

Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for the substances: sodium chromate, sodium dichromate and 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol A)

(Text with EEA relevance)

(2008/C 152/02)

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 Regulations (EC) No 143/97 ⁽²⁾ and (EC) No 2364/2000 ⁽³⁾ respectively concerning the third and fourth list of priority substances as foreseen under Regulation (EEC) No 793/93:

- sodium chromate,
- sodium dichromate,
- 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol A).

The rapporteur Member States 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 ⁽⁴⁾ 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) and the Scientific Committee on Health and Environmental Risks (SCHER) have been consulted and have issued an opinion 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 2008/454/EC ⁽⁵⁾, provides the results of risk evaluations ⁽⁶⁾ 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 237, 25.10.2000, p. 5.

⁽⁴⁾ OJ L 161, 29.6.1994, p. 3.

⁽⁵⁾ OJ L 158, 18.6.2008.

⁽⁶⁾ 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: 7775-11-3

Einecs No: 231-889-5

Molecular formula:	Na ₂ CrO ₄
Einecs name:	Sodium chromate
IUPAC name:	Sodium chromate
Rapporteur:	United Kingdom
Classification (1):	Carc. Cat. 2; R45 Muta. Cat. 2; R46 Repr. Cat. 2; R60-61 T+; R26 T; R25-48/23 C; R34 Xn; R21 R42/43 N; R50-53

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

The risk assessment has, based on the available information, determined that in the European Community the five chromium (VI) compounds are mainly used as source materials for other chromium (VI) and chromium (III) compounds, in wood preservatives, in metal treatment products, in wax and vitamin K manufacture, in pigments and catalysts.

Other uses are as oxidants in dyeing of cotton, in photography, and as a corrosion inhibitor in cooling water and in manufacture of activated carbon.

RISK ASSESSMENT:**A. Human health**

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 for all exposure scenarios because of:

- concerns for respiratory tract sensory irritation,
- concerns for eye and skin irritation,
- concerns for acute toxicity as a consequence of short-term peak inhalation exposure,
- concerns for skin sensitisation,
- concerns for occupational asthma,
- concerns for reproductive toxicity (fertility and developmental toxicity) as a consequence of repeated inhalation exposure,
- concerns for mutagenicity and carcinogenicity.

(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. 125).

(2) 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/>

The substance has not been sufficiently tested for effects to the respiratory tract and to the kidney as a consequence of repeated inhalation exposure to the chromium (VI) compounds, specifically to identify the NOAELs and dose-response characteristics. 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.

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 mutagenicity and carcinogenicity as a consequence of dermal exposure arising from handling of dry copper chrome arsenate (CCA)-treated wood, both for adults and for children exposed via wooden playing structures because no threshold below which there would be no risk to human health can be identified for these endpoints. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

No formal risk characterisation has been conducted for consumer exposure to wet CCA treated wood. In the UK the supply of wood not fully dried following CCA treatment is prohibited as a condition of approval under the Control of Pesticides Regulations (1986). Similar controls may already exist in all other Member States. However, if specific controls are not available in each Member State, then there would be concerns for all relevant human health endpoints.

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:

- for mutagenicity and carcinogenicity because no threshold below which there would be no risk to human health can be identified for these endpoints. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

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 risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the assessment of the risks to the

ATMOSPHERE

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 risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the environment for

AQUATIC ECOSYSTEM AND TERRESTRIAL ECOSYSTEM

1. is that there is a need for further information and/or testing. This conclusion is reached because:

- concerns for effects on the sediment compartment as a consequence of exposure arising from production, pigment production, chromium oxide production, tanning salts, wood preservative formulation, wood preservative applications, treated wood in use, metal treatment formulation, and metal treatment.

The information and/or testing requirements are:

- toxicity testing on sediment organisms.

However, the implementation of the strategy for limiting risks for the environment in, together with the corresponding Commission Recommendation 2008/454/EC ⁽¹⁾, is expected to eliminate the need for further information requirements,

- concerns for non-compartment specific effects as a consequence of indirect exposure of predators through the mussel-based food chain arising from pigment production, chromium oxide production, tanning salts, wood preservative formulation, treated wood in use, metal treatment formulation, and metal treatment.

The information and/or testing requirements are:

- further investigation of the uptake of chromium into organisms other than fish, characterisation of the nature of the chromium in organisms and consideration of the toxicity of chromium in other forms to organisms consuming prey containing chromium.

However, the implementation of the strategy for limiting the risks for the environment in Section II, together with the corresponding Recommendation 2008/454/EC, is expected to eliminate the need for further information requirements;

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

- concerns for effects on the aquatic and terrestrial environment as a consequence of exposure arising from production (aquatic only, 1 site), pigment production, chromium oxide production, tanning salts, wood preservative formulation, wood preservative applications, treated wood in use, metal treatment formulation, and metal treatment.

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 of:

- concerns for effects on the functioning of waste water treatment plants due to pigment production, chromium oxide production, tanning salts, wood preservative formulation, treated wood in use, metal treatment formulation, and metal treatment.

STRATEGY FOR LIMITING RISKS

For WORKERS

The legislation for workers' protection currently in force at Community level, particularly Directive 2004/37/EC of the European Parliament and of the Council ⁽²⁾ (the Carcinogens and Mutagens Directive), is generally considered to give an adequate framework to limit the risks of the substances to the extent needed and shall apply.

Within this framework it is recommended:

- to establish at Community level occupational exposure limit values for chromium (VI) compounds according to Directive 98/24/EC ⁽³⁾ or Directive 2004/37/EC as appropriate,
- to establish at Community level a biological limit value for chromium (VI) compounds according to Directive 98/24/EC.

For CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

- the existing legislative measures for consumer protection and humans exposed via the environment, in particular the provisions of Council Directive 98/8/EC (the Biocidal Products Directive), and the provisions under Council Directive 76/769/EEC as regards CMR substances, are considered sufficient to address the identified risks to consumers.

⁽¹⁾ OJ L 158, 18.6.2008.

⁽²⁾ OJ L 158, 30.4.2004, p. 50.

⁽³⁾ OJ L 131, 5.5.1998, p. 11.

For ENVIRONMENT

- it is recommended that the Commission considers the merit of including chromium in the revision of the list of priority substances under the Water Framework Directive (Annex X of Directive 2000/60/EC),
- with particular regard to the on-site reduction of Cr (VI) compounds to Cr (III) tanning salts by plants involved in the tanning of hides and skins, it is recommended that in the next amendment of the BAT reference document for plants involved in the tanning of hides and skins, appropriate references are included to indicate that the on-site reduction of Cr (VI) substances for the production of Cr (III) tanning salts should not be considered as BAT,
- it is recommended that the Commission considers the need to include limits on the contents of chromium (VI) in sewage sludge and in soils as well as a limit on the annual load in the Directive 86/278/EEC on Sewage Sludge,
- the legislation currently in force at Community level for biocides (Directive 98/8/EC) is considered to give an adequate framework to limit the risks associated with the use of wood preservatives that contain chromium (VI) substances and the risks associated with the use of wood treated domestically with wood preservatives that contain chromium (VI) substances.

PART 2

CAS No: 10588-01-9

Einecs No: 234-190-3

Molecular formula:	Na ₂ Cr ₂ O ₇
Einecs name:	Sodium dichromate
IUPAC name:	Sodium dichromate
Rapporteur:	United Kingdom
Classification ⁽¹⁾ :	O; R8 Carc. Cat. 2; R45 Muta. Cat. 2; R46 Repr. Cat. 2; R60-61 T+; R26 T; R25-48/23 C; R34 Xn; R21 R42/43 N; R50-53

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

The risk assessment has, based on the available information, determined that in the European Community the five chromium (VI) compounds are mainly used as source materials for other chromium (VI) and chromium (III) compounds, in wood preservatives, in metal treatments, in wax and vitamin K manufacture, in pigments and catalysts.

Other uses are as oxidants in dyeing of cotton, in photography, and as a corrosion inhibitor in cooling water and in manufacture of activated carbon.

⁽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. 125).

⁽²⁾ 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/>

RISK ASSESSMENT**A. Human health**

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 for all exposure scenarios because of:

- concerns for respiratory tract sensory irritation,
- concerns for eye and skin irritation,
- concerns for acute toxicity as a consequence of short-term peak inhalation exposure,
- concerns for skin sensitisation,
- concerns for occupational asthma,
- concerns for reproductive toxicity (fertility and developmental toxicity) as a consequence of repeated inhalation exposure,
- concerns for mutagenicity and carcinogenicity.

The substance has not been sufficiently tested for effects to the respiratory tract and to the kidney as a consequence of repeated inhalation exposure to the chromium (VI) compounds, specifically to identify the NOAELs and dose-response characteristics. 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.

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 of:

- concerns for mutagenicity and carcinogenicity as a consequence of dermal exposure arising from handling of dry copper chrome arsenate (CCA)-treated wood, both for adults and for children exposed via wooden playing structures because no threshold below which there would be no risk to human health can be identified for these endpoints. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

No formal risk characterisation has been conducted for consumer exposure to wet CCA treated wood. In the UK the supply of wood not fully dried following CCA treatment is prohibited as a condition of approval under the Control of Pesticides Regulations (1986). Similar controls may already exist in all other Member States. However, if specific controls are not available in each Member State, then there would be concerns for all relevant human health endpoints.

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:

- for mutagenicity and carcinogenicity because no threshold below which there would be no risk to human health can be identified for these endpoints. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

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 risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the assessment of the risks to the

ATMOSPHERE

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 risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the environment for

AQUATIC ECOSYSTEM AND TERRESTRIAL ECOSYSTEM

1. is that there is a need for further information and/or testing. This conclusion is reached because:

- concerns for effects on the sediment compartment as a consequence of exposure arising from production, pigment production, chromium oxide production, tanning salts, wood preservative formulation, wood preservative applications, treated wood in use, metal treatment formulation, and metal treatment.

The information and/or testing requirements are:

- toxicity testing on sediment organisms.

However, the implementation of the strategy for limiting risks for the environment in Section II, together with the corresponding Recommendation 2008/454/EC ⁽¹⁾, is expected to eliminate the need for further information requirements,

- concerns for non-compartment specific effects as a consequence of indirect exposure of predators through the mussel-based food chain arising from pigment production, chromium oxide production, tanning salts, wood preservative formulation, treated wood in use, metal treatment formulation, and metal treatment.

The information and/or testing requirements are:

- further investigation of the uptake of chromium into organisms other than fish, characterisation of the nature of the chromium in organisms and consideration of the toxicity of chromium in other forms to organisms consuming prey containing chromium.

However, the implementation of the strategy for limiting the risks for the environment in Section II, together with the corresponding Recommendation 2008/454/EC, is expected to eliminate the need for further information requirements;

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

- concerns for effects on the aquatic and terrestrial environment as a consequence of exposure arising from production (aquatic only, 1 site), pigment production, chromium oxide production, tanning salts, wood preservative formulation, wood preservative applications, treated wood in use, metal treatment formulation, and metal treatment.

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:

- concerns for effects on the functioning of waste water treatment plants due to pigment production, chromium oxide production, tanning salts, wood preservative formulation, treated wood in use, metal treatment formulation, and metal treatment.

STRATEGY FOR LIMITING RISKS

For WORKERS

The legislation for workers' protection currently in force at Community level, particularly Directive 2004/37/EC ⁽²⁾ (the Carcinogens and Mutagens Directive), is generally considered to give an adequate framework to limit the risks of the substances to the extent needed and shall apply.

⁽¹⁾ OJ L 158, 18.6.2008.

⁽²⁾ OJ L 158, 30.4.2004, p. 50.

Within this framework it is recommended:

- to establish at Community level occupational exposure limit values for chromium (VI) compounds according to Directive 98/24/EC ⁽¹⁾ or Directive 2004/37/EC as appropriate,
- to establish at Community level a biological limit value for chromium (VI) compounds according to Directive 98/24/EC.

For CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

- the existing legislative measures for consumer protection and humans exposed via the environment, in particular the provisions of Directive 98/8/EC (the Biocidal Products Directive), and the provisions under Directive 76/769/EEC as regards CMR substances, are considered sufficient to address the identified risks to consumers.

For ENVIRONMENT

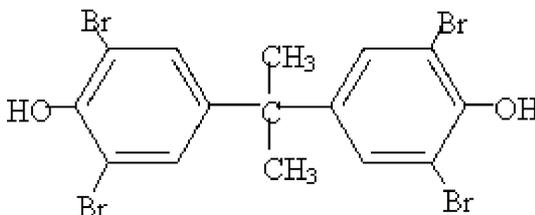
- it is recommended that the Commission considers the merit of including chromium in the revision of the list of priority substances under the Water Framework Directive (Annex X of Directive 2000/60/EC),
- with particular regard to the on-site reduction of Cr (VI) compounds to Cr (III) tanning salts by plants involved in the tanning of hides and skins, it is recommended that in the next amendment of the BAT reference document for plants involved in the tanning of hides and skins, appropriate references are included to indicate that the on-site reduction of Cr (VI) substances for the production of Cr (III) tanning salts should not be considered as BAT,
- it is recommended that the Commission considers the need to include limits on the contents of chromium (VI) in sewage sludge and in soils as well as a limit on the annual load in the Directive 86/278/EEC on Sewage Sludge,
- the legislation currently in force at Community level for biocides (Directive 98/8/EC) is considered to give an adequate framework to limit the risks associated with the use of wood preservatives that contain chromium (VI) substances and the risks associated with the use of wood treated domestically with wood preservatives that contain chromium (VI) substances.

PART 3

CAS No: 79-94-7

Einecs No: 201-236-9

Structural formula:



Einecs name: 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol A)

IUPAC name: 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol

Rapporteur: United Kingdom

Classification ⁽²⁾: None

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 ⁽³⁾.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a reactive and additive flame retardant in plastics. The main uses as a reactive flame retardant (chemically bonded into the polymeric material) are in epoxy and polycarbonate resins. The main uses as an additive flame retardant are in acrylonitrile-butadiene-styrene (ABS) resins.

⁽¹⁾ OJ L 131, 5.5.1998, p. 11.

⁽²⁾ This chemical substance is currently not included in the Annex I of Directive 67/548/EEC.

⁽³⁾ 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/>

RISK ASSESSMENT**A. Human health**

The conclusion of the assessment of the risks to

WORKERS, CONSUMERS AND HUMANS EXPOSED VIA THE ENVIRONMENT

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

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

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 testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the assessment of the risks to the

ATMOSPHERE

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

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

AQUATIC AND TERRESTRIAL ECOSYSTEM

1. is that there is a need for further information and testing.

This conclusion is reached because:

- it is possible that TBBPA may be degraded to bisphenol-A in anaerobic freshwater and marine sediments. This conclusion should be reconsidered once future aquatic effects data has been generated and the corresponding PNECs for bisphenol-A are determined,
- another possible metabolite/degradation product — tetrabromobisphenol-A bis(methyl ether) — possibly meets the screening criteria for a PBT substance. Although the results from present studies are inconclusive, it is suggested that it is a very minor degradation product. Given that a need for risk reduction measures has already been identified for some uses (which should reduce the environmental burden of the parent compound), no further specific work is recommended to address this issue at the present time,
- the risk characterisation ratios for the marine environment indicate a possible risk from some applications. The need for further toxicity data with marine organisms should be evaluated once the implications of any risk reduction activities resulting from the assessment for fresh water and freshwater sediment are known.

However, the implementation of the strategy for limiting the risks for the environment in Section II, together with the corresponding Recommendation 2008/454/EC ⁽¹⁾, is expected to sufficiently reduce the concentrations in the aquatic and terrestrial ecosystem and to eliminate the need for further information requirements;

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

- the PEC/PNEC is > 1 for surface water and sediment at compounding sites where TBBPA is used as an additive flame retardant in ABS (acrylonitrile-butadiene-styrene resins),

(¹) OJ L 158, 18.6.2008.

- the PEC/PNEC is > 1 for the terrestrial compartment, where TBBPA is used as an additive flame retardant in ABS from compounding and conversion sites. The conclusion for conversion sites is dependent on whether or not sewage sludge from the site is applied to agricultural land (no risk is identified where sewage sludge is not applied to land). For ABS compounding sites a risk is identified regardless of the assumptions made over the spreading of sewage sludge.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

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 risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

The results of the strategy for limiting the risks are set out in the corresponding Recommendation 2008/454/EC.
