B4 (2006) A \ 4163.

KEMI
KEMIKALIEINSPEKTIONEN
SWEDISH CHEMICALS INSPECTORATE

International Secretariat
Swedish National Inspectorate
Kirsti Siirala
☎ 08-519 412 54
e-post: kirstis@kemi.se

Diarienummer:
320-173-06

European Comission
Directorate General Environment
Attn. Julian Foley
BU 5 2/125
149 Brussels
BELGIUM

2006-02-06

Dear Julian Foley,

Hereby we send the original copies of the notifications of metallic mercury and paraquat in accordance to article 10.7 of Regulation 304/2004.
They are signed, dated and stamped by the Swedish Designated Authority.

Best regards,

Kirsti Siirala

Kirsti Siirala

Swedish Designated Authority

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Interim Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

UNEP

FORM
FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: SWEDEN

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	paraquat, paraquat dichloride
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	IUPAC: 1,1'-dimethyl-4,4'-bipyridinium
1.3	**Trade names and names of preparations**	Gramoxone Weedol (diquat+paraquat)
1.4	**Code numbers**	
1.4.1	**CAS number**	4685-14-7 (paraquat) 1910-42-5 (paraquat dichloride) 2074-50-2 (paraquat dimetyl, bis)
1.4.2	**Harmonized System customs code**	
1.4.3	**Other numbers (specify the numbering system)**	EINECS No: 225-141-7 (paraquat) 217-615-7 (paraquat dichloride)* 218-196-3 (paraquat dimetyl, bis)* CIPAC No: 56 (paraquat) * salts of paraquat

1.5	**Indication regarding previous notification on this chemical, if any**
1.5.1	θ This is a first time notification of final regulatory action on this chemical.

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

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OR

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UNEP Chemicals
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CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
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1.5.2	θ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: ______ X This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: Effective date 1983-12-31

1.6 Information on hazard classification where the chemical is subject to classification requirements

International classification systems	Hazard class
The United Nations Committee of Experts on the Transportation of Dangerous Goods[1]	Hazard Class 6.1: poisonous substance. Packing Group II: substances and preparations presenting a serious risk of poisoning, when the active ingredient is within the range of 40-100%. Packing Group III: substance presenting a relatively low risk of poisoning in transport, when the active ingredient is in the range of 8-40%.
WHO recommended classification of pesticides by hazard	Moderately hazardous (Class II)
Other classification systems	**Hazard class**
EEC classification Annex I classification	T+; R26 T; R24/25-48/25 Xi; R36/37/38 N; R50-53 (paraquat salts)
EEC label *(Only paraquat salts have been classified, since it was recognised that the paraquat ion is not a substance on its own*[2]*)*	T+, N, R24/25-26-36/37/38-48/25-50/53 S(1/2)-22-28-36/37/39-45-60-61 (paraquat salts)

1.7 Use or uses of the chemical

1.7.1	**X Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	The substance used to be approved for weed control in agriculture, horticulture and orchards
1.7.2	**θ Industrial**
	Describe the industrial uses of the chemical in your country:

1.8 Properties

1.8.1	**Description of physico-chemical properties of the chemical**

Molecular Formula: $C_{12}H_{14}N_2$ (paraquat)
$C_{12}H_{14}N_2Cl_2$ (paraquat dichloride)

Molecular mass: 186.3 (paraquat)
257.2 (paraquat dichloride)

Melting and boiling point: Not applicable since paraquat dichloride decomposes at elevated temperature (>340°C)

Density: 1.5 g/cm3 at 25°C

Vapor pressure: $<<10^{-8}$ Pa at 25°C

Appearance, physical state: Off-white solid, dark red-brown liquid (technical)

Solubility in water: 620 g/l at 20°C and pH 7.2

Solubility in organic solvents: <0.1 g/l in most organic solvents

Partition coefficient: log Kow = –4.5 at 20°C

1.8.2 Description of toxicological properties of the chemical

The Swedish Environmental Protection Agency in 1982 sponsored a literature study about the toxicological profile of paraquat[3]. The study built on a number of published articles and in particular a number of different review articles. Original references are continuously given in the text.

Uptake:
Paraquat can be absorbed through the intestine, after dermal exposure or via inhalation. Between 5 and 10 % of an oral dose is absorbed. The absorption through intact skin is small but is increased at the occurrence of dermatitis. Lethal dermal exposure has been reported for humans in the literature[4].

Distribution:
After oral exposure, a high initial concentration is found in the liver and the kidneys. The concentration is gradually reduced in these organs thereafter[5]. Plasma concentration is relatively stable for 30 hours, while the concentration in the lungs increases. Paraquat is actively concentrated in the lungs[6].

Toxicity:
Larger doses result in cramps, central nervous disorder and respiratory symptoms. If the animals survive they often die within 10 days due to damage on the lungs[7]. Damage on the lungs is overall the most characteristic effect following paraquat exposure. After acute cell damage a slower differentiation of mesenchymal cells into fibroblasts is resulting in permanent lung damage alternative death from lung dysfunction. Rabbits receiving 7 mg/kg b.w. and day through dermal application displayed signs of lung damage after 20 days, while 3 mg/kg and day did not produce any adverse effects on the lungs[8]. Inhalation of paraquat can result in the same kinds of effects. A concentration of 0.7-1.0 mg/m^3 for 6 h resulted in a 50 % mortality for rat, while 0,4 mg/m^3 6 h a day for 3 weeks produced inflammatory effects in the lungs. A dose of 0.1 mg/m^3 did not produce any changes[9].

Similar symptoms have been seen in man after exposure to paraquat. More than 500 lethal intoxications were registered between 1964 and the late 70ies[10], [11]. In Sweden two serious intoxications were registered since 1975, one boy acquired permanent eye damage from getting concentrated solution of paraquat in the face and one young man died 10 days after ingestion of paraquat in suicidal purpose. Higher doses of 5-10 g are always lethal via a progressive development of respiratory dysfunction through lung fibrosis, often in combination with renal failure, painful mucosal ulcerations and lung haemorrhage. Death may occur as late as two weeks after exposure to paraquat and there is no effective antidote[4]. An oral dose of one g or lower doesn't seem to be lethal in most cases[12].

The authors of the Swedish compilation of scientific data however noted the apparent absence of studies of possible effects on humans after chronic sub lethal exposure. It was mentioned however that chronic exposure to low doses of paraquat most likely would damage the lungs or the respiratory capacity[3].

Later studies using conventional tests of lung-capacity have not shown a significant relation between exposure to paraquat and reduced respiratory efficiency, but a recent study from South Africa has shown that working with paraquat under usual field conditions can be associated with abnormal exercise physiology due to arterial oxygen desaturation[13]. Increased risks for Parkinson's disease has also been connected to similar long-term exposure to paraquat[14].

Another sub lethal adverse effect of Paraquat is due to the strongly corrosive properties of both concentrated solution as well as more diluted mixtures. It can cause damage on the eyes, skin (discoloration and dermatitis) and nail destruction[15], [16].

The following table is a compilation of **LD50 data** from three different review articles[17], [18], [7]

	Exposure			
Species	Oral (mg/kg)	Interperitoneal (mg/kg)	Subcutaneous (mg/kg)	Dermal (mg/kg)
Rat	40-200	14-34	19-26	80-90
Mouse	120	30		
Guinea pig	22-80	3		
Rabbit	49-150	18		
Sheep	50-75			
Cat	26-50			
Dog	25-50			
Monkey	50			
Man	40-60		4	

1.8.3 Description of ecotoxicological properties of the chemical

The Swedish Environmental Protection Agency in 1982 sponsored a literature study about the fate and effects of paraquat in agricultural soil. There are some references to the general ecotoxicological properties of paraquat, but the information mainly concerned the persistence and physical behaviour of paraquat in agricultural soil[19]. The following information is based on the content of this report but original references are continuously given in the text.

Persistence

The fraction of paraquat that reaches the soil depends on the amount of vegetation on the field, the intensity of the UV-radiation and the wind speed at the time of spraying. Field trials have shown that the fraction can vary between 10 and 100 % depending on these factors[20]. Paraquat can be subjected to photochemical degradation as long as the substance is on the foliage or the uppermost surface of the soil[21], but the photochemical degradation is insignificant in daylight in natural water bodies or on the soil surface[22].

The substance is rather quickly adsorbed to organic material (e.g. decaying plant material) or clay minerals in the soil. The adsorption on organic material is less strong than on clay minerals, and allows some bioavailability of the substance. This may lead to reabsorption by plant roots but also some biodegradation through microbial action. The dominant feature of paraquat regarding its behaviour in soil is however the very strong adsorption to clay minerals giving a deactivation of the effect of the herbicide[23]. Riley and Wilkinson (1976)[20], showed that no degradation at all occurred during a period of 4.5 years in five different kinds of soils, where the concentration of paraquat was measured yearly from the time of application. Similar results were found in a Swedish experiment, where no degradation was found after a period of 250 days[24]. Other experiments have consequently shown an accumulation of paraquat in the soil with yearly applications[22].

When paraquat is used on water vegetation, it is known that the herbicide disappears relatively quickly from the water, mainly due to adsorption onto organic material in the water and to the sediment. Paraquat can be detected in the sediment for long period of times, up to 4 years after application in one study[22].

Effects

Earthworms don't seem to be adversely affected by conventional doses of paraquat but they might play a role as transporters of paraquat in the soil[19]. Some negative effects have been shown on springtails and acarides[25], [26]. A Swedish review article also came to the conclusion that soil micro organisms, and a number of different microbial processes, are affected by the application of paraquat, which might lead to minor disturbances in functional aspects of the soil[27].

The only additional ecotoxicity test data that are referred to in the background material for the regulatory action is that:

- *LC50 fish is between 25 and 800 ppm (mg/l) depending on species*
- *Paraquat is not toxic to birds*

The test data for fish has been confirmed from other sources[28]. It has also been confirmed that Paraquat is less toxic for birds than for mammals. The acute oral LD_{50} for the hen is 262 - 380 mg/kg body weight. The acute oral and 24-h percutaneous (applied to feet) LD_{50} for mallards are 200 and 600 mg/kg body weight, respectively[29].

PART II: FINAL REGULATORY ACTION

2.	FINAL REGULATORY ACTION
2.1	**The chemical is: Banned**
2.2	**Information specific to the final regulatory action**
2.2.1	**Summary of the final regulatory action**

Paraquat was banned in Sweden in 1983 due to its acute high toxicity, risk for irreversible effects on health and for accidents during handling and use of the substance.

2.2.2 **Reference to the regulatory document**

Decision by the Swedish National Chemicals Inspectorate, published in KIFS 1998:8, Annex 5

2.2.3 **Date of entry into force of the final regulatory action**

31/12 1983

2.3 **Was the final regulatory action based on a risk or hazard evaluation?** X **Yes** θ **No**

If yes, give information on such evaluation

- The risk for intoxication due to accidents when handling the substance was considered unacceptably high. Mechanical failure of e.g. spraying equipment or protective clothing could easily lead to excessive exposure.
- In case of intoxication, either deliberate or accidental, no antidote or remedial cure exists, leading to unacceptable high risks.

Reference to the relevant documentation

The regulatory action was based on two Swedish dossiers where relevant literature was reviewed. All information in sections 1.8.2 and 1.8.3 refers to the information in these documents.

Lennart Torstensson (1982), Litteraturgenomgång rörande herbiciden paraquats uppträdande i mark och vatten. Sveriges Lantbruksuniversitet, Institutionen för mikrobiologi.

U. G. Ahlborg, S. Skerving (1982) PARAQUAT - En diskussion av toxicitet och human risk.
Statens Miljömedicinska Laboratorium Box 60208, 104 01 Stockholm / Yrkesmedicinska kliniken, Lasarettet, 221 85 LUND

2.4 **Reasons for the final regulatory action**

2.4.1 **Is the reason for the final regulatory action relevant to the human health?** X **Yes** θ **No**

If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers

For the toxicological profile of paraquat and effects on human health, see section 1.8.2

In Sweden two serious intoxications were registered since 1975, one boy acquired permanent eye damage from getting concentrated solution of paraquat in the face and one young man died 10 days after ingestion of paraquat for suicidal purpose. The rather common situation where suicidal attempts are not truly seriously meant where noted in the background dossier and the absence of an antidote or efficient treatment to paraquat intoxication. The high risks of accidental poisoning for agricultural workers were also stated as a reason for the regulatory action. This referred both to accidents due to the high acute toxicity of paraquat and the possibility of adverse lung effects after long-term low dose exposure. The background dossier gave reference to the high number of known cases of intoxications by paraquat and the risks for additional such cases in Sweden was considered too high. The background information also referred to several cases where single or repeated dermal exposure resulted in mortal intoxication. Some examples of intoxication after inhalation were also noted although there was scarce evidence of permanent lung-damage. As described in section 1.8.2 later studies have however confirmed the presence of adverse effects on human health after long-term low dose exposure to paraquat.

Reference to the relevant documentation

See sections 2.2, 2.3 and footnotes

Expected effect of the final regulatory action

Risk reduction in the agricultural sector

2.4.2 Is the reason for the final regulatory action relevant to the environment? X Yes No

If yes, give summary of the known hazards and risks to the environment

The high persistence of paraquat in soil and sediment and possible effects on sediment dwelling organisms is a matter of concern, but the regulatory action was mainly due to risks for adverse effects on human health and occupational safety.

Reference to the relevant documentation

Expected effect of the final regulatory action

2.5 Category or categories where the final regulatory action has been taken

2.5.1 Final regulatory action has been taken for the chemical category θ **Industrial**

Use or uses prohibited by the final regulatory action

Use or uses that remain allowed

2.5.2 Final regulatory action has been taken for the chemical category X **Pesticide**

Formulation(s) and use or uses prohibited by the final regulatory action

All uses of paraquat as a pesticide

Formulation(s) and use or uses that remain allowed

Non

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.

	Quantity per year (MT)	Year
Produced	----	
Imported	----	
Exported	----	
Used	----	

2.6 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

(This section contains reference to publications and studies made at a more recent date since the current situation in other states and regions are analysed.)

The use of paraquat at the time of authorization in Sweden was conditioned with a certificate of adequate instruction and knowledge about safe use and handling of pesticides (compulsory for pesticides in "class I and II"). The high risk for irreversible effects on human health makes paraquat especially dangerous for use in home gardening and by consumers in general. Risk reduction in connection to the use of paraquat is highly dependent on adequate information and knowledge of potential adverse effects on human health. Conditions of use in many developing countries mean it is difficult to follow label instructions and recommendations for use. The use in some developing countries is therefore a matter of concern. High temperature in tropical and subtropical areas also increases the risk for the inadequate use of protective clothing.

For workers in the agricultural sector, the main route of exposure is through the skin[30, 31]. Continued exposure, as encountered by spray operators on plantations, is reported to affect the skin via mild irritation, blistering and ulceration. The eyes, nose and fingernails can also be affected and severe cases may include peeling of the outer layer of the skin and cell necrosis[3]. Severe exposure on hands has resulted in nail damage, ranging from localised discoloration to temporary nail loss[32]. A study in Thailand found clear indications of caustic burns on the feet after working with spinning disk applicators[33].

The use of paraquat as an herbicide is requiring a strict use of protecting clothing. Model estimations and field operator exposure studies have shown that the use of full-body protection equipment is necessary to guarantee an exposure below the Acceptable Operational Exposure Level (AOEL)[30]. However, taking all precautionary measures into account, the margin of safety is still small. Practical experience from both developing and developed countries has also shown that professional users of paraquat often don't use sufficient protection[30]. A study of small farmers in Kenya for instance showed that no protective clothing was worn, and argued that the price of a pair of protective gloves was equivalent to a day's wage of a plantation worker[34]. The risks are also illustrated by the frequent reports of injuries and deaths due to the use of the substance, mostly in developing countries but also within the EU. The majority of cases could be attributed to suicide, but accidental cases also occurred[35].

2.7 Other relevant information that may cover:

2.7.1 Assessment of socio-economic effects of the final regulatory action

Limited effects in Sweden since there are alternative herbicides on the market and alternative agricultural practices.

2.7.2 Information on alternatives and their relative risks

Safer alternatives do exist like glyphosate and sulfonylureas with low acute and chronic toxicity and lower risks for toxic effects on non-target organisms like ground nesting birds and hares. Glyfosate and sulfonylurea herbicides are acting as inhibitors of the synthesis of amino acids in plants and micro-organisms via the inhibition of specific enzymes. These enzymes are not present in animals, giving a much lower toxicity of the compound for mammals, insects and molluscs etc.

2.7.3 Relevant additional information

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Ministry of the Environment
Address	SE-103 33 Stockholm SWEDEN *Visitors adress:* Tegelbacken 2
Telephone	+ 46 8 405 10 00
Telefax	+46 8 24 16 29
E-mail address	registrator@environment.ministry.se
Designated National Authority	
Institution	National Swedish Chemicals Inspectorate
Address	P.O. Box 2 SE-172 13 Sundbyberg Sweden
Name of person in charge	Dr Kirsti Siirala Dr Bo Nyström
Position of person in charge	Senior Technical Officer Senior Technical Officer
Telephone	+46 8 519 412 54 +46 8 519 411 03
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Date, signature of DNA and official seal: 2006-04-16 Kirsti Siirala

SWEDEN

REFERENCES

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[1] IPCS INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY, Health and Safety Guide No. 51

[2] SUMMARY RECORD Meeting of the Commission Working Group on the Classification and Labelling of Dangerous Substances Pesticides, ECB Ispra, 18-20 November

[3] PARAQUAT – En diskussion av toxicitet och human risk. Authors Ulf Ahlborg and Staffan Skerfving. Document reference date 13 of May 1982, Swedish Chemicals Inspectorate

[4] Howard J.K., 1978, Lancet 1:1100

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UNEP

FORM
FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: SWEDEN

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	Mercury
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	
1.3	**Trade names and names of preparations**	
1.4	**Code numbers**	
1.4.1	**CAS number**	7439-97-6
1.4.2	**Harmonized System customs code**	280540
1.4.3	**Other numbers (specify the numbering system)**	Transport classification UN nr: 2809 EEC nr: 231-106-7 RTECS: OV4550000 EC: 080-001-00-0

1.5	**Indication regarding previous notification on this chemical, if any**
1.5.1	X This is a first time notification of final regulatory action on this chemical.

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
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Viale delle Terme di Caracalla
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Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.5.2

θ This is a modification of a previous notification of final regulatory action on this chemical.

The sections modified are: ____________________

θ This notification replaces all previously submitted notifications on this chemical.

Date of issue of the previous notification: ____________________

1.6 Information on hazard classification where the chemical is subject to classification requirements

International classification systems	Hazard class
IARC	Metallic mercury and inorganic mercury compounds: group 3

Other classification systems	Hazard class
EEC classification	Mercury: T; R23 R33 N; R50-53
EEC label	Mercury: T, N; R23-33-50/53 S (1/2)-7-45-60-61

1.7 Use or uses of the chemical

1.7.1 θ **Pesticide**

Describe the uses of the chemical as a pesticide in your country:

1.7.2 X **Industrial**

Describe the industrial uses of the chemical in your country:

Mercury is used in light sources (low-energy lamps and fluorescent tubes), neon tubes, button cell batteries, measuring instruments in equipment, dental amalgam, chlor-alkali industry, medicinal products and cosmetics. Another professional handling of mercury is the extraction of mercury from the bedrock by the mining/metals industry. In Sweden the major areas of use today are batteries (100-140 kg), light sources (121 kg), dental amalgam (103 kg) and analytical chemicals (53 kg). All the data refer to 2003. See also point 2.5.3

1.8 Properties

1.8.1 **Description of physico-chemical properties of the chemical**

Chemical formula: Hg
Molecular mass: 200,59
Freezing point: -39 °C
Boiling point: 356,6 °C
Melting point: -38,86 °C
Vapour pressure: 0,16Pa (20°C)
Relative density: 13,595 g/cm^3, 0°C
Water solubility: 0.05 mg/l

1.8 Properties

1.8.2 Description of toxicological properties of the chemical

The following information about acute and chronic toxicity endpoints can be found in report 10/89 from the Swedish Chemicals Inspectorate *"Miljöfarliga Ämnen – exempellista och vetenskaplig dokumentation"*. The original source is referenced in brackets.

LD$_{50}$, (interperitoneal) mouse: 14-17 mg Hg/kg ($\underline{CH_3HgCl}$), (Laveskog et al, 1976, *"Om metaller"* Report Swedish Environmental Protection Agency).
LD$_{50}$, (interperitoneal) mouse: 12-15 mg Hg/kg ($\underline{EtHgCl}$), (Laveskog et al, 1976).
LD$_{50}$, (oral) rat: 37 mg Hg/kg ($\underline{HgCl_2}$), (Pomeroy et al. 1980, Validation of the OECD Ecotoxicology Testing Scheme Set. Battelle Columbus Labs., Columbus, Ohio, USA)
LD$_{50}$, (oral) mouse: 10 mg/kg ($\underline{HgCl_2}$), (Lewis & Tatken, (edts) 1979, Registry of Toxic Effects of Chemical Substances. U.S. Dept. Health and Human Services. Natl. Inst. Occup. Safety Health (NIOSH).
NOEC (inhalation) rat: 3 µg/m^3, Hg vapour, (Nordberg G. F., 1981, *Kvicksilver från hälsosynpunkt*, Projekt Kol-Hälsa-Miljö, Rapport 192)

Mercury exists in metallic and inorganic forms as well as in organic forms. One main route of exposure for metallic mercury in its vaporized form is the use of mercury in dental amalgam, where such use is common. Other exposures from vaporized mercury may occur in the working environment. For organic mercury compounds the predominant exposure is through food intake. Metabolism of mercury from inorganic to organic forms of mercury occurs within different compartments of the ecosystems. This explains why a systems approach is necessary to understand and assess how the use of metallic mercury may affect human health. Emissions of metallic mercury are transformed into organic forms by microbial activity and humans may absorb these toxic organic species or compounds of mercury via food. This process is further described in section 1.8.3.

For metallic mercury, the main route of exposure is by inhalation. 80% of inhaled mercury is retained and absorbed. Metallic mercury is lipid soluble and easily penetrates biological membranes, including the blood-brain barrier and the foetus.

Inorganic mercury compounds may be absorbed through the skin and the primary effect of long-term exposure to low amounts of inorganic mercury compounds is renal damage. Neurological and behavioural disorders in humans have also been observed following ingestion or dermal application of mercury-containing medicinal products, or via inhalation of metallic mercury vapour.

Methyl mercury compounds present in seafood are almost completely absorbed from the gastrointestinal tract and are distributed to most tissues with the highest concentration in the kidneys. In one of the most recent extensive evaluations of methyl-mercury it was concluded by U.S. National Research Council that the most well documented effects judged from the evidence from human exposure and animal studies can be found in the developing nervous system in unborn and newborn children. Furthermore, from research on animals there is evidence of effects on the immune system and the reproductive system

WHO/FAO has estimated a Provisional Tolerable Weekly Intake (PTWI) for total mercury of 5 µg/kg body weight (bw), of which no more than 3,3 µg /kg bw should be present as methyl mercury. The PTWI gives no safety margin for pregnant women and a very small margin for breast-feeding women. The value for methyl mercury has therefore recently been revised to 1,6 µg/kg bw.

If these figures are applied to Swedish conditions it can be mentioned that consumption of 200 g of fish containing 500µg mercury/kg (a very common concentration in fish from Swedish lakes) will result in the intake of 100µg mercury, predominately methyl mercury. A woman with a body weight of 60 kg will therefore exceed the PTWI (96 µg) only by eating fresh-water fish once a week, regardless of all other sources of mercury.

Concise International Assessment Document (CICAD) Vol: 50 (2003)
Nordic paper on mercury - TemaNord 2002:516, Nordic Council of Minister. see:
http://www.norden.org/pub/miljo/miljo/sk/TN02_516.asp
U.S. National Research Council. NRC. 2000. Mercury – a global pollutant requiring global initiatives
UNEP. Chemicals. Global Mercury Assessment. 2002.
*see:*http://www.chem.unep.ch/mercury/Report/GMA-report-TOC.htm

1.8.3	**Description of ecotoxicological properties of the chemical**

The following information about acute and chronic toxicity endpoints can be found in report 10/89 from the Swedish Chemicals Inspectorate *"Miljöfarliga Ämnen – exempellista och vetenskaplig dokumentation"*. The original source is referenced in brackets.

EC_0, algae, Microsystis aeruginosa,: 0,05 mg/l $HgCl_2$, *(DABAWAS, 1982, Datenbank für wassergefährende Stoffe, Dortmund, Germany)*
EC_0, algae, Scenedesmus quadricauda,: 0,07 mg/l $HgCl_2$, *(DABAWAS, 1982)*
LC_{50} (48 h), evertebrates, Daphnia: 0,005 mg/l $HgCl_2$, *(Biesinger & Christensen, 1972, Effects of various metals on survival, growth, reproduction and metabolism of Daphnia magna. J. Fish. Res. Bd. Can. 29:1691-1700.)*
LOEC reproduction (3 weeks), evertebrates, Daphnia: 0,0034 mg/l $HgCl_2$, *(Biesinger & Christensen, 1972)*
LOEC growth, (16+21 days) *Salvelinus fontinalis* (Brook trout) 0.0009 mg/l CH_3HgCl, (Christensen 1975, *Biochemical effects of methyl-mercuric chloride, cadmium chloride and lead nitrate on embryos and alevins of the brook trout, Salvelinus fontinalis.* Toxicol. Appl. Pharmacol. 32:191-197
LOEC, evertebrate, Artemia salina: 0,002 mg/l, CH_3HgCl, (*Cunningham & Grosch, 1978, A comparative study of the effects of mercuric chloride and methyl mercury chloride on reproductive performance in the brine shrimp, Artemia salina.* Environ. Poll. 15:83)
LC_{50},(96 h) fish, Salmo gairdneri: 0,024-0,042 mg/l CH_3HgCl, *(Perwak et al, 1985, An Exposure and Risk Assessment for Mercury,* U.S. EPA 4404-85-011*)*
Long-term effect, marine phytoplankton: 0,0005 mg/l CH_3HgCl, *(Knauer & Martin, 1972, Mercury in a marine pelagic food chain. Limnol. Oceanogr. 17(6):868-876)*
Long-term effect, fresh water and marine phytoplankton: 0,001 mg/l $HgCl_2$, *(Knauer & Martin, 1972)*
BCF, pike: >100 000, CH_3HgCl , *(Monitor, 1987, Tungmetaller – förekomst och omsättning i naturen, Naturvårdsverket informerar,* Swedish Environmental Protection Agency)
Depuration time to 50% of initial concentration: 1000 days *(Monitor1987)*

Mercury is one of the heavy metals, which has the highest toxicity. Compared with other heavy metals it is more mobile and is thereby emitted to the atmosphere and water. Mercury vapor has an atmospheric residence time of between 0,4 and 3 years and is transported globally to regions far from the emission source. Natural transformation of mercury to other forms of mercury takes place in the environment. There is a well-recognized global cycle for mercury, whereby emitted mercury vapor is converted to soluble forms and deposited by rain onto soil and water. Mercury deposited on soils is usually bound to soil particles. However, mercury is transported in substantial amounts to the aquatic environment fixed to humic substances.

The Swedish Environmental Protection Agency has estimated the mercury deposition over Sweden at approx. 4.2 tonnes per annum, of which most comes via long-distance atmospheric transfer, principally from Europe but also from other parts of the world. Swedish emissions to the air are calculated to be 0.7 tonnes. According to KemI Report no 10/97 ca 10 % of the wet deposition input in Scandinavia in mid 1990's originates from the use of mercury-containing products in Europe.

In the aquatic environment mercury is methylated by microbial activity to the highly toxic methylmercury, which has a high potential for bioaccumulation. Methylmercury enters the food chain by rapid diffusion and tight binding to proteins. As a result of food-chain biomagnification, highest levels are found in tissues of predatory species.

The organic forms of mercury are generally more toxic than inorganic forms. Inorganic mercury compounds have been reported to have effect on microorganisms at concentrations of the metal at 5 µg/l, and organomercury compounds at least ten times lower. Short-term acute toxicity has been reported as low as 1 µg Hg/l for aquatic organisms and for the embryo-larval stage even at concentrations <0,1 µg Hg/l. The most sensitive part in the aquatic environment is the non-plant biota.

Mercury is thus highly toxic, nondegradable, long-range transportable, bio-accumulative and bio-magnified. It becomes concentrated in soil, water and living organisms. The more mercury is supplied to society the more the levels in the environment will increase.

WHO working group, Environmental Health Criteria, 101(1990)
OECD cooperative risk reduction activities for certain dangerous substances - Nordic paper on mercury. OECD Environment Directorate. Chemicals Group and Management Committee 1991. ENV/MC/CHEM(91)4
TemaNord 2002:516, Nordic Council of Ministers, TemaNord 2002:516
Swedish Chemical Inspectorate (KemI) Report, No 10/97, Mercury in products – a source of transboundary pollutant transports, 1997

PART II: FINAL REGULATORY ACTION

2. FINAL REGULATORY ACTION

2.1 The chemical is: severely restricted

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

The Ordinance (1998:944) prohibits
- the commercial export of *mercury* and *chemical compounds and preparations* containing mercury from Sweden.
Thus export of metallic mercury and as well as chemical products containing mercury, e.g. dental amalgam and analytical chemicals, are prohibited.

- certain *goods/articles* containing mercury to be manufactured or sold commercially. The prohibition covers electrical components such as *thermometers*, *switches*, *thermostats*, *relays*, and *circuit breakers* and other measuring instruments.

- these certain *goods/articles* to be imported from third countries and to be commercially exported from Sweden.

- the regulated *goods/articles* to be used if they were not in use before 1 January 1995.

This provision is an accommodation to Sweden's accession to the EU and the difficulty of preventing imports from other EU countries. It also counteracts the possibility to circumvent the prohibitions by selling empty goods, which are then filled with mercury by the user.

If there exist exceptional reasons the Swedish National Chemicals Inspectorate may, according to the Ordinance, grant exemptions in individual cases.

2.2.2 Reference to the regulatory document

Ordinance 1998:944 Concerning Bans etc in Certain Cases in Connection with the Handling, Import and Export of Chemical Products.

2.2.3 Date of entry into force of the final regulatory action

The original ordinance was passed in 1991 and most of the prohibitions came into force in 1992-93. The latest amendment was implemented in 1 January, 1999

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	X Yes
	If yes, give information on such evaluation	
	The action programmes Marine pollution 90, Fresh water 90 and Air 90 as well as Report 3764 on Mercury - Problems, Environmental Objectives, Measures, produced by the Swedish Environmental Protection Agency, provided information on deposition, effects from mercury and results from monitoring programmes. These reports constituted the basis for the Swedish Government Bill 1990/91:90, in which the Government concluded that the emissions of mercury have to be reduced to reach levels without risks. According to these reports as well as a more recent report produced by the Swedish Environmental Protection Agency, 2002, (Rapport 5184, Metaller i stad och land) the levels of mercury in the soil in forests and in the arable fields suggest risks for negative effects on important biological processes, especially in the south of Sweden. The levels are 3-5 times higher than the natural levels. The situation is similar in arable fields. Further, the increased amount of mercury in the soil is directly linked to the strongly increased levels of mercury in fish in lakes in large parts of Sweden. In the south of Sweden the levels in fish are 5 times higher than natural levels. The coastal areas in the Baltic Sea also display increased background concentrations of mercury. The limit value of 0,5 mg/kg, which is recommended by WHO/FAO is exceeded in pike of a weight of 1 kg in about half of the lakes (ca 50 000) in Sweden. The National Food Administration consequently recommends pregnant women not to eat fresh-water fish at all. The rest of the population is recommended not to eat fresh-water fish more than once a week. Since two decades there is a decreasing trend of the concentration of mercury both in the water and in the fish, reflecting measures taken against mercury emissions. The explanation for the decreased levels is assumed to be the decreased atmospheric deposition directly onto the surfaces of the lakes. According to the Swedish Environmental Protection Agency the deposition has to decrease further by 80 % to reach acceptable levels, which is also the reason for the stringent Swedish measures.	
	Reference to the relevant documentation	
	Swedish Environmental Protection Agency, Marine pollution 90, Fresh water 90 and Air 90, 1990 *Swedish Environmental Protection Agency, Report 3764, Mercury problems, environmental objectives, measures, 1990* *Swedish Environmental Protection Agency, Report 5184, Stad & Land, 2002* *UNEP, Chemicals, Global Mercury Assessment, 2002, see:* http://www.chem.unep.ch/mercury/Report/GMA-report-TOC.htm	
2.4	**Reasons for the final regulatory action**	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	X Yes
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers	

As described in section 2.3, the National Food Administration recommends pregnant women not to eat fresh-water fish at all. The rest of the population is recommended not to eat fresh-water fish more than once a week. Section 1.8.2 shows that very stringent measures have been necessary to reduce the exposure to mercury for major parts of the Swedish population. The restrictions on the occupational use of mercury have also been considered necessary since the normal background exposure to mercury is already too high. Any additional exposure to mercury is therefore linked to unacceptable risks for negative effects on human health.

Reference to the relevant documentation

See section 2.3

Expected effect of the final regulatory action

Decreased emission and thereby decreased levels in fish for consumption.

2.4.2 Is the reason for the final regulatory action relevant to the environment? X Yes

If yes, give summary of the known hazards and risks to the environment

There has been an atmospheric deposition since decades and the levels are high enough to disturb important biological processes in the soil, especially in the south of Sweden. These processes are essential to maintain the ecosystem in the forests including the production capacity. Even though the emissions have decreased the last few decades there is still a continued accumulation of mercury in the top layer of the soil in forests. The levels are now up to five times the natural levels. Likewise, the levels in arable land are close to the concentrations where the productivity of the soil is at risk.

Regarding fish and wildlife there have been no reports on adverse effect on fish species at present concentrations. It is however likely that predatory mammals might be at risk due to high concentrations of mercury in predatory fish, such as pike. The US EPA has developed methylmercury wildlife criteria for mink and otter (Mercury study report to congress. US EPA, Dec. 1997), and these are exceeded already at, for Swedish conditions, relatively common mercury concentration of 1 ng/l in fresh-water (UNEP, Global Mercury Assessment). Considering the high concentration of mercury in Swedish fish, it is therefore realistic to assume negative effects on mammals living primarily on a fish diet.

Reference to the relevant documentation

Swedish Environmental Protection Agency, Marine pollution 90, Fresh water 90 and Air 90, 1990
Mercury study report to congress. US EPA, Dec. 1997
UNEP, Chemicals, Global Mercury Assessment, 2002

Expected effect of the final regulatory action

Decreased emission levels and thereby decreased risks for negative effects on the ecosystem in the soil, lakes and coastal areas in the Baltic Sea.

2.5 Category or categories where the final regulatory action has been taken

2.5.1 Final regulatory action has been taken for the chemical category X **Industrial**

Use or uses prohibited by the final regulatory action

See section 2.2.1

Use or uses that remain allowed

Mercury might still be used in certain kinds of equipment where mercury-containing measurement instruments form an integral part of the final product. Other uses are light sources (low-energy lamps and fluorescent tubes), neon tubes, button cell batteries, dental amalgam, medicinal products, analytical chemicals and cosmetics.

Although mercury is prohibited for use in electrical components such as relays and electrical contacts, etc. and measuring instruments, mercury is allowed for use in electrical components and measuring instruments that were in use before 1 January 1995. The major areas of use today are batteries (100-140 kg), light sources (121 kg), dental amalgam (103 kg) and analytical chemicals (53 kg). All the data refer to 2003.

2.5.2	**Final regulatory action has been taken for the chemical category**	θ **Pesticide**
	Formulation(s) and use or uses prohibited by the final regulatory action	
	Formulation(s) and use or uses that remain allowed	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.

	Quantity per year (MT)	Year
Produced		
Imported	**1991/92**: 56000 kg **2003**: 3000 kg	
Exported	**1991/92**: 59 000 kg **2003**: 1000 kg	
Used	*Yearly supply of mercury (kg) to society via chemical products and articles. Data for the years 1991/92 and 1997 originates from KemI Report No 5/98.*	

	1991/92	**1997**	**2003**
Thermometers	328[1]	0,13[2*]	0,07[2] (1-2)[13*]
Electrical components	4500[3]	3[2*]	-[2]
Measuring instruments		17[2*]	20[2*]
Batteries	2300[4]	800[4]	100-140[4]
Light sources	300[5]	150[6]	121[6]
Neon tubes		30[7]	18[7]
Equipment		40-50[8]	
Dental amalgam	1700[9]	980[10]	103[10]
Medicinal products, veterinary medicinal products, cosmetics		>0,2[11]	0,2[11]
Analytical chemicals		<45[12]	53[14]
Total	**>9100**	**2060**	**416-456**

- Granted exemptions

[1] KemI PM 6/96 [2] information on exemptions [3] incl. measuring instruments, KemI PM 6/96 [4] Naturvårdsverket [5] KemI rapport 8/94 [6] LAMPA 1998; 2004 amended to cover the market [7] Ljusreklamförbundet 1998; 2004 amended to cover the market [8] Kemiinformation AB, 1998 [9] Information referred to in "Arbete och Hälsa" 1998:2, and in KemI PM 4/96 [10] Branschkansliet & Föreningen Svensk Dentalhandel, 1998; 2004 [11] Läkemedelsverket & Apoteksbolaget [12] according to Section 17, permit at county councils (see 3.1.3) [13] Sale of termometers for determination of flammability, Göteborgs Termometerfabrik AB, 2004 [14] Chemical suppliers of analyses and reagents (VWR International AB, Hach Lange AB, Bergman Labora AB and Tamro Medlab AB).

KemI Report No 4/04, Mercury – investigation of a general ban

2.6 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

There is a great need for global phasing out of mercury as it is long-range transportable, highly toxic, non-degradable, bio-accumulative and bio-magnified. The more mercury is supplied to society the more the levels in the environment will increase. Due to long-range atmospheric transport and ocean currents, methylmercury is present in the environment far away from local or regional mercury emission sources. It is likely that populations anywhere on the globe, dependent on a fish diet are particularly at risk due to methylmercury exposure. Studies reviewed by the U.S. National Academy of Sciences for example associate chronic low-dose prenatal methyl mercury exposure with poor performance by children on neurobehavioral tests that measure such things as attention, language ability, fine motor skills, and intelligence. (See: http://www.ijc.org/php/publications/html/12br/english/report/chemical/mhh.html)

2.7 Other relevant information that may cover:

2.7.1 Assessment of socio-economic effects of the final regulatory action

The socio-economic effects have been minor since alternative technique was in most cases available when the Ordinance came into force. If there are exceptional reasons exemptions may be granted in individual cases according to the Ordinance 1998:944.

2.7.2 Information on alternatives and their relative risks

More modern technique, such as digital temperature-measuring devices and electronic techniques have replaced some mercury-containing instruments. Below are some examples.

- Mercury-thermometers have been replaced by electrical or electronic thermometers
- Pressure measuring instruments have been replaced by technology based on gas, other liquids or mechanical spring
- Tilt-switches have been replaced by e.g. manual/mechanical micro-switches
- Electronic switches have been replaced by solid state-switches or optical switches
- Proximity sensor/switch have been replaced by inductive/capacitive/photoelectric sensors

To our knowledge no significant risks from the use of the alternatives have been identified.

2.7.3 Relevant additional information

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action

Institution	Ministry of the Environment
Address	SE-103 33 Stockholm, SWEDEN
Telephone	+46 8 405 10 00

Telefax	+ 46 8 24 16 29
E-mail address	registrator@sustainable.ministry.se
Designated National Authority	
Institution	Swedish National Chemicals Inspectorate
Address	P.O. Box 2 SE-172 13 Sundbyberg SWEDEN
Name of person in charge	Dr Kirsti Siirala Ms Ulla Falk Dr Bo Nyström
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