data a BLV of 150 µg/L would correlate to an 8 h TWA of 11.5 µg/m3. This relationship is taken from Table S-1 on page 3 in OEHHA (2013). However, this relationship referred to by ECHA is based on the 50th percentile of the blood lead level. An OEL should not be derived on a 50th percentile value only applicable to 50% of the total workforce exposed but better on the 95% percentile. In doing so, the OEL derived from table S-1 would be 3.9 µg/m³. This is a value which is sevenfold lower than the OEL of 30 µg/m³ proposed by ECHA. https://oehha.ca.gov/air/document/estimating-workplace-air-and-worker-blood-lead-concentration-using-updated-pbpk-model With respect to the uncertainties in establishing an airborne lead concentration limit departing from the blood lead level it is questionable whether an OEL for lead may be derivable at all which is able to adequately take into account former lead exposures. This is due to the fact that the current blood lead level in workers is to a more or less (unknown) extent determined by past exposures, i.e. the bone lead level. Currently, the Technical Rule for Hazardous Substances (TRGS) for lead and its compounds is being processed in Germany because the Committee for Hazardous Substances (AGS) proposed a new biological limit value for lead in 2018. The discussion in the associated working group did not establish an OEL for lead due to the known				

uncertainties described above. Thus, if it is considered necessary to establish an OEL for lead on the European level by departing from the blood lead level past lead exposures in addition to current lead exposures need to be discriminated by means of an evaluation with extreme scrutiny.
It is likely that a relevant portion of exposed employees will exceed the new biological limit value when it comes into force. The current exposure situation via air is not directly relevant for those individuals, since the blood lead levels of these workers are mainly caused by past exposures. It is known that even employees who have retired from active service may show no significant reduction in blood lead in aftercare for longer periods of time.
Thus, the implementation of a very conservative (binding) OEL for lead in air currently will not be helpful for those workers with relevant exposures from the past.

ECHA/RAC response

The factors influencing the correlation between air and blood Pb levels and the related uncertainties are now described more in detail. Also to approaches and correlations used by ANSES, Safe Work Australia and California EPA are described more in detail. The wording of the proposed air value (OEL) has been revised accordingly. The uncertainties in relation to correlation between air and blood levels are noted.

Date	Country	Organisation	Type of Organisation	Comment number
16.12.2019	Sweden	<confidential>	Company Manufacturer	16

Comment received

8.2.3

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment ECHA_Boliden.docx

ECHA/RAC response

Your considerations in relation to BLV, air value and women in childbearing age are noted.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2019	France	Ateliers d'Art de France	Industry or Trade Association	17

Comment received

Page 109

ECHA note – An attachment was submitted with the comment above. Refer to public attachment questionnaire word entreprises concernées par la révision de la valeur VLB .docx
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment QUESTIONNAIRE 1.pdf

ECHA/RAC response

Your comments presenting your practices are noted.

Date	Country	Organisation	Type of Organisation	Comment number
15.12.2019	Germany	Deutsche Gesetzliche Unfallversicherung	National Authority	18

Comment received

Arbeitsplatzgrenzwerte und Kurzzeitwerte
In der Europäischen Gemeinschaft gilt derzeit ein verbindlicher Grenzwert von 0,15 mg/m³ für anorganische Bleiverbindungen (RL 98/24/EG).
Zurzeit gibt es in Deutschland keinen eigenen Arbeitsplatzgrenzwert nach TRGS 900 für Blei und seine anorganischen Verbindungen. Grund dafür ist, dass die inhalative Exposition nicht alleine für die innere Belastung bei Tätigkeiten mit bleihaltigen Gefahrstoffen entscheidend ist, sondern die orale Bleiaufnahme, die bei Beschäftigten individuell sehr unterschiedlich ist. Aktuell gilt national noch die Forderung, eine Arbeitsplatzkonzentration von 0,10 mg Blei/m³ einzuhalten bzw. sie so weit wie möglich zu unterschreiten (TRGS 505).

Ein Zusammenhang zwischen der Bleistaubkonzentration in der Luft am Arbeitsplatz und der Höhe des Blutbleispiegels ist kausal nicht ableitbar. Deshalb ist auch bei Einhaltung der Arbeitsplatzkonzentration von 0,10 mg Blei/m³ ein erhöhter Blutbleispiegel aufgrund oraler Aufnahme möglich. Eine orale Aufnahme besteht durch mangelnde Hygiene am Arbeitsplatz. Bleihaltige Stäube können durch verschmutze Hände in den Körper gelangen, z.B. bei der Nahrungsmittelaufnahme (Essen und Trinken) oder durch Rauchen. Da das persönliche Verhalten der Beschäftigten in Bezug auf die Hygiene entscheidend für die Aufnahme von Blei in den Körper und damit für den Blutbleispiegel ist, wurden neben den technischen und organisatorischen Schutzmaßnahmen, die individuellen Schutzmaßnahmen in den Vordergrund gestellt.

In Deutschland hat der Ausschuss für Gefahrstoffe (AGS) aufgrund der oben ausgeführten Zusammenhänge keinen Arbeitsplatzgrenzwert für Blei und seine anorganischen Verbindungen sowie keinen Kurzzeitwert abgeleitet, sondern lediglich einen Biologischen Grenzwert (BGW).

Ein von der ECHA vorgeschlagener Arbeitsplatzgrenzwert von 30 g/m³ für anorganische und organische Bleiverbindungen, der aufgrund von Berechnungen ausgehend vom Biologischen Wert von 150 g/L ermittelt wurde, halten wir aufgrund der oben genannten Gründe für nicht sinnvoll. Die Berechnung basiert auf einem monokausalen Zusammenhang zwischen dem Anstieg des Blutbleispiegels und der Erhöhung der Bleikonzentration in der Luft am Arbeitsplatz, der aber so nicht zutreffend ist.

Wir weisen außerdem darauf hin, dass der vorgeschlagene Arbeitsplatzgrenzwert von 30 □g/m³ in Betrieben mehrerer Branchen derzeit nicht eingehalten werden könnte.

Der Meinung der ECHA, dass kein Kurzzeitwert abgeleitet werden kann, folgen wir. Es wird beschrieben, dass die Toxizität von Blei und seinen Verbindungen auf einer chronischen Wirkung beruht. Mehrere Studien weisen darauf hin, dass eine akute Wirkung nicht vorwaltend ist.

Biologische Grenzwerte (BGW nach TRGS 903) werden zur Bewertung der Ergeb-nisse aus dem Biomonitoring herangezogen. Aufgrund der oben beschriebenen Problematik, hat das Biomonitoring eine besondere Bedeutung. Für Blei wurde seinerzeit ein BGW von 400 g/L und für Frauen unter 45 Jahre von 300 g/L in der TRGS 903 festgelegt. Für Bleiverbindungen gelten andere Werte.
Dieser BGW konnte nach unserem Kenntnisstand in der Regel in den Betrieben eingehalten werden.

In Deutschland hat der zuständige Ausschuss für Gefahrstoffe die Absenkung des BGW für Blei und seine anorganischen Verbindungen im Blut auf 150 g/L beschlossen. Der BGW gilt nicht für Frauen im gebärfähigen Alter. Die Veröffentlichung wird nach Überarbeitung der TRGS 505 erfolgen. Grundlage für die Neufestsetzung waren vorliegende Studien und

Erkenntnisse zur Toxizität, zur Ablagerung im Körper und Remobilisierung von Blei im Körper. Die Anwendung oder Nicht-Anwendung des neuen BGW für berufstätige Frauen im gebärfähigen Alter und Schwangere muss in Deutschland noch durch den Ausschuss für Mutterschutz geklärt werden.

Die ECHA folgt dem Vorschlag des AGS und schlägt ebenfalls einen BGW für Blei und seine Verbindungen von 150 g/L im Blut vor. Der BGW kann jedoch die Fruchtschädigung bei Frauen im gebärfähigen Alter nicht sicher ausschließen. Die ECHA schlägt aufgrund zahlreicher Studien vor, die Exposition von Frauen im gebärfähigen Alter gegenüber Blei am Arbeitsplatz zu vermeiden bzw. auf < 50 g/L zu minimieren. Grundlage für die Ableitung des BGW waren Humandaten aus verschiedenen Studien. Diesen Vorschlag nehmen wir zur Kenntnis. Wir geben aber zu Bedenken, dass der Vorschlag letztlich zur Konsequenz hat, gebärfähige Frauen von Arbeiten auszuschließen, bei denen Tätigkeiten mit Blei durchzuführen sind (Beschäftigungsverbot). Hier sollte man die Verhältnismäßigkeit der Mittel im Blick behalten.

Den Daten aus dem deutschen Umweltbundesamt kann entnommen werden, dass die Hintergrundbelastung der Allgemeinbevölkerung durch Blei seit Jahren abnimmt, wenn auch der Abbau von Blei im Körper sehr langsam erfolgt. Die Bleibelastung der Allgemeinbevölkerung resultierte vor allem aus Lebensmitteln und in der Vergangenheit durch Umweltbelastungen durch Ottomotoren (Tetraethylblei) oder durch bleihaltige Wasserleitungen. Außerdem variiert die Hintergrundbelastung der Allgemeinbevölkerung je nach Region in Deutschland, weil die Bleibelastung in Böden eine Rolle spielt. Nur noch vereinzelt in Regionen, wie z. B. dem Ruhrgebiet, dem Saarland und einigen Gebieten in Ostdeutschland, sind Bleibelastungen des Bodens festzustellen.

Die ECHA vertritt die Meinung, dass der Blutbleispiegel für Frauen im gebärfähigen Alter nicht höher sein sollte als die Hintergrundbelastung der Allgemeinbevölkerung. Es ist jedoch anzumerken, dass es schwierig ist die Hintergrundbelastung einheitlich festzulegen, weil sie von unterschiedlichen Faktoren (s. o.) abhängig ist und regional variiert.

Die deutsche MAK-Kommission der Deutschen Forschungsgemeinschaft gibt einen Biologischen Arbeitsstoff-Referenzwert (BAR) für Blei und seine Verbindungen (außer Bleiarsenat, Bleichromat und Alkylbleiverbindungen) von 30 /L für Frauen an. Dieser BAR beschreibt die Hintergrundbelastung von beruflich nicht exponierten Personen im erwerbsfähigen Alter. Dieser Wert hat keinen Bezug zu gesund-heitlichen Effekten und ist von verschiedenen Faktoren (s. o.) abhängig

Der Meinung der ECHA, dass kein BAR abgeleitet werden sollte, folgen wir, da schon die Hintergrundbelastung der Allgemeinbevölkerung regional variiert und bereits ein BGW abgeleitet wurde. Bei Einhaltung eines BAR wäre das Risiko einer Beeinträchtigung der Gesundheit auch nicht auszuschließen.

Weiterhin hat die MAK-Kommission der DFG einen Biologischen Leitwert (BLW) für Blei und seine Verbindungen (außer Bleiarsenat, Bleichromat und Alkylbleiverbindungen) von 200 /L für Frauen über 45 Jahre abgeleitet. Ein BLW für Frauen unter 45 Jahre konnte nicht festgelegt werden. Der BLW beschreibt die Quantität eines Arbeitsstoffes bzw. Arbeitsstoffmetaboliten oder die dadurch ausgelöste Abweichung eines biologischen Indikators von seiner Norm beim Menschen, die als Anhalt für die zu treffenden Schutzmaßnahmen heranzuziehen ist, für die keine anderen biologischen Grenzwerte beschrieben werden können. Es wird eine Arbeitsstoffbelastung von maximal 8 Stunden täglich und 40 Stunden wöchentlich über die Lebensarbeitszeit zugrunde gelegt. Auch bei Einhaltung des BLW ist das Risiko einer Beeinträchtigung der Gesundheit nicht

auszuschließen.
Die angegebenen Werte der MAK-Kommission für Männer sind nicht Gegenstand dieser Stellungnahme. Es ist zu beachten, dass die Angaben der MAK-Kommission der DFG wissenschaftliche Empfehlungen und kein geltendes Recht sind.

Fazit
Eine weitere Absenkung des Luftgrenzwertes für Blei ist nicht zielführend. Vielmehr sollte der Luftgrenzwert von 0,15 mg/m³ für anorganische Bleiverbindungen (RL 98/24/EG) zugunsten eines Biologischen Grenzwertes in Höhe von 150 g/L zurückgezogen werden.

Ein wesentlicher Grund hierfür ist, dass bei Tätigkeiten mit Blei und seinen Verbindungen der wesentliche Aufnahmepfad die orale Aufnahme darstellt und keine evidenten Korrelationen zwischen inhalativer Aufnahme und innerer Belastung bestehen.

Die Überlegung, bei gebärfähigen Frauen berufliche Expositionen gegenüber Blei zu vermeiden oder einen biologischen Grenzwert von < 50 g/L zu setzen, sehen wir kritisch, da dies einem Beschäftigungsverbot für einschlägige Tätigkeiten bedeuten würde. Hier sollte man die Verhältnismäßigkeit der Mittel im Blick behalten.

ECHA/RAC response

Your comments on an air value not being useful, on the practices and assessments in Germany, on challenges related to a lowered air value and your preference to give only a BLV and withdraw the air value are noted.
Regarding your comments on women in childbearing age, please notice that the RAC opinion and its Annex assesses the scientific information available and makes a proposal based on that information. The socio-economic aspects are considered at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC.

Date	Country	Organisation	Type of Organisation	Comment number
13.12.2019	Netherlands	The Health Council of the Netherlands	National Authority	19

Comment received

Overall, the draft scientific report is well documented and the critical studies on the adverse health effects are sufficiently described. The report also includes the most relevant evaluations published by other scientific authorities (ACG, Anses, ATSDR, IARC, SCOEL). Specific comments are given below.

Existing Occurrence, Existing Occupational Exposure Limits, Biological Guidance Values and Biological Limit Values
• Page 20, Table 12: Add that in the Netherlands a legally binding OEL of 0.15 mg/m3 (TWA 8-hour) for 'lead and inorganic lead compounds' is set.
• Page 21, Table 12, Notes: Add "I" Inhalable fraction.
• Page 21, Table 13: Add that in the Netherlands for 'lead' a Biological Limit Value of 70 µg/100 ml blood is set.

Cancer Risk Assessment and Exposure Limit Values
• P107, Section 8.1 Published Approaches for cancer risk assessment: The ECHA concludes that "it seems plausible that lead has no direct genotoxic effect". However, the DECOS noted that in the draft report at several places, induction of micronuclei and chromosomal aberrations are mentioned without indication why these are considered to result from indirect genotoxic effects (see Section 7.6 Genotoxicity and Section 7.9.5 Genotoxic effects and Induction of oxidative stress). Therefore, in the view of the DECOS,

in the conclusions it would be appropriate to more clearly explain why all positive results in genotoxicity assays are considered to result from indirect genotoxic effects, so that establishment of an OEL is warranted.
• P113, Section 8.2.1 Occupational Exposure Limits: The DECOS misses the scientific justification to propose an OEL of 30 µg lead/m3. In addition, the DECOS would like to urge a note of caution on comparing the OEL with the OELs set by others. For instance, Anses also proposes an OEL of 30 µg lead/m3 by calculating an "air slope factor" (ASF) that reflects the linear increase in blood lead levels for an increase in lead concentration in the air. The Anses used a linear extrapolation of the blood lead levels to lead concentrations in the air based on a study by Chavalitnitikul et al. (1984), whereas in fact it should be a non-linear extrapolation that will result in a lower OEL. Indeed, the ECHA cites Safe Work Australia (P113): “ASF is non-linear and the relative contribution of PbAir to PbB is greater at low air concentrations relative to high concentrations.” Overall, there is a high level of uncertainty around the data of the epidemiological studies that were used to calculate air slope factors, especially in the lower air exposure range. Given these uncertainties, ECHA should further clarify the scientific base for proposing an OEL of 30 µg lead/m3.
• Page 113-114, Section 8.2.1 Occupational Exposure Limits: The DECOS questions the usefulness of setting an OEL due to the cumulative properties of lead and the long half-life in the bones. This indicates that disease development by lead, whether occupational or environmental, is most likely caused by the cumulative exposure from different sources starting early in life. It also means that it is hard to assess the degree of contribution of occupational exposure to the total lead body burden. In such a case, from a toxicological point of view, there is little point to recommend an atmospheric OEL; also a pragmatic OEL would not add to the safety of the worker’s health. Therefore, the DECOS advices the ECHA to abstain from proposing an OEL.
• Page 118, Women of childbearing age: ECHA proposes a BLV of 150 µg lead/L blood, writing that “this BLV is not protective for the offspring of female lead-exposed workers at childbearing age”. Subsequently, for these women, it gives three options for a separate BLV. It is not clear to the DECOS why a separate BLV for fertile women is proposed instead of proposing a BLV that would be sufficiently protective for all workers including women of childbearing age. In general and by definition, a BLV or OEL should also protect against reproduction and developmental effects. Therefore, the DECOS urges the ECHA to propose only one BLV that protects the whole working population, including fertile women.
• Page 118, Option 1: Please justify the proposed BLV of < 50 µg lead/L blood.
• Page 119, Section 8.3 Notation: On Page 44, Absorption through the skin, ECHA writes that certain lead alkyls can be taken up through the skin. Related to this, on Page 119 the ECHA concludes that no skin notation is needed. This should be further clarified, because when dermal exposure adds significantly to systemic exposure (irrespective of the type of effect), a skin notation might be warranted. Whether or not a skin notation should then be applied, depends on the proposed BLV or OEL.

Other related comments
• Page II, Preamble: The sentence “In support … at the workplace” is written twice, please remove one of these sentences.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 459-F76 Health Council Netherlands - Comments on lead and lead compounds ECHA december 2019.pdf

ECHA/RAC response

- The OEL and BLV values for inorganic lead in the Netherlands have been added to tables 12 and 13.
- Sections on genotoxicity and air value have been modified.

- The rationale for proposing a separate approach for women at childbearing age is now described more in detail.
- The section on skin notation has been updated.
- Your editorial comments are taken into account.

Date	Country	Organisation	Type of Organisation	Comment number
13.12.2019	Sweden	Teknikföretagen	Industry or Trade Association	20

Comment received

Lead – biological limit value

The biological limit value (BLV) suggested in the ECHA study is very low (150µg/l), almost three times lower than the current Swedish BLV (414 µg/l) and two times lower than the BLV that will come into force in Sweden in 2021 for men and women older than 50 years (310 µg/l).

In Sweden, since there is a new BLV waiting to come into force, we have had reason to look at how a lower BLV will affect the industry and especially some type of foundries. Lowering the BLV in Sweden will have a major impact on these foundries. An even lower BLV, that is suggested by ECHA, will of course have even greater consequences. The foundries that are affected are usually SMEs with less possibilities for automation or to operate in closed systems.

Before deciding on a new BLV an analysis of the economic consequences is needed. Are the benefits in health of the suggested very low BLV in proportion to the costs? How will a BLV like the one proposed by ECHA affect, for example, smaller foundries in Europe? Since Sweden just decided to lower our BLV we would find it very interesting if a comparison was done between the value we have decided on with the one suggested by ECHA. What additional health benefits would be made and what would they cost? These, and more, questions and consequences must be analyzed before deciding on a specific value.

With the BLV proposed by ECHA there is a risk that products that are currently manufactured in Europe will be imported from other parts of the world.

ECHA/RAC response

The RAC opinion and its Annex assesses the scientific information available and makes a proposal based on that information. The socio-economic aspects are considered at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC.

Date	Country	Organisation	Type of Organisation	Comment number
13.12.2019	France	Fédération du Cristal et du Verre	Industry or Trade Association	21

Comment received

See attached document presenting the common position of the Fédération du Cristal et du Verre and European Domestic Glass

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2019-BLV Pb-ECHA-Public consultation-EDG-FCV.pdf

ECHA/RAC response

Your considerations in relation to challenges in lowering the blood levels and issues of women in childbearing age are noted. Please notice that the RAC opinion and its Annex assesses the scientific information available and makes a proposal based on that information. The socio-economic aspects are considered at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC.

Date	Country	Organisation	Type of Organisation	Comment number
12.12.2019	Sweden	The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals (NEG)	International NGO	22

Comment received

For comments, see attached zip file with the following pdf files:
NEG comments on ECHA Lead and its compounds 2019
Steenland2019_Lead_cancer_cohort
Finnish lead blood and urine data 2000-2014

ECHA note – An attachment was submitted with the comment above. Refer to public attachment NEG comments on ECHA Lead and its compounds 2019.zip

ECHA/RAC response

- The section “ECHA recommendation” has been deleted.
- Your suggestions for editorial changes have been considered/implemented.

Chapter 4

- OELs and BLVs for Norway have been included.
- A more detailed table of BLVs is now available (including BLVs for Sweden, Finland, Denmark and Norway).
- The table now makes clear that the values for tetraethyl and tetremethyl lead are expressed “as lead”.
- Table 16 has been corrected to make clear that the BLVs are for lead in urine.

Comments on human data

- The study of Steenland et al 2019 has been included in the tables and is described in the text
- The rationale of describing some general population studies is included and an explanation added why they are not considered relevant for OEL setting (section 7.3).
- It is now clarified that the value of 180 µg/L in the Schwartz study is a NOAEL with a further justification why.
- BMD95% has been explained (95% lower confidence limit).

- Your support for a BGV, relevant for women in childbearing age, is noted.

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2019	Germany	RUAG Ammotec GmbH	Company-Downstream User	23

Comment received

General Comments

RUAG Ammotec GmbH supports and shares the comments on the 17 October “ECHA scientific report for evaluation of limit values for lead and its compounds at the workplaces”, as submitted by ILA (international Lead Association, Inc.)/Pb REACH

Consortium.

Page 32) ECHA provides a review of the 'production and uses information' related to Pb and Pb compounds in section 5.2, and addresses the use of Lead (5.2.2) in the production of ammunition in point 5.2.2.6. In the mentioned section, at the end of the paragraph, the report states:

"On 17 August 2018, ECHA sent the opinion of its scientific committees supporting a restriction on the use of lead for shooting in terrestrial areas, ammunition and fishing tackle, in addition to action on lead shot in wetlands."

This section reports incorrect and particularly misleading information.
First, the content of the mentioned section conflicts with the content of Section 3.4, which correctly enunciates that "ECHA […] has been requested by the European Commission to investigate the need for a restriction to address the risk" related to be same uses of lead ammunition and gunshot.

Second, the formal discussions at RAC and SEAC pertaining to the proposal of a terrestrial restriction of the use of lead ammunition and gunshot have not started yet. Moreover, there is no Annex XV report recommending a restriction at this stage, but only the ECHA Investigation Report. De facto, this means that the ECHA Investigation Report, which was published in September 2018, was not subject to stakeholder scrutiny via an ECHA public consultation so far.

RUAG Ammotec GmbH wants to stress the shortcoming of such assertion and the deceptive meaning it holds, for the sake of the veracity of the present ECHA scientific report and of a possible future Annex XV report recommending such restriction on the use of lead for shooting in terrestrial areas.

ECHA/RAC response

Your comments are noted. The text in the Annex is now corrected and updated.

Date	Country	Organisation	Type of Organisation	Comment number
11.12.2019	Finland		Individual	24

Comment received

Sallmén

Comments refer to pages 83-90 and 188-201 (Human carcinogenic risks); and 95-97 (Reproductive toxicity, human data, male fertility).

Dear Sirs/Madams,

We generally agree with the proposal of the ECHA Lead for the new Biological Limit Value of 150 µg Pb/L in blood for lead and its compounds and the respective proposed Occupational Exposure Limit values. Steenland et al., 2017 already provided significant information on, among others, carcinogenic risk of lead. There are new studies on carcinogenic risks in employees biologically monitored for exposure to lead, published after the data retrieval period of the draft report (Steenland et al., 2019) or in preparation (Annex 1). The new follow-up study in the monitored workers (Steenland et al., 2019) and the information from the Finnish cohort in the Annex 1 further strengthen the information on carcinogenic risks of lead, particularly for lung cancers. The potential

confounders, including smoking, do not explain the findings in the Finnish cohort. Concerning reproductive toxicity in humans, male effects on couple fertility may appear at PbB levels well below 400 µg /L (Sallmén et al., 2000b).
To our understanding, there are shortcomings in the report in the sections we reviewed. Therefore, we suggest the following detailed comments and changes in its revision and to modify accordingly also the summary and conclusions of the below sections.

Human carcinogenic risks (section 7.7. on pages 83–90, and Tables 54–57)

In the Steenland et al. (2017) study, the trend test was for the log Maximum PbB. Then also the individual values within the grouped levels affected. This should be corrected in the tables and text. The same holds for tables citing this reference on other health outcomes.
Please add amongst the most relevant cohort studies also the attached, most recent publication by Steenland et al. (2019) on cancer incidence. There is further relevant information particularly on increased risks of lead for cancers of the lung, and brain and central nervous system.
Below please find new unpublished results on lung cancer incidence in 1973–2014 from the Finnish cohort (Anttila et al., 2017) included in Steenland et al. (2019), see Tables 1 – 3 of the Annex 1 of this statement. In these analyses of lung cancer, we have adjusted for occupational co-exposures (FINJEM) and occupation and gender specific smoking. Also, because the Finnish data included a wide lead exposure level spectrum, it was possible to use a lower limit for unexposed or minimally exposed reference than used in the international pooled analyses (Steenland et al 2019). We also show results by length of monitored employment period. These results indicate that other occupational carcinogenic exposures or tobacco smoking are unlikely to explain the increased risk of lung cancer in the Finnish data or in Steenland et al (2019). The findings show strong dose-response relationship. The new Finnish data further suggest slightly increased lung cancer risk already in the blood lead level 104–207 µg Pb/L.
Furthermore, there are uncertainties in several of those studies that have been included among the “most relevant human studies” in Tables 54 —57 and respective text, also on lung cancer in the Table 57. In the population-based case-control studies prevalence of lead exposure was small leading to lack of statistical power and (if personal blood lead level was not available) misclassification of exposure due to overlap in the exposure levels from occupational and environmental sources. Some of the heavily exposed cohorts have serious shortcomings in the information provided. In the Australian cohort (Gwini et al. 2012) only 35% of cohort members could be identified accurately. For others, the linkages using incomplete date of birth was not accurate. Without doubt this problem has affected the results. In the Bertker et al. (2016), study the follow-up time was initiated in the beginning or after a year since the start of employment, not when the upper limit of a given category had been reached (as should have been done). This causes uncertainties and probable underestimates in the RRs by high cumulative exposure categories with long duration of employment, when compared with groups with a shorter duration.
Taking together, the recent follow-up studies in workers biologically monitored for exposure to lead (Steenland et al., 2017 and 2019 and the information in the Annex 1) provide already significant further information on carcinogenic risks, particularly for lung, when compared with data that was available in the previous IARC evaluation (2006). It would be essential to inform employees about such carcinogenic risks and improve thus implementation of the new limit value. Considering that lead is an animal carcinogen, we cannot rule out that there can be some, even though relatively smaller, cancer risks in long-term exposure below the suggested BLV level and it would be worthwhile considering how to communicate and improve information also on such risks.

Reproductive toxicity, human data, male fertility (section 7.8.1, pages 95–97)

Two Finnish studies (Sallmén et al. 2000a and 2000b) were missing from the ECHA report Table 34, restricted to studies in 2000 or later. Findings from the study on time to pregnancy (Sallmén et al., 2000a) were in line with the three studies included in Table 34 (Apostoli et al., 2000, Shiau at al., 2004, and Joffe et al., 2003) showing limited support for the association between exposure to lead and prolonged time to pregnancy.
The other Finnish study (Sallmén et al., 2000b), was a register -based study focused on infertility, defined as nonoccurrence of marital pregnancy. Studies on time to pregnancy typically exclude infertile couples and are restricted to couples achieving pregnancy. In addition to fertility effects of lead exposure, this study focused on the potential bias due excluding infertile couples.
Probable paternal exposure to lead was associated with infertility already at low blood lead level, ≥104 µg Pb/L, compared with PbB below that level (Sallmén et al., 2000b) (104 µg Pb/L corresponds to 0.5 µmol/L as used in the article). Similarly, in the follow-up analysis of fertile and infertile couples, a delayed pregnancy was observed among men probably exposed to lead. Exclusion of infertile couples from this analysis diluted the association between lead exposure and infertility by 11 to 29 % along with increasing exposure (ANNEX 2).
The findings of the study of infertility (Sallmén et al., 2000b) supported the view that the results in the study on time to pregnancy (Sallmén et al., 2000a) could be biased towards no association. It is possible that the included studies (Apostoli et al., 2000, Shiau at al., 2004, and Joffe et al., 2003) are subject to bias due to exclusion of infertile couples.
To summarize, there is evidence that exclusion on infertile couples may bias the results towards unity. Male effects on couple fertility may appear at PbB levels well below 400 µg /L.

Sincerely yours,

Ahti Anttila Markku Sallmén
Research Director Senior Research Scientist
Finnish Cancer Registry Finnish Institute of Occupational Health
Helsinki Helsinki

References cited
Steenland K, Barry V, Anttila A, Sallmén M, McElvenny D, Straif K. A cohort mortality study of lead-exposed workers in the US, Finland, and the UK. Occup Environ Med 2017;74:785–791.
Steenland K, Barry, Anttila A, Sallmen M, Mueller W, Ritchie P, McElvenny DM, Straif K. Cancer incidence among workers with blood lead measurements in two countries. Occup Environ Med. 2019;76:603–610.
Anttila A, Uuksulainen S, Rantanen M, Pukkala E, Sallmén M. Exposure to lead and risk of cancer. Finnish Work Environment Fund, 2017, Project 113246 (unpublished, in Finnish).
Sallmén M, Lindbohm M-L, Anttila A, Taskinen H, Hemminki K. Time to pregnancy among the wives of men occupationally exposed to lead. Epidemiology 2000a; 11:141–147.
Sallmén M, Lindbohm M-L, Nurminen M. Paternal exposure to lead and infertility. Epidemiology 2000b; 11:148–152.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Three published studies and one Word document.zip
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment ECHA Consultation Ahti Anttila and Markku Sallmén_ANNEX 1 11122019.docx

ECHA/RAC response

Comments on human carcinogenicity studies

- The study of Steenland et al 2019 has been included in the tables and is described in the text. The text has been revised to describe more exactly how the continuous trend test was performed in the earlier Steenland et al study
- The methodological problems of Gwini et al 2014 and Bertke et al 2016 are now described
- The confidential information concerning a draft scientific paper planned to be submitted later could not be taken on board in the Annex of the opinion due to its confidential and preliminary nature.

Comments on reproductive toxicity:

- The rationale for proposing a separate approach for women at childbearing age is now described more in detail.

Date	Country	Organisation	Type of Organisation	Comment number
10.12.2019	Italy		Individual	25
Comment received				
coat the lead				
ECHA/RAC response				
Your comment is noted.				

Date	Country	Organisation	Type of Organisation	Comment number
09.12.2019	Germany	WVMetalle	Industry or Trade Association	26
Comment received				

• The International Lead Association (ILA) and Pb REACH Consortium provide detailed commentary and criticism on the ECHA report with respect to all aspects regarding health effects, toxicology, epidemiology and modes of action based on information contained in the REACH Registration dos-siers. A special emphasize is given to the quality of the report which included numerous hints on errors, omissions and shortcomings. We abstain from re-submitting detailed information on this aspect but express our concerns that the report can serve as a valid basis for the discussion within RAC in this status. A thorough re-evaluation should be performed prior the RAC debate. For more details we refer to the ILA comment.

• We would like to re-emphasize that under the umbrella of the German Committee on Hazardous Substances (AGS), a Tripartite Committee advising the Federal Ministry of Labour and Social Af-fairs (BMAS), a long debate on an update of the national OELs for Lead and its compounds took place recently. Two issues had been assessed. First, the introduction of a limit value on air lead concentrations and, second, the revision of the current biological limit value. As a result, the Sub-committee III on Hazard Risk Assessment developed a scientific opinion for a health based Biologi-cal Limit Value (BGW) which was concluded on at AGS level in Mai 2017.With respect to a limit value for air lead concentrations, the UA III considered the uncertainties in the correlation of blood lead values and an air lead concentrations as so relevant that a scientifically sufficient quali-ty of a corresponding air concentration (AGW) can't be guaranteed. That means that only biomon-itoring is considered as scientifically adequate in the case of lead and no air limit value is estab-lished. The resulting Biological Limit Value was fixed at the same level as RAC proposes: 150 µg Pb/l blood. ECHA took this information into account but failed to abstain from proposing an occu-pational exposure limit (OEL). Although WVMetalle recognize that derivation of an OEL may be wished it must much more clearly stated that

the level of uncertainty in deriving air levels from blood lead measurements cannot be representative for all workplaces and in any case extremely uncertain. The currently proposed OEL value of 30µg/m³ (8hr TWA) is by no means scientifically sound and would result in nearly impossible demands for affected companies and is at the same time not ensuring a significant reduction of workers with blood lead levels below the target values.

• Regarding actual information on exposure levels WVMetalle already submitted recent information from our own yearly surveys. Of course, WVMetalle is willing to share further information on that database upon request. We urge ECHA to take this into account instead of outdated information from different other sources. ECHA should as well make benefit from the recent "Study to collect recent information relevant to modernizing EU Occupational Safety and Health chemicals legisla-tion with a particular emphasis on reprotoxic chemicals with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC and Directive 98/24/EC" (https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8220&furtherPubs=yes). The study includes illustrative case studies for the following substances including lead and lead com-pounds. In addition, ECHA should contact DG EMPL in order to receive information from the ongo-ing study collecting most recent information for inorganic lead and its compounds with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to expo-sure to carcinogens or mutagens at work. The Final Report of this report shall be available in due time and might be a valuable piece of information for a sound limit value assessment for inorganic lead and its compounds.

• German AGS recognizes that the envisaged reduction of the blood lead level at workplaces is ex-tremely difficult and needs a thorough analysis of the situation in all affected areas as well as a description of dedicated and state of the art protective measures for relevant uses of Lead and its compounds. Therefore, the recent conclusion on the new Biological Limit Value in Germany for lead in blood to 150 µg/l is not yet legally implemented and will only be installed once the revised Technical Rule on Hazardous Substances (TRGS) 505 "Lead" is updated correspondingly. The TRGS 505 is directed to employers and contains special protective measures for uses involving Lead and inorganic Lead compounds as well as mixtures containing Lead. The process to reevaluate the TRGS 505 on Lead started in 2017 and is envisaged to be finalized end of 2020. WVMetalle em-phasizes on this activity as ECHA explicitly requested information on uses and experiences within the call for evidence for the Lead OELs. This practical aspect should as well be reflected within the OEL report for lead and its inorganic compounds.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2019-12-16_WVMetalle Comment on ECHA OEL report.pdf

ECHA/RAC response

- Uncertainties related to the derivation of an air OEL are now described more in detail
- The study "Study to collect recent information relevant to modernizing EU Occupational Safety and Health chemicals legisla-tion with a particular emphasis on reprotoxic chemicals with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC and Directive 98/24/EC" is now described (Chapter 3.1) with further references how it was considered.

- Your considerations in relation to the challenges of a lowered BLV and the experience from Germany are noted. The RAC opinion and its Annex assesses the scientific information available and makes a proposal based on that information. The socio-economic aspects are considered at a later stage of the decision-making that follows the procedures defined by Directive 98/24/EC.

Date	Country	Organisation	Type of Organisation	Comment number
06.12.2019	United Kingdom	International Lead Association	Industry or Trade Association	27

Comment received

To keep within the 9000 character requirement we have restricted our feedback in this section to high level comments on the scientific report. Our detailed comments can be found in the non-confidential attachment included with this submission. Whilst the ECHA Scientific Report attempts to provide evidence supporting the derivation of a health-based OEL we would like to emphasize that there is a great deal of uncertainty in this. The decades of experience obtained from our member companies illustrates that risk management measures based upon internal dose (i.e blood lead measurements) are the most effective method of controlling lead exposure in the workplace.

1. The OEL report fails to systematically and critically assess, correct, and synthesize the literature to give an accurate synthesis of knowledge and uncertainty about lead health effects: This is especially relevant for complex findings from human epidemiology studies that form the basis for dose response estimates for several endpoints. The authors of the report have failed to undertake the necessary systemic quality evaluation of the epidemiology studies available in the literature (methods, design, analysis) or attempt to undertake a tiered evaluation of study quality (e.g. studies that are of different quality should thus be weighted differently in order to obtain a shared understanding of the dose-response). ECHA has an obligation to conduct its own rigorous analysis and should not simply repeat selected opinions and findings from the literature. Developing an accurate view of what is currently known and not known about health effects of lead requires very active reading, critical assessment, and new synthesis of original articles. The OEL report does not appear to have undertaken the role of critically assessing, correcting, and synthesizing information from the literature to provide an accurate view of what is known and what is not about lead health effects. Uncritical repetition, tabulation, and summary of selected claims from the literature stops well short of such a critical survey and synthesis

2. The health effects section of ECHA's OEL report (Section 7.0) contains a generally superficial discussion of the known lead health effects literature: The OEL report could fairly be described as "a review of reviews" in that little effort was made to critically review and analyze the original lead health effects literature to construct an independent opinion regarding appropriate workplace OELs, and more emphasis was placed on summarizing existing reviews of the health effects literature and formulating an opinion on OELs from those. A total of 5 (relatively) recent exposure limit reviews (SCOEL 2002, ANSES 2017, AGS 2017, ACGIH 2017, and Safe Work Australia 2014) were listed and described in the ECHA scientific report, but rather than critically evaluating the approaches and conclusions of these preceding reviews and their individual relevance to establishing appropriate OELs for the EU, ECHA simply adopts the numerical BLV and OEL values cited and avoids formulating an original opinion from the primary health effects literature.This results in a scientific report that merely re-enforces and presents opinions derived from other recent reviews and is a fundamental shortcoming that regrettably precludes any original scientific critique of the evidence for dose-response relationships for health effects resulting from occupational lead exposure.

3. There is lack of clarity in statements as to whether lead exposure is associated with or causative of stated health effects: Causal statements throughout the OEL report – e.g., "SCOEL (2002) summarised that studies of peripheral nerve toxicity, based upon measurement of nerve conduction velocity (NCV) provide evidence of a causal relationship between a reduction in NCV and PbB greater than 700 µg/L, with effects possible at PbB levels as low as 300 µg/L" (p. 48) – are often unclear about what specific kind(s) of causality are being asserted. For example, a causal claim of the form "Exposure to substance X increases rates of an adverse health effect (e.g., cardiovascular disease, renal disease, neurological disease, etc.) among exposed workers by R additional expected cases per person-year per unit of exposure to the substance" can be interpreted in several ways. Current practice in health risk assessment and communication for lead often intermixes distinct causal concepts, as well as related concepts such as controlled direct effects, natural direct effects, and total effects of exposures on outcome risks. Unfortunately, by far the most common causal concepts used are associational and attributive. IARC is relatively explicit in explaining that it addresses associational causation; e.g., IARC 2006, p. 11.). For risk managers and policy makers, manipulative causation is key, insofar as the goal of decision-making is to choose policies or interventions that cause desired outcomes, in the sense of making them more probable. Manipulative causation is implied by mechanistic causation – if there is a network of mechanisms by which acts change the probabilities of outcomes (mechanistic causation), then taking the acts will indeed change the probabilities of outcomes (manipulative causation) – but neither one is implied by any of the other concepts of causation. Therefore, from statements of the general form used throughout the ECHA scientific report, that lead exposure increases risk of an adverse response by some amount, there is no valid way to deduce what would happen to risk if exposure to lead were reduced by a given amount. This is because the word "increases" in this context does not necessarily or usually refer to manipulative causation. But this is the crucial causal information needed for RAC to make well-informed risk management decisions.
4. The Scientific report does not account for model uncertainties: Effects of model selection biases, model specification errors, and assumption violations in the literature cited are not quantified or corrected for. Resulting uncertainties in conclusions and estimates are not quantified. Model uncertainties are not well characterized in the tables and discussions presented. They are usually understated, e.g., by treating highly uncertain estimates, models, and assumptions as if they were error-free observations that are known to be correct.
5. Exposure estimation errors are not modeled and corrected for: Estimated exposures are frequently misrepresented throughout the scientific report as being true exposures. Exposure estimation errors are not quantified or corrected for in presenting results. The scientific report in its summary tables and throughout the text repeatedly intermixes true and estimated exposure values. It refers to estimated cumulative exposure as "cumulative exposure," even when true cumulative exposure values are missing and unknown for every worker. Many of the original articles cited also make this mistake, so it is important for ECHA to be alert to this error in interpreting, evaluating, and synthesizing claims from the literature, so as not to propagate the error.
6. Modeled, reported, and estimated health effects are misinterpreted as true health effects: Throughout the scientific report, estimated, attributed, reported, and modeled health effects (e.g., cases of cardiovascular disease) are cited as if they were known to be true health effects, without quantifying or correcting for errors and biases in diagnosis and reporting or in estimation and modeling.
7. Original literature sources are not summarized accurately: Original sources are often misrepresented, or important uncertainties omitted and as such the scientific report tends to exaggerate risks associated with lead exposure.
8. Selection of the critical health end-point. ECHA's proposed BLV (Biological Limit Value, or blood lead) should be based on the health effect endpoint best supported by the

scientific literature, and not on one for which the data are conflicting, often difficult to interpret and the dose-response is ill-defined (e.g. clastogenicity). In our opinion, which is consistent with that of recent expert panels, effects on adult neurological function should be the focus of establishing a BLV in adult male working populations.
9. Failure to consider fact that primary literature relied on to establish a health protective BLV indexes reported health effects indexed against population mean blood lead:
The proposal in the scientific report for a health protective BLV for adult males fails to consider the statistical indexing of reported health effects associated with measured cohort blood lead levels in the primary literature. As an example, the threshold of 180µg/L for subtle neurological effects reported in Schwartz et al (2001) that is used to establish the proposed BLV is derived from the cohort mean concurrent blood lead levels. Assuming a GSD of 1.5-1.7 typical in workplace blood lead measurements would allow for a BLV as high as 300µg/L to be derived as this would ensure that workplace population blood lead mean values would be at or below the NOAEL reported by Schwartz. The failure to account for the fact that epidemiology often indexes effects to population mean blood lead results in the derivation of a BLV that is very precautionary in nature. We strongly recommend that this is an issue that RAC is requested to consider in more detail.
10. Derivation of air limit from the BLV: The scientific report correctly concludes that the BLV should be used as the primary tool for protecting workers from lead exposure and describes the uncertainty in deriving a scientifically sound correlation between blood lead concentrations and air levels. However, the pragmatic approach to derive an OEL suggested in the report using the ratio of the existing BLV and BOELV in the CAD is unsound and lacks scientific rigor. RAC should be requested to consider developing a more robust method to derive a workplace OEL that ensures that the majority of workers are kept below the target BLV and highlight the scientific uncertainties in this estimate.
11. Evaluation of scientific evidence on organic lead compounds is superficial and insufficient: The scientific report does not provide sufficient information to allow RAC to form an opinion. We recommend that ECHA undertake a more thorough review of the toxicokinetics and toxicodynamics of organic lead compounds as the conclusion in the scientific report that the OEL derived for inorganic lead compounds would be health protective is not supported by the scientific evidence presented

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ECHA OEL report ILA Comments-Final Draft 4_12_19-clean.pdf

ECHA/RAC response

General comments on scientific assessment of literature

- The Annex is based on a critical review of a vast amount of published papers of the last ten years and the international reviews and evaluations as listed in the section Literature. Your comment to systematically and critically assess, correct, and synthesize the literature to give an accurate synthesis of knowledge and uncertainty about lead health effects is taken into account, as far as possible, during the opinion development process and the alignment of the Annex. Furthermore, additional relevant literature and reviews, based on comments received during the Consultation are included in the Annex.

Human data general methodological comments

- It is noted that true exposure is never known in an occupational epidemiological study assessing the exposure over a longer period as no worker carries an exposure measuring instrument continuously. Therefore exposure has to be estimated with one way or another. This leads, indeed, to measurement error which needs to be minimised in the study design. However, it is important to note that any residual measurement error in exposure, if non-differential (i.e. not correlated with outcome measurement), attenuates the observed relation between

exposure and health outcome. I.e. it does not lead to falsely observed associations, but tends to obscure observing the true effect. Only in case of differential measurement error, could the measurement error lead to “exaggerated” exposure-response relationships. Furthermore it is noted that lead literature is rather unique as the by far most often used exposure metric is blood lead which is a surrogate of internal exposure, and thus not subject to some problems inherent when relating external exposure estimates to systemic health effects. The use of the wording cumulative exposure has been checked throughout.

- Related to the above comment is the problem of lead release from bones representing higher past environmental and/or occupational exposures which causes uncertainty associating current health outcomes to recent blood lead measurements. There indeed, the health outcomes migh be caused by higher past exposures not correctly reflected by current measurements. This uncertainty is now more explicitely explained in Chapters 7.1.5 and 8.2.3.
- Trend analysis is a standard method in epidemiology and reporting the p values tells whether a statistically significant trend was observed or not. ECHA/RAC has followed standard reporting principles for such analyses and is confident that the users of the Annex are familiar in interpreting whether the p value indicates a statistically significant trend or not.

Human data on renal effects

- The summary texts Chapters 7.3 and 8.2.3 are extended in the Annex making it clearer what are the effect and/or no-effect levels for sub-clinical and more severe renal outcomes.

Human data on cardiovascular effects

- The supportive comments are acknowledged. Dose-responses for cardiovascular effects have not been derived.

Human data on carcinogenicity

- Your support for the conclusion is acknowledged. The potential confounding by smoking and other factors is already mentioned in the document. The study by Steenland et al (2019) was published just before the consultation was launched. It has now been added to the document together with other recent cancer epidemiology studies that were submitted during the consultation.

Other comments

- Comments on Section 5 on use and exposure have all been addressed and the text modified accordingly.
- ECHA/RAC has considered your arguments related to OEL, BLV, intraspecies assessment factor, point of departure.
- Detailed list of BLVs mainly based on the reference provided has been included.
- The section on approaches for derivation of OEL and BLV has been extended.
- Informaton on organic lead compounds has been slightly extended.
- Your editorial suggestions have been considered/implemented.

Date	Country	Organisation	Type of Organisation	Comment number
26.11.2019	Italy		Individual	28
Comment received				
per quanto riguarda l'uso del piombo in campo professionale e in tutte le attività in cui viene utilizzato ci sarebbe un danno economico enorme per tutta l'europa , dato di fatto è				

che già viviamo in un epoca di crisi e la messa al bando del piombo scatenerebbe lo sgretolarsi di un sistema economico gia in bilico . Per quanto concerne i dati tossicologici ed effetti sulla salute le attivita come la caccia e la pesca incidono pochissimo sull inquinamento , sono oltre 100 anni che si utlizza il piombo in determinate attività e non vi sono dati che affermano un inquinamento dato dalle suddette attività.
ECHA/RAC response
The RAC opinion and its Annex do not concern a proposed restriction under REACH (Annex XV dossier), but concern a scientific evaluation of limit values for lead and its compounds at the workplace (CAD).

Date	Country	Organisation	Type of Organisation	Comment number
22.11.2019	Italy		Individual	29
Comment received				
Buon giorno, vi state concentrando sull'esposizione di piccolissime quantità di Piombo, mentre tralasciate il vero e unico problema altamente inquinante. La Plastica. Oggi cartucce e borraggi sono per lo più prodotte in tutta plastica. Mentre il bossolo esploso può e dovrebbe essere recuperato, la stessa cosa non accade per la borra in plastica che rimane dispersa nell'ambiente per decine di anni o finire in acqua e in mare senza alcuna possibilità di recupero. E nella limitazione della plastica che occorre agire e intervenire, non nel piombo, che può essere comunque limitato imponendo una riduzione nella grammatura massima utilizzabile nelle cartucce, in tutti gli stati europei.				
ECHA/RAC response				
The RAC opinion and its Annex do not concern a proposed restriction under REACH (Annex XV dossier), but concern a scientific evaluation of limit values for lead and its compounds at the workplace (CAD).				

Date	Country	Organisation	Type of Organisation	Comment number
22.11.2019	Italy		Individual	30
Comment received				
Do not ban lead in munitions				
ECHA/RAC response				
The RAC opinion and its Annex do not concern a proposed restriction under REACH (Annex XV dossier), but concern a scientific evaluation of limit values for lead and its compounds at the workplace (CAD).				

Date	Country	Organisation	Type of Organisation	Comment number
20.11.2019	Italy		Individual	31
Comment received				
I do not agree with the indication that lead in ammunitions for hunting and shooting activities could have a dangerous impact on health. The scientific literature on the topic is controversial and there is not a clear result that suggests a negative impact of the lead used in the ammmunitions for hunting and shooting activites. According to my review, the report lacks of several scientific evidences and data capable to clearly demonstrate the negative impact of the lead for ammunition. Any restriction that will be taken about the use of lead for ammunitions could be considered not sufficiently suppoted and also ideologic, especially by specific categories of european citizens which use ammunitions made by lead, like hunters, shooters and so no. I suggest to deepen the scientific aspects				

with further research in order to collect reliable and clear results and to act with restrictions (if needed) afterwards.
ECHA/RAC response
The RAC opinion and its Annex do not concern a proposed restriction under REACH (Annex XV dossier), but concern a scientific evaluation of limit values for lead and its compounds at the workplace (CAD).

Date	Country	Organisation	Type of Organisation	Comment number
30.10.2019	Germany	<confidential>	Company-Downstream User	32
Comment received				
p. 30 5.2.2.4 Lead Alloys, p. 34 5.4 Routes of exposure and uptake Delivered articles in the industrial gas business (packaging, incl. valves or even smallest pieces of a composite article) may contain LEAD as an inorganic compound (EC N°: 231-100-4, CAS N°: 7439-92-1) to more than 0.1%. Since lead is bound as an alloying element and therefore no exposure to worker or general population by operating gas packages (e.g. pressurized receptacles) or valves is expected, no additional information on safe use is necessary. Products, substances (pure gases or mixtures) does not contain LEAD above the default limit.				
ECHA/RAC response				
Comment is noted. This section is about the most common uses of lead and lead compounds in the largest quantities where exposures may occur, including for example the use of lead to “manufacture alloys” (before the lead is bound). These alloys have many further uses, where there might be more than 0.1% lead bound in the article where no exposure is expected, but it is not the intention to exhaustively cover all possible uses (particularly those with no exposure), and especially as there is little value with regards to a potential OEL.				

Date	Country	Organisation	Type of Organisation	Comment number
23.10.2019	United States	<confidential>	Company Manufacturer	33
Comment received				
please use Option 3: It is recommended to make qualitative statement in the Chemical Agents Directive that the exposure of fertile women to lead should be minimised or avoided in the workplace because the BLV for lead is not protective of the offspring of women of childbearing age. Proper PPE and Ventilation contains and prevents exposure to our employees when working with powders which include Lead. It has been scientifically proven that Lead in Glass or Ceramic Matrix is not bio-available and that the Lead compound will not leach or release from the glass. The European Glass Agency notes that: Under the REACH Regulation glass is considered as a uvcb substance (substance of unknown or variable composition, complex reaction products or biological materials. We support that, thank you ECHA note – An attachment was submitted with the comment above. Refer to public attachment Lead Glass REACH DOSSIER.pdf				
ECHA/RAC response				
Your opinion in relation to lead exposure of women in childbearing age and on glass under REACH is noted.				

PUBLIC ATTACHMENTS
1. FEEM_STATEMENT_Public consultation Pb.pdf [Please refer to comment No. 2]
2. Ceemet response_ECHA consultation on Lead and its inorganic compounds.pdf [Please refer to comment No. 4]
3. 191216_Comments_on_the_OEL_report_PIC.pdf [Please refer to comment No. 5]
4. Réponse FFB consultation européenne abaissement VLB plomb.pdf [Please refer to comment No. 6]
5. 19.35.ECHA OEL report ILA Comments-Final Draft 4_12_19-clean (003).pdf [Please refer to comment No. 7]
6. 2019 12 16 Stanowisko IGMNiR-skonwertowany(1).pdf [Please refer to comment No. 9]
7. Report CeramTec GmbH_DLAC GmbH_01_20191216_fin.pdf [Please refer to comment No. 11]
8. questionnaire word entreprises concernées par la révision de la valeur VLB .docx [Please refer to comment No. 17]
9. 459-F76 Health Council Netherlands - Comments on lead and lead compounds ECHA december 2019.pdf [Please refer to comment No. 19]
10. 2019-BLV Pb-ECHA-Public consultation-EDG-FCV.pdf [Please refer to comment No. 21]
11. NEG comments on ECHA Lead and its compounds 2019.zip [Please refer to comment No. 22]
12. Three published studies and one Word document.zip [Please refer to comment No. 24]
13. 2019-12-16_WVMetalle Comment on ECHA OEL report.pdf [Please refer to comment No. 26]
14. ECHA OEL report ILA Comments-Final Draft 4_12_19-clean.pdf [Please refer to comment No. 27]
15. Lead Glass REACH DOSSIER.pdf [Please refer to comment No. 33]

CONFIDENTIAL ATTACHMENTS
1. Austin Detonator_ STATEMENT_ Call for evidance Pb.pdf [Please refer to comment No. 3]
2. Worker Exposure to Lead Titanate_Roy.pdf [Please refer to comment No. 11]
3. ECHA_Boliden.docx [Please refer to comment No. 16]
4. QUESTIONNAIRE 1.pdf [Please refer to comment No. 17]
5. ECHA Consultation Ahti Anttila and Markku Sallmén_ANNEX 1 11122019.docx [Please refer to comment No. 24]