Committee for Risk Assessment

RAC

Annex 1

Background document

to the Opinion proposing harmonised classification and labelling at EU level of

Lead

EC Number: 231-100-4
CAS Number: 7439-92-1

CLH-O-0000001412-86-260/F

The background document is a compilation of information considered relevant by the dossier submitter or by RAC for the proposed classification. It includes the proposal of the dossier submitter and the conclusion of RAC. It is based on the official CLH report submitted to public consultation. RAC has not changed the text of this CLH report but inserted text which is specifically marked as 'RAC evaluation'. Only the RAC text reflects the view of RAC.

Adopted

30 November 2018

CLH report

Proposal for Harmonised Classification and Labelling

Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2

Substance Name: Lead metal

EC Number: 231-100-4

CAS Number: 7439-92-1

Index Number: 082-013-00-1 and 082-014-00-7

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Part A.

Part A.

1 PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING

1.1 Substance

Table 1: Substance identity

Substance name:	Lead
EC number:	231-100-4
CAS number:	7439-92-1
Annex VI Index number:	082-013-00-1 and 082-014-00-7
Degree of purity:	80-100%
Impurities:	

1.2 Harmonised classification and labelling proposal

Table 2: The current Annex VI entry and the proposed harmonised classification

	CLP Regulation
Current entry in Annex VI, CLP Regulation	The RAC opinion on the harmonised classification of lead metal (massive and powder) as toxic to reproduction (Repr. 1A – H360FD) has been adopted in December 2013. The resulting new entries were included in Table 3.1 of Annex VI with the 9th ATP to CLP.
Current proposal for consideration by RAC	Aquatic Acute 1; M-factor = 10 Aquatic Chronic 1; M-factor = 10
Resulting harmonised classification (future entry in Annex VI, CLP Regulation)	Aquatic Acute 1; M-factor = 10 Aquatic Chronic 1; M-factor = 10

1.3 Proposed harmonised classification and labelling based on CLP Regulation criteria

Aquatic Acute 1; H400: Very toxic to aquatic life with an M-factor of 10

Aquatic Chronic 1: H410: Very toxic to aquatic life with long lasting effects with an M-factor of 10

Table 3: Proposed classification according to the CLP Regulation (See also Background document to the RAC opinion on Pb adopted in December 2013 available on ECHA's website[1])

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[1] https://echa.europa.eu/opinions-of-the-committee-for-risk-assessment-on-proposals-for-harmonised-classification-and-labelling/-/substance-rev/2142/del/50/col/staticField_-105/type/asc/pre/3/view

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification [1)]	Reason for no classification [2)]
2.1.	Explosives	Not in the scope of this proposal			
2.2.	Flammable gases	Not in the scope of this proposal			
2.3.	Flammable aerosols				n.a.
2.4.	Oxidising gases				n.a.
2.5.	Gases under pressure				n.a.
2.6.	Flammable liquids				n.a.
2.7.	Flammable solids	Not in the scope of this proposal			
2.8.	Self-reactive substances and mixtures				n.a.
2.9.	Pyrophoric liquids				n.a.
2.10.	Pyrophoric solids				n.a.
2.11.	Self-heating substances and mixtures				n.a.
2.12.	Substances and mixtures which in contact with water emit flammable gases				n.a.
2.13.	Oxidising liquids				n.a.
2.14.	Oxidising solids				n.a.
2.15.	Organic peroxides				n.a.
2.16.	Substance and mixtures corrosive to metals				n.a.
3.1.	Acute toxicity - oral	Not in the scope of this proposal			
	Acute toxicity - dermal	Not in the scope of this proposal			
	Acute toxicity - inhalation	Not in the scope of this proposal			
3.2.	Skin corrosion / irritation	Not in the scope of this proposal			
3.3.	Serious eye damage / eye irritation	Not in the scope of this proposal			
3.4.	Respiratory sensitisation	Not in the scope of this proposal			

3.4.	Skin sensitisation	Not in the scope of this proposal			
3.5.	Germ cell mutagenicity	Not in the scope of this proposal			
3.6.	Carcinogenicity	Not in the scope of this proposal			
3.7.	Reproductive toxicity	Not in the scope of this proposal			
3.8.	Specific target organ toxicity –single exposure	Not in the scope of this proposal			
3.9.	Specific target organ toxicity – repeated exposure	Not in the scope of this proposal			
3.10.	Aspiration hazard	Not in the scope of this proposal			
4.1.	Hazardous to the aquatic environment	Aquatic Acute 1 Aquatic Chronic 1	M = 10 M = 10	Not classified	
5.1.	Hazardous to the ozone layer	Not in the scope of this proposal			

[1] Including specific concentration limits (SCLs) and M-factors

[2] Data lacking, inconclusive, or conclusive but not sufficient for classification

Labelling: Pictogram:

GHS09

Signal word: Warning

Hazard statements: H410: Very toxic to aquatic life with long lasting effects

Precautionary statements:
P273: Avoid release to the environment
P391: Collect spillage
P501: Dispose of contents/container to …

Proposed notes assigned to an entry: -

2 BACKGROUND TO THE CLH PROPOSAL

2.1 History of the previous classification and labelling

The current CLH proposal only addresses the environmental classification of lead. Note that a proposal for classification of lead as toxic to reproduction has been submitted by the Swedish CA and the opinion was adopted by RAC in December 2013 and published with the 9th ATP to CLP (Commission Regulation (EU) 2016/1179) on the 19th July 2016.

At the Commission Working Group on the Classification and Labelling of Dangerous Substances in June 2002 (document ECBI/37/02 Rev.2, see relevant parts in the Annex to this document) it was concluded that metallic lead was not included in the entry of “Lead compounds with the exception of those specified elsewhere in the annex” in Annex I of the Dangerous Substances Directive (DSD) and the harmonised classification was postponed. As a result, despite the well-known and extensively studied toxic properties of lead, there is currently no harmonised environmental classification for lead in its metallic form (be it either massive lead or lead powder). The current self-classifications for metallic lead are inconsistent and the joint REACH registration dossier (ECHA, 2016) further distinguishes between lead metal massive and lead metal powder with regard to environmental hazards.

With the exception of lead methane sulphonate which is classified with N; R58 (DSD), or no environmental classification (CLP), all other lead compounds in CLP Annex VI are classified as environmentally hazardous with N; R50-53 (DSD), or as Aquatic Acute 1 and Aquatic Chronic 1 (CLP).

2.2 Short summary of the scientific justification for the CLH proposal

Self-classifications vary from “No classification” to “Acute 1 and Chronic 1” (see below).

As mentioned above almost all lead compounds in CLP Annex VI are classified as Aquatic Acute 1 and Aquatic Chronic 1. Lead powder is classified (self-class.) as Aquatic Acute 1 and Aquatic Chronic 1. In the joint REACH registration dossier for lead metal (CAS 7439-92-1) different self-classifications are suggested for lead metal massive and lead metal powder, respectively. The massive form is not classified whereas lead in powder form is self-classified as Aquatic Acute 1 and Aquatic Chronic 1, with an M-factor of 10 and 1 respectively. However, we do not agree that it is justified to have different entries for lead “massive” and lead powder as the two forms are not different physically or chemically apart from the particle size, and the fact that the solubility of a substance increases with decreasing particle size, and it is further probable that lead “massive” could lead to particles in the “powder” range (e.g. lead films with a thickness of 25 µm are on the market, see section 5.5, last paragraph).

The lead ion is highly toxic to aquatic organisms with EC_{50} values between 10 – 100 µg/L and EC_{10} or NOEC values between 1 – 10 µg/L. Thus lead metal should be classified as Aquatic Acute 1 and Aquatic Chronic 1, both with an M-factor of 10, given that the concentrations in the Transformation/Dissolution protocol tests (T/Dp) reach the levels of the Ecotoxicity Reference Values (ERVs) at the appropriate loadings. Metallic forms are normally regarded as “insoluble”, and a full T/Dp test at pH 5.5-8.5 for 28 days for long-term classification (pH 6 – 8.5 for 7 days for acute classification) is recommended for metallic forms in the ECHA guidance on the application of the CLP criteria (section IV.2.2) and Annex 10 to the UN GHS (2015). The 24 hours screening test for T/D is normally used only for assessing the solubility of sparingly soluble metal *compounds*. However, the metal industry has performed a 24 hours T/Dp screening test with the powder, but there is no data for a full T/Dp test at a loading of 1 mg/L and less with the powder.

On the other hand the concentration obtained at a loading of 100 mg/L in the 24 hours T/Dp screening test with lead powder at pH 6 was 3211 µg/L (REACH registration, ECHA 2016[2]) and it is unlikely that the concentration achieved in a 7 days and a 28 days full T/Dp test at loadings of 1 mg/L and 0.1 mg/L will be below the respective EC_{50} or EC_{10} (NOEC). Furthermore, according to the REACH registration, industry has also performed a T/Dp test at pH 6 with particles corresponding to spheres with a diameter of *1 mm* at a loading of 1 mg/L for 28 days. The resulting concentration was 14 µg/L which is above the lowest chronic ERV of 1.7 µg/L (for both the crustacean *Ceriodaphnia dubia* and the snail *Lymnaea stagnalis*).

The predictions of the local risk assessment tool, the "TICKET Unit World Model" (included in the joint REACH registration for lead), are not accepted as an analogy to degradation (see part B of this report), and there is no evidence of rapid environmental transformation of lead . This means that lead "massive" should be classified under CLP as Aquatic Acute 1 and Aquatic Chronic 1 with an M-factor (acute and chronic) of 10, respectively.

As given in the REACH registration, the results of the T/Dp tests at a loading of 1 mg/L at pH 6 for 7 and 28 days with 1 mm spheres further show that there is a marked *increase* in the achieved concentration of soluble forms from day 7 (5.1 µg/L) to day 28 (14.2 µg/L) indicating no rapid transformation from soluble forms to insoluble forms.

2.3 Current harmonised classification and labelling

2.3.1 Current classification and labelling in Annex VI, Table 3.1 in the CLP Regulation

None as hazardous to the aquatic environment. However, the RAC opinion on the harmonised classification of lead metal (massive and powder) as toxic to reproduction (Repr. 1A – H360FD) has been adopted in December 2013. The resulting new entries were included in Table 3.1 of Annex VI with the 9th ATP to CLP.

Lead powder; [particle diameter < 1 mm]

Repr. 1A – H360FD

Lact. – H362

SCL Repr. 1A; H360D: C ≥ 0,03 %

Lead massive; [particle diameter > 1 mm]

Repr. 1A – H360FD

Lact. – H362

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[2] Non-confidential information provided in the registration dossier for Pb can be found on ECHA's dissemination website under https://echa.europa.eu/registration-dossier/-/registered-dossier/16063. Further information on the T/Dp studies can be found under 'Physical & Chemical properties': Water solubility.

2.4 Current self-classification and labelling

2.4.1 Current self-classification and labelling based on the CLP Regulation criteria

The following self-classifications for environmental hazards of lead metal can be found in the Classification and Labelling Inventory (checked in December 2016):

1 No classification

2 Aquatic Acute 1

3 Aquatic Chronic 1

4 Aquatic Acute 1 + Aquatic Chronic 1

5 Aquatic Acute 1 + Aquatic Chronic 4

The most frequently used self-classifications for lead are either Aquatic Acute 1 + Aquatic Chronic 1 or No classification. The majority of self-classifications as Aquatic Acute 1 and/or Aquatic Chronic 1 have not included an M-factor. Where an M-factor is included it is M = 10 and/or M = 1.

In the joint REACH registration (ECHA, 2016) lead "massive" and lead powder are classified differently (No classification and Aquatic Acute 1 + Aquatic Chronic 1 incl. M (acute) = 10 and M (chronic) = 1), respectively).

RAC general comment
The current CLH proposal addresses only the environmental classification of lead. As agreed at RAC 47, the opinion of RAC on the environmental classification of lead as a whole (powder and massive forms) is presented here. The view of a minority of members that a separate classification of lead powder and massive lead was possible is also reflected here. Even though the latter was not ultimately supported by RAC, these alternative classifications are given in the interests of balance (See Appendix 1).

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

1. Self-classifications vary widely from "No classification" to "Aquatic Acute 1" plus "Aquatic Chronic 1" with M = 10. This may have clear implications on downstream legislations on e.g. Ecolabel, Seveso and waste.

There are furthermore some important principal questions that need to be addressed concerning among other things:

2. the split of classification for massive and powder forms; and

3. the use of the “TICKET Unit World Model” (including amongst other things partitioning to organic matter) as an analogy to degradation.

The joint REACH registration for lead has in fact utilised both of these principles/models.

Part B.

SCIENTIFIC EVALUATION OF THE DATA

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 5: Substance identity

EC number:	231-100-4
EC name:	Lead
CAS number (EC inventory):	
CAS number:	7439-92-1
CAS name:	Lead
IUPAC name:	
CLP Annex VI Index number:	082-013-00-1 and 082-014-00-7
Molecular formula:	Pb
Molecular weight range:	207.2 g/mol

Structural formula: na

1.2 Composition of the substance

Table 6: Constituents (non-confidential information)

Constituent	Typical concentration	Concentration range	Remarks
Metallic lead	95%	80 – 100%	

Current Annex VI entry: see Part A, section 2.3.1 of this report

Table 7: Impurities (non-confidential information) (taken from the Background document to the RAC opinion on Pb adopted in December 2013))

Impurity	Typical concentration	Concentration range	Remarks
Antimony EC no.: 231-146-5		0.0 - 15.0 % (w/w)	
Tin EC no.: 231-146-5		0.0 - 15.0 % (w/w)	
Sulphur EC no.: 231-722-6		0.0 - 10.0 % (w/w)	Only in elemental form
Oxygen EC no.: 231-956-9		0.0 - 10.0 % (w/w)	Only in elemental form
Copper EC no.: 231-159-6		0.0 - 10.0 % (w/w)	
Nickel EC no.: 231-111-4		0.0 - 1.0 % (w/w)	
Aluminium EC no.: 231-072-3		0.0 - 10.0 % (w/w)	
Zinc EC no.: 231-175-3		0.0 - 10.0 % (w/w)	
Iron EC no.: 231-096-4		0.0 - 10.0 % (w/w)	
Selenium EC no.: 231-957-4		0.0 - 5.0 % (w/w)	
Cobalt EC no.: 231-158-0		0.0 - 1.0 % (w/w)	
Chromium EC no.: 231-157-5		0.0 - 10.0 % (w/w)	
Magnesium EC no.: 231-104-6		0.0 - 10.0 % (w/w)	
Manganese EC no.: 231-105-1		0.0 - 10.0 % (w/w)	
Sodium EC no.: 231-132-9		0.0 - 10.0 % (w/w)	
Barium EC no.: 231-149-1		0.0 - 10.0 % (w/w)	
Strontium EC no.: 231-133-4		0.0 - 10.0 % (w/w)	
Indium EC no.: 231-180-0		0.0 - 10.0 % (w/w)	
Gallium EC no.: 231-163-8		0.0 - 10.0 % (w/w)	
Tellurium EC no.: 236-813-4		0.0 - 10.0 % (w/w)	
Calcium EC no.: 231-179-5		0.0 - 10.0 % (w/w)	
Silicon EC no.: 231-130-8		0.0 - 10.0 % (w/w)	
Potassium EC no.: 231-119-8		0.0 - 10.0 % (w/w)	
Bismuth EC no.: 231-177-4		0.0 - 2.0 % (w/w)	
Others		Metal impurities in the range <0.25% (w/w): e.g. Pt, Ag, Au; metal impurities in the range <0.1% (w/w): Tl; metal	

		impurities in the range <0.025% (w/w): As, Cd, Hg.	

Table 8: Additives (non-confidential information)

Additive	**Function**	**Typical concentration**	**Concentration range**	**Remarks**
n/a				

Current Annex VI entry: n/a

1.2.1 Composition of test material

Lead metal massives (high purity grade) = 99.9% (w/w, average concentrations)

Lead metal massives (general grade) = 95% (w/w, average concentrations)

1.3 Physico-chemical properties

Table 9: Summary of physico - chemical properties (taken mainly from the Background document to the RAC opinion on Pb adopted in December 2013 and published on ECHA's website)

Property	**Value**	**Reference**	**Comment (e.g. measured or estimated)**
State of the substance at 20°C and 101,3 kPa	Lead is available on the market in both powder and massive forms. In both forms it is a solid, grey-blue element.		Visual inspection
Melting/freezing point	Melting temperature: 326ºC (599 K)	*Franke (2005b)*	measured
Boiling point	The test item has no boiling point at atmospheric pressure up to the final temperature of 600 °C (873 K)	*Franke (2005b)*	measured
Relative density	Density at 23.8 °C = 11.45 g/cm3 D4R: 11.45	*Smeykal (2005a)*	measured
Vapour pressure	n/a Vapour pressure is only relevant for solids with a melting point below 300 ºC (Lead melts at 326ºC).		
Surface tension	n/a Lead is a solid at ambient temperature (20 ºC).		
Water solubility	185 mg/L [20 °C, at pH = 10.96] 7 day tests at pH = 6 and at loadings of: 100 mg/L: 567 µg/L 10 mg/L: 57 µg/L 28 day test at pH = 7 and at a loading of: 1 mg/L: 15 µg/L	*Heintze (2005)* *ECHA (2016)* *ECHA (2016)*	measured measured measured
Partition coefficient n-octanol/water	n/a The solubility of metallic lead in octanol/water is negligible.		
Flash point	n/a Lead is a solid, flash point is only relevant for liquid substances.		
Flammability	Non flammable	*Smeykal (2005b)*	measured
Explosive properties	n/a Lead is metallic and therefore considered inert		

Self-ignition temperature	n/a Lead metal powder has been tested to be ‘not flammable’. Furthermore, no exothermic decomposition (DSC analysis) was reported up to a temperature of 600 °C. Therefore, it can be assumed that lead metal powder is not ignitable or auto-flammable.		measured
Oxidising properties	n/a		
Granulometry	Lead is placed on the market in both massive and powder forms. The mean particle size of a representative lead metal powder sample has been determined (laser diffraction method): D50 = 12.7 µm. Mass median aerodynamic diameter of airborne fraction (rotating drum method, distribution fitted to cascade impactor data): MMAD = 33.7 µm.	*Franke (2005a), Selck (2003)*	measured
Stability in organic solvents and identity of relevant degradation products	n/a This study is only conducted on organic substances, metallic lead is inorganic.		
Dissociation constant	n/a Lead does not contain relevant functional groups for assessment of a dissociation constant.		
Viscosity	n/a Viscosity is a property of fluids. Lead is a solid at ambient temperature (20 ºC).		

2 MANUFACTURE AND USES

2.1 Manufacture

Lead does occur in its metallic form in nature, but it is rare. Lead is usually found in ore with zinc, silver and (most abundantly) copper, and is extracted together with these metals. The main lead mineral is galena (PbS), which contains approximately 85% lead. Other common varieties are cerussite ($PbCO_3$) and anglesite ($PbSO_4$).

Most ores contain less than 10% lead, and ores containing as little as 3% lead can be economically exploited. Sulphide ores are roasted, producing primarily lead oxide and a mixture of sulphates and silicates of lead and other metals contained in the ore *(Samans 1949*). Lead oxide from the roasting process is then reduced in a coke-fired blast furnace where most of the lead is converted to its metallic form.

Metallic lead can then be further processed to produce e.g. lead batteries, lead sheets, lead powder, leaded steels, lead oxide and other lead compounds, and in the production of other articles containing lead (see next *section 2.2; Identified uses*).

2.2 Identified uses

Lead has a large variety of uses, both for industrial purposes as well as in consumer products. It is used e.g. in lead-acid batteries, bullets- shots and fishing sinkers and in aviation fuel. It is also frequently used in solders and other metal alloys such as “tin soldiers” and in brass which typically contains around 3 % lead. Brass can be found in various consumer articles such as coffee machines, water faucets and as buttons and zippers on clothing; thus making them lead-containing articles. Examples of other uses for lead are as a constituent in paints, varnishes and crystal glass, in electronics, machinery, and in jewellery.

3 CLASSIFICATION FOR PHYSICO-CHEMICAL PROPERTIES

Classification for physical hazards is not considered in this dossier.

4 HUMAN HEALTH HAZARD ASSESSMENT

Classification for health hazards is not considered in this dossier.

5 ENVIRONMENTAL HAZARD ASSESSMENT

5.1 Degradation

The substance is an element, and hence doesn't degrade.

5.2 Environmental distribution

5.2.1 Adsorption/Desorption

Suspended matter – water partition coefficient ($K_{suspended\text{-}water}$):

K_P of 295,121 $L.kg^{-1}$ (50^{th} percentile). Range 50,119 - 1.698,244 $L.kg^{-1}$

$K_{sediment}$:

K_P of 154,882 $L.kg^{-1}$ (50^{th} percentile). Range 35,481 - 707,946 $L.kg^{-1}$

5.2.2 Volatilisation

Vapour pressure (Pa): 0 mbar at 20ºC (Voluntary Risk Assessment Report, VRAR 2008)

5.2.3 Distribution modelling

5.3 Aquatic Bioaccumulation

5.3.1 Aquatic bioaccumulation

5.3.1.1 Bioaccumulation estimation

5.3.1.2 Measured bioaccumulation data

Table 22: Summary of relevant information on aquatic bioaccumulation

Method	Results	Remarks	Reference
BCF	728 :$L.kg^{-1}$ wwt (mean). 424 $L.kg^{-1}$ wwt (50^{th} percentile)	See table 3.2.4-1 from VRAR below	VRAR (2008)

BAF	1553 L.kg^{-1} wwt (50th percentile at environmentally relevant concentrations)	See table 3.2.4-2 and 3.2.4-4 from VRAR below	VRAR (2008)

Bioaccumulation factor (BAF):

1554 L.kg^{-1} wwt (mean). 440 L.kg^{-1} wwt (50th percentile). Range 7 – 15,400 L.kg^{-1} wwt (VRAR 2008).

Bioconcentration factor (BCF):

728 L.kg^{-1} wwt (mean). 424 L.kg^{-1} wwt (50th percentile). Range 5 – 8,000 L.kg^{-1} wwt (VRAR 2008).

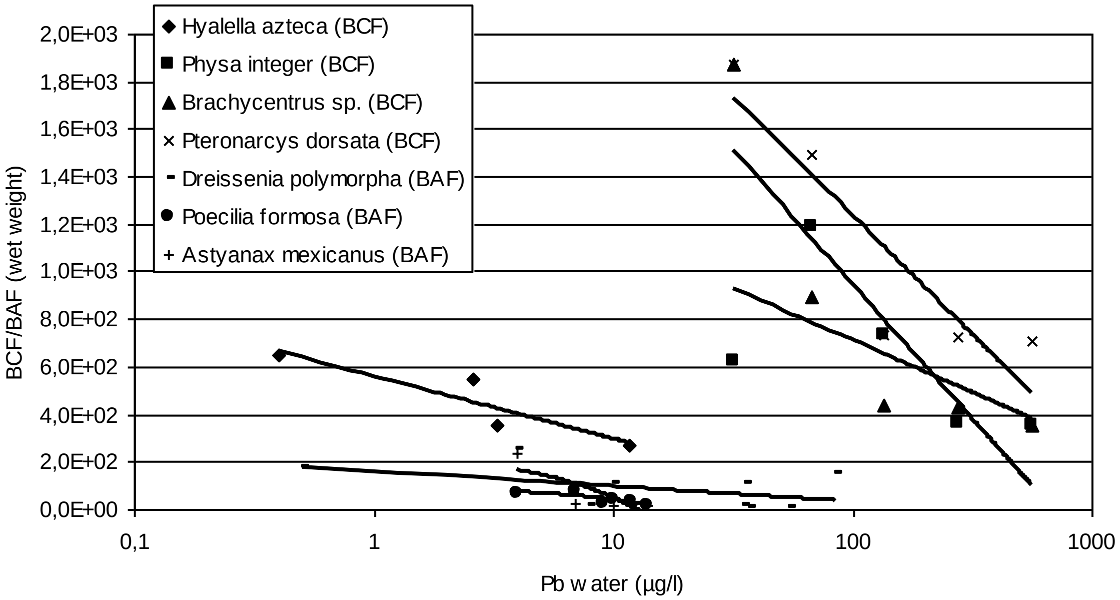

Figure 3.2.4-1-1 from the VRAR (2008): The whole-body bioconcentration/bioaccumulation factors (BCF/BAF) of invertebrates/fish as a function of the Pb concentration in water.

Table 3.2.4-1 from VRAR (2008): The whole-body bioconcentration factor (BCF) of Pb in freshwater organisms.

Species	**organism**	**Tissue (mg/kg dw)**	**Tissue (mg/kg ww)**	**Water (µg/L)**	**BCF (dw)**	**BCF (ww)**	**Reference (VRAR, 2008)**
crustaceans							
Asellus meridianus	isopod	20,000	4,000	500	40,000	8,000	Brown, 1977
Hyalella azteca	amphipod	1.3	0.26	0.4	3250	650	Borgmann et al., 1993
Hyalella azteca	amphipod	5.8	1.16	3.3	1758	352	Borgmann et al., 1993
Hyalella azteca	amphipod	7.1	1.42	2.6	2731	546	Borgmann et al., 1993
Hyalella azteca	amphipod	15.8	3.16	11.6	1362	272	Borgmann et al., 1993
Hyalella azteca	amphipod	1.1	0.21	0.2	5,000	1,000	Maclean et al., 1996
Hyalella azteca	amphipod	6.8	1.35	2.1	3,250	650	Maclean et al., 1996
Hyalella azteca	amphipod	25.9	5.18	20.7	1,250	250	Maclean et al., 1996
Hyalella azteca	amphipod	113.9	22.77	207.0	550	110	Maclean et al., 1996
Daphnia magna	cladoceran	4.9	0.98	0.9	5,765	1,153	Cowgill, 1976
Daphnia pulex	cladoceran	3.6	0.72	0.9	4,235	847	Cowgill, 1976
molluscs							
Dreissenia polymorpha	mussel	0.9	0.09	0.5	1,800	180	Kraak et al., 1994
Dreissenia polymorpha	mussel	10	1	4	2,500	250	Kraak et al., 1994

Species	**organism**	**Tissue (mg/kg dw)**	**Tissue (mg/kg ww)**	**Water (µg/L)**	**BCF (dw)**	**BCF (ww)**	**Reference (VRAR, 2008)**
Dreissenia polymorpha	mussel	11	1.1	10	1,100	110	Kraak et al., 1994
Dreissenia polymorpha	mussel	40	4	36	1,111	111	Kraak et al., 1994
Dreissenia polymorpha	mussel	130	13	85	1,529	153	Kraak et al., 1994
Lymnaea palustris	snail	8.5	2.5	1	8,500	2,500	Borgmann et al., 1978
Physa integer	snail	100	20	32	3,125	625	Spehar et al., 1978
Physa integer	snail	400	80	67	5,970	1,194	Spehar et al., 1978
Physa integer	snail	500	100	136	3,676	735	Spehar et al., 1978
Physa integer	snail	500	100	277	1,805	361	Spehar et al., 1978
Physa integer	snail	1,000	200	565	1,770	354	Spehar et al., 1978
insects							
Brachycentrus sp.	caddisfly	300	60	32	9,375	1,875	Spehar et al., 1978
Brachycentrus sp.	caddisfly	300	60	67	4,478	896	Spehar et al., 1978
Brachycentrus sp.	caddisfly	300	60	136	2,206	441	Spehar et al., 1978
Brachycentrus sp.	caddisfly	600	120	277	2,166	433	Spehar et al., 1978
Brachycentrus sp.	caddisfly	1,000	200	565	1,770	354	Spehar et al., 1978
Pteronarcys dorsata	stonefly	300	60	32	9,375	1,875	Spehar et al., 1978
Pteronarcys dorsata	stonefly	500	100	67	7,463	1,493	Spehar et al., 1978
Pteronarcys dorsata	stonefly	500	100	136	3,676	735	Spehar et al., 1978
Pteronarcys dorsata	stonefly	1,000	200	277	3,610	722	Spehar et al., 1978
Pteronarcys dorsata	stonefly	2,000	400	565	3,540	708	Spehar et al., 1978
fish							
Poecilia reticulata	fish	4.1	0.82	3.1	265	1,322	Vighi, 1981
Poecilia reticulata	fish	12	2.4	27.5	87	436	Vighi, 1981
Salvelinus fontanilis	brook trout	8	1.6	34	235	47	Holcombe et al., 1976
Salvelinus fontanilis	brook trout	12.7	2.54	58	219	44	Holcombe et al., 1976
Salvelinus fontanilis	brook trout	0.36	0.072	0.9	400	80	Holcombe et al., 1976
Lepomis macrochirus	Blue gill sunfish	1.4	0.28	14.1	100	20	Wiener and Giesy, 1979
Lepomis macrochirus	Blue gill sunfish	1.0	0.20	14.1	70	14	Wiener and Giesy, 1979
Micropterus salmoides	Black bass	0.65	0.13	14.1	45	9	Wiener and Giesy, 1979
Esox niger	Chain Pickerel	1.25	0.08	14.1	25	5	Wiener and Giesy, 1979
Anguilla rostrata	American eel	0.5	0.10	14.1	35	7	Wiener and Giesy, 1979
Erimyzon sucetta	lake chubsuckers	0.5	0.10	14.1	35	7	Wiener and Giesy, 1979
Perca flavescens	Yellow perch	1.1	0.22	0.5	2,025	405	Draves and Fox, 1998
Perca flavescens	Yellow perch	0.5	0.10	0.2	2,120	424	Draves and Fox, 1998

Table 3.2.4-2 from VRAR: The whole-body bioaccumulation factors (BAF) of Pb in freshwater organisms

Species	**organism**	**Tissue (mg/kg dw)**	**Tissue (mg/kg ww)**	**Water (µg/L)**	**BAF (dw)**	**BAF(ww)**	**Analysis of Pb in aqueous media**	**Reference (VRAR, 2008)**
crustaceans								
Asellus	isopod	3.44	0.688	<0.2	>17,200	>3,440	Filtered (0.45 µm)	Timmermans et al., 1989
Gammarus	amphipod	1.65	0.33	<0.2	>8,250	>1,650	Filtered (0.45 µm)	Timmermans et al., 1989
Cyclops		3.78	0.756	<0.2	>18,900	>3,780	Filtered (0.45 µm)	Timmermans et al., 1989
Daphnia magna	cladoceran	23	4.6	3.1	7,400	1,500	Filtered (0.45 µm)	Vighi, 1981
Daphnia magna	cladoceran	68	13.6	27.5	2,500	495	Filtered (0.45 µm)	Vighi, 1981
Daphnia magna	cladoceran	187	37.4	13	14,380	2,877	Filtered (0.45 µm)	Lu et al., 1975
Daphnia magna	cladoceran	154	30.8	2	77,000	15,400	Filtered (0.45 µm)	Lu et al., 1975
Daphnia magna	cladoceran	85	17	2	42,500	8,500	Filtered (0.45 µm)	Lu et al., 1975
molluscs								
Amblema plicata	clam	13.5	1.35	2	6,750	675	Filtered (filter size not reported)	Mathis and Cummings, 1973
Dreissena	mussel	0.12	0.024	<0.2	>600	>120		Timmermans et al., 1989

Species	**organism**	**Tissue (mg/kg dw)**	**Tissue (mg/kg ww)**	**Water (µg/L)**	**BAF (dw)**	**BAF(ww)**	**Analysis of Pb in aqueous media**	**Reference (VRAR, 2008)**
Dreissena polymorpha	mussel	5.1	0.51	35	146	15	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	3.7	0.37	54	69	7	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	3.2	0.32	37	86	9	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	1.9	0.19	12	158	16	Unfiltered	Chevreuil et al., 1996
Dreissena polymorpha	mussel	1.4	0.14	8	175	18	Unfiltered	Chevreuil et al., 1996
Fusconaia flava	clam	18.5	1.85	2	9,250	925	Filtered (filter size not reported)	Mathis and Cummings, 1973
Lymnaea	snail	0.79	0.079	<0.2	>3,950	>395	Filtered (0.45 µm)	Timmermans et al., 1989
Potamopyrgus	snail	7.7	0.77	<0.2	>38,500	>3,850	Filtered (0.45 µm)	Timmermans et al., 1989
Quadrula quadrula	clam	11	1.1	2	5,500	550	Filtered (filter size not reported)	Mathis and Cummings, 1973
Physa	snail	334	33.4	13	25,692	2,570	Filtered (0.45 µm)	Lu et al., 1975
Physa	snail	88	8.8	2	44,000	4,400	Filtered (0.45 µm)	Lu et al., 1975
Physa	snail	56	5.6	2	28,000	2,800	Filtered (0.45 µm)	Lu et al., 1975
insects								
Chironomus	midge	1.83	0.366	<0.2	>9,150	>1,830	Filtered (0.45 µm)	Timmermans et al., 1989
Glyptotendipes	midge	0.44	0.088	<0.2	>2,200	>440	Filtered (0.45 µm)	Timmermans et al., 1989
Holocentropus	caddisfly	1.32	0.264	<0.2	>6,600	>1,320	Filtered (0.45 µm)	Timmermans et al., 1989
Ischnura	damselfly	1.75	0.35	<0.2	>8,750	>1,750	Filtered (0.45 µm)	Timmermans et al., 1989
Limnephilus	caddisfly	4.36	0.872	<0.2	>21,800	>4,360	Filtered (0.45 µm)	Timmermans et al., 1989
Stictochironomus	chironomid	5.31	1.062	<0.2	>26,550	>5,310	Filtered (0.45 µm)	Timmermans et al., 1989
Micronecta	corixid	1.87	0.374	<0.2	>9,350	>1,870	Filtered (0.45 µm)	Timmermans et al., 1989
annelids								
Erpobdella	leech	1.62	0.324	<0.2	>8,100	>1,620	Filtered (0.45 µm)	Timmermans et al., 1989
acarides								
Hygrobates	mite	1.73	0.346	<0.2	>8,650	>1,730	Filtered (0.45 µm)	Timmermans et al., 1989
fish								
Astyanax mexicanus	fish	1	0.2	14	71	14	Unfiltered	Villarreal-Trevino et al., 1986
Astyanax mexicanus	fish	0.9	0.18	12	75	15	Unfiltered	Villarreal-Trevino et al., 1986
Astyanax mexicanus	fish	0.86	0.172	10	86	17	Unfiltered	Villarreal-Trevino et al., 1986
Astyanax mexicanus	fish	0.8	0.16	7	114	23	Unfiltered	Villarreal-Trevino et al., 1986
Astyanax mexicanus	fish	4.74	0.948	4	1,185	237	Unfiltered	Villarreal-Trevino et al., 1986
Cichlasoma cyanoguttatum	fish	0.5	0.1	9	56	11	Unfiltered	Villarreal-Trevino et al., 1986
Cichlasoma cyanoguttatum	fish	1.36	0.272	14	97	19	Unfiltered	Villarreal-Trevino et al., 1986
Cichlasoma cyanoguttatum	fish	1.3	0.26	10	130	26	Unfiltered	Villarreal-Trevino et al., 1986

Species	**organism**	**Tissue (mg/kg dw)**	**Tissue (mg/kg ww)**	**Water (µg/L)**	**BAF (dw)**	**BAF(ww)**	**Analysis of Pb in aqueous media**	**Reference (VRAR, 2008)**
Micropterus salmoides	fish	0.46	0.092	9	51	10	Unfiltered	Villarreal-Trevino et al., 1986
Notropos lutrensis	fish	0.8	0.16	14	57	11	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia reticulata	Fish	16	3.2	3.1	5,160	1,032	Filtered (0.45 µm)	Vighi, 1981
Poecilia reticulata	fish	36	7.2	27.5	1,300	260	Filtered (0.45 µm)	Vighi, 1981
Poecilia formosa	fish	0.9	0.18	14	64	13	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia formosa	fish	1.3	0.26	9	144	29	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia formosa	fish	2.26	0.452	12	188	38	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia formosa	fish	2.16	0.432	10	216	43	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia formosa	fish	1.3	0.26	4	325	65	Unfiltered	Villarreal-Trevino et al., 1986
Poecilia formosa	fish	2.8	0.56	7	400	80	Unfiltered	Villarreal-Trevino et al., 1986

Further information on the bioaccumulation studies can be found under “Environmental fate and pathways/Bioaccumulation/Bioaccumulation: aquatic / sediment” in the REACH registration disseminated on the website of ECHA (https://echa.europa.eu/registration-dossier/-/registered-dossier/16063). Hardness (H) is given as mg/L of $CaCO_3$. DOC = dissolved organic carbon, DO = dissolved oxygen:

Reference	**Water chemistry etc.**	**Remarks**	**Species**
Borgmann *et al.* 1978 (publication)	pH 7.8, H 139, 21°C	120 days. Just hatched, Flow through, Test substance: $Pb(NO_3)_2$	*Lymnaea palustris*
Borgmann *et al.* 1993 (publication)	pH 7.9-8.6, 25°C	Semi *static*	*Hyalella azteca*
Brown 1977 (publication)	20°C	Semi static Test substance: $Pb(NO_3)_2$	*Asellus meredianus*
Chevreuil *et al.* 1996 (publication)		Field study	*Dreissena polymorpha*
Cowgill 1976		90 days	*Daphnia magna*

(publication)		Semi static	*Daphnia pulex*
Draves & Fox 1998 (publication)		Field study	*Perca flavescens*
Holcombe *et al.* 1976 (publication)	pH 6.8-7.6, H 44.3, DO 8.5 mg/L	105 weeks (3 generations) Test substance: $Pb(NO_3)_2$	*Salvelinus fontinalis*
Kraak *et al.* 1994 (publication)		Field study	*Dreissena polymorpha*
Lu *et al.* 1975 (publication)		33 days microcosmos	*Physa sp.* *Daphnia magna*
MacLean *et al.* 1996 (publication)	pH 7.8-8.6, H 130, DOC 2.3 mg/L, 25°C	8 days Newly hatched Test substance $PbCl_2$	*Hyalella azteca*
Mathis & Cummings 1973 (publication)		Field study	*Amblema plicata* *Quadrula quadrula* *Fusconaia flava*
Spehar *et al.* 1978 (publication)	pH 7.1-7.7, H 44-48, DO 10-11 mg/L, 15°C	28 days Test substance: $Pb(NO_3)_2$	*Pteronarcys dorsata* *Brachycentrus sp.* *Physa integer*
Timmermans *et al.* 1989 (publication)		Field study	*Glyptotendipes sp.* *Asellus sp.* *Hygrobates sp.* *Micronecta sp.* *Holocentropus sp.* *Chironomus sp.* *Potamopyrgus sp.* *Stictochironomus sp.*

		Limnephilus sp. *Erpopdella sp.* *Dreissenis sp.* *Cyclops sp.* *Lymnaea sp.* *Ischnura sp.* *Gammarus sp.*
Vighi 1981 (publication)	4 weeks, flow-through. Test substance: $Pb(NO_3)_2$	*Poecilia reticulata* *Daphnia magna*
Villareal-Trevino *et al.* 1986 (publication)	Field study	*Poecilia formosa* *Cichlasoma cyanoguttatum* *Astyanax mexicanus* *Notropos lutrensis* *Micropterus salmoides*
Wiener & Giesy 1979 (publication)	Field study	*Micropterus almoides* *Lepomis macrochirus* *Erimyzon sucetta* *Anquilla rostrata* *Esox niger*

Table 3.2.4-4 from VRAR: The range of bioaccumulation factors (BAF in L/kg$_{ww}$) of Pb in the mixed diet.

Diet	variable	10th%	50th %	90th %	n
Mixed food diet	All exposures	921	1,472	3,740	49
	0.18-15 µg/L	988	1,553	3,890	44
Mollusc food diet	All exposures	11	473	3,535	14
	0.18-15 µg/L	18	675	3,850	11

5.3.2 Summary and discussion of aquatic bioaccumulation

The variation in BAF and BCF values is very high, and from the VRAR it is clear that a huge part of that variation is due to a negative correlation between BAF or BCF and the water concentration (see Figure 3.2.4-1 1from the VRAR above). There is, however, also a substantial variation between species, not only in the degree of accumulation, but also in the slope of the relationship. At environmentally relevant concentrations the degree of bioaccumulation will generally be at the higher level of the range, and the VRAR estimates 50th percentile BAF for a mixed seafood sample at 1553 L/kg$_{WW}$ at environmentally relevant concentrations in the water (see Table 3.2.4-4 from VRAR above).

Lead thus has a clear potential to bioaccumulate at environmentally relevant concentrations, though is does not biomagnify (VRAR 2008).

5.4 Aquatic toxicity

The joint REACH registration (ECHA, 2016) has been used as the primary source of data. Data was also extracted from the VRAR (2008).

Table 23: Summary of relevant information on aquatic toxicity. All values in this table refer to dissolved Pb. Further information on the studies can be found under "Ecotoxicological information/Aquatic toxicity" in the REACH registration (https://echa.europa.eu/registration-dossier/-/registered-dossier/16063). Hardness (H) is given as mg/L of $CaCO_3$. DOC = dissolved organic carbon, DO = dissolved oxygen

Species and method	**Results (µg/L, dissolved)**	**Remarks**	**Reference**

Acute toxicity data			
Algae			
Phaeodactylum tricornutum 48h EC$_{50}$ Guideline ISO 10253	1690 µg/L	1 test, lead chloride. Given a Klimisch rate of 3 although the REACH registration has given a Klimisch rate of 2. See text below. pH 8, DO 7.2 mg/L, salinity 33.4 ‰, 20°C	ECHA, 2016 Unpublished study report (2012) See also: ILA Environmental Research Programme 2006-2016
Chlamydomonas reinhardtii 48 h EC$_{50}$ OECD 201	171.8 µg/L	1 test Test-substance: PbCl$_2$ pH 6, H 24 mg/L	ECHA, 2016 Unpublished study report (2012)
Chlorella kessleri 48 h EC$_{50}$ OECD 201	388 µg/L	1 test Test-substance: PbCl$_2$ pH 6, H 24 mg/L, 25°C	VRAR, 2008 ECHA, 2016 Unpublished study report (2007)
Pseudokirchneriella subcapitata 72 h EC$_{50}$	20.5 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. DOC 2.1 mg/L, pH 7.6, Ca 0.122 mM. Test-substance: PbCl$_2$	ECHA, 2016 Unpublished study report (2008)
Crustacea			
Ceriodaphnia dubia 48 h EC$_{50}$	26 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: PbN$_2$O$_6$ pH 8-8.2, H 20-30 mg/L, 20°	VRAR 2008ECHA, 2016 Diamond *et al.* 1997 (publication)
Daphnia magna 48 h EC$_{50}$	107 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: Not indicated 107 µg/L given in REACH registration, but no reference given. pH 8.1, H 110 mg/L	VRAR, 2008 ECHA, 2016 Unpublished study report (1980)
Insects			

Benacus sp. 96 h EC_{50}	1360 µg/L	1 test Test-substance: $Pb(NO_3)_2$ - analytical grade (as provided in the VRAR)	ECHA, 2016; VRAR, 2008 Oladimeji & Offem (1989) (publication)
Chironomus tentans 96 h EC_{50}	1770 µg/L	1 test Test-substance: $Pb(NO_3)_2$ - analytical grade (as provided in the VRAR)	ECHA, 2016; VRAR, 2008 Oladimeji & Offem (1989) (publication)
Fish			
Pimephales promelas 96 h LC_{50}	40.8µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: PbN_2O_6 pH 5.7, H15.9, 26°C	ECHA, 2016 Unpublished study report (2010)
Oncorhynchus mykiss 96 h LC_{50}	107 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: $Pb(NO_3)_2Pb(NO_3)_2$. In REACH reg. 107 µg/L, a value estimated from a total value of 1470 µg/L in Davies *et al.* using the conversion equation according to Blust (2010) pH 8.15, H 385, DO 8.7 mg/L, 14°C	ECHA, 2016; VRAR, 2008 Davies *et al.* 1976 (publication)
Micropterus dolomieui 96 h LC_{50}	2800 µg/L	1 test Nominal concentration. Rated with R.I.3 in REACH registration because among other things dissolved Pb concentration did not increase linearly with the nominal Pb concentration Test-substance: PbN_2O_6 pH8.25, H 151 mg/L, DO 9.2 mg/L, 16.2°C	ECHA, 2016; VRAR, 2008 Coughlan & Gloss 1986 (publication)

Clarias lazera 96 h LC_{50}	1720 µg/L	1 test Nominal concentration. In the REACH registration rated with Klimisch 3, because of "Limited details on test conditions and test setup. No measured values". Checking the reference it is noted that information on mortality in control, and duration of acclimation period is lacking, and only 4 test concentrations were employed. As $Pb(NO_3)_2$ is highly soluble nominal and measured concentration probably won't differ significantly. We would probably rate the study RI2. Test-substance: $Pb(NO_3)_2$ pH 6.8-7.8, H 4.5-6 mg/L, DO 5.5-6.9 mg/L, 22°C	ECHA, 2016; VRAR, 2008 Oladimeji & Offem, 1989 (publication)
Oreochromis niloticus 96 h LC_{50}	2150 µg/L	1 test See remarks under *C. lazera* Test-substance: PbN_2O_6 pH 6.8-7.8, H 4.5-6 mg/L, DO 5.5-6.9 mg/L, 22°C	ECHA, 2016; VRAR, 2008 Oladimeji & Offem, 1989 (publication)
Chronic toxicity data			
Algae			
Champia parvula 48 h NOEC/EC_{10}	11.9 µg/L	1 test Test-substance: PbN_2O_6 pH 7.8-7.9, salinity 30‰, 23°C	ECHA, 2016, Unpublished study report (2012)
Pseudokirchneriella subcapitata 72 h EC_{10}	6.1 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: $PbCl_2$? pH 7, H 24 mg/L, DOC 2.1 mg/L	ECHA, 2016 Unpublished study report (2008)
Chlamydomonas reinhardtii 48 h EC_{10}	82.3 µg/L	1 test Test-substance: $PbCl_2$? pH 6, H 24 mg/L, 25°C	ECHA, 2016 Unpublished study report (2012)

Dunaliella tertiolecta 96 h NOEC/EC_{10}	1232 µg/L	1 test Test-substance: PbN_2O_6 pH 8.2, DO 1.32 mg/L, 20°C, salinity 30‰	ECHA, 2016 Unpublished study report (2010) See also: ILA Environmental Research Programme 2006-2016
Chlorella kessleri 72 h EC_{10}	99 µg/L	1 test Test-substance: Not indicated	VRAR, 2008 De Schamphelaere & Janssen 2007 ECHA, 2016 Unpublished study report (2007)
Skeletonema costatum 96 h NOEC/EC_{10}	52.9 µg/L	1 test Test-substance: PbN_2O_6 pH 8.1, DO 1.32 mg/L, 19-20°C, salinity 38 ‰	ECHA, 2016 Unpublished study report (2010) See also: ILA Environmental Research Programme 2006-2016
Phaeodactylum tricornutum 48 h EC_{10}	(1234 µg/L)(100)	1 test Test-substance: $PbCl_2$ 1234 µg/L is the value given in ECHA, 2016. However, the right value must be around 100 µg/L. See text below. pH 8.02, DO 7.2 mg/L, 20.2°C, salinity 33.4‰	ECHA, 2016 Unpublished study report (2012) See also: ILA Environmental Research Programme 2006-2016
Vascular plants			

Lemna minor 7 d NOEC/EC$_{10}$	19.3 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: $Pb(NO_3)_2$ pH 7.7-8.0, H 29 Average specific growth rate in dry weight	ECHA, 2016 Unpublished study report (2010) See also: ILA Environmental Research Programme 2006-2016
Rotifers			
Brachionus calyciflorus 48 h EC$_{10}$	57 µg/L	1 test Test-substance: $PbCl_2$ pH 7.6, DOC 1,2 mg/L, Ca 0.27 mM	ECHA, 2016 Unpublished study report (2013) See also: ILA Environmental Research Programme 2006-2016
Philodina rapida 96 h EC$_{10}$	2.4 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: PbN_2O_6 pH 7.2, H 5 mg/L, 25°C	ECHA, 2016 Esbaugh *et al.* 2012 (publication)
Polychaeta			
Neanthes arenaceodentata 126 d EC$_{10}$	95.9 µg/L	1 test Test-substance: PbN_2O_6 pH 7.6-8.3, 19°C, salinity 31.4 ‰	ECHA, 2016 Unpublished study report (2010)
Insects			
Baetis tricaudatus 10 d EC$_{10}$	37 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: $PbCl_2$ pH 6.6, H 20.7, DO 10.1, 9.3°C	ECHA, 2016 Mebane *et al.* (2008) (publication)
Chironomus riparius 14 d NOEC	225 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: $PbCl_2$ pH 7.5, H 42.7, DOC 5.6 mg/L	ECHA, 2016 Unpublished study report (2012) See also: ILA Environmental Research Programme 2006-2016

Chironomus tentans 34 d NOEC	109 µg/L	1 test Test-substance: PbN_2O_6 pH 7.9, H46, DO 7.9 mg/L, 25 °C	ECHA, 2016 Grosell *et al.* 2006b (publication) See also: ILA Environmental Research Programme 2006-2016
Crustacea			
Alona rectangular 25 dg NOEC/EC_{10}	40.2 µg/L	1 test Test-substance: $PbCl_2$ pH 7-7.5, H 94, 23°C	ECHA, 2016 Garcia-Garcia *et al.* 2006 (publication)
Hyalella azteca 42 d NOEC	6.3 µg/L	1 test Test-substance: Not indicated	ECHA, 2016; VRAR (2008) Besser *et al.* 2005 (publication)
Ceriodaphnia dubia 7 d EC_{10}	1.7 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: PbN_2O_6 pH 7.5, H 82.4, DO 88.3%, 25.3°	ECHA, 2016Cooper *et al.* 2009 (publication)
Daphnia magna 21 d NOEC	9 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: PbN_2O_6 pH 7.2-7.6, H 52, DO 6.6 mg/L, 25.3 °C	VRAR, 2008 Chapman *et al.* 1980 ECHA, 2016 Unpublished study report (1980)
Diaphanosoma birgei 25 d EC_{10}	13.3 µg/L	1 test Test-substance: $PbCl_2$ pH 7-7.5, H 94, 23°C	ECHA, 2016 Garcia-Garcia *et al.* 2006 (publication)
Americamysis bahia 30 d EC_{10}	9.9 µg/L	1 test Test-substance: Not indicated	ECHA, 2016 Unpublished study report (2013) See also: ILA Environmental Research Programme 2006-2016

Tisbe battagliai 18 d NOEC/EC_{10}	397.3 µg/L	1 test Test-substance: PbN_2O_6 pH 8.15-8.23, salinity 30-35‰ 20°C	ECHA, 2016 Unpublished study report (2013) See also: ILA Environmental Research Programme 2006-2016
Molluscs			
Lymnaea palustris 120 d NOEC	12 µg/L	1 test Test-substance: PbN_2O_6 pH 7.8, H 139, 21°C	ECHA, 2016; VRAR, 2008 Borgmann *et al.* 1978 (publication)
Lymnaea stagnalis 30 d EC_{10}	1.7 µg/L	Lowest value. 6 tests at different life stages, test durations, pH, hardness and DOC. Test-substance: PbN_2O_6 pH 7.3, H 83, DOC<0.5 mg/L	ECHA, 2016 Unpublished study report (2007) VRAR, 2008 Parametrix (2007) See also: ILA Environmental Research Programme 2006-2016
Crassostrea gigas 48 h embryos EC_{10}	930.8 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: PbN_2O_6 pH 8.2, DO 1.32 mg/L, salinity 30.7 ‰, 20°C	ECHA, 2016 Unpublished study report (2010) See also: ILA Environmental Research Programme 2006-2016
Mytilus galloprovincialis 48 h, NOEC/EC_{10}, embryos	9.9 µg/L	Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: PbN_2O_6 pH 7.8, salinity 33‰, 20 °C	ECHA, 2016 Unpublished study report (2010)

Mytilus trossolus 48 h EC_{10}, embryos	9.2	1 test Test-substance: PbN_2O_6 pH 7.8, salinity 33 ‰, 20°C	ECHA, 2016 Unpublished study report (2010)
Echinoderms			
Dendraster excentricus 72 h EC_{10}, embryos	249,8	1 test Test-substance: PbN_2O_6 pH 8.1, DO 1.32 mg/L, salinity 30.5 ‰, 15 °C	ECHA, 2016 Unpublished study report (2010) See also: ILA Environmental Research Programme 2006-2016
Paracentrotus lividus 48 h EC_{10}, embryos	119 µ/l	1 test Test-substance: Not indicated pH 8.2, DO>5mg/L, salinity 35 ‰	ECHA, 2016 Unpublished study report (2012) See also: ILA Environmental Research Programme 2006-2016
Strongylocentrotus purpuratus 72 h NOEC/EC_{10}, embryos	111.8 µg/L	1 test Test-substance: PbN_2O_6 pH 8.2, DO 1.32 mg/L, salinity 30‰, 15 °C	ECHA, 2016 Unpublished study report (2010) See also: ILA Environmental Research Programme 2006-2016.
Fish			

Oncorhynchus mykiss **570 d EC_{10}**	**9 µg/L**	**Lowest value. Geometric mean not used as tests were performed under very varying conditions. The NOEC or EC_{10} is not given in the article, but the EC_{10} can be deduced from the data given in the article's Tab. 4.** **Did not follow a guideline, but well described, including water chemistry, and a control mortality between 0% and 0.6%.** **Test-substance: $Pb(NO_3)_2$** **pH 6.7-7.3, H 28, DO 8.3 mg/L, 11.1 °C**	**VRAR, 2008** **Davies *et al.* 1976** **(publication)**
Salmo salar 90 d NOEC	48 µg/L	1 test Test-substance: PbN_2O_6 pH 6.3, H11, Egg stage 4°C, Until feeding 6°G Rest of time 8°C	ECHA, 2016; VRAR, 2008 Grande & Andersen, 1983 (publication)
Ictalurus punctatus 60 d NOEC	70.5 µg/L	1 test Value in Sauter *et al.* 75 µg/L. Corrected for solubility in VRAR. Test-substance: $Pb(NO_3)_2$ pH 6.8-7.3, H 36, DO 8.5 mg/L, 22°C	VRAR, 2008 Sauter *et al.* 1976 ECHA, 2016; Unpublished study report (1976)
Salvelinus fontinalis 1095 d NOEC	52.8 µg/L	1 test Value in Holcombe *et al.*, 58 µg/L. Corrected for solubility in VRAR Test-substance: $Pb(NO_3)_2$ pH 6.8-7.6, H 44.3, DO 8.5 mg/L, 9°	ECHA, 2016; VRAR, 2008 Holcombe *et al.*, 1976 (publication)
Salvelinus namaycush 60 d NOEC	45.8 µg/L	1 test Value in Sauter *et al.* 48 µg/L. Corrected for solubility in VRAR. Test-substance: $Pb(NO_3)_2$ pH 7-7.3, H 32.6, DO 9.7 mg/L, 10°C	VRAR, 2008 Sauter *et al.* 1976 ECHA, 2016; Unpublished study report (1976)
Lepomis macrochirus 60 d NOEC	63.7 µg/L	1 test Value in Sauter *et al.* 70 µg/L. Corrected for solubility in VRAR. Test-substance: PbN_2O_6 pH 6.7-7.2, H 40.7, DO 6.9 mg/L, 25°	VRAR, 2008 Sauter *et al.* 1976 ECHA, 2016; Unpublished study report (1976)

Cyprinus carpio 7 d EC_{10}	17.8 µg/L	1 test. VRAR: 20 µg/L. In REACH reg. corrected for pH dependence to 17.8 µg/L according to Blust 2010. Test-substance: PbN_2O_6 pH 5.6, H 35, 23°	ECHA, 2016; VRAR, 2008 Stouthart *et al.* 1994 (publication)
Pimephales promelas 30 d LC_{10}	20 µg/L (0.9 µg/L)	Lowest value. Geometric mean not used as tests were performed under very varying conditions. In the REACH registration the 0.9 µg/L value was rated with R.I.3. Test-substance: PbN_2O_6 pH 7.4, H 19, 23°C	ECHA, 2016 Unpublished study report (2006) Grosell *et al.* 2006a (publication)
Cyprinodon variegatus 28 d EC_{10}	229.6 µg/L	1 test Test-substance: PbN_2O_6 pH 7.7-8.1, DO 0.7 mg/L, salinity 28.2‰	ECHA, 2016 Unpublished study report (2010) See also: ILA Environmental Research Programme 2006-2016
Acipenser sinensis 112 d NOEC	129 µg/L	1 test Test-substance: PbN_2O_6 pH 7.55,H 64.2, DO > 6 mg/L	ECHA, 2016 Hou *et al.* 2011 (publication)

5.4.1 Fish

See Table 23, the VRAR (2008) and the information disseminated on ECHA's website from the joint REACH registration for lead (ECHA, 2016).

All studies cited in Table 23 are rated with a reliability index (R.I.) (Klimisch) of 1 or 2 unless otherwise stated. The rating was done by the registrant and by the Danish EPA in the case of Esbaugh et al. 2013 (*P. promelas*) and Davies et al. 1976 (*O. mykiss*).

5.4.1.1 Short-term toxicity to fish

The lowest acute fish LC_{50} is 40.8 µg/L for *Pimephales promelas*. There are many LC_{50} values for this and other species, and provided the studies have been performed under similar conditions the geometric mean for each species, with at least 4 data points, would normally be used. The studies given, however, have been performed under very varying conditions (varying pH, hardness, and DOC), and so the lowest LC_{50} for each species has been employed.

5.4.1.2 Long-term toxicity to fish

The lowest long-term fish EC_{10} or NOEC is 0.9 µg/L for *Pimephales promelas*. However, in the REACH registration the study giving this value (a "publication" 2006) was rated with R.I.3 because the buffer MOPS was used. Esbaugh *et al.* (2013) investigated the effects on toxicity to *P. promelas* of different pH manipulation methods, concluded that the use of MOPS had a significant effect, increasing the toxicity. In their conclusion they recommend not to use buffers as they affect the ionoregulatory processes. There are, on the other hand, quite some uncertainties connected to the study of Esbaugh *et al.* (2013) with respect to the water chemistry of the different series treated with different kinds of pH regulators, which varied significantly between the series. Also, according to De Schamphelaere *et al.* (2004) MOPS had no influence on the toxicity of Cu and Zn to *Daphnia* sp. and *Pseudokirchneriella* sp.. On the other hand, 0.9 µg/L is close to 1 µg/L and would be the only value below 1 µg/L. Also, if a species sensitivity distribution (SSD) analysis including data for 38 species is employed (see section 5.5 of this document), it makes little difference if the 0.9 µg/L value is changed to 20 µg/L as the HC_5 will in any case be between 1-10 µg/L.

Disregarding the value of 0.9 µg/L the lowest long-term fish EC_{10} or NOEC is 9 µg/L for *Oncorhynchus mykiss*.

Also in this case there is a number of data for each species, and the lowest value for each species has been chosen for the same reason as for the acute LC_{50} above.

5.4.2 Aquatic invertebrates

See Table 23 and the VRAR (2008) and the information disseminated on ECHA's website from the joint REACH registration for lead.

All studies cited in Table 23 are rated with a reliability index (Klimisch) of 1 or 2 by the registrant, and by the Danish EPA in the case of the studies of Diamond et al 1997 (*C. dubia*), Cooper et al. 2009 (*C. dubia*), and the study report 2007 on *L. stagnalis*.

5.4.2.1 Short-term toxicity to aquatic invertebrates

The lowest acute EC_{50} is 26 µg/L for the crustacean *Ceriodaphnia dubia* (Diamond et al. 1997). For this and other species there are multiple EC_{50} values and given the studies have been performed under similar conditions the geometric mean for each species, with at least 4 data-points, would normally be used. The studies given, however, have been performed under very varying conditions (varying pH, hardness, and DOC) and so the lowest EC_{50} for each species has been employed.

The Diamond et al. study has been given a Klimisch score of R.I. 2 in the REACH registration. The Danish EPA has given it an R.I. of 2 – 3. There are several other values for C. dubia in this range: 29 (several), 46 and 74 µg/l, and the study is regarded as reliable.

5.4.2.2 Long-term toxicity to aquatic invertebrates

The lowest long-term EC_{10} or NOEC is 1.7 µg/L for both the snail *Lymnaea stagnalis* and for the crustacean *Ceriodaphnia dubia*. For *C. dubia* and other species the lowest value was chosen for the same reasons as for the EC_{50} above.

5.4.3 Algae and aquatic plants

The lowest acute EC_{50} value for algae is a 72 h EC_{50} of 20,5 µg/L for *Pseudokirchneriella subcapitata.*

The lowest long-term result for algae is a 72 h EC_{10} = 6.1 µg/L for the green algae *Pseudokirchneriella subcapitata*. This study (ECHA, 2016) included 13 tests with varying pH, hardness and DOC. Two types of buffers were applied, 5 tests with MES and 8 with MOPS. There was no statistical significant difference between the EC_{10}s of the MES and MOPS tests (Mann-Whitney U = 21, P > 0.2, two-tailed) whereas there is a significant correlation between pH and EC_{10} when the hardness level is held constant (H = 24 mg/L, Spearman rank $r_s = -0.846$, N = 8, $0.01 < P < 0,02$) (These statistical tests were made by DK-EPA). Thus there is no indication of a significant effect of the choice of buffer.

All studies cited in table 23 are rated with a reliability index (Klimisch) of 1 or 2 by the registrants and, in the case of the tests on P. subcapitata mentioned above and P. tricornutum, by the Danish EPA. An exception is the study with *Phaeodactylum tricornutum* with the EC_{50} value of 1690 µg/L(ECHA, 2016) . In this study the dissolved lead concentration had dropped at the end of the test, and there was a clear relationship between the start concentrations and the degree of decrease. Thus at the highest initial concentration (3408 µg/L) the decrease was 80%, whereas at 128 µg/L it was only 4%. Therefore the EC_{50} value (1690 µg/L) is regarded as unreliable.

The EC_{10} value for *Phaeodactylum tricornutum* (1234 µg/L) (ECHA, 2016) is as well regarded as unreliable, because looking at the data below it is apparent that the figure cannot be true, because the growth equal to 90% of the control (10% effect) corresponds to a dissolved concentration around 100 µg/L or lower.

A study conducted with *Lemna* sp. available in the joint registration dossier (ECHA, 2016) claim the root elongation in *Lemna* sp. is a more sensitive parameter than frond number and dry weight (all based on average specific growth rate). This, however, is not apparent when looking at the data in their Table 8, and for the EC_{10} dry weight (19.3 µg/L) is the most sensitive.

Antunes and Kreager (2014) reported an EC_{10} for *Lemna* sp. of 30.7 µg/L (148 nM/l) for root elongation while the corresponding figure in ECHA, 2016 (Unpublished study report, 2010), for the same water was 74.5 µg/L.

None of the studies of De Schamphelaere and Janssen give any information on the lead compound employed, neither the kind of compound, where it was purchased nor the purity. In the REACH registration it is, however, in a number of cases indicated that $PbCl_2$ was used. The results of the quoted reports are also summarised in De Schamphelaere *et al.* 2014, which is readily accessible.

5.4.4 Other aquatic organisms (including sediment)

The VRAR (2008) and the REACH registration (ECHA, 2016) present data on 7 species of sediment dwelling organisms from freshwater and 2 species from salt water. The values are in mg Pb/kg sediment, and cannot be employed in classification.

5.5 Comparison with criteria for environmental hazards (sections 5.1 – 5.4)

The lowest reliable acute and chronic toxicity results for the lead ion reported in the VRAR (2008) are an EC_{50} = 26 µg/L (crustacea; study with *C. dubia*, Diamond *et al.*, 1997) and NOEC/EC_{10} = 0.9 µg/L (fish; study with *P. promelas*, Grosell *et al.*, 2006a) and 1.7 µg/L (snails; study with *L. stagnalis*, Parametrix, 2007). According to the REACH registration the lowest EC_{50} is 20.5 µg/l (algae: study with *P. subcapitata*, ECHA (2016)), and the lowest EC_{10} or NOEC is 1.7 µg/L for snails and 1.7 µg/L for crustacea (study with *C.dubia*, Cooper *et al.* 2009). The NOEC of 0.9 µg/L was discarded in the REACH registration because of the use of the MOPS buffer (see above).

In the REACH registration the lowest EC/LC_{50} and EC_{10}/NOEC values from the pH interval 5.5-6.5 were chosen as the acute and chronic ERVs, respectively (acute: 73.6 µg/l, chronic: 17.8 µg/l). As noted below this procedure is not recommended.

If data are available for both dissolution and toxicity at different pH levels the corresponding toxicity values and dissolution values at different pHs may be compared. In the current case the powder has only been tested in a full T/Dp test at pH 6.

Further, if we look at the two most sensitive species, *Lymnaea stagnalis* and *Ceriodaphnia dubia*, then *L. stagnalis* has been tested only in the pH interval from 7.1 to 8.6, and there is no indication of a correlation between pH and toxicity. In fact the correlation (Spearman rank) is $r_s = 0.000$ (but there are only 4 values covering the same life stage, effect type and test duration).

With *C. dubia* there are 39 EC_{10} or NOEC values for reproduction from 7 days tests, and the pH-span is from 6.05 to 8.5. However there is a much stronger relationship between DOC and toxicity than between pH and toxicity. Without taking DOC and hardness into account the correlation between pH and EC_{10} or NOEC is $r_s = 0.237$, $P > 0.1$ (two-tailed), while for the relationship between DOC and EC_{10} or NOEC the correlation is $r_s = 0.335$, $P < 0.05$, without taking pH and hardness into account.

Thus, a comparison between the toxicity at different pH levels with the T/Dp test results at the same levels is not possible and as well not recommendable.

Twenty-four hours screening tests for Transformation/Dissolution would normally only be used with metal compounds, while the metallic forms usually are regarded as “insoluble” and the ERVs for acute and chronic toxicity (EC_{50}= 20.5 µg/L and the chronic EC_{10} = 1.7 µg/L or HC_5 = 3 µg/L) should normally be compared to the metal ion concentration achieved in full 7 and 28 days Transformation/Dissolution tests, respectively[3]. The 24 hours screening test for Transformation/ Dissolution with lead powder at a loading of 100 mg/L led to 3211 µg/L in solution (REACH registration). A 28 days T/Dp test at pH 6 and 1 mg/L loading with 1 mm particles (i.e. not powder) led to 14.2 µg/L, while a 7 days T/Dp at pH 6, 1 mg/L loading and 1 mm particles resulted in a dissolved concentration of 5.1 µg/L.

If it is assumed that a 100 times decrease in loading will also decrease the concentration of metal in solution a hundred times then a 24 hours T/Dp test with the powder at a loading of 1 mg/L would result in a dissolved concentration of 32 µg/L. (Actually the concentration at a loading of 1 mg/L is likely to be greater, as the dissolved concentration will level off, i.e. reach an upper level with increasing loading). This concentration (32 µg/L) would be expected to increase substantially in a 7 days test.

So, the 7 days T/Dp test with the powder is likely to result in a dissolved concentration well above the acute ERV of 20.5 µg Pb/L for *P. subcapitata*, resulting in a classification as **Aquatic Acute 1**.

For the long-term hazard classification the CLP and UN GHS guidances recommend 28 days T/Dp testing at pH 5.5 to 8.5 at loadings of 1 mg/L and 0.1 mg/L with the lowest particle size on the market.

The dissolved concentration of 14.2 µg/L from the 28 days T/Dp with 1 mm particles (i.e. not powder) is well above the chronic ERV of 1.7 µg Pb/L for aquatic invertebrates, and the dissolved concentration in a corresponding T/Dp test with the powder would result in a much higher concentration.

Thus a classification as **Aquatic Chronic 1** is warranted.

As the database on chronic data comprises data for 39 species representing 9 major taxonomic groups an SSD analysis can be employed with this dataset. The ETX 2.0 programme has been used to

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[3] Guidance on the application of the CLP criteria, Annex IV on the classification strategies for metals and inorganic metal compounds (2014)

calculate the HC_5. HC_5 = 3.0 µg/L with lower and upper 90% limits of 1.4 µg/L and 5.5 µg/L. Normality was accepted by the Anderson-Darling, Kolmogorov-Smirnov and Cramer von Mises tests for normality.

According to the CLP guidance it may be considered to employ an SSD analysis when the data-set is sufficient. On the other hand we don’t really have experience using this approach. In any case the HC_5 = 3 µg/L is close to the lowest species EC_{10} or NOEC of 1.7 µg/L, and the conclusion would be the same whichever value is used.

According to the joint REACH registration (ECHA, 2016) the lowest acute ERV is 20.5 µg/L (algae, pH 7.5-8.5) and chronic ERV is 6.1 µg/L (algae, pH 7.5-8.5) when looking at toxicity in their three selected pH-bands. The selection of these values are the result of a procedure where, within each pH-band, the geometric mean is employed whenever there are four or more values. As the toxicity values for e.g. *C. dubia*, apart from pH, represent greatly varied conditions of hardness and DOC, and as there is a very weak, if any, correlation between the toxicity and pH for e.g. *C. dubia*, mean values cannot be employed, and the toxicity cannot be related to pH bands.

While the toxicity values from the pH-band 5.5-6.5 were employed for the classification as such in the REACH registration, the lowest (geometric mean) value from the whole dataset was employed in the REACH registration for setting the M-factors.

The ERVs are both far below the concentration obtained in the 24 hours screening test (EC_{10} is more than 1200 times lower), and it is unlikely that the concentration achieved in full 28 days T/Dp tests will be lower than the reference values. This conclusion is further supported by the result of the 28 days T/Dp test with 1 mm particles resulting in a concentration that is above the chronic ERV at a loading of 1 mg/L.

In the current CLP guidance document the M-factor is set by dividing the concentration achieved in the T/Dp test (7 days for acute and 28 days for chronic) with a loading of 1 mg/L by the ERV. In our opinion this is a wrong methodology because the M-factor should reflect how much a substance contributes to the toxicity of a mixture. As the T/Dp test has shown that the toxicity of the ion in fact is being expressed, the right thing to do would be to set the M-factor directly in relation to the ERV as for all other kinds of substances.

With lead, we do not have 7 days or 28 days T/D data for the powder.

Whether the 7 days T/Dp concentration at a loading of 1 mg/L will be more than 10 times greater than the acute ERV is difficult to assess, but not unlikely.

The 28 days T/Dp test with 1 mm particles and a loading of 1 mg/L resulted in a dissolved concentration of 14.2 µg/L. This concentration is 4.7 times the HC_5 of 3 µg/L and 8.4 times the lowest EC_{10} or NOEC of 1.7 µg/L. Thus it is highly likely that a 28 days T/Dp test with the powder at a loading of 1 mg/L will result in a concentration well above ten times the chronic ERV.

If instead we employ the same methodology as with other kinds of substances, then an acute ERV of 26 µg/L would result in an M-factor of 10 and a chronic ERV between 1 and 10 µg/L would result in an M-factor of 10.

So in the case of lead, an M-factor of 10 is set for acute and for chronic classification regardless of the methodology employed.

Therefore lead metal should be classified as Aquatic Acute 1, and Aquatic Chronic 1, both with separate M = 10.

The joint REACH registration argued that lead should be regarded as being rapidly eliminated from the water column (regarded as equivalent to rapid degradation). This was based on the “TICKET Unit World Model” which includes among other things adsorption to and sedimentation with particulate organic matter and binding in the sediment.

There are many freshwater habitats with no significant amount of organic sediment.

Adsorption to and sedimentation with particulate organic matter and binding in the sediment is not an irreversible process, and the density of particulate organic matter varies greatly from place to place and among seasons. Organic substances may as well undergo the same process, but this was not accepted when the classification criteria were developed.

The adsorption and sedimentation also will be dependent on the water depth. Volatilisation of substances was not accepted as means of removal when the classification criteria were developed because of the dependence on water depth – in the oceans the mean water depth is several kilometres.

Further, the model is not yet validated for and thus not applicable to running water conditions, but designed for predicting water concentrations in lakes without currents or turbulence.

Thus the “TICKET Unit World Model” is clearly a (local-) **RISK** assessment tool, and cannot be used in classification.

Also, the results of the T/Dp tests at a loading of 1 mg/L, pH 6 and for 7 and 28 days show that there is a marked increase in the achieved concentration of soluble forms from day 7 to day 28 indicating no rapid transformation from soluble forms to insoluble forms.

There is no evidence of rapid environmental transformation of lead metal which implies that the chronic M-factor should be 10 for long-term (chronic) hazard classification.

Furthermore, in the joint REACH registration it is argued that the classification of lead metal should be split in two entries, “lead powder” (aerodynamic diameter of 75 µm), and “lead massive”.

We do not think this split of classifications is justified. The powder and “massive” forms do not exhibit different crystal structures or differences in important chemical/physical properties (e.g. the powder being explosive) and it is not improbable that “massive” forms can produce powder-like particles. A brick or piece of lead could under “reasonably expected use” e.g. be melted; an example is casting of bullets and fishing weights in the home. This type of exposure has been shown to increase blood lead levels in humans *(MMWR 2011).* The metal can also be ground into smaller pieces or polished. Also there are, on the market, lead films with a thickness of only 25 µm (see e.g. http://www.gammadata.se/sv/produkter/stralningsmatning/stralskydd/blyfolie/blyfolie-075-mm/, http://www.holger.no/index.php/produkter/ndt/radiografi/rontgenfilm-og-kjemi/rontgenfilm, http://www.tasma.ru/en/products/17/32/), while the powder particles have a diameter around 75 µm. Such films are especially used in connection with x-ray films and are employed in great amounts in industrial equipment and also by dentists, and can easily be worn into small fragments with a relative surface area greater than that of the powder particles, especially when disposed of. In fact, one mg of the film would have a greater surface area than one mg of the powder, and a T/Dp test with the film would produce greater concentrations of Pb in solution than the powder would.

Thus, there is no clear distinction between the “massive” form and the powder, and it is probable that “massive” lead will lead to lead particles in “powder” size which can enter the environment e.g. as dust or through industrial and other discharge to surface water directly or via sewage treatment plants.

In conclusion, the classification should be Aquatic Acute 1 with an M-factor of 10 and

Aquatic Chronic 1 with an M-factor of 10.

5.6 Conclusions on classification and labelling for environmental hazards (sections 5.1 – 5.4)

CLP - Classification: Aquatic Acute 1, H400 with an M = 10

Aquatic Chronic 1, H410 with an M = 10

CLP – Labelling: see section 1.3 of this report.

RAC evaluation of aquatic hazards (acute and chronic)

Summary of the Dossier Submitter's proposal

The Dossier Submitter (DS) proposed to classify lead (powder and massive forms) as Aquatic Acute 1 - H400 and Aquatic Chronic 1 - H410, both with an M-factor of 10, given that the concentrations in the Transformation/Dissolution protocol tests (T/Dp) reached the levels of the Ecotoxicity Reference Values (ERVs) at the appropriate loadings and with the consideration that there is no evidence of rapid environmental transformation.

Degradation

The substance is a natural element and so is not degradable by definition. It is therefore not relevant to assess degradation rate as is usually done for organic compounds. Furthermore, the results from a full Tranformation/Dissolution protocol test (T/Dp) (loading of 1mg/L for 28 days at pH 6) demonstrate an increase in the dissolved metal ion concentrations from 5.1 µg/L (at day 7) to 14.2 µg/L (at day 28). Consequently, the DS concludes that there is no evidence of rapid environmental transformation of lead from soluble to insoluble forms.

Bioaccumulation

There is quite a large database of whole-body bioaccumulation and bioconcentration factors (BCF and BAF respectively). The DS states that variation in BAF and BCF values is very high and that a large part of that variation is due to the fact that there is no correlation between either BAF or BCF and the water concentration (VRAR, 2008). There is also a substantial variation between species, not only in the degree of accumulation, but also in the slope of the relationship. At environmentally relevant concentrations, the degree of bioaccumulation will generally be at the higher area of the range. The DS therefore concludes that lead has a clear potential to bioaccumulate at environmentally relevant concentrations for the purposes of classification and labelling.

Aquatic toxicity

The available database for lead (II) cations is large because several soluble lead compounds (mainly $Pb(NO_3)_2$ and $PbCl_2$) have been tested under a wide range of conditions involving a variety of species.

The DS used the joint REACH registration dossier as the primary source of data. Data is also extracted from the VRAR (2008). The CLH report presents data from aquatic toxicity tests with 13 (acute) and 38 (chronic) standard and non-standard species. The DS proposes to use the lowest value for each species by stating that the studies have been performed under very varying conditions (pH, hardness and DOC). In addition, splitting the data into pH bands is not considered appropriate by the DS, as no correlation could be established between toxicity and pH for the two most sensitive species (toxicity vs pH (1) *Lymnaea stagnalis*: rs = -0.075 (2) *Ceriodaphnia dubia*: rs = 0.237).

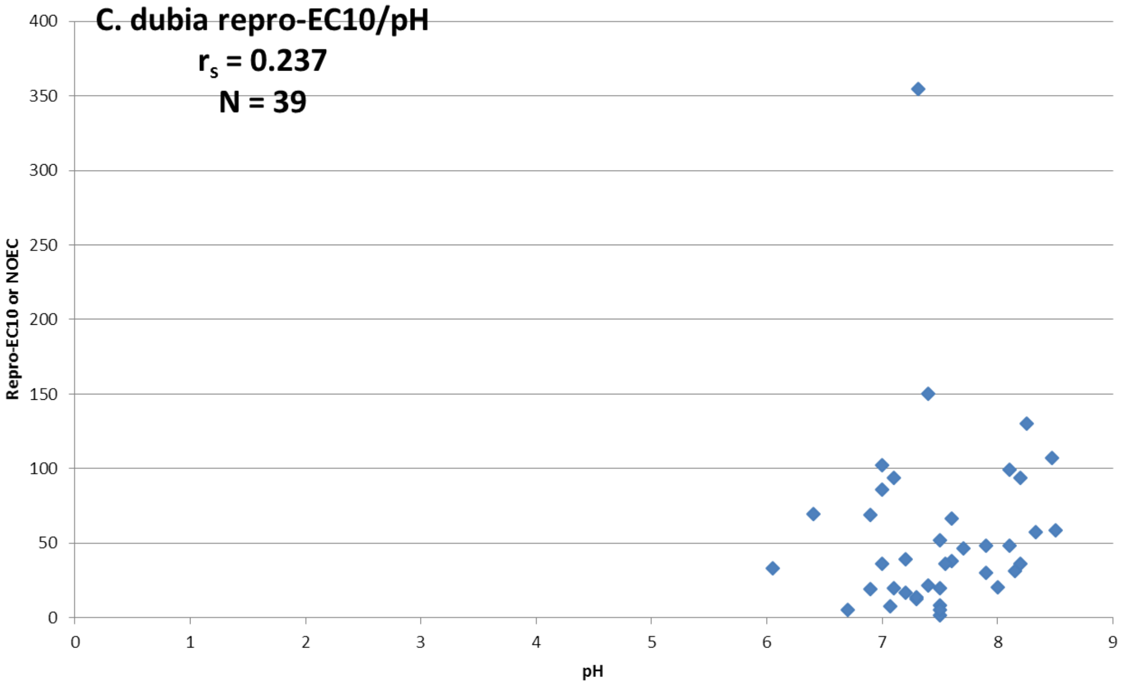

Figure: Correlation between toxicity and pH for *C. dubia*.

Furthermore, the DS is of the opinion that the normalisation techniques (such as the Biotic Ligand Model (BLM)) applied by industry on the data points does not provide any reduction in the variability as the span between the minimum and maximum values is not reduced.

The following description presents the available toxicity information for each trophic level, with the lowest values highlighted in bold.

Acute fish toxicity

Acute data is reported for five fish species, all with standard 96 h LC_{50} values. The lowest acute fish LC_{50} is **40.8 µg/L** for *Pimephales promelas* (pH 5.7, H 15.9, 26°C).

Long-term fish toxicity

There is data for ten fish species with a lowest long-term NOEC of **0.9 µg/L** for *Pimephales promelas*. The study (Grosell *et al*., 2006a) was rated with Reliability 3 in the REACH registration because the buffer MOPS (3-(N-morpholino)propanesulfonic acid) was used. The DS states in the CLH report that by disregarding the value of 0.9 µg/L the lowest long-term fish EC_{10} is 9 µg/L for *O. mykiss* (Davies *et al.*, 1976). This study is rated as Reliability 2 by the registrant although it does not follow a guideline; it is well described including water chemistry and had a control mortality between 0% and 0.6% ($Pb(NO_3)_2$; pH 6.7-7.3; H 28, Dissolved Oxygen, 8.3 mg/L, 11.1 °C).

Short-term toxicity to aquatic invertebrates

There are several studies available with the crustacean *Ceriodaphnia dubia* with EC_{50} values in the range of 26 to 74 µg/L, the lowest reliable EC_{50} reported in the CLH report being **26 µg/L** from Diamond *et al.* (1997).

Long-term invertebrate toxicity

There is data for several different invertebrate species. The lowest long-term EC_{10} and NOEC value identified by the DS is **1.7 µg/L** for both the snail *Lymnaea stagnalis* and for the crustacean *Ceriodaphnia dubia*.

Algal/aquatic plants toxicity

The lowest acute and long-term toxicity values reported by the DS are a 72 h EC_{50} of **20.5** and an EC_{10} of **6.1 µg/L**, respectively, for the green algae *Pseudokirchneriella subcapitata*. The study (ECHA, 2016) included 13 individual tests with varying pH, hardness and DOC. Two types of buffers were applied, 5 tests with MES (2-(N-morpholino)ethanesulfonic acid) and 8 with MOPS. The analysis performed by the DS does not show any statistically significant difference between the EC_{10}s of the MES and MOPS tests (Mann-Whitney U = 21, P > 0.2, two-tailed) whereas a significant correlation between pH and EC_{10} when the hardness level is held constant (H = 24 mg/L, Spearman rank $r_s = -0.846$, n = 8, 0.01 < P < 0,02) is calculated. Thus, the DS concludes that there is no indication of a significant effect related to the choice of buffer.

ERV and M-factor derivation

The CLH report lists the acute and chronic ERVs chosen by the REACH registrant for classification, *i.e.* 73.6 and 17.8 µg dissolved Pb/L (studies conducted at the acidic pH of 5.5 – 6.5), respectively, as well as the acute and chronic ERVs, *i.e.* 20.5 and 6.1[4] µg dissolved Pb/L (studies conducted at the alkaline pH band of 7.5 – 8.5) selected for deriving the M-factors. The lowest acute and chronic ecotoxicity reference values (ERVs) selected by the DS are summarised in the following table. Following the methodology applied by the DS, these values represent the lowest available results from relevant acute and chronic aquatic toxicity studies.

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[4] In the CLH report the DS refers to the lowest EC_{10} or NOEC of 1.7 µg/L for both *L. stagnalis* and *C. dubia*. While these two studies are indeed reported in the REACH registration dossier, the chronic ERV chosen by the registrant for hazard classification purposes is the EC_{10} of 6.1 µg/L conducted with *P. subcapitata* (growth rate).

Table: *ERVs used by the Dossier Submitter (µg/L)*

Acute ERV	**EC_{50}**	**20.5** (*P. subcapitata, lowest value; growth rate*)
Chronic ERV	**EC_{10}/NOEC**	**1.7** (*L. stagnalis, lowest value; growth* and *C. dubia, lowest value; reproduction)*

T/Dp data

Based on the CLP Guidance (Guidance on the Application of the CLP criteria, version 5.0, 2017), the classification of metals is based on a comparison of acute and chronic ERVs (derived from soluble metal species) with the concentration of metal ions in solution after a period of 7 days (short-term test) and 28 days (long-term test), respectively, at different loadings following the T/D protocol. Several studies with different particle size of lead (75 µm and 1 mm) are available.

For lead with a particle diameter of 1 mm, the CLH report lists results of **5.1 µg Pb/L** and **14.2 µg Pb/L** from 7 and 28 day full T/Dp tests at pH 6 and at a loading of 1 mg/L.

For lead with a particle diameter of 75 µm, only the result from a 24 hour screening T/Dp test at pH 6 and a loading of 100 mg/L is included in the CLH report, indicating a dissolved Pb ion concentration of **3211 µg/L**. The DS emphasised that 24 hour screening T/Dp tests are normally conducted for metal compounds only (CLP guidance, Annex IV.2.2.2). However, the REACH registration does not include 7 and 28 days full T/Dp tests using lead with a particle diameter of 75 µm. Based on this supposed lack of information, the DS furthermore assumed that a 100 times decrease in loading will also decrease the concentration of metal in solution a hundred times, hence a 24 hour T/Dp test using lead with a particle diameter of 75 µm at a loading of 1 mg/L would result in a dissolved concentration of 32 µg/L. This concentration (32 µg/L) is expected to increase substantially in a 7 days T/Dp test.

Proposed classification

The DS concludes that it cannot be excluded that under 'reasonably expected use' the massive form of lead could result in lead particles in powder form which can enter the environment (e.g. by casting of bullets and fishing weights in the home or by grinding it into smaller pieces or polishing). Consequently, splitting the classification is not justified for lead and the proposed classification should apply to both forms as they currently appear in annex VI to CLP, massive and powder.

The acute and chronic ERVs are both far below the concentration obtained in the 24 hour screening T/D test and it is unlikely that the concentration achieved in a 28 days full T/Dp test will be lower than the ERV. This conclusion is further supported by the result of the 28 day full T/Dp test with 1 mm particles. This resulted in a concentration at a loading of 1 mg/L (14.2 and 2 µg Pb/L at pH 6 and 7, respectively) that was found to be greater than the chronic ERV selected by the DS (1.7 µg/L for *L. stagnalis* and *C. dubia*).

Based on the above considerations and by concluding that there was no evidence for rapid environmental transformation, the DS proposes to classify lead (powder and massive forms) as **Aquatic Acute 1 - H400** and **Chronic 1 - H410**.

In addition, the DS proposes an **M-factor of 10** for both acute and chronic aquatic hazards following the approach as applied for organic substances, as the M-factor should reflect how much a substance contributes to the toxicity of a mixture.

Comments received during public consultation

Four Member State Competent Authorities (MSCAs) supported the proposal to classify lead as Aquatic Acute 1 and Chronic 1, one MSCA asked for clarification of the impurity content, while another MSCA asked for clarification as to whether the acute and chronic endpoints reported in table 23 of the CLH report (at least the key ones used for classification) are based on mean measured test concentrations, and asked for clarification that the acute and chronic endpoints for algae (at least the key ones in relation to classification) are based on growth rate. All other comments were submitted by industry and individual. The comments cover a range of issues, which can be summarised as follows:

a) *Concerns regarding the classification of alloys, mainly aluminium ones. Comments on the melting process of scrap and the manufacturing of recycled aluminium alloys, does not produce particles. Information on thesolubility of alloys (test with Al-alloy and massive lead, lower migration from alloy), the elimination of lead from the aluminium recycling stream is not yet technically practicable.*
RAC notes that it is possible to test Al-alloys according to the T/D protocol in order to assess their potential classification. Furthermore, alloys need not be labelled if they do not pose a risk to human health or the environment.

b) *Concerns regarding one single classification proposal for lead, industry proposes not to classify the massive form for acute and chronic environmental hazards.*
Lead has two separate entries (one for the massive and one for the powder form; distinguished by a particle diameter of 1 mm) in Annex VI of the CLP Regulation for health hazards with the only difference that an SCL was specified for the powder form. This is addressed at the end of this opinion.

c) *Concerning the use of the C. dubia 7-days test for long-term hazard classification.*
This test is clearly a chronic test as three broods are produced within the test duration, which compares to three broods in a 21 days *Daphnia magna* reproduction test. In the CLP Guidance (Annex I.2) it is stated that: *"Chronic testing involves an exposure that covers a significant period of time when compared to the organism´s life cycle. The term can signify periods from days to a year, or more depending on the reproductive cycle of the aquatic organism."* On this basis, RAC concludes the use of long-term test results from tests using *C. dubia* is justified. This is also consistent with previous cases, such as granulated copper.

d) One MSCA questioned whether nano-sclae forms of lead (i.e. nanoparticles and nanoforms) currently being manufactured are also covered by the proposed environmental classification. In his response, the DS clarified that the proposal does not cover nanoforms of lead. RAC has included an explicit statement in the opinion that nanoforms should be considered separately.

e) *Preference to use data from "standard test species"*.
   RAC is of the opinion that, in principle, it is preferable to base classification decisions on data from standard test guideline studies, since these methods have been ring-tested and approved for regulatory purposes. However, where valid data are available from non-standard species and from non-standard testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/2006. In general, both freshwater and marine species toxicity data are considered suitable for use in classification provided the test methods used are equivalent.

f) Concerning the use of the Lymnaea stagnalis study (growth rate, chronic ERV).
   According to the CLP Guidance (Annex IV.4.1.3.1.2): *"Where valid data are available from non-standard testing and from non-testing methods, these shall be considered in classification provided they fulfil the requirements specified in section 1 of Annex XI to Regulation (EC) No 1907/2006".* RAC notes that the quality of the Parametrix (2007) study with *Lymnaea* sp. was rated by the REACH registrants as reliable without restriction (as also pointed out by the DS). It has also been used in the species sensitivity distribution used to set the PNEC in the joint REACH registration dossier, which indicates the level of hazard for risk assessment purposes.

g) Question regarding the setting of M-factors.
   The comments received suggest to follow the CLP Guidance for metals and poorly soluble metal compounds and not to use alternative ways for deriving of M-factors. However, the DS clarified during RAC discussions that they have applied the CLP Guidance method for calculating the M-factors as well, although this was hampered by lack of the suitable data. Consequently, extrapolation was necessary to a concentration after 24 hours at a loading of 100 mg/L instead of the concentration after 28 days at a loading of 1 mg/L according to the CLP Guidance (Annex IV.5.4).

   In addition, the DS also applied the GHS method given the same result in this specific case. RAC confirms that the approach by the DS likely underestimates the concentration after 28 days.

h) Supplemental industry comments of the International Lead Association (ILA), submitted in August 22, 2018, on normalising the test results to comparable conditions by two methods, Biotic Ligand Modelling (BLM), and selection of data generated under "similar conditions".

   In response to these supplemental comments, the DS noted that from the lists of chronic ERVs for the two most sensitive species, *C. dubia* and *L. stagnalis,* it is not possible to find, within each pH-band (5.5-6.5, 6.5-7.5, 7.5-8.5), four values that have been derived from studies performed under equal conditions.

   From the normalisation results presented (using BLM), the DS concluded that the normalisation generally does not reduce the variability in the data compared to the non-normalised data. There is no general reduction in the span between the minimum and maximum values. In conclusion and as the normalisation procedures do not reduce the overall variability in the differing test conditions, the DS therefore re-enforced their opinion that geometric means cannot be used.

The DS also stated that for the two most sensitive species *C. dubia* and *L. stagnalis,* there is no correlation between toxicity and pH (rs = -0.075 and rs = 0.237 respectively). Therefore, grouping according to pH is not approriate.

RAC agrees with the DS and considers that splitting the data to reflect pH bands defined for T/Dp testing is not appropriate in this case. RAC also recognises that there are no clear trends in the data driven by the water quality parameters and therefore does not see a need to normalise the data. However, RAC does not agree with the DS on the selection of the lowest value in every case. The latter is addressed in the next section of this opinion.

Assessment and comparison with the classification criteria

Degradation

RAC agrees with the conclusions of the DS that lead is not rapidly transformed by normal environmental processes.

Aquatic Bioaccumulation

According to the CLP Guidance (Annex IV.4), assessing bioconcentration factors for non-essential metals, should preferably be done from BCF studies using environmentally relevant concentrations in the test media (NOEC). The BCF value for fish is the preferred information for classification purposes.

There are several BCF values for different fish species:

Species	**Water Pb (µg/L)**	**BCF (ww)**
Poecilia reticulata (guppy)	3.1	1,322
Salvelinus fontanilis (brook trout)	0.9	80
Perca flavescens (yellow perch)	0.5	405

There are three different values available, one above the classification cut-off value for BCF of ≥500 and two below. If high-quality BCF values for different fish species are available, generally the highest valid value should be used as the basis for classification.

RAC agrees with the DS that lead can be considered as bioaccumulative under CLP at environmentally relevant concentrations.

Aquatic toxicity

Following the CLP Guidance (Annex IV.2), the classification of metals is based on a comparison of acute and chronic ERVs (derived from soluble metal species) with the concentration of metal ions in solution after a period of 7 days (short-term test) and 28 days (long-term test), respectively, at different loadings and at the pH that maximises the concentration of dissolved metal ions in solution and expresses the highest toxicity.

There is acute and chronic aquatic toxicity data available for all tree trophic levels. Based on the information provided in the CLH report, as well as clarifications provided by the DS and industry experts during RAC discussions (see Background document), RAC considers that the following ERVs are most appropriate:

Acute ERV	**EC_{50}**	**20.5 µg Pb/L** (*P. subcapitata, lowest value; growth rate*)
Chronic ERV	**EC_{10}**	**1.7 µg Pb/L** (*L. stagnalis, lowest value; growth)*

The CLP Guidance (Annex IV.4.1.3.2.4.3) allows the calculation of geometric mean values as the representative toxicity value for that species, where four or more data points are available for the same species. In estimating a mean value, the CLP Guidance further specifies that it is not advisable to combine tests of different species within a different taxonomic group or in different life stages or tested under different conditions or duration. In addition, the CLP Guidance (Annex IV.2.3) also allows splitting the acute and chronic ERVs according to the pH used during the T/Dp test in case a more extensive toxicity/dissolution dataset is available. The geometric means split in the pH bands are used in the REACH registration dossier. RAC agrees with the DS that splitting into pH bands is not appropriate, given that no clear trend could be seen in any of the three water quality parameters (pH, DOC, hardness). This was supported by the information in the CLH report and additional clarifications provided by the DS following RAC discussions, demonstrating that for the two most sensitive species, no correlation between toxicity and pH could be established (toxicity vs pH (1) *Lymnaea stagnalis*: rs = -0.075 (2) *Ceriodaphnia dubia*: rs = 0.237).

RAC disagrees with the DS on the selection of the lowest NOEC of 1.7 µg/L for *Ceriodaphnia dubia* (reproduction) for chronic ERV derivation and used the geometric mean instead, finding that it appropriately summed up the available data.

Independent of the above, the highest toxicity of dissolved lead ions was observed in a study conducted with *L. stagnalis* larvae resulting in a chronic EC_{10} of 1.7 µg/L (measured; growth (wet weight)). This study was conducted according to GLP standards with newly hatched snails under static renewal conditions using standard synthetic freshwater and natural water collected from South Platte river. After 30 days of exposure growth (wet weight) was measured. While there is no existing standard OECD TG for testing with larvae of this species, the available OECD TG 243[5] on adult *L. stagnalis*, allows the use of individual growth of the reproducting snails and the number of eggs produced per snail as additional test endpoints. Acknowledging that the study was not conducted according to a standardised test guideline, RAC agrees with the DS to consider the study as reliable and valid for classification purposes and to use the EC_{10} of 1.7 µ/L for chronic ERV derivation. This value was also used for PNEC (Predicted-No-Effect-Concentration) derivation and employed in the Species Sensitivity Distribution (SSD) in the REACH registration dossier by the registrants, which further supports its use in hazard classification.

Solubility of Pb

In accordance with the CLP Guidance (Annex IV.2.2.3), full T/Dp tests (7 days for short-term and 28 days for long-term hazards) should be carried out at the pH that maximises the concentration of dissolved metal ions in solution and that expresses the highest toxicity. Based

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[5] OECD TG 243… this Test Guideline is designed to assess effects of prolonged exposure to chemicals on the reproduction and survival of the hermaphrodite freshwater snail *Lymnaea stagnalis* (the Great Pond Snail).

on the data from these tests, it is possible to generate a concentration of the metal ions in solution after 7 days (short-term test) for each of the three loadings (*i.e.* 1 mg/L as 'low', 10 mg/L as 'medium' and 100 mg/L as 'high loading') used in the tests. If the purpose of the test is to assess the long-term hazard of the substance, then the loadings should be 0.01 mg/L, 0.1 mg/L or 1 mg/L depending on the transformation rate and the duration of the test should be extended to 28 days (long-term test).

For lead, 24 hour T/Dp test data with 75 µm particles at a loading of 100 mg/L and pH 6 are available, resulting in dissolved lead ion concentrations of **3211 µg Pb/L**.

There is also 7 and 28 day full T/Dp test data available with 1 mm particles at a loading of 1 mg/L at pH 6, which resulted in dissolved lead ion concentrations of **5.1 µg/L** and **14.2 µg/L**, respectively.

The T/Dp results indicate different dissolution kinetics for both tested forms of lead which can be attributed to the different particle size tested. RAC acknowledges the differences in the dissolution rate between the tested particles 75µm and 1mm, but shares the opinion of the DS that the solubility may not be considered as an argument in its own right which would justify a split classification. It is furthermore concluded that the CLP Regulation addresses this substance property with regards to the derogation from labelling requirements of massive forms (CLP Regulation, Article 23), acknowledging that larger particles (*i.e.* massive) are less soluble than smaller particles.

The CLP Guidance (Annex IV.5.5[6]) specifies that *"normally the classification data generated would have used the smallest particle size marketed to determine the extent of transformation. There may be cases where data generated for a particular metal powder are not considered as suitable for classification of the massive forms. For example, where it can be shown that the tested powder is structurally a different material (e.g. different crystallographic structure)."* RAC notes that the massive and the powder forms of lead do not exhibit different crystallographic structures and thus, deviation from the default classification approach according to the CLP Guidance was not considered warranted.

A further exemption from the default approach listed in the CLP Guidance - allowing for a separate classification of the massive form based on testing of a more representative particle size or surface area - refers to the manufacturing of the powder form by a special process and that it is not generally generated from the massive metal. One previous metal case with an existing entry in Annex VI to CLP for which a split classification was considered justified is nickel, taking into consideration that the fine powder is produced by a special process, the so-called Nickel Carbonyl Gas process. In the case of nickel, RAC concludes that a split classification between the two forms seems warranted. However, in the case of lead RAC is of the opinion that it is unclear whether the manfucaturing of lead powder constitutes a special

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[6] CLP Guidance, Annex IV.5.5 (version 5.0, July 2017): Normally, the classification data generated would have used the smallest particle size marketed to determine the extent of transformation. There may be cases where data generated for a particular metal powder are not considered as suitable for classification of the massive forms. For example, where it can be shown that the tested powder is structurally a different material (e.g. different crystallographic structure) and/or it has been produced by a special process and is not generally generated from the massive metal, classification of the massive can be based on testing of a more representative particle size or surface area, if such data are available. The powder may be classified separately based on the data generated on the powder. However, in normal circumstances it is not anticipated that more than two classification proposals would be made for the same metal.

process, taking into consideration that for lead and other metals, powder is intentionally and commonly produced by melting and dispersing the molten metal in an air jet-stream to form small particles.

In agreement with the DS view, RAC concludes that evidence was not provided to show that lead massive cannot form fine particles spontaneously which can then enter the environment.

In addition to the conditions specified in the CLP Guidance, the DS refers to previous metal classification cases where a split classification was warranted based on specific physico-chemical properties between the two forms, *i.e.* they are flammable or even explosive. For example, for aluminium powder both existing entries in Annex VI to CLP are classified for physical hazards, while no classification was concluded for the massive form of Aluminium. Similar conditions apply to the entries for zinc powder (pyrophoric and stabilised), where the pyrophoric entry is also classified for physical hazards. RAC is of the opinion, that a split in classifications between the powder and massive form must be justified by a significant difference in physico-chemical properties, which is not the case for lead.

Overall, RAC shares the view of the DS that the conditions of the CLP Guidance for an exemption are not met in the case of lead. RAC therefore proposes to classify lead on the basis of the available T/Dp data with the smallest particle size marketed (*i.e.* 75 µm), comparing that with the acute and chronic ERVs to decide on the appropriate classification.

Acute toxicity

The available 24 hour Screening T/Dp data with 75 µm particles at a loading of 100 mg/L and pH 6 resulted in **3211 µg Pb/L** in solution. According to the CLP Guidance, classification as Aquatic Acute 1 shall apply, if the dissolved metal ion concentration at a loading rate of 1 mg/L after 7 days exceeds the acute ERV. There is no full T/Dp test available for lead powder and as a consequence, the DS assumed that a 100 times decrease in loading will also decrease the concentration of metal in solution a hundred times. Consequently, a 24 hour Screening T/Dp test with the 75 µm particle diameter at a loading of 1 mg/L would result in a dissolved concentration of 32 µg/L. (the concentration at a loading of 1 mg/L is likely to be greater, as the dissolved concentration will reach saturation with increased loading). The DS concluded that this concentration (32 µg/L) would be expected to increase substantially in a 7 day full T/Dp test. RAC agrees with the DS conclusion, noting that the approach is rather conservative and also assumes a linear kinetic model for the dissolution of lead.

Table: *Dissolved lead concentration (µg Pb/L) achieved in available T/Dp test data*

Particle diameter	T/Dp test duration	Result (µg Pb/L)
1 mm	7 days T/Dp test with a loading of 1 mg/L (pH 6)	5.1 µg/L
75 µm	7 days full T/Dp test with a loading of 1 mg/L	not available
	24 hours Screening T/D test with a loading of 100 mg/L (pH 6)	3211 µg/L
	24 hours Screening T/D test with a loading of 1 mg/L (extrapolated)	> 32 µg/L

RAC concludes that a 7 day T/Dp test with 75 µm particles is likely to result in a dissolved concentration well above the acute ERV of 20.5 µg Pb/L for *P. subcapitata*, resulting in a classification as **Aquatic Acute 1 – H400**.

The CLP Guidance specifies the setting of M-factors for metals and poorly soluble metal compounds by dividing the concentration achieved in the T/Dp test (7 days for acute and 28 days for chronic with a loading of 1 mg/L) with the appropriate ERV and to set the appropriate M-factor(s) based on the resulting calculated ratio(s). In the DS's opinion, approach is problematic because the M-factor should reflect how much a substance contributes to the toxicity of a mixture. As the T/Dp test has shown that the toxicity of the ion in fact is being expressed, the right thing to do would be to set the M-factor directly in relation to the ERV as for all other kinds of substances. With lead, there is no 7 or 28 days T/Dp data available for the 75 µm particle diameter. Whether the 7 day T/Dp concentration at a loading of 1 mg/L will be more than 10 times greater than the acute ERV is difficult to assess, but is not unlikely and for this reason the DS assigned an acute M-factor of 10. RAC does not support this view and prefers the methodology for metals as specified in the CLP Guidance.

The acute M-factor calculated from the ratio of the soluble metal ion concentrations obtained from the available T/Dp test (in this case > 32 µg/L for an estimated loading of 1 mg/L) and the acute ERV of the dissolved metal ion (20.5 µg Pb/L): **> 1.6**. Based on the resulting ratio, the corresponding **M-factor is 1**.

Chronic toxicity

For classification purposes (CLP Guidance, Annex IV.5.2.2.1) the dissolved metal ion concentration obtained from a 28 day T/Dp test in comparison with the chronic ERV should be used to derive the relevant chronic hazard category.

For 75 µm particles, only the result of the 24 hour Screening T/Dp test is available (*i.e.* 3211 µg Pb/L). From this result it is difficult to estimate a 28 day T/Dp value. However, during RAC discussions the industry representative confirmed that the 24 hour screening results mean that the 75 µm particle size should effectively be considered equivalent to a soluble lead salt. It is assumed that a 1000 times decrease in loading will also decrease the concentration of metal in solution a thousand times, then a 28 day full T/Dp test at a loading of 0.1 mg Pb/L would result in a dissolved concentration of 3.2 µg/L. This concentration (3.2 µg/L) would be expected to increase substantially in a 28 days test and is furthermore exceeding the chronic ERV of 1.7 µg Pb/L for *L. stagnalis*. Given there is no evidence of rapid environmental transformation, this results in a classification of lead as Aquatic Chronic 1 – H410.

The corresponding ratio of the soluble metal ion concentrations and chronic ERV is:

ratio (*L. stagnalis):* >32/1.7 = >19

From the above calculated ratios with the lowest NOEC the corresponding M-factor for lead is 10.

Resulting classification of lead agreed by RAC:

Acute (short-term) aquatic hazard: **Aquatic Acute 1 - H40), M-factor = 1.**

Long-term aquatic hazard: **Aquatic Chronic 1 - H410, M-factor = 10.**

Although not agreed by RAC, there was considerable discussion whether the intentional production of lead powder is considered as sufficiently special to meet the conditions of the

CLP Guidance and the possibility of an alternative classification for 1mm Pb particles. In the interests of balance, this view is presented in Appendix 1.

The opinion does not address nanoforms of lead. These should be considered separately.

Appendix 1

Considerations (not supported by RAC) on the classification of lead with a particle diameter ≥ 1 mm.

In the view of some RAC members the intentional production of lead powder is considered as sufficiently 'special' to meet the conditions of the CLP Guidance (exemptions). In particular, the production techniques applied for powders by gas atomisation of molten lead using a jet of high temperature gas allows for the conclusion that these are different compared to those applied for the massive form (such as rolling, extrusion, pressing, stamping, etc.). Moreover, due to its malleability, a spontaneous generation of relevant amounts of fine particles from the massive lead and in a timeframe relevant for hazard classification is considered unlikely. As a consequence, the environmental classification of lead should reflect the differences in the dissolution kinetics, as demonstrated in available full 7 and 28 days T/Dp test data performed with 1 mm lead particles.

In addition, considerations were made as regards consistency with existing metal entries, however, the information available to RAC was not considered conclusive in all cases. In some cases the massive and powder forms were assessed separately (*i.e.* separate T/Dp data were looked at), based on which the classification decision was taken – either to apply the same classification (*e.g.* cadmium), due to the high release rates for both forms resulting in a classification in the most severe hazard category or, both forms did not show any relevant release and were thus not classifiable, such as aluminium.

Overall and by taking into consideration the malleable structure of lead, which will not allow 'fines' to be produced when *e.g.* drilling, there is no reason to neglect the T/Dp data for the massive form and as a consequence there is no justification to not split the classification.

The available full T/Dp data performed at pH 6 with lead particles of 1 mm (default diameter value for T/Dp testing of massive metal) at a loading rate of 1 mg/L indicate a dissolved lead ion concentration after a period of 7 days of 5.1 µg Pb/L. As this concentration does not exceed the acute ERV of 20.5 µg Pb/L, lead particles with a diameter of ≥ 1 mm would not meet the classification criteria for acute aquatic hazard.

Following the CLP Guidance, classification as Aquatic Chronic 1 shall apply, if the dissolved metal ion concentration obtained at a loading rate of 0.1 mg/L is greater than the chronic ERV. In absence of measured T/Dp data at a loading rate of 0.1 mg Pb/L and by assuming a linear relationship between the different loadings, the extrapolated metal ion concentration at a loading rate of 0.1 mg/L after a period of 28 days is 1.42 µg Pb/L. This value does not exceed the chronic ERV of 1.7 for *L. stagnalis*, hence a classification as Aquatic Chronic 1 for particles ≥ 1 mm is not warranted. The next step in the classification scheme for metals is to consider if the dissolved metal ion concentration obtained at a loading rate of 1 mg/L is greater than or equal to the chronic ERV. There is data for a 28 day full T/Dp test at pH 6 with 1 mm particles at a loading rate of 1 mg/L, resulting in a dissolved lead ion concentration of 14.2 µg/L. This value exceeds the chronic ERV of 1.7 µ/L and there is no evidence of rapid environmental transformation and would have resulted in a classification for lead particles with a diameter of ≥ 1 mm as Aquatic Chronic 2 - H411.

Supplemental information - In depth analyses by RAC

RAC discussed if it is appropriate to consider the result of the study (Grosell *et al*., 2006a) as an outlier and not to use it in the chronic classification. Compared to other data points with this species the result of this the study (Grosell *et al*., 2006a) is significantly lower by a factor of around 20 as well as compared to other species it is also an order of magnitude lower. In the exposure medium of the study (Grosell *et al*., 2006a) the organic buffer 3-(*N*-morpholino)propanesulfonic acid (MOPS) was used for pH maintenance, which may affect the ion regulation of fish at the gill surface and thus may influence the toxicity of lead to fish. On the other hand, RAC notes that the calculated Acute-to-Chronic Ratio (ACR) is 1.8, which is within the bounds of biological variability and therefore this data point could be used for ERV derivation. The results of two follow-up studies performed with *P. promelas* at different pHs (7.4 as control without MOPS and 8.1 using MOPS) showed stronger effects when the buffer was used (studies with 6.7 and 8.1) compared to the control study performed at pH 7.4. However, Esbaugh *et al.* (2013) found that compared to $C0_2$ and acid-base addition, the effect of pH manipulation with MOPS on acute toxicity on *P. promelas* at pH 6.7 was with only 15 % the lowest of the three methods. Grosell *et al*. (2006a) state that MOPS buffer was also used to control the acidic pH of the exposure solution the target acid pH of 6.3 was not achieved and the test was performed in water with pH of 6.7, which is close to neutral pH conditions.

It should be also noted that the Mager *et al.* (2011) study repeating the Grosell *et al.* (2006a) study in the same laboratory under similar conditions but without MOPS has given different results (30-d LC_{10} at pH 6.4 was 33 µg/L Pb).

Esbaugh *et al.* (2013) revealed that acidification of test water affected the LC_{50} value. RAC notes that under acidic pH conditions the MOPS buffer significantly impairs the ion transport across fish gills, which may lead to an overestimated Pb toxicity compared to what is expected from pH alone. However this effect is not seen for neutral or alkalinised pH values.

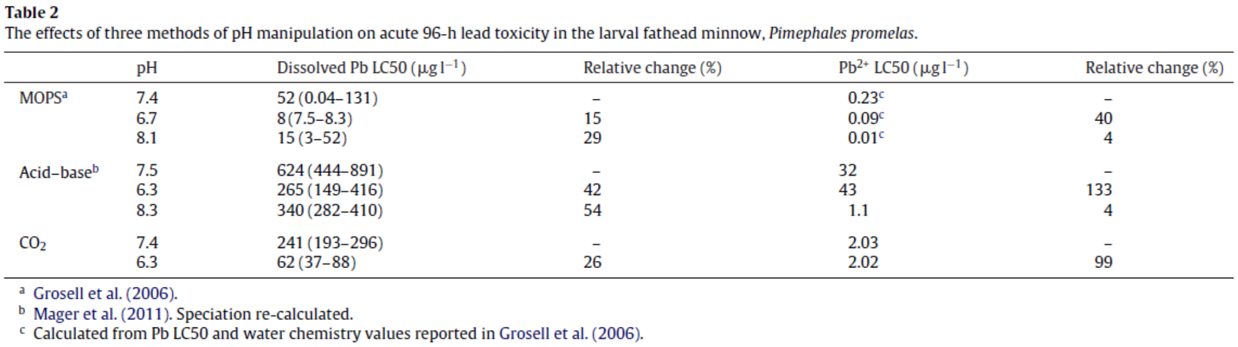

Table 2

The effects of three methods of pH manipulation on acute 96-h lead toxicity in the larval fathead minnow, *Pimephales promelas*.

	pH	Dissolved Pb LC50 ($\mu g\,l^{-1}$)	Relative change (%)	Pb^{2+} LC50 ($\mu g\,l^{-1}$)	Relative change (%)
MOPS[a]	7.4	52 (0.04–131)	–	0.23[c]	–
	6.7	8 (7.5–8.3)	15	0.09[c]	40
	8.1	15 (3–52)	29	0.01[c]	4
Acid–base[b]	7.5	624 (444–891)	–	32	–
	6.3	265 (149–416)	42	43	133
	8.3	340 (282–410)	54	1.1	4
CO_2	7.4	241 (193–296)	–	2.03	–
	6.3	62 (37–88)	26	2.02	99

[a] Grosell et al. (2006).
[b] Mager et al. (2011). Speciation re-calculated.
[c] Calculated from Pb LC50 and water chemistry values reported in Grosell et al. (2006).

RAC therefore considers the NOEC of **0.9 µg/L** for *Pimephales promelas* as not relevant for use in classification, due to uncertainties concerning the use of MOPS buffer.

6 OTHER INFORMATION

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8 ANNEXES

Annex 1

EUROPEAN COMMISSION
DIRECTORATE GENERAL JRC
JOINT RESEARCH CENTRE

INSTITUTE FOR HEALTH AND CONSUMER PROTECTION

UNIT: TOXICOLOGY AND CHEMICAL SUBSTANCES –

European Chemicals Bureau

ECBI/37/02 Rev.2

8th November 2002

SUMMARY RECORD

Commission Working Group on the
Classification and Labelling of Dangerous Substances

Meeting on Environmental Effects

Ispra (Room 3) **11-13** June 2002

The meeting started on **11th June** at **14h00** and finished on **13th June** 2002 at **16:30**.

The session on general issues was also open
to participants of the previous pesticides-environmental effects meeting
started on **11th June** at **14h00** and finished at **12:30 on 12th June**

Mario Nichelatti (MN) and Elisabet Berggren (EB) chaired the meeting.

1. Adoption of the draft agenda (ECBI/86/01 Rev. 4)

The draft agenda (Revision 4) including reference to room document was adopted.

2. Last meetings summary records

(Clarification of Summary Record ECBI/31/00 Rev. 5)

2.1 Draft summary record of the meeting held on 21 -23 November 2001 (ECBI/91/01 Rev.2), participants' list (rev.1)

The Summary Record (Revision 2) of the meeting held on 21 -23 November 2001 was adopted.

Session on general issues

(This session was open to participants of the previous pesticides-environmental effects meeting)

7. Name of Annex I Entries

7.1 Generic entries for compounds (e.g metal / metal compounds)

List of metal compounds: is the metal itself included ? ECBI/26/02

Lead metal	*EC No 231-100-4*	**ECBI/12/02**

In June 2001, **N** asked about lead metal classification.

In November 2001, **ECB** proposed to consider Lead metal as classified in Annex I within the entry: Lead compounds with the exception of those specified elsewhere in the annex:

Name:	Lead compounds with the exception of those specified elsewhere in the annex:
Classification:	Repr.1; R61 Repr.3; R62 Xn; R20/22 R33 N; R50-53
Annex I/ Index No	082-001-00-6
EC No:	231-100-4
CAS No:	7439-92-1
ATP:	25

For both environmental effects and human health the classification of lead metal is the same as all lead compounds constituting the entry because there is no specified separate entry. N-Class database list lead as a substance covered by the above entry: lead compounds.

S asked whether the entry was before called lead and lead compounds. ECB said that if it were unclear we would change the entry in a next ATP. Both **F** and **IND** had another opinion, i.e. that the metal itself not would be included in the general entry. ECB suggested that this must be clarified for all metals and that in cases, as for lead, when it was assumed that the metal would be included this must be changed in the name of the entry. ECB would put the issue on the agenda of the CMR group for discussion also in that group. The discussion would continue at the next meeting.

After the meeting in November 2001, **UK** had sent a document where they expressed their opinion that metal compounds and metal were differentiated and that lead metal was not included in the current Annex I entry. The **Group** agreed with **UK.**

Last Health (CMR) meeting there had also been a discussion and the conclusion was then that the general entry for the metal compounds would not include the metal itself. ECB had listed the general entries for metal compounds as defined in Annex I, which represented a list of only 5 entries. It was suggested that no further concern was raised to the other ones besides the one on lead compounds. Cadmium for example, was already discussed within the RA procedure and listed separately on the agenda of this meeting for environment. At the CMR meeting it had been concluded that MS should send in a proposal in case they would like to suggest classifying lead.

13. Classification of metals and metal compounds

- OECD Guidance Documents N° 28: Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media (July 2001)

	Zinc, massive metal (NL)	*EC No 231-175-3*	*ECBI/48/00 Add. 1 part **I** , II , Add. 6 , Add.7 , Add.8 , Add.9 , Add.10 , Add. 11, Add. 12, Add. 14 Add. 15 , Add 16 & 17 , Add. 18 , Add.19, Add.20, Add.21, Add.22, Add.23, Add.24, Add.25, Add.26,* ***Add.27, Add.28,*** **Add.29, Add.30, Add.31, Add.32, Add.33, Add.34**

Follow-up Documents: Add.37 (F letter in French + English Translation) , Add. 38 , Add.45, Add.47, Add.48 & Add.49

Proposal: n.c.

In September 2000 **NL** argued that a classification of zinc as massive form was currently not considered relevant as no particle size of < 1 mm was to be expected but this should be confirmed by industry. This was supported by **UK** adding that no decision was possible, as it was not clear which particle size needed to be evaluated and how much zinc would be dissolved from this. **S** expressed doubts about the value of the particle size as the international zinc association (65/96 add. 57) had suggested that data from handling and use would justify a common size of 1 mm. **S** stressed that the standard surface area was the crucial value. **Eurométaux** clarified that the particle size of 1 mm had been taken as a default value but that following the request of TMII/2000 more data on the particle size would be provided. Awaiting the further data **ECB** proposed to postpone the decision. The **Group** agreed this.

UK stated that different entries for zinc, massive and zinc, powder were necessary in Annex I.

In June 2001 **NL** as rapporteur MS for the Risk Assessment under Regulation EEC/793/93 proposed to postpone the discussion as the Technical Meeting is still evaluating the ecotoxicity data. Furthermore **NL** had submitted two papers (ECBI/48/00 Add. 6 and Add. 7). In the discussion on current information available **B**, **IRL** (with nota), **NL**, **A** and **UK** preferred no classification for zinc whereas **DK**, **F**, **FIN**, **S** would classify with N; R50-53. **D** would like to split the Annex I entry for particle sizes or find another pragmatic solution. **E** saw the need for more testing. (**N** would follow the majority). The discussion was postponed to the next meeting. The **Group** is invited to send written proposals (made orally in the meeting) and comments within 2 months (15 August), then comments on the proposals.

NL had finalised their proposal how to classify zinc. This was in line with the solution as proposed by some Member States at earlier meetings, i.e. to define separate entries for the massive metal and the powder, and it the latter entry define the particle size. The proposal would be to classify small particles with a diameter up to 10 mm with N; R50-53 and larger particles would then be considered as massive metal and not trigger any environmental classification.

S argued that the whole issue of classification of zinc metal now entered in the area of risk assessment and that this would go beyond the provisions of the Directive 67/548/EEC. They further said that they agreed to the derogation for labelling of the massive metal, but that the classification should reflect the hazard properties. **S** said that they appreciated the effort of NL to provide a new proposal but could not agree with it because it did not meet their concern.

UK agrees with **S** that the classification should be based on the intrinsic properties but they would not agree that this would lead to classification for massive zinc metal.

DK would agree that the classification must cover all possible uses and that form of the metal possible could change during a certain use and then change to a more available form and in this case split to particles of a critical size. This was a parallel problem to the discussion of pesticides that should cover the full life cycle of the active substance and not only the intended use of the pesticide formulation.

F informed that since the meeting in June they had discussed the new approach as presented by the NL with both NL and **IND**. They would agree with this proposal, as they though this would be a helpful and good approach in this case. However they made a reservation that this decision not would preclude their position in discussion of other metals.

S asked **IND** about the representative particle size. **IND** said that the studies of zinc were made with standard particle sizes and that this would be in line with testing of intrinsic properties of a metal.

UK appreciated this approach but wondered which standard particle size could be used.

IND stated that two years ago they had agreed with the transformation protocol to identify the toxic part of the metal, which was the ion. Than they had been looking for the conditions when the ion could be found in water. The particle size is the major reason why the ion would go into water solution and be available in the environment. They had provided data on particle sizes available on the market and smaller sizes as dust would not be of interest, as misuses should not be dealt here. The Directive only refers to normal handling and use. **IND** had a complete set of data to identify particles that were placed on the market.

EB said that, as mentioned by some Member States, the Directive indeed covered whole life cycle of a substance and not only the product placing on the market. Further the **Chair** recognised the large data set available for zinc and would in this case very much favour a compromise solution as put forward by NL. It was then suggested that Member States that so far not had given their opinion should inform on their position.

ES would prefer not to classify according particle size as this could change according the market. They would therefor tend to agree with the **S** position.

IRL would in principle agree with NL but could also go along with **S**. They would at this stage have some more time to reflect on the NL proposal.

N would go along with **S** and the discussion on intrinsic properties, but they would also like to help the discussion move forward and go further discuss a compromise solution.

FIN would support classification and agree with **S**.

DK quoted a part of OECD transformation protocol. **IND** asked why the Group not would use the transformation protocol in their evaluation if they were to stick to the intrinsic properties. **S** did not agree with the interpretation made by **IND**.

The **Chair** interrupted the discussion at this stage, as it did not seem to come to any conclusion. Further she summed up that several Member States was in favour for classification, some had still to make their mind and several would be able to support the pragmatic approach and split the zinc entry into massive metal and particles. It was also recognised that **D** and B that earlier had been very active in the discussions not were present at this meeting. **ECB** then proposed the following solution to come forward with the discussions; all Member States should send in their position with written comments before the 31 January to the ECB. It would then be possible to see whether it would be worthwhile to continue the discussion in this Group at their June meeting, or if it would be more reasonable to present a Commission proposal directly on the basis of the received comments. This would be discussed internally between the ECB and DG ENV after the Member States comments had been examined. Member States should send in their positions to the ECB as by the end of January. The Commission will then agree whether to put the zinc on the agenda for further discussion in this group. The different positions and the Commission proposal how to further handle the discussion will be communicated to the Group in due time prior the June meeting.

Documents from **IND** were received and distributed to the Group during the meeting.

NL explained that they had first sent in a proposal with a cut off value for the particle size higher than the one for the powder to be covered by the classification N; R50-53 and then not to classify zinc in its massive form. However after reconsideration the particle size had been estimated to be so large that they gave up this idea. They had then made another proposal, which was to classify the massive zinc differently from the powder. This was after that the additional information, which indicated toxicity at different pH, had been made available by Industry. The toxicity on *Cerodaphnia* was found lower at lower pH but they questioned the validity of the study because the hardness of the water had not been within standard values. They added that particles that were larger than 11 mm should not be classifiable at pH 8 but questioned whether this would be true at pH 6. They said that the classification should be made although not all the data was available as a basis for decision of the Group. They proposed to classify zinc massive form with R53.

The Chair (EB) gave the floor to **S** who had previously a proposal with N; R50-53. **S** was still convinced that this classification would be more appropriate but they acknowledged the fact this was not accepted by the Group and they would accept R53 for zinc massive without any further discussion on cut-off value.

The Chair saw that there was some support in the Group for this proposal and added that it should be an acceptable solution also for **IND** as particles over 1 mm size would not be classified with N; R50-53, and further the R53 classification did not have any consequences in downstream legislation while meeting the concern of MS. It was also pointed out that metal blocks already were excluded from labelling provisions and the resulting classification for zinc massive only would be noted in the Safety Data Sheet.

The Chair asked the opinion of the Group.

DK declared that the situation was getting absurd to classify on basis of dissolution tests of particles of 5 cm. They were of the opinion that the particle size and the percentage of production were still irrelevant; what was relevant was the amount that was produced by year. The small particles are produced at hundred tons a year so their proposal was still N; R50-53 but they could agree with R53, which at least would flag the concern for the massive form of zinc.

UK would have supported no classification but agreed with NL that not all information at different pH was available and based on the potential concern they supported R53.

FIN supported R53 but expressed that it would be difficult to apply the system for metals.

N agreed with R53 as a compromise.

I still supported no classification.

IRL could go with R53 and agreed with **UK**.

F supported R53 as proposed by NL.

E supported R53 but would prefer to get more information as a basis for a final decision.

D were not able to come to this meeting with an agreement on R53 and did still have to come to an agreement at a national level.

B did neither have a final position for this meeting and asked the possibility to consult back home.

The Chair concluded that the majority was with R53. They invited **IND** to comment on the room documents they sent during the meeting. **IND** found R53 was a courageous compromise, after a long discussion, however they were not comfortable with this agreement because they felt it was an administrative decision. They heard that **UK** and **NL** still expressed concern for lack of data. They had provided data that they would like to present and also the status of lack of information. They apologised for sending the new documents so late, but they had made their best however they had been waiting for the studies to be finalised. Zinc was produced in EU in different sizes. The bulk of the zinc on the market was rather from 10 kg to 4 tons. They indicated that 5 cm particles were the first size for massive form. From the available ecotoxicity data, the short and long-term transformation protocols, numbers of data at pH 8 and also ecotoxicity data at pH 6, they could propose a critical particle size. They referred to table four. They were in favour of no classification.

The Chair proposed the Group as a follow-up action to look at the new data provided by Industry and asked MS to react during the follow-up period if they want to come back on the C&L of this substance based on the new data.

UK appreciated the **IND** effort to provide information but supported NL that there was still not enough data at pH 6. **S** supported NL and **UK** in that R53 was a safety net and that data at ph 6 was not enough.

It was questioned how this decision would effect the strategy of metal classification. The Group then stressed that this proposal was specific to zinc classification and not a rule.

Conclusion: A majority of the **Group** agreed to classify **Zinc massive** with **R53** for environmental effects (**R-phrases: 53 and S-phrases: 61**). The proposal will be sent to **DG ENV** for inclusion in a future TPC unless MS ask to come back to this substance on basis of the room documents sent by **IND** within the follow-up period.

Classification	Toxicity	Degradation	Bioaccumulation	Escape clause

R53	Soluble forms $L(E)C_{50} < 100$ mg/L	No rapid partitioning from the water column (default in absence of information)	No relevant information	No relevant information

As a follow-up, IND room documents were made available on the home page with their revised position. **F, A, E, IRL** and **B** sent comments. **F** sent a revised position, where they could not agree with a global classification with R53. **A**, who could not attend the meeting recalled their former position. **E, IRL and B** were in favour to go on technical discussion with **IND** on their latest results. ECB sent a note to indicate that they needed a written position from MS to indicate whether they could still agree with R53 and if it was not the case to send their detailed and argued classification proposal within the 2nd deadline of next November meeting, **20th October 2002**. The outcome of this written procedure would be the basis of the discussion that would take place in Next November meeting.

	Zinc distearate (NL)	*EC No 209-151-9*	*ECBI/48/00 Add. 1 part I and II , Add.7 , Add. 13 ,* ***Add. 35 part I*** *, II and III,* ***Add. 35 part IV*** *; ECBI/78/00 Add.2*

Proposal: N; R50-53

In September 2000 **NL** explained that the LC50 for fish (*Oncorhynchus mykiss:* 96-hour LC50 of 0.14 mg/L) was greater than the water solubility (0.9 mg/L, which corresponds to about 0.09 mg Zn^{2+}/l) which was confirmed by the three available short-term toxicity tests with fish for zinc distearate. For the one test available on Daphnia magna (RWTuV, 1997) an EC0 of > 13 g/l was measured. This test result could not be brought in line with the available data for daphnids for soluble zinc salts. Concentrations equal to the water solubility of zinc distearate were found to affect daphnids. A very important shortcoming of the daphnid test with zinc distearate was that the dissolved Zn concentration has not been measured. Because of this limitation the water solubility of zinc distearate would be related to the L(E)C50 of soluble zinc salts for obtaining a classification proposal. The water solubility of zinc distearate (0.9 mg/L, which corresponds to about 0.09 mg Zn^{2+}/l) was greater than the lowest EC50 values for *Daphnia magna* (48-hour EC50 of 0.07 mg/L) and *Selenastrum capricornutum* (72 hour EC50 of 0.03 mg/L). Zinc distearate would be classified accordingly with N; R50-R53.

UK that this case together with the massive zinc metal was likely to be affected by changes in the data as the solubility data were only slightly above the toxicity data. If the lowest data would not be regarded as representative the proposal should be changed. Therefore the decision was provisional and **the Group** would come back to zinc distearate on request of **NL**.

In June 2001 the Group decided to **postpone** the discussion as a new study was in course.

IND had unsuccessfully tried a technique to separate the ion and ask NL if they can change to another technique. **IND** reported that they would have the results of the study available early next year. The discussion was postponed until new data would be available.

NL asked **IND** whether they tried to measure the stearate, **IND** explained they had an impurity they could not separate. **IND** summarised their testing strategy: they followed the OECD dissolution protocol. **IND** informed that different test results would be available by the end of next year. ECB invited to send any results of the new studies as soons as possible.

Conclusion: The discussion on this substance would continue when **IND** would make available the results of their further testing.

	Cadmium, massive form (B)	*EC No 231-152-8*	*ECBI/48/00 Add. 2, 4 part **I** , part II , part III and part IV*

Proposal: To await the transformation/dissolution test requested by a Commission regulation

In September 2000 **B** explained that no transformation test was performed on cadmium in massive form (default average particle size: 1mm diameter). **S** pointed out that as there was a strong concern for the massive form regarding the results of the powder N; R50-53 should apply. **B** preferred a classification based on a dissolution protocol on the massive form. **UK** wondered whether the data from the dissolution test for the powder could be regarded as representative for the massive cadmium. If this was not the case the default classification with R53 should apply. This was supported by **D**. **S** stated that as long as no dissolution data on the massive cadmium were provided N; R50-53 should apply which was supported by **DK, F, E** and **N**. **B** felt that R53 would be a good interim solution until TM would decide what relevant testing was needed on the massive metal. **DK** asked whether there was indication that the massive form might produce particles in the size range of the powder. **Eurometaux** clarified that totally different techniques were used to manufacture cadmium powder and massive cadmium, which is used to produce alloys for batteries. **Eurometaux** stated that a dissolution protocol had never been requested and therefore the classification should not be based on assumptions. **S** and **D** proposed to inform the **TM** that a transformation protocol on cadmium in massive form (default average particle size: 1mm diameter) was required to find an appropriate classification. The Group supported this. **DK, EL, E, F, N, A, FIN** and **S** supported a provisional classification as N; R50-53 whereas **B, D, IRL, I, NL** and **UK** preferred R53 as default for the time being awaiting the results of the transformation protocol of the massive cadmium. As there was no clear majority, **the Group** decided to postpone the discussion on the classification of massive cadmium awaiting the dissolution protocol.

In February 2001 the **Chair** reported he had presented the request on a dissolution/transformation test to the 26th **TM** (TM IV, 00; 4th-7th December 2000). The TM agreed to ask for the test according to Art. 10 of Regulation (EEC) No 793/93. This was confirmed by the CA-Meeting in February 2001 in form of a Draft Commission Regulation stating that ‘The test shall be performed according to the test protocols specified by the Member State «Rapporteur». Member States have still a deadline till 15th March to comment on this proposal. Then the committee according to Art. 15 of the ESR will decide on this Regulation. The Regulation is supposed to be published in May or June 2001. **IND** remarked that they would be able to provide the test within 6 month. **The Group** agreed to postpone the decision until the transformation protocol on cadmium in massive form (default average particle size: 1mm diameter) is available.

In June 2001 **EUROMETAUX** announced that the test results would be available prior the next meeting. The **Group** agreed to **postpone** the decision until next meeting.

IND informed that a transformation protocol study was on-going and that the results would be available early next year. The discussion was postponed until new date would be available.

The Risk assessment report had been updated recently and discussed in a RA meeting just a week before. The transformation/dissolution test had been achieved and the results lead the RMS to revise their classification proposal for environment. This updated draft proposal was made available by ECB as a room document at the meeting.

IND could agree with N; R50-R53 that was supported by RMS. They could not explain the absence of relation between loading and dissolution they observed in the test. **B** confirmed that their proposal was N; R50-53. **S** regretted that the test was only performed at pH 8. **IND** indicated that testing the particles with such a heavy load made it difficult to maintain low concentrations by diluting. B would transmit to the Rapporteur that it should be read Cadmium scrap instead of shots. **IND** asked why cadmium and cadmium oxide altogether were in one entry ECB explained that this usually was made for substances that would have the same classification and for this case this had been the assumption from the CMR Group. **N** asked about note 1 and 3 but **S** said it was not applicable to such an entry as cadmium and asked **IND** whether it was necessary to distinguish cadmium massive and cadmium powder. **IND** did not think so, they would check back home. **NL** asked about classification of preparations. **D** answered that alloys are apart from preparation directive. **DK** said that there were other preparations containing cadmium and cadmium oxide others than alloys but responded to **IND** that they were not thinking of a specific substance.

Conclusion: The **Group** agreed to classify **Cadmium** with **N; R50-53** for environmental effects **(Symbol: N; R-phrases: 50/53 and S-phrases: 60/61**). As they had already agreed to classify Cadmium oxide, the same entry for both Cadmium and Cadmium oxide proposal would be sent to **DG ENV** for possible inclusion in a next TPC after agreement on classification for health effects has been reached.

Classification	Toxicity	Degradation	Bioaccumulation	Escape clause
N; R50-53	$10 < L(E)C_{50} \leq 100$ µg/L specific concentration limits to be added in Annex I	No rapid partitioning from the water column (default in absence of information)	No relevant information	No relevant information
Specific concentration limits				
$C_n \geq 2.5\%$: **N, R50-53** $0.25\% \leq C_n < 2.5\%$: **N, R51-53** $0.025\% \leq C_n < 0.25\%$: **R52-53**				