

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.

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 9 th 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 website¹)

| 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 | | | |

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

| | | | | | |
|-------|--|--------------------------------------|------------------|----------------|--|
| 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

Warning

Signal word:

Hazard statements:

H410: Very toxic to aquatic life with long lasting effects

P273: Avoid release to the environment

P391: Collect spillage

P501: Dispose of contents/container to ...

Precautionary statements:

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 EC₅₀ values between 10 – 100 µg/L and EC₁₀ 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 2016²) 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 EC₅₀ or EC₁₀ (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]

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.

Repr. 1A – H360FD

Lact. – H362

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).

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: 326°C (599 K) | <i>Franke (2005b)</i> | measured |
| Boiling point | The test item has no boiling point at atmospheric pressure up to the final temperature of 600 °C (873 K) | <i>Franke (2005b)</i> | measured |
| Relative density | Density at 23.8 °C = 11.45 g/cm ³ D4R: 11.45 | <i>Smeykal (2005a)</i> | measured |
| Vapour pressure | n/a Vapour pressure is only relevant for solids with a melting point below 300 °C (Lead melts at 326°C). | | |
| Surface tension | n/a Lead is a solid at ambient temperature (20 °C). | | |
| 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 | <i>Heintze (2005)</i> <i>ECHA (2016)</i> <i>ECHA (2016)</i> | 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 | <i>Smeykal (2005b)</i> | 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. | <i>Franke (2005a), Selck (2003)</i> | 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 °C). | | |

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 (PbCO₃) and anglesite (PbSO₄).

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 ($K_{\text{suspended-water}}$):

K_P of 295,121 L.kg⁻¹ (50th percentile). Range 50,119 - 1.698,244 L.kg⁻¹

K_{sediment} :

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

5.2.2 Volatilisation

Vapour pressure (Pa): 0 mbar at 20°C (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 (50 th percentile at environmentally relevant | See table 3.2.4-2 and 3.2.4-4 from VRAR | VRAR (2008) |

| | | | |
|--|-----------------|-------|--|
| | concentrations) | below | |
|--|-----------------|-------|--|

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).

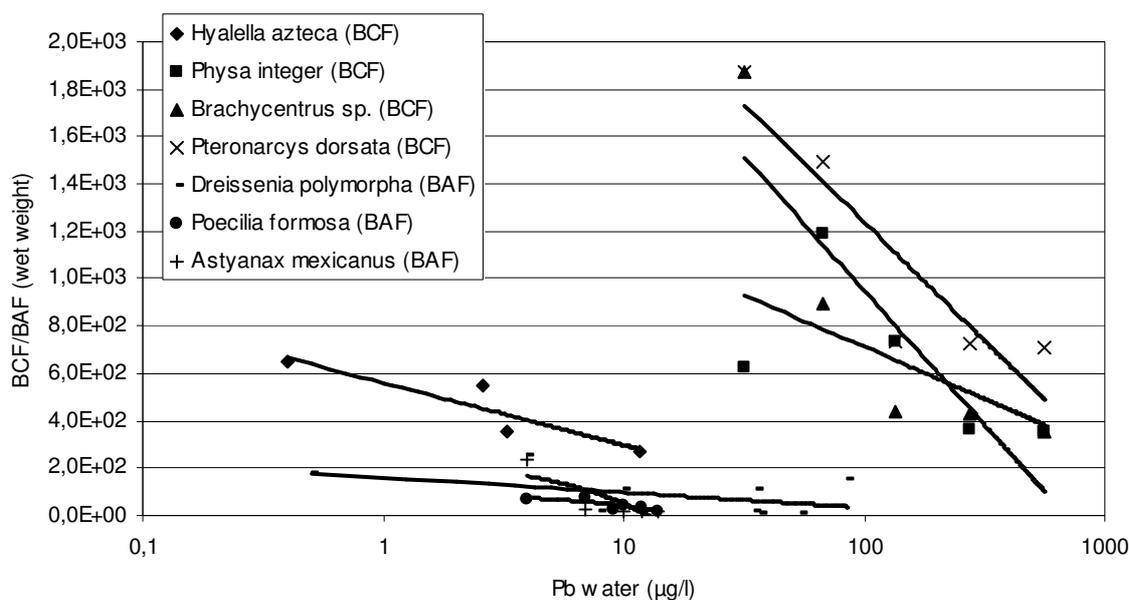


Figure 3.2.4-1-1 from the VRAR (2008): The whole-body bioconcentration/bioaccumulation factors (BCF/BAF) of invertebrates/fish as a function of the Pb concentration in water.

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 | | | | | | | |
| <i>Asellus meridianus</i> | isopod | 20,000 | 4,000 | 500 | 40,000 | 8,000 | Brown, 1977 |
| <i>Hyalella azteca</i> | amphipod | 1.3 | 0.26 | 0.4 | 3250 | 650 | Borgmann et al., 1993 |
| <i>Hyalella azteca</i> | amphipod | 5.8 | 1.16 | 3.3 | 1758 | 352 | Borgmann et al., 1993 |
| <i>Hyalella azteca</i> | amphipod | 7.1 | 1.42 | 2.6 | 2731 | 546 | Borgmann et al., 1993 |
| <i>Hyalella azteca</i> | amphipod | 15.8 | 3.16 | 11.6 | 1362 | 272 | Borgmann et al., 1993 |
| <i>Hyalella azteca</i> | amphipod | 1.1 | 0.21 | 0.2 | 5,000 | 1,000 | Maclean et al., 1996 |
| <i>Hyalella azteca</i> | amphipod | 6.8 | 1.35 | 2.1 | 3,250 | 650 | Maclean et al., 1996 |
| <i>Hyalella azteca</i> | amphipod | 25.9 | 5.18 | 20.7 | 1,250 | 250 | Maclean et al., 1996 |
| <i>Hyalella azteca</i> | amphipod | 113.9 | 22.77 | 207.0 | 550 | 110 | Maclean et al., 1996 |
| <i>Daphnia magna</i> | cladoceran | 4.9 | 0.98 | 0.9 | 5,765 | 1,153 | Cowgill, 1976 |
| <i>Daphnia pulex</i> | cladoceran | 3.6 | 0.72 | 0.9 | 4,235 | 847 | Cowgill, 1976 |
| molluscs | | | | | | | |
| <i>Dreissenia polymorpha</i> | mussel | 0.9 | 0.09 | 0.5 | 1,800 | 180 | Kraak et al., 1994 |
| <i>Dreissenia polymorpha</i> | mussel | 10 | 1 | 4 | 2,500 | 250 | Kraak et al., 1994 |
| <i>Dreissenia polymorpha</i> | mussel | 11 | 1.1 | 10 | 1,100 | 110 | Kraak et al., 1994 |

| Species | organism | Tissue (mg/kg dw) | Tissue (mg/kg ww) | Water (µg/L) | BCF (dw) | BCF (ww) | Reference (VRAR, 2008) |
|------------------------------|-------------------|-------------------|-------------------|--------------|----------|----------|------------------------|
| <i>Dreissenia polymorpha</i> | mussel | 40 | 4 | 36 | 1,111 | 111 | Kraak et al., 1994 |
| <i>Dreissenia polymorpha</i> | mussel | 130 | 13 | 85 | 1,529 | 153 | Kraak et al., 1994 |
| <i>Lymnaea palustris</i> | snail | 8.5 | 2.5 | 1 | 8,500 | 2,500 | Borgmann et al., 1978 |
| <i>Physa integer</i> | snail | 100 | 20 | 32 | 3,125 | 625 | Spehar et al., 1978 |
| <i>Physa integer</i> | snail | 400 | 80 | 67 | 5,970 | 1,194 | Spehar et al., 1978 |
| <i>Physa integer</i> | snail | 500 | 100 | 136 | 3,676 | 735 | Spehar et al., 1978 |
| <i>Physa integer</i> | snail | 500 | 100 | 277 | 1,805 | 361 | Spehar et al., 1978 |
| <i>Physa integer</i> | snail | 1,000 | 200 | 565 | 1,770 | 354 | Spehar et al., 1978 |
| insects | | | | | | | |
| <i>Brachycentrus sp.</i> | caddisfly | 300 | 60 | 32 | 9,375 | 1,875 | Spehar et al., 1978 |
| <i>Brachycentrus sp.</i> | caddisfly | 300 | 60 | 67 | 4,478 | 896 | Spehar et al., 1978 |
| <i>Brachycentrus sp.</i> | caddisfly | 300 | 60 | 136 | 2,206 | 441 | Spehar et al., 1978 |
| <i>Brachycentrus sp.</i> | caddisfly | 600 | 120 | 277 | 2,166 | 433 | Spehar et al., 1978 |
| <i>Brachycentrus sp.</i> | caddisfly | 1,000 | 200 | 565 | 1,770 | 354 | Spehar et al., 1978 |
| <i>Pteronarcys dorsata</i> | stonefly | 300 | 60 | 32 | 9,375 | 1,875 | Spehar et al., 1978 |
| <i>Pteronarcys dorsata</i> | stonefly | 500 | 100 | 67 | 7,463 | 1,493 | Spehar et al., 1978 |
| <i>Pteronarcys dorsata</i> | stonefly | 500 | 100 | 136 | 3,676 | 735 | Spehar et al., 1978 |
| <i>Pteronarcys dorsata</i> | stonefly | 1,000 | 200 | 277 | 3,610 | 722 | Spehar et al., 1978 |
| <i>Pteronarcys dorsata</i> | stonefly | 2,000 | 400 | 565 | 3,540 | 708 | Spehar et al., 1978 |
| fish | | | | | | | |
| <i>Poecilia reticulata</i> | fish | 4.1 | 0.82 | 3.1 | 265 | 1,322 | Vighi, 1981 |
| <i>Poecilia reticulata</i> | fish | 12 | 2.4 | 27.5 | 87 | 436 | Vighi, 1981 |
| <i>Salvelinus fontinalis</i> | brook trout | 8 | 1.6 | 34 | 235 | 47 | Holcombe et al., 1976 |
| <i>Salvelinus fontinalis</i> | brook trout | 12.7 | 2.54 | 58 | 219 | 44 | Holcombe et al., 1976 |
| <i>Salvelinus fontinalis</i> | brook trout | 0.36 | 0.072 | 0.9 | 400 | 80 | Holcombe et al., 1976 |
| <i>Lepomis macrochirus</i> | Blue gill sunfish | 1.4 | 0.28 | 14.1 | 100 | 20 | Wiener and Giesy, 1979 |
| <i>Lepomis macrochirus</i> | Blue gill sunfish | 1.0 | 0.20 | 14.1 | 70 | 14 | Wiener and Giesy, 1979 |
| <i>Micropterus salmoides</i> | Black bass | 0.65 | 0.13 | 14.1 | 45 | 9 | Wiener and Giesy, 1979 |
| <i>Esox niger</i> | Chain Pickerel | 1.25 | 0.08 | 14.1 | 25 | 5 | Wiener and Giesy, 1979 |
| <i>Anguilla rostrata</i> | American eel | 0.5 | 0.10 | 14.1 | 35 | 7 | Wiener and Giesy, 1979 |
| <i>Erimyzon sucetta</i> | lake chubsuckers | 0.5 | 0.10 | 14.1 | 35 | 7 | Wiener and Giesy, 1979 |
| <i>Perca flavescens</i> | Yellow perch | 1.1 | 0.22 | 0.5 | 2,025 | 405 | Draves and Fox, 1998 |
| <i>Perca flavescens</i> | 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 | | | | | | | | |
| <i>Asellus</i> | isopod | 3.44 | 0.688 | <0.2 | >17,200 | >3,440 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Gammarus</i> | amphipod | 1.65 | 0.33 | <0.2 | >8,250 | >1,650 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Cyclops</i> | | 3.78 | 0.756 | <0.2 | >18,900 | >3,780 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Daphnia magna</i> | cladoceran | 23 | 4.6 | 3.1 | 7,400 | 1,500 | Filtered (0.45 µm) | Vighi, 1981 |
| <i>Daphnia magna</i> | cladoceran | 68 | 13.6 | 27.5 | 2,500 | 495 | Filtered (0.45 µm) | Vighi, 1981 |
| <i>Daphnia magna</i> | cladoceran | 187 | 37.4 | 13 | 14,380 | 2,877 | Filtered (0.45 µm) | Lu et al., 1975 |
| <i>Daphnia magna</i> | cladoceran | 154 | 30.8 | 2 | 77,000 | 15,400 | Filtered (0.45 µm) | Lu et al., 1975 |
| <i>Daphnia magna</i> | cladoceran | 85 | 17 | 2 | 42,500 | 8,500 | Filtered (0.45 µm) | Lu et al., 1975 |
| molluscs | | | | | | | | |
| <i>Amblema plicata</i> | clam | 13.5 | 1.35 | 2 | 6,750 | 675 | Filtered (filter size not reported) | Mathis and Cummings, 1973 |
| <i>Dreissena</i> | mussel | 0.12 | 0.024 | <0.2 | >600 | >120 | | Timmermans et al., 1989 |
| <i>Dreissena polymorpha</i> | mussel | 5.1 | 0.51 | 35 | 146 | 15 | Unfiltered | Chevreuil et al., |

| 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) |
|---------------------------------|------------|-------------------|-------------------|--------------|----------|---------|-------------------------------------|---------------------------------|
| | | | | | | | | 1996 |
| <i>Dreissena polymorpha</i> | mussel | 3.7 | 0.37 | 54 | 69 | 7 | Unfiltered | Chevreuil et al., 1996 |
| <i>Dreissena polymorpha</i> | mussel | 3.2 | 0.32 | 37 | 86 | 9 | Unfiltered | Chevreuil et al., 1996 |
| <i>Dreissena polymorpha</i> | mussel | 1.9 | 0.19 | 12 | 158 | 16 | Unfiltered | Chevreuil et al., 1996 |
| <i>Dreissena polymorpha</i> | mussel | 1.4 | 0.14 | 8 | 175 | 18 | Unfiltered | Chevreuil et al., 1996 |
| <i>Fusconaia flava</i> | clam | 18.5 | 1.85 | 2 | 9,250 | 925 | Filtered (filter size not reported) | Mathis and Cummings, 1973 |
| <i>Lymnaea</i> | snail | 0.79 | 0.079 | <0.2 | >3,950 | >395 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Potamopyrgus</i> | snail | 7.7 | 0.77 | <0.2 | >38,500 | >3,850 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Quadrula quadrula</i> | clam | 11 | 1.1 | 2 | 5,500 | 550 | Filtered (filter size not reported) | Mathis and Cummings, 1973 |
| <i>Physa</i> | snail | 334 | 33.4 | 13 | 25,692 | 2,570 | Filtered (0.45 µm) | Lu et al., 1975 |
| <i>Physa</i> | snail | 88 | 8.8 | 2 | 44,000 | 4,400 | Filtered (0.45 µm) | Lu et al., 1975 |
| <i>Physa</i> | snail | 56 | 5.6 | 2 | 28,000 | 2,800 | Filtered (0.45 µm) | Lu et al., 1975 |
| insects | | | | | | | | |
| <i>Chironomus</i> | midge | 1.83 | 0.366 | <0.2 | >9,150 | >1,830 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Glyptotendipes</i> | midge | 0.44 | 0.088 | <0.2 | >2,200 | >440 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Holocentropus</i> | caddisfly | 1.32 | 0.264 | <0.2 | >6,600 | >1,320 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Ischnura</i> | damselfly | 1.75 | 0.35 | <0.2 | >8,750 | >1,750 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Limnephilus</i> | caddisfly | 4.36 | 0.872 | <0.2 | >21,800 | >4,360 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Stictochironomus</i> | chironomid | 5.31 | 1.062 | <0.2 | >26,550 | >5,310 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| <i>Micronecta</i> | corixid | 1.87 | 0.374 | <0.2 | >9,350 | >1,870 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| annelids | | | | | | | | |
| <i>Erpobdella</i> | leech | 1.62 | 0.324 | <0.2 | >8,100 | >1,620 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| acarides | | | | | | | | |
| <i>Hygrobatas</i> | mite | 1.73 | 0.346 | <0.2 | >8,650 | >1,730 | Filtered (0.45 µm) | Timmermans et al., 1989 |
| fish | | | | | | | | |
| <i>Astyanax mexicanus</i> | fish | 1 | 0.2 | 14 | 71 | 14 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Astyanax mexicanus</i> | fish | 0.9 | 0.18 | 12 | 75 | 15 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Astyanax mexicanus</i> | fish | 0.86 | 0.172 | 10 | 86 | 17 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Astyanax mexicanus</i> | fish | 0.8 | 0.16 | 7 | 114 | 23 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Astyanax mexicanus</i> | fish | 4.74 | 0.948 | 4 | 1,185 | 237 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Cichlasoma cyanoguttatum</i> | fish | 0.5 | 0.1 | 9 | 56 | 11 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Cichlasoma cyanoguttatum</i> | fish | 1.36 | 0.272 | 14 | 97 | 19 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Cichlasoma cyanoguttatum</i> | fish | 1.3 | 0.26 | 10 | 130 | 26 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Micropterus salmoides</i> | fish | 0.46 | 0.092 | 9 | 51 | 10 | 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) |
|----------------------------|----------|-------------------|-------------------|--------------|----------|---------|---------------------------------|---------------------------------|
| <i>Notropis lutrensis</i> | fish | 0.8 | 0.16 | 14 | 57 | 11 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Poecilia reticulata</i> | Fish | 16 | 3.2 | 3.1 | 5,160 | 1,032 | Filtered (0.45 µm) | Vighi, 1981 |
| <i>Poecilia reticulata</i> | fish | 36 | 7.2 | 27.5 | 1,300 | 260 | Filtered (0.45 µm) | Vighi, 1981 |
| <i>Poecilia formosa</i> | fish | 0.9 | 0.18 | 14 | 64 | 13 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Poecilia formosa</i> | fish | 1.3 | 0.26 | 9 | 144 | 29 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Poecilia formosa</i> | fish | 2.26 | 0.452 | 12 | 188 | 38 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Poecilia formosa</i> | fish | 2.16 | 0.432 | 10 | 216 | 43 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Poecilia formosa</i> | fish | 1.3 | 0.26 | 4 | 325 | 65 | Unfiltered | Villarreal-Trevino et al., 1986 |
| <i>Poecilia formosa</i> | 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 CaCO₃. DOC = dissolved organic carbon, DO = dissolved oxygen:

| Reference | Water chemistry etc. | Remarks | Species |
|--|----------------------|--|--|
| Borgmann <i>et al.</i> 1978 (publication) | pH 7.8, H 139, 21°C | 120 days. Just hatched, Flow through, Test substance: Pb(NO ₃) ₂ | <i>Lymnaea palustris</i> |
| Borgmann <i>et al.</i> 1993 (publication) | pH 7.9-8.6, 25°C | Semi static | <i>Hyalella azteca</i> |
| Brown 1977 (publication) | 20°C | Semi static Test substance: Pb(NO ₃) ₂ | <i>Asellus meredianus</i> |
| Chevreuil <i>et al.</i> 1996 (publication) | | Field study | <i>Dreissena polymorpha</i> |
| Cowgill 1976 (publication) | | 90 days Semi static | <i>Daphnia magna</i> <i>Daphnia pulex</i> |

| | | | |
|---|---|---|--|
| Draves & Fox 1998 (publication) | | Field study | <i>Perca flavescens</i> |
| Holcombe <i>et al.</i> 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 | <i>Salvelinus fontinalis</i> |
| Kraak <i>et al.</i> 1994 (publication) | | Field study | <i>Dreissena polymorpha</i> |
| Lu <i>et al.</i> 1975 (publication) | | 33 days microcosmos | <i>Physa sp.</i> <i>Daphnia magna</i> |
| MacLean <i>et al.</i> 1996 (publication) | pH 7.8-8.6, H 130, DOC 2.3 mg/L, 25°C | 8 days Newly hatched Test substance PbCl ₂ | <i>Hyaella azteca</i> |
| Mathis & Cummings 1973 (publication) | | Field study | <i>Amblema plicata</i> <i>Quadrula quadrula</i> <i>Fusconaia flava</i> |
| Spehar <i>et al.</i> 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 | <i>Pteronarcys dorsata</i> <i>Brachycentrus sp.</i> <i>Physa integer</i> |
| Timmermans <i>et al.</i> 1989 (publication) | | Field study | <i>Glyptotendipes sp.</i> <i>Asellus sp.</i> <i>Hygrobates sp.</i> <i>Micronecta sp.</i> <i>Holocentropus sp.</i> <i>Chironomus sp.</i> <i>Potamopyrgus sp.</i> <i>Stictochironomus sp.</i> <i>Limnephilus sp.</i> |

| | | | |
|--|--|--|--|
| | | | <i>Erpopdella sp.</i> <i>Dreissenis sp.</i> <i>Cyclops sp.</i> <i>Lymnaea sp.</i> <i>Ischnura sp.</i> <i>Gammarus sp.</i> |
| Vighi 1981 (publication) | | 4 weeks, flow-through. Test substance: Pb(NO ₃) ₂ | <i>Poecilia reticulata</i> <i>Daphnia magna</i> |
| Villareal-Trevino <i>et al.</i> 1986 (publication) | | Field study | <i>Poecilia formosa</i> <i>Cichlasoma cyanoguttatum</i> <i>Astyanax mexicanus</i> <i>Notropis lutrensis</i> <i>Micropterus salmoides</i> |
| Wiener & Giesy 1979 (publication) | | Field study | <i>Micropterus almoides</i> <i>Lepomis macrochirus</i> <i>Erimyzon sucetta</i> <i>Anquilla rostrata</i> <i>Esox niger</i> |

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 | 10 th % | 50 th % | 90 th % | 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 from 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 it 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 CaCO₃. DOC = dissolved organic carbon, DO = dissolved oxygen

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

| Acute toxicity data | | | |
|---|------------|--|--|
| Algae | | | |
| <i>Phaeodactylum tricornutum</i> 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 |
| <i>Chlamydomonas reinhardtii</i> 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) |
| <i>Chlorella kessleri</i> 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) |
| <i>Pseudokirchneriella subcapitata</i> 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 | | | |
| <i>Ceriodaphnia dubia</i> 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 2008 ECHA, 2016 Diamond <i>et al.</i> 1997 (publication) |
| <i>Daphnia magna</i> 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 | | | |
| <i>Benacus</i> 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) |
| <i>Chironomus tentans</i> 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 | | | |
| <i>Pimephales promelas</i> 96 h LC ₅₀ | 40.8µg/L | Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: PbN ₂ O ₆ pH 5.7, H15.9, 26°C | ECHA, 2016 Unpublished study report (2010) |
| <i>Oncorhynchus mykiss</i> 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) ₂ Pb(NO ₃) ₂ . In REACH reg. 107 µg/L, a value estimated from a total value of 1470 µg/L in Davies <i>et al.</i> 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 <i>et al.</i> 1976 (publication) |
| <i>Micropterus dolomieu</i> 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 ₂ O ₆ pH8.25, H 151 mg/L, DO 9.2 mg/L, 16.2°C | ECHA, 2016; VRAR, 2008 Coughlan & Gloss 1986 (publication) |
| <i>Clarias lazera</i> 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) |

| | | | |
|---|-----------|--|--|
| <i>Oreochromis niloticus</i> 96 h LC ₅₀ | 2150 µg/L | 1 test See remarks under <i>C. lazera</i> Test-substance: PbN ₂ O 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 | | | |
| <i>Champia parvula</i> 48 h NOEC/EC ₁₀ | 11.9 µg/L | 1 test Test-substance: PbN ₂ O ₆ pH 7.8-7.9, salinity 30‰, 23°C | ECHA, 2016, Unpublished study report (2012) |
| <i>Pseudokirchneriella subcapitata</i> 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) |
| <i>Chlamydomonas reinhardtii</i> 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) |
| <i>Dunaliella tertiolecta</i> 96 h NOEC/EC ₁₀ | 1232 µg/L | 1 test Test-substance: PbN ₂ O 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 |
| <i>Chlorella kessleri</i> 72 h EC ₁₀ | 99 µg/L | 1 test Test-substance: Not indicated | VRAR, 2008 De Schampelaere & Janssen 2007 ECHA, 2016 Unpublished study report (2007) |
| <i>Skeletonema costatum</i> 96 h NOEC/EC ₁₀ | 52.9 µg/L | 1 test Test-substance: PbN ₂ O ₆ pH 8.1, DO 1.32 mg/L, 19-20°C, salinity 38 ‰ | ECHA, 2016 Unpublished study report (2010) |

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|---|------------------|---|--|
| | | | See also: ILA Environmental Research Programme 2006-2016 |
| <i>Phaeodactylum tricornutum</i> 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 | | | |
| <i>Lemna minor</i> 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 | | | |
| <i>Brachionus calyciflorus</i> 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 |
| <i>Philodina rapida</i> 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 ₂ O ₆ pH 7.2, H 5 mg/L, 25°C | ECHA, 2016 Esbaugh <i>et al.</i> 2012 (publication) |
| Polychaeta | | | |
| <i>Neanthes arenaceodentata</i> 126 d EC ₁₀ | 95.9 µg/L | 1 test Test-substance: PbN ₂ O ₆ pH 7.6-8.3, 19°C, salinity 31.4 ‰ | ECHA, 2016 Unpublished study report (2010) |

| Insects | | | |
|---|-----------|---|---|
| <i>Baetis tricaudatus</i> 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 <i>et al.</i> (2008) (publication) |
| <i>Chironomus riparius</i> 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 |
| <i>Chironomus tentans</i> 34 d NOEC | 109 µg/L | 1 test Test-substance: PbN ₂ O ₆ pH 7.9, H46, DO 7.9 mg/L, 25 °C | ECHA, 2016 Grosell <i>et al.</i> 2006b (publication) See also: ILA Environmental Research Programme 2006-2016 |
| Crustacea | | | |
| <i>Alona rectangular</i> 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 <i>et al.</i> 2006 (publication) |
| <i>Hyaella azteca</i> 42 d NOEC | 6.3 µg/L | 1 test Test-substance: Not indicated | ECHA, 2016; VRAR (2008) Besser <i>et al.</i> 2005 (publication) |
| <i>Ceriodaphnia dubia</i> 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 ₂ O ₆ pH 7.5, H 82.4, DO 88.3%, 25.3° | ECHA, 2016 Cooper <i>et al.</i> 2009 (publication) |
| <i>Daphnia magna</i> 21 d NOEC | 9 µg/L | Lowest value. Geometric mean not used as tests were performed under very varying conditions. Test-substance: PbN ₂ O ₆ pH 7.2-7.6, H 52, DO 6.6 mg/L, 25.3 °C | VRAR, 2008 Chapman <i>et al.</i> 1980 ECHA, 2016 Unpublished study report |

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|---|------------|--|--|
| | | | (1980) |
| <i>Diaphanosoma birgei</i> 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 <i>et al.</i> 2006 (publication) |
| <i>Americamysis bahia</i> 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 |
| <i>Tisbe battagliai</i> 18 d NOEC/EC ₁₀ | 397.3 µg/L | 1 test Test-substance: PbN ₂ O 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 | | | |
| <i>Lymnaea palustris</i> 120 d NOEC | 12 µg/L | 1 test Test-substance: PbN ₂ O ₆ pH 7.8, H 139, 21°C | ECHA, 2016; VRAR, 2008 Borgmann <i>et al.</i> 1978 (publication) |
| <i>Lymnaea stagnalis</i> 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 ₂ O 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 |
| <i>Crassostrea gigas</i> 48 h embryos EC ₁₀ | 930.8 µg/L | Lowest value. Geometric mean not used as tests were performed under | ECHA, 2016 Unpublished |

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| | | very varying conditions. Test-substance: PbN ₂ O ₆ pH 8.2, DO 1.32 mg/L, salinity 30.7 ‰, 20°C | study report (2010) See also: ILA Environmental Research Programme 2006-2016 |
| <i>Mytilus galloprovincialis</i> 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 ₂ O ₆ pH 7.8, salinity 33‰, 20 °C | ECHA, 2016 Unpublished study report (2010) |
| <i>Mytilus trossolus</i> 48 h EC ₁₀ , embryos | 9.2 | 1 test Test-substance: PbN ₂ O ₆ pH 7.8, salinity 33 ‰, 20°C | ECHA, 2016 Unpublished study report (2010) |
| Echinoderms | | | |
| <i>Dendraster excentricus</i> 72 h EC ₁₀ , embryos | 249,8 | 1 test Test-substance: PbN ₂ O 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 |
| <i>Paracentrotus lividus</i> 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 |
| <i>Strongylocentrotus purpuratus</i> 72 h NOEC/EC ₁₀ , embryos | 111.8 µg/L | 1 test Test-substance: PbN ₂ O 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 | | | |
|--|-----------|---|---|
| <i>Oncorhynchus mykiss</i> 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 <i>et al.</i> 1976 (publication) |
| <i>Salmo salar</i> 90 d NOEC | 48 µg/L | 1 test Test-substance: PbN ₂ O ₆ pH 6.3, H11, Egg stage 4°C, Until feeding 6°C Rest of time 8°C | ECHA, 2016; VRAR, 2008 Grande & Andersen, 1983 (publication) |
| <i>Ictalurus punctatus</i> 60 d NOEC | 70.5 µg/L | 1 test Value in Sauter <i>et al.</i> 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 <i>et al.</i> 1976 ECHA, 2016; Unpublished study report (1976) |
| <i>Salvelinus fontinalis</i> 1095 d NOEC | 52.8 µg/L | 1 test Value in Holcombe <i>et al.</i> , 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 <i>et al.</i> , 1976 (publication) |
| <i>Salvelinus namaycush</i> 60 d NOEC | 45.8 µg/L | 1 test Value in Sauter <i>et al.</i> 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 <i>et al.</i> 1976 ECHA, 2016; Unpublished study report (1976) |
| <i>Lepomis macrochirus</i> 60 d NOEC | 63.7 µg/L | 1 test Value in Sauter <i>et al.</i> 70 µg/L. Corrected for solubility in VRAR. Test-substance: PbN ₂ O ₆ pH 6.7-7.2, H 40.7, DO 6.9 mg/L, 25° | VRAR, 2008 Sauter <i>et al.</i> 1976 ECHA, 2016; Unpublished study report (1976) |

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|---|--------------------|--|--|
| <i>Cyprinus carpio</i> 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 ₂ O ₆ pH 5.6, H 35, 23° | ECHA, 2016; VRAR, 2008 Stouthart <i>et al.</i> 1994 (publication) |
| <i>Pimephales promelas</i> 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 ₂ O ₆ pH 7.4, H 19, 23°C | ECHA, 2016 Unpublished study report (2006) Grosell <i>et al.</i> 2006a (publication) |
| <i>Cyprinodon variegatus</i> 28 d EC ₁₀ | 229.6 µg/L | 1 test Test-substance: PbN ₂ O 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 |
| <i>Acipenser sinensis</i> 112 d NOEC | 129 µg/L | 1 test Test-substance: PbN ₂ O ₆ pH 7.55, H 64.2, DO > 6 mg/L | ECHA, 2016 Hou <i>et al.</i> 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 LC₅₀ is 40.8 µg/L for *Pimephales promelas*. There are many LC₅₀ 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 LC₅₀ for each species has been employed.

5.4.1.2 Long-term toxicity to fish

The lowest long-term fish EC₁₀ 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 Schampelaere *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 HC₅ will in any case be between 1-10 µg/L.

Disregarding the value of 0.9 µg/L the lowest long-term fish EC₁₀ 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 LC₅₀ 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 EC₅₀ is 26 µg/L for the crustacean *Ceriodaphnia dubia* (Diamond *et al.* 1997). For this and other species there are multiple EC₅₀ 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 EC₅₀ 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 EC₁₀ 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 EC₅₀ above.

5.4.3 Algae and aquatic plants

The lowest acute EC₅₀ value for algae is a 72 h EC₅₀ of 20,5 µg/L for *Pseudokirchneriella subcapitata*.

The lowest long-term result for algae is a 72 h EC₁₀ = 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 EC₁₀s of the MES and MOPS tests (Mann-

Whitney U = 21, P > 0.2, two-tailed) whereas there is a significant correlation between pH and EC₁₀ 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. tricorutum*, by the Danish EPA. An exception is the study with *Phaeodactylum tricorutum* with the EC₅₀ 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 EC₅₀ value (1690 µg/L) is regarded as unreliable.

The EC₁₀ value for *Phaeodactylum tricorutum* (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 EC₁₀ dry weight (19.3 µg/L) is the most sensitive.

Antunes and Kreager (2014) reported an EC₁₀ 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 PbCl₂ 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 EC₅₀ = 26 µg/L (crustacea; study with *C. dubia*, Diamond *et al.*, 1997) and NOEC/EC₁₀ = 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 EC₅₀ is 20.5 µg/l (algae: study with *P. subcapitata*, ECHA (2016)), and the lowest EC₁₀ 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/LC₅₀ and EC₁₀/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 EC₁₀ 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 EC₁₀ or NOEC is $r_s = 0.237$, $P > 0.1$ (two-tailed), while for the relationship between DOC and EC₁₀ 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 (EC₅₀ = 20.5 µg/L and the chronic EC₁₀ = 1.7 µg/L or HC₅ = 3 µg/L) should normally be compared to the metal ion concentration achieved in full 7 and 28 days Transformation/Dissolution tests, respectively³. 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

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

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 calculate the HC₅. HC₅ = 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 HC₅ = 3 µg/L is close to the lowest species EC₁₀ 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 (EC₁₀ 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 HC₅ of 3 µg/L and 8.4 times the lowest EC₁₀ 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.

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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

| | | |
|-------------------|------------------------|--------------------------|
| <i>Lead metal</i> | <i>EC No 231-100-4</i> | <u><i>ECBI/12/02</i></u> |
|-------------------|------------------------|--------------------------|

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 in 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 thought 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. Then 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 therefore 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 *Ceriodaphnia* 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 | No rapid partitioning from | No relevant | No relevant |

| | | | | |
|--|--------------------------------|---|-------------|-------------|
| | L(E)C ₅₀ < 100 mg/L | the water column (default in absence of information) | information | 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.

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| 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 Zn²⁺/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 Zn²⁺/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 soon 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 | $10 < L(E)C_{50} \leq 100 \mu\text{g/L}$ 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 | | | | |