Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for the substances: cadmium and cadmium oxide

(Text with EEA relevance)

(2008/C 149/03)

Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ([1]) involves the data reporting, priority setting, risk evaluation and, where necessary, development of strategies for limiting the risks of existing substances.

In the framework of Regulation (EEC) No 793/93 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulation (EC) No 143/97 ([2]) concerning the third list of priority substances as foreseen under Regulation (EEC) No 793/93:

— cadmium,

— cadmium oxide.

The rapporteur Member State designated pursuant to those Regulations have completed the risk evaluation activities with regard to man and the environment for those substances in accordance with Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances ([3]) and have suggested a strategy for limiting the risks in accordance with Regulation (EEC) No 793/93.

The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) has been consulted and has issued opinions with respect to the risk evaluations carried out by the rapporteurs. These opinions can be found on the website of the Scientific Committees.

Article 11(2) of Regulation (EEC) No 793/93 stipulates that the results of the risk evaluation and the recommended strategy for limiting the risks shall be adopted at Community level and published by the Commission. This Communication, together with the corresponding Commission Recommendation 2008/446/EC ([4]), provides the results of risk evaluations ([5]) and strategies for limiting the risks for the above mentioned substances.

The results of the risk evaluation and strategies for limiting the risks provided for in this communication are in accordance with the opinion of the Committee set up pursuant to Article 15(1) of Regulation (EEC) No 793/93.

([1]) OJ L 84, 5.4.1993, p. 1.
([2]) OJ L 25, 28.1.1997, p. 13.
([3]) OJ L 161, 29.6.1994, p. 3.
([4]) OJ L 156, 14.6.2008.
([5]) The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the Internet site of the European Chemicals Bureau:
http://ecb.jrc.it/existing-substances/

ANNEX

PART 1

CAS No: 7440-43-9	Einecs No: 231-152-8

Einecs name:	Cadmium
IUPAC name:	Cadmium
Rapporteur:	Belgium
Classification ([1]):	Carc. Cat. 2; R45 Muta. Cat. 3; R68 Repr. Cat. 3; R62-63 T; R48/23/25 T+; R26 N; R50-53

The risk assessment is based on current practices related to the life-cycle of the substance produced in or imported into the European Community as described in the risk assessment forwarded to the Commission by the Member State Rapporteur ([2]).

Based on the available information, the risk assessment has determined that in the European Community, the substance is mainly used in the manufacture of nickel-cadmium batteries but also as starting material for a wide variety of other cadmium compounds (mainly pigments and stabilisers). It is also used in coatings and in the treatment of surfaces (plating) as well as in components of alloys. Cadmium may also be present as an impurity and exposure may occur during several activities involving the use of (non-) ferrous materials (a.o. foundry and (re-) melting processes). In occupational settings where cadmium is produced or used, workers may be exposed to cadmium metal dust and/or cadmium oxide fumes formed when the metal is heated, mainly by inhalation. Dermal exposure may occur when cadmium metal powder/dust is handled or during maintenance operations.

For the general population non-occupationally involved in the cadmium industry, uptake of cadmium (generic, not specifically cadmium metal) occurs mainly via the ingestion of food contaminated by cadmium. Tobacco smoking is an important additional source of cadmium exposure by inhalation.

The environmental exposure to cadmium is calculated based on all known current anthropogenic emissions of cadmium, i.e. cadmium that is emitted by the cadmium/cadmiumoxide producers and processors and cadmium in diffuse sources such as fertilisers, steel production, oil and coal combustion, traffic, waste incineration, landfills, etc. Local exposure assessment is based on emissions from cadmium/cadmium oxide producers and processors and includes the regional predicted environmental concentration. Regional and continental exposure assessment is based on all anthropogenic cadmium emissions, including diffuse emissions, and reflects the concentration reached after 60 years of diffuse emissions. Actual cadmium concentrations in the environment (ambient concentrations) also include the natural background of cadmium (from geological origin or from natural processes) and cadmium that was added to the environment in the past by man (historical pollution).

RISK ASSESSMENT

A. **Human health**

This substance has not been sufficiently tested for possible neurotoxic effects, especially on the developing brain. Further epidemiological and experimental information would be required to identify more precisely the nature of the effects, the characterisation of the exposure and the mechanism of action related to neurotoxicity. However, as the substance has been identified as a non-threshold carcinogen, it normally requires control measures that would not be influenced by further information on the endpoint developmental toxicity.

([1]) The classification of the substance is established by Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 152, 30.4.2004, p. 1, amended by OJ L 216, 16.6.2004, p. 3).

([2]) The comprehensive Risk Assessment Report can be found on the Internet site of the European Chemicals Bureau: http://ecb.jrc.it/existing-substances/

The conclusion of the assessment of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because:

— concerns for acute toxicity as a consequence of inhalation exposure that may arise from cadmium production, alloys and brazing, soldering and welding scenarios,

— concerns for effects on fertility and reproductive organs as a consequence of inhalation exposure arising from cadmium metal production, batteries manufacture and recycling, pigments production, alloys and brazing scenarios,

— concerns for respiratory irritation, for kidney and bone repeated dose toxicity, for genotoxicity, and for carcinogenicity as a consequence of inhalation exposure arising from all industrial uses, as the substance is considered as a non-threshold carcinogen.

The conclusion of the assessment of the risks to

CONSUMERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because:

— concerns for acute respiratory effects as a consequence of inhalation exposure that may arise when using cadmium-containing brazing sticks (as a Do-It-Yourself application),

— concerns for genotoxicity and carcinogenicity irrespective of the route of exposure, as the substance is considered as a non-threshold carcinogen, arising from wearing (imported) jewellery and/or from the use of cadmium containing brazing sticks (as a Do-It-Yourself application).

The conclusion of the assessment of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because:

— concerns for respiratory toxicity as a consequence of exposure (mainly by inhalation) that may arise near some point sources,

— concerns for kidney and bone repeated dose toxicity as a consequence of environmental exposure arising in adults who smoke or/and with depleted body iron stores, or/and living near point sources,

— concerns for genotoxicity and carcinogenicity as a consequence of environmental exposure arising from all exposure scenarios, since the substance is considered as a non-threshold carcinogen.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physico-chemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because the given the level of control in manufacture and use, the risks from physicochemical properties are small.

B. **Environment**

The conclusion of the assessment of the risks to the

AQUATIC ECOSYSTEM INCLUDING SEDIMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because:

— concern for the local aquatic ecosystem at five cadmium production (cadmium metal: one site) or cadmium processing (two pigments producing sites, plating and alloy) sites/scenarios,

— concern for the local aquatic ecosystem at one recycling site,

— concern for a landfill site leaching directly to surface water with a cadmium concentration of 50 μg/l,

— concerns for waters in the UK and the Walloon region of Belgium based on the regional averages of the 90th percentiles of measured cadmium concentrations in rivers and lakes,

— concern for sediment dwelling organism for cadmium plating and cadmium alloys sector,

— concern for sediment dwelling organism at four sites (one cadmium metal production, two cadmium pigment production and one cadmium recycler) and four disposal scenarios (1 MSW incineration, 3 MSW landfill) if the lowest regional 10th percentile of the EU regions (German data from three river systems) from the acid volatile sulphides database is used for the bioavailability correction.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

is that there is a need for specific measures to limit the risks. This conclusion is reached because:

— concern for cadmium plating and alloy production sites,

— concern for one region (UK) based on the 90th percentiles of measured cadmium concentrations of European soils.

The conclusion of the assessment of the risks to the

ATMOSPHERE

No conclusion is reached because:

no risk characterisation was done for the atmosphere.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for specific measures to limit the risks. This conclusion is reached because:

— concern for on-site and off-site STP for plating and alloy industry,

— concerns for the micro-organisms of the STP for one Nickel-cadmium battery recycling plant discharging its effluent to an off-site STP.

The conclusion of the assessment of the risks to the

SECONDARY POISONING

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

— concern for one region (UK) based on the 90th percentile of measured cadmium concentrations of European soils.

STRATEGY FOR LIMITING RISKS

For WORKERS

The legislation for workers' protection currently in force at Community level, particularly Council Directive 2004/37/EC [1] (Carcinogens — Mutagens Directive), is generally considered to provide an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

— to set at community level occupational exposure limit values and a biological limit value for cadmium according to Directive 98/24/EC [2] or Directive 2004/37/EC as appropriate.

For CONSUMERS

— to consider at Community level marketing and use restrictions in Council Directive 76/769/EEC [3] (Marketing and Use Restrictions Directive) for brazing sticks and jewellery containing cadmium intended to come into contact with the skin.

[1] OJ L 158, 30.4.2004.
[2] OJ L 131, 5.5.1998, p. 11.
[3] OJ L 262, 27.9.1976, p. 201.

For HUMANS EXPOSED VIA THE ENVIRONMENT

— to consider a revision of the limits for cadmium in foodstuff set in the Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs ([1]),

— to consider setting a limit for cadmium in tobacco blend/leaves under the Council Directive 2001/37/EC ([2]) (Tobacco Products Directive),

— to consider at Community level setting maximum concentrations for cadmium in fertilizers, taking into account the variety of conditions throughout the Community.

PART 2

CAS No: 1306-19-0	Einecs No: 215-146-2

Molecular formula:	CdO
Einecs name:	Cadmium oxide
IUPAC name:	Cadmium oxide
Rapporteur:	Belgium
Classification ([3]):	Carc. Cat. 2; R45 Cat. 3; R68 Cat. 3; R62-63 T; R48/23/25 T+; R26 T+; R26 N; R50-53

The risk assessment is based on current practices related to the life-cycle of the substance produced in or imported into the European Community as described in the risk assessment forwarded to the Commission by the Member State Rapporteur.

Based on the available information, the risk assessment has determined that in the European Community, the main use of the substance is in the manufacture of nickel-cadmium batteries, but also as a starting material for a wide variety of other cadmium compounds and mainly pigments and stabilisers. Cadmium oxide may also be present as an impurity and exposure may occur during several activities involving the use of (non-)ferrous materials (a.o. foundry and (re-) melting processes). In occupational settings where cadmium oxide is produced or used, workers may be exposed to dusts or fumes mainly by inhalation. Dermal exposure may occur when cadmium oxide powder/dust is handled or during maintenance operations. For the general population non-occupationally involved in the cadmium industry, uptake of cadmium (generic, not specifically cadmium oxide) occurs mainly via the ingestion of food contaminated by cadmium. Tobacco smoking is an important additional source of cadmium (mainly cadmium oxide) exposure by inhalation.

The environmental exposure to cadmium is calculated based on all known current anthropogenic emissions of cadmium, i.e. cadmium that is emitted by the cadmium/cadmium oxide producers and processors and cadmium in diffuse sources such as fertilisers, steel production, oil and coal combustion, traffic, waste incineration, landfills etc. Local exposure assessment is based on emissions from cadmium/cadmium oxide producers and processors and includes the regional predicted environmental concentration. Regional and continental exposure assessment is based on all anthropogenic cadmium emissions, including diffuse emissions, and reflects the concentration reached after 60 years of diffuse emissions. Actual cadmium concentrations in the environment (ambient concentrations) also include the natural background of cadmium (from geological origin or from natural processes) and cadmium that was added to the environment in the past by man (historical pollution).

([1]) OJ L 394, 20.12.2006, p. 5.
([2]) OJ L 194, 18.7.2001.
([3]) The classification of the substance is established by Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 152, 30.4.2004, p. 1, amended by OJ L 216, 16.6.2004, p. 3).

RISK ASSESSMENT

A. **Human health**

This substance has not been sufficiently tested for possible neurotoxic effects, especially on the developing brain. Further epidemiological and experimental information would be required to identify more precisely the nature of the effects, the characterisation of the exposure and the mechanism of action related to neurotoxicity. However, as the substance has been identified as a non-threshold carcinogen, it normally requires control measures that would not be influenced by further information on the endpoint developmental toxicity.

The conclusion of the assessment of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because:

— concerns for acute toxicity as a consequence of inhalation exposure that may arise from cadmium oxide production,

— concerns for effects on fertility and reproductive organs as a consequence of inhalation exposure arising from cadmium oxide production, batteries manufacture and recycling and the production of pigments,

— concerns for respiratory irritation, for kidney and bone repeated dose toxicity, for genotoxicity, and for carcinogenicity as a consequence of inhalation exposure arising from all industrial uses, as the substance is considered as a non-threshold carcinogen.

The conclusion of the assessment of the risks to

CONSUMERS

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

— among the scenarios examined in the risk assessment, Cadmium oxide is only used for the manufacture of Nickel-cadmium batteries and, in this case, consumer exposure is considered to be non-existent or negligible.

The conclusions of the assessment of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

— concerns for respiratory toxicity as a consequence of exposure (mainly by inhalation) that may arise near some point sources,

— concerns for kidney and bone repeated dose toxicity as a consequence of environmental exposure arising in adults who smoke or/and have depleted body iron stores or/and living near point sources,

— concerns for genotoxicity and carcinogenicity as a consequence of environmental exposure arising from all scenarios, since the substance is considered as a non-threshold carcinogen.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physico-chemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied.

This conclusion is reached because:

— given the level of control in manufacture and use, the risks from physicochemical properties are small.

B. **Environment**

The conclusion of the assessment of the risks to the

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is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

— concern for the local aquatic ecosystem at five cadmium production (cadmium metal: one site) or cadmium processing (two pigments producing sites, plating and alloy) sites/scenarios,

— concern for the local aquatic ecosystem at one recycling site,

— concern for a landfill site leaching directly to surface water with a cadmium concentration of 50 µg/l,

— concerns for waters in the UK and the Walloon region of Belgium based on the regional averages of the 90th percentiles of measured cadmium concentrations in rivers and lakes,

— concern for sediment dwelling organism for cadmium plating and cadmium alloys sector,

— concern for sediment dwelling organism at four sites (one cadmium metal production, two cadmium pigment production and one cadmium recycler) and four disposal scenarios (one MSW incineration, three MSW landfill) if the lowest regional 10th percentile of the EU regions (German data from three river systems) from the acid volatile sulphides database is used for the bioavailability correction.

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— concern for one region (UK) based on the 90th percentiles of measured cadmium concentrations of European soils.

The conclusion of the assessment of the risks to the

ATMOSPHERE

No conclusion is reached because: no risk characterisation was done for the atmosphere.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for specific measures to limit the risks. This conclusion is reached because:

— concern for on-site and off-site STP for plating and alloy industry,

— concerns for the micro-organisms of the STP for one NickelCadmium battery recycling plant discharging its effluent to an off-site STP.

The conclusion of the assessment of the risks to the

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— concern for one region (UK) based on the 90th percentile of measured cadmium concentrations of European soils.

STRATEGY FOR LIMITING RISKS

For WORKERS

The legislation for workers' protection currently in force at Community level, particularly Directive 2004/37/CE [1] (Carcinogens — Mutagens Directive), is generally considered to provide an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

— to set at community level occupational exposure limit values and a biological limit value for cadmium oxide according to Directive 98/24/EC [2] or Directive 2004/37/EC as appropriate.

[1] OJ L 158, 30.4.2004.
[2] OJ L 131, 5.5.1998, p. 11.

For HUMANS EXPOSED VIA THE ENVIRONMENT

— to consider a revision of the limits for cadmium oxide in foodstuff set in the Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs ([1]),

— to consider setting a limit for cadmium in tobacco blend/leaves under the Directive 2001/37/EC ([2]) (Tobacco Products Directive),

— to consider at Community level setting maximum concentrations for cadmium oxide in fertilizers, taking into account the variety of conditions throughout the Community.

([1]) OJ L 394, 20.12.2006, p. 5.
([2]) OJ L 194, 18.7.2001.