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Interim Chemical Review Committee
Fourth session
Rome, 3 – 7 March 2003
Item 5 a) iii) of the provisional agenda*

INCLUSION OF CHEMICALS IN THE INTERIM PRIOR INFORMED CONSENT PROCEDURE - REVIEW OF NOTIFICATIONS OF FINAL REGULATORY ACTIONS TO BAN OR SEVERELY RESTRICT A CHEMICAL

Tetramethyl lead

Note from the Secretariat

1. In line with Article 5 of the Rotterdam Convention, when the Secretariat has received at least one notification from each of two interim PIC regions, that contain the information required in Annex I of the Convention, it shall forward the notifications and accompanying documentation to the members of the Interim Chemical Review Committee. The Committee shall review the information provided in such notifications and, in accordance with the criteria set out in Annex II, recommend to the Intergovernmental Negotiating Committee whether the chemical in question should be made subject to the interim PIC procedure and a decision guidance document drafted.

2. The Intergovernmental Negotiating Committee, in decision INC.7/6, adopted a process for drafting decision guidance documents. The process is based on that developed by the Interim Chemical Review Committee at its first session in Geneva, February 2000. An excerpt of the decision is contained in document UNEP/FAO/PIC/ICRC.4/INF.5.

3. The Secretariat has identified two verified notifications from two interim PIC regions relating to tetramethyl lead in gasoline (North America - Canada and Europe – European Community). Summaries of these notifications were included in PIC Circulars XII December 2000 and XVI December 2002.

4. This note contains the two notifications as they were circulated to the members of the Interim Chemical Review Committee in a letter the week of 25 November 2002 in line with Article 5 of the Convention.

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* UNEP/FAO/PIC/ICRC.4/1

5. The relevant documentation provided by Canada and the European Community in conjunction with their respective notifications were circulated to members of the Interim Chemical Review Committee with a letter the week of 18 November 2002 and are available as addenda to this note (UNEP/FAO/PIC/ICRC.4/16/Add.1 and UNEP/FAO/PIC/ICRC.4/16.Add.2 respectively).

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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: Canada

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	Tetramethyl lead
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	Plumbane, Tetramethyl-
1.3	**Trade names and names of preparations**	Lead tetramethyl, motor fuel anti-knock compound, TML
1.4	**Code numbers**	
1.4.1	**CAS number**	75-74-1
1.4.2	**Harmonized System customs code**	381111
1.4.3	**Other numbers (specify the numbering system)**	UN/NA 1649, RTECS TP7250000

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

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.5	Indication regarding previous notification on this chemical, if any
1.5.1	☐ This is a first time notification of final regulatory action on this chemical.
1.5.2	☐ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ☑ 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**
Other classification systems	**Hazard class**
National Fire Protection Association (NFPA)	Health:3, Flammability: 3, Reactivity:3

1.7	Use or uses of the chemical
1.7.1	☐ **Pesticide** **Describe the uses of the chemical as a pesticide in your country:**
1.7.2	☑ **Industrial** **Describe the industrial uses of the chemical in your country:** Tetramethyl lead (TML) is used mainly in gasoline as a motor anti-knock additive.

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

Colourless liquid, but may be dyed red, orange or blue. With a slight musty odour.
Melting point: -27.5 °C
Boiling point: 110 °C
Specific Gravity: 1.995 at 20/4 °C
Vapour pressure: 23 mm Hg at 20 °C
Insoluble in water
Slightly soluble in petroleum ether, toluene and benzene.

1.8.2	Description of toxicological properties of the chemical

Acute Effects:

- TML can irritate the eyes with possible loss of vision.
- Exposure to TML can cause poor appetite, weight loss, upset stomach, nausea, vomiting and metallic taste in the mouth.
- High exposure can cause headache, irritability, disturbed sleep, tiredness, reduced memory, personality changes, hallucinations, convulsions and death.

Chronic Effects:

The following chronic (long-term) health effects can occur at some time after exposure to TML and can last for months or years:

- High levels can cause muscle and joint pains, weakness, muscle cramps and easy fatigue.
- Repeated exposure causes lead to accumulate in the body. It can take months or years for the body to get rid of excess lead.

Carcinogenicity:

- TML has not been shown to cause cancer in animals.

Reproductive/Developmental Effects:

- While TML has not been identified as a teratogen or a reproductive hazard, lead and certain lead compounds have been determined to be teratogens and may also cause reproductive damage, such as reduced fertility and interference with menstrual cycles

Data:

LD_{Lo} (rabbit, skin): 3,300 µg/kg
LD_{Lo} (rabbit, oral): 24 mg/kg

References:

Hazardous Substance Fact Sheet, Tetramethyl Lead, New Jersey Department of Health and Senior Services, Date: September 1986, Revision: December 1995
(http://www.state.nj.us/health/eoh/rtkweb/1831.pdf)

NTP Chemical Health and Safety Data
(http://ntp-db.niehs.nih.gov/NTP_Reports/NTP_Chem_H&S/NTP_Chem7/Radian75-74-1.txt)

1.8.3	Description of ecotoxicological properties of the chemical

No information available.

PART II: FINAL REGULATORY ACTION

2. FINAL REGULATORY ACTION

2.1 The chemical is: ☐ banned OR ☑ severely restricted

2.2 Information specific to the final regulatory action

2.2.1 Summary of the final regulatory action

The Gasoline Regulations regulate the concentration of phosphorus and lead permitted in leaded and unleaded fuels manufactured in or imported into Canada, and offered for sale or sold. The Regulations apply to gasoline producers and importers. The Regulations set maximum lead concentration limits for leaded gasoline to be used in farm equipment, boats or heavy trucks. The Regulations do not apply to aircraft. Amendments were made in 1994, 1997 and 1998 to exempt high performance competition vehicles. The latest amendment extended the exemption until December 31, 2002.

2.2.2 Reference to the regulatory document

Gasoline Regulations (SOR/90-247), *Department of the Environment Omnibus Amendment Order, 1992* (SOR/92-587), and *Regulations Amending the Gasoline Regulations* (SOR/94-335; SOR/97-147; and SOR/98-217) under the *Canadian Environmental Protection Act*.

2.2.3 Date of entry into force of the final regulatory action

SOR/90-247: April 26, 1990
SOR/92-587: October 9, 1992
SOR/94-335: May 16, 1994
SOR/97-147: March 19, 1997
SOR/98-217: March 26, 1998

2.3 Was the final regulatory action based on a risk or hazard evaluation? ☑ Yes ☐ No

If yes, give information on such evaluation

Background

The assessment of substances to determine if they are "toxic" under the *Canadian Environmental Protection Act* (CEPA) is a shared responsibility of Environment Canada and Health Canada. Environment Canada assesses the environmental risks, and Health Canada assesses the human health risks. An assessment is conducted to determine if a substance is likely to harm the environment or the health of humans, taking into account the likelihood and magnitude of releases at levels occurring in the Canadian environment. Thus "toxic" in the context of CEPA is a function of both the inherent properties of a substance and the amounts, concentrations, or nature of entry of the substance in the Canadian environment.

The assessment process thus provides a framework for making science-based decisions on the effective management of toxic substances that are of concern. The determination of whether or not a substance is "toxic" must be based on sound, scientifically reliable data. Under CEPA, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
(b) constitute or may constitute a danger to the environment on which life depends; or
(c) constitute or may constitute a danger in Canada to human life or health.

Information on risk or hazard evaluation (cont'd)

For substances determined to be "toxic", management options are identified and implemented, in consultation with stakeholders to reduce or eliminate the risks the substances pose to human health or the environment. Management strategies, which integrate socio-economic considerations, may include voluntary controls, process changes, substitutions, economic measures, regulations, guidelines, codes of practice, or a combination of these measures. It should be noted that the designation of a substance as "toxic" does not necessarily mean that controls will be imposed. Such decisions are made in a risk management phase that includes a judicious balancing of the risks and benefits associated with continued use of the substance.

Summary of risk assessment

Health Canada determined from studies that adverse health effects can occur at blood lead levels of 20-30 µg/dL. Furthermore, these studies indicated that:

- significant numbers of Canadian children could have blood lead levels in this range and could therefore be at risk. Results from a study in Toronto in 1982, indicated that 1% of children aged 0-4 years have blood lead concentrations greater than 30 µg/L and 12% greater than 20 µg/L; and
- gasoline lead contributed an estimated 30-35% of the lead in the blood of urban adults. The proportion of gasoline lead in children's blood may range from 30-40%.

Reference to the relevant documentation

Socio-economic Impact Analysis of Lead Phase-down Control Options, Environmental Strategies Directorate, Environmental Protection Service, February 1984.

2.4	**Reasons for the final regulatory action**	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	☑ Yes ☐ 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

The effects of lead exposure include interference in the proper functioning of the human biochemical system that regulates the synthesis of blood and its use in the body; impairment or perturbation of certain metabolic pathways and enzyme systems that involve essential features of certain basic cellular processes and brain functions; interference with the learning and behavioural development among young children and pre-term delivery and low birth weights of infants.

Reference to the relevant documentation

Regulatory Impact Assessment Study for the *Gasoline Regulations*.

Expected effect of the final regulatory action

The emissions of lead particulates to the atmosphere is of particular concern. The largest single source is gasoline lead particulates of small size (less than 1 micrometre in diameter) resulting from the combustion of TEL and TML anti-knock agents. Gasoline lead contributes significantly to the total uptake of lead in urban areas, especially where traffic is heavy.

As a result of the *Gasoline Regulations* (SOR/90-247), it was expected that there would be a reduction of lead emissions that should significantly decrease lead uptake, and consequently, blood lead levels in Canadians. This would reduce the health effects of lead exposure, especially among young children.

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	☐ Yes ☑ No
	If yes, give summary of the known hazards and risks to the environment	
	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**	☑ **Industrial**
	Use or uses prohibited by the final regulatory action	
	All purposes other than those described below must use unleaded gasoline (lead content limited to 5 mg/L).	
	Use or uses that remain allowed	
	The lead content of gasoline for aircraft and high performance competition vehicles is not regulated. Leaded gasoline, which is subject to certain lead content restrictions, is still allowed for the following uses: a) tractors, combines, swathers or any other machinery used in farming. b) boats, or c) trucks whose gross vehicle weight rating is greater than 3 856 kg.	

2.5.2	**Final regulatory action has been taken for the chemical category**	☐ **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		
Exported		
Used		

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

2.7 Other relevant information that may cover:	
2.7.1	Assessment of socio-economic effects of the final regulatory action

Canada has adopted regulations on gasoline since 1973 to limit the concentration of lead in gasoline. Due to health and environmental concerns, the regulations were amended from time to time, always with the intent of further reducing the lead content. In the end, the lead concentration has been decreased according to the following schedule:

- Commencing July 1, 1974, the maximum concentration of elemental lead in gasoline represented as lead-free was limited to 13 mg/L.
- Commencing January 1, 1976, the maximum concentration of lead in gasoline to which lead was added during the production process (leaded gasoline) was limited to 770 mg/L. This restriction did not apply to gasoline for use in aircraft.
- As of January 1, 1987, the maximum concentration of lead in gasoline to which lead was added during the production process (leaded gasoline) was limited to 290 mg/L. Again, this restriction did not apply to gasoline for use in aircraft.
- Since December 1, 1990, the average concentration of lead in leaded gasoline produced in Canada is specified at 26 mg/L, with a maximum concentration limit of 30 mg/L. The maximum concentration for leaded gasoline imported to Canada is limited to 26 mg/L. The utilization of leaded gasoline is restricted to specific uses (see Section 2.5.1). For all other purposes, the lead content in gasoline is limited to 5 mg/L. These restrictions do not apply to gasoline for use in aircraft. They also do not apply until December 31, 2002 to gasoline for use in high performance competition vehicles. These requirements were specified in the *Gasoline Regulations* (SOR/90-247) and subsequent modifications.

The reduction of lead in gasoline to 290 mg/L, effective January 1, 1987, was expected to have the following costs:

- increased refinery capital and operating costs due to increased processing requirements; and,
- decommissioning costs due to the closure and dismantling of lead-additives manufacturing plants.

2.7.1 Assessment of socio-economic effects of the final regulatory action (cont'd)

Those costs were expected to range from $114 million to $452 million (1983 dollars), depending on the assumptions made.

Further, the reduced demand for lead additives was expected to cause a decline in the demand for primary (as opposed to secondary/recycled) refined lead. In 1981, lead additives manufacture accounted for about 6% of total Canadian primary refined lead production. It was forecasted that the production of primary refined lead accounted for by lead additives would decline to 1.5%. Closure of one of the two lead-additives manufacturing plant was therefore projected.

Impact upon employment was also anticipated. Loss of jobs in the lead-additives industry was expected to be greater than increased employment realized in the petroleum refining industry (158 VS 100).

The foreseen allocative benefits produced by the 290 mg/L limit consisted of a reduction of automotive lead emissions with a resulting reduction of the human lead burden. The emission reduction from 1987 to 2006 was estimated at 71 800 tonnes. No monetary value was assigned to human health.

The expected costs from the *Gasoline Regulations* (SOR/90-247) were capital and operating costs for refineries. The *Light Duty Vehicles* (LDV) *Regulations*, effective since 1987, made the use of unleaded fuel mandatory for light duty vehicles. This requirement had greatly accentuated the demand for unleaded gasoline. It was expected that the *Gasoline Regulations* (SOR/90-247) would further increase this demand. It was estimated that the petroleum refining industry had spent about $500 million (1984 dollars) to complete its modernization program to respond to the expected increase in demand for unleaded gasoline as a result of the LDV Regulations. To meet the increase from the *Gasoline Regulations*, it was estimated that the oil refining industry would incur incremental costs in the order of $100 million. Most of this amount was deemed to represent interest payments resulting from advancing the date of completion of refinery modernization programs by two to three years.

Industry estimated that accelerating the elimination of lead additives would increase refineries' cost of production by some $120 million annually as a result of using higher octane blending components and running octane generating processes at higher severity in refineries. The incremental operating cots were, however, expected to decrease as plant modernization and upgrading were completed, and more efficient state-of-the-art refining processes used.

It was estimated that after December 1, 1990, lead emissions from gasoline combustion would be reduced to about 12 tonnes per annum.

The amendment to exempt high performance competition vehicles until 2002 engenders some costs. Sellers and importers have to assume certain costs associated with keeping records. These are estimated to be $12,000 per annum (1994 dollars). It is also believed that vehicle owners had to assume costs associated with obtaining a letter of certification. This cost was determined at $8,000 total (1994 dollars).

On the other hand, the exemption generates benefits to the industry. Some benefits will be felt in terms of local economic spin-offs resulting from continuance of significant racing events in Canada. It is estimated that racing events in Canada in 1996 generated about $44 million (1996 dollars) in direct sales of tickets and fuel. From these direct revenues, it is estimated that the racing sector engenders indirect economic activity between $88 million and $110 million (1996 dollars) each year. The extension of the time limit to 2002 is expected to remove regulatory uncertainty. Overall, the economic impacts estimated by race-sanctioning bodies is an increase of about $2.5 million in direct revenues, $5 million in indirect revenues and 90 jobs.

The time limit for the applications of the amendment will give producers of gasoline the time to develop acceptable unleaded gasoline for use in competition vehicles.

2.7.1 **Assessment of socio-economic effects of the final regulatory action (cont'd)**

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The time limit for the applications of the amendment will give producers of gasoline the time to develop acceptable unleaded gasoline for use in competition vehicles.

2.7.2	**Information on alternatives and their relative risks**

Currently, the methods of meeting the desired octane number in reduced-lead or lead-free gasoline is by increasing the percentage of high-octane hydrocarbons, methanol, ethanol, methyl tertiary butyl ether (MTBE) and methyl cyclopentadienyl manganese tricarbonyl (MMT).

a) Methanol: it has satisfactory combustion qualities and an excellent octane rating, but can be difficult to handle in the normal gasoline distribution system. Methanol can also create vapour pressure problems that require removal of more valuable butane components from gasoline in summer months.
b) Ethanol: it is produced from fermentation of agricultural crops, and is not thought likely to be a competitive source of significant quantities of motor gasoline blending component. It is more stable than methanol in a mixture with hydrocarbons, and is less difficult to handle in normal gasoline distribution systems. In addition, it does not increase the vapour pressure of gasoline to the same extent as methanol.
c) Methyl Tertiary Butyl Ether: it is water-tolerant in the distribution system, and present no problems of stability, volatility or corrosion. Whether or not MTBE will be produced in Canada depends upon the economic evaluation versus other processing alternatives.
d) Methyl Cyclopentadienyl Manganese Tricarbonyl (MMT): its impact on octane is very significantly positive, but the cost of producing octane by the use of MMT is much more than the cost of using lead compounds.

2.7.3	**Relevant additional information**

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Environment Canada Environmental Protection Service Commercial Chemicals Evaluation Branch Chemicals Control Division
Address	Place Vincent Massey Ottawa, Ontario K1A 0H3
Telephone	(819) 994-3648
Telefax	(819) 994-0007
E-mail address	Bernard.Made@ec.gc.ca
Designated National Authority	
Institution	Environment Canada Environmental Protection Service Commercial Chemicals Evaluation Branch
Address	Place Vincent Massey Ottawa, Ontario K1A 0H3
Name of person in charge	John Buccini
Position of person in charge	Director
Telephone	(819) 997-1499
Telefax	(819) 953-4396
E-mail address	John.Buccini@ec.gc.ca

Date, signature of DNA and official seal: John Buccini 17/05/2000

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: EUROPEAN COMMUNITY
(Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and United Kingdom)

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	**Tetramethyl lead**
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	Chemical Abstract Name: Plumbane, tetramethyl-
1.3	**Trade names and names of preparations**	Lead tetramethyl TML Tetramethyl plumbane
1.4	**Code numbers**	
1.4.1	**CAS number**	75-74-1
1.4.2	**Harmonized System Customs Code**	3811 11 90
1.4.3	**Other numbers (specify the numbering system)**	UN: 1649 EC: 200-897-0

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
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11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.5	**Indication regarding previous notification on this chemical, if any**
1.5.1	☒ This is a first time notification of final regulatory action on this chemical.
1.5.2	❑ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ❑ 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**
UN Hazard class (Pack group)	6.1 (I)
Classification in the EC in accordance with Directive 67/548/EEC (as amended by Commission Directive 98/98/EC, adapting to technical progress for the 25th time Council Directive 67/548/EC)	T+ (very toxic) N (dangerous for the environment). R61 May cause harm to the unborn child. R26/27/28 Very toxic by inhalation, in contact with skin and if swallowed. R33 Danger of cumulative effects. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effect in the aquatic environment R62 Possible risk of impaired fertility.
Other classification systems	**Hazard class**

1.7 Use or uses of the chemical	
1.7.1	❑ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	No known use.
1.7.2	☒ **Industrial**
	Describe the industrial uses of the chemical in your country:
	Tetramethyl lead (TML) was used in petrol as a motor anti-knock additive. It was added to fuels to raise its octane rating so as to allow for higher compression ratios without the damaging effects of knock; also called pre-detonation, pre-ignition. No other applications are known.

1.8 Properties

1.8.1 Description of physico-chemical properties of the chemical

Formula	$Pb(CH_3)_4$
Molecular weight	267.3 g/mol
Appearance	Colourless liquid
Melting point	-27.5 °C
Boiling point	110 °C at 1.33 kPa
Flash point	37.7 °C
Relevant density	1.99 at 20°C
Vapor pressure	3.0 kPa at 20°C (22 mmHg at 25 °C)
Solubility in water	Insoluble
Solubility in organic solvents	Slightly soluble in benzene, ethyl alcohol and ethyl ether
Partition coefficient	Soluble lipid of high volatility.
Photostability	Decomposed by ultraviolet light

- International Programme on Chemical Safety, 1977. Environmental Health Criteria No.3: Lead. IPCS/ WHO, Geneva. (available at: http://www.inchem.org/documents/ehc/ehc/ehc003.htm)
- International Chemical Safety Cards (ICSCs), peer-reviewed: March 1995 (available at http://www.inchem.org/documents/icsc/icsc/eics0200.htm)
- International Programme on Chemical Safety, 1991. Poison Information Monograph (PIM 302): Organic, Lead. Geneva. (available at: http://www.inchem.org/documents/pims/chemical/organlea.htm)

1.8.2 Description of toxicological properties of the chemical

Clinical effects

Poisoning by organic lead compounds causes mainly acute effects on the central nervous system. Ingestion is not a significant occupational hazard. Respiratory and percutaneous absorption are the main routes of exposure. Mild manifestations are: insomnia and nervous excitation, nausea, vomiting, associated with tremor, hyperreflexia, muscular contractions, bradycardia, arterial hypertension, and hypothermia. Most severe cases present episodes of complete disorientation, mania, ataxia, hallucinations, exaggerated muscular activity, and violent convulsive seizures, which may terminate in coma and death. In severe cases, muscle, hepatic and renal damage may occur. The clinical picture may persist for days and weeks.

Metabolism

- TML is dealkylated in the liver to trimethyllead. The trimethyl lead concentrations then fall only slowly.

Toxicological properties:

- Very acutely toxic by oral, dermal and inhalation route:
  - Lowest oral toxic dose (rat): 112 mg/kg
  - Lowest oral toxic dose (rabbit): 24 mg/kg
  - LD_{50} (rat, oral): 105 mg/kg
  - LC_{50} (rat, inhalation): 8.87 mg/L
  - Lowest dermal lethal dose (rabbit): 3391 mg/kg

Chronic effects

Repeated exposure causes lead accumulation, which can cause long-term adverse effects.

Mutagenicity

TML did not induce mutation in bacteria.

Carcinogenicity

The evidence for carcinogenicity is inadequate (IARC, 1987).

Nervous system

Tetramethyl lead injected into rats in overtly neurotoxic doses did not depress ability to learn a simple task.

	• International Programme on Chemical Safety, 1977. Environmental Health Criteria No.3: Lead., IPCS/ WHO, Geneva. (available at: http://www.inchem.org/documents/ehc/ehc/ehc003.htm) • International Programme on Chemical Safety, 1991. Poison Information Monograph (PIM 302): Organic, Lead. Geneva. (available at: http://www.inchem.org/documents/pims/chemical/organlea.htm)

1.8.3	**Description of ecotoxicological properties of the chemical**	
	Fate and behaviour • TEL is volatile and poorly soluble in water. However, trialkylated compounds are formed in the environment by the breakdown of tetraalkylleads. These are less volatile and more readily soluble in water. • Lead remains in the environment and can cause long-term adverse effects. **Ecotoxicology** • In micro-organisms, tetraalkyllead becomes toxic by decomposition into the ionic trialkyllead. • Trialkyllead compounds produced effects on starlings dosed at 0.2 mg/day. 2 mg/day was invariably fatal. • Lead concentrations were found to be highest in soils and organisms close to roads where traffic density is high. The lead measured is inorganic and derives almost exclusively from alkyllead compounds added to petrol.	
	• International Programme on Chemical Safety, 1989. Environmental Health Criteria No.85: Lead – Environmental Aspects, IPCS/ WHO, Geneva. (available at: http://www.inchem.org/documents/ehc/ehc/ehc85.htm).	

PART II: FINAL REGULATORY ACTION

2.	**FINAL REGULATORY ACTION**	
2.1	**The chemical is:** ❑ **banned** **OR** ☒ **severely restricted**	

2.2	**Information specific to the final regulatory action**	
2.2.1	**Summary of the final regulatory action**	
	As from 1 January 2000, the placing on the market of leaded petrol for vehicles was banned.	
2.2.2	**Reference to the regulatory document**	
	Council Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC (Official Journal of the European Communities L350 of 28/12/1998, p. 58) (copy attached; available at http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_350/l_35019981228fr00580067.pdf). Other relevant regulatory actions: Council Directive 78/611/EEC of 29 June 1978 on the approximation of the laws of the Member States concerning the lead content of petrol (Official Journal of the European Communities L197 of 22/07/1978, p. 19), Council Directive 85/210/EEC of 20 March 1985 on the approximation of the laws of the Member States concerning the lead content of petrol (Official Journal of the European Communities L096 of 03/04/1985, p. 25), Council Directive 87/416/EEC of 21 July 1987 amending Directive 85/210/EEC on the approximation of the laws of the Member States concerning the lead content of petrol (Official Journal of the European Communities L225 of 13/08/1987, p. 33)	
2.2.3	**Date of entry into force of the final regulatory action**	

	The regulatory action entered into force on the day of its publication in the Official Journal of the European Communities (*i.e.* 28/12/1998). The Member States of the European Community were required to apply the measures as from 1 January 2000.

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	☒ **Yes** ❑ **No**
	If yes, give information on such evaluation	

Council Directive 98/70/EC was the latest in a series of measures introducing progressively more stringent controls on the use of lead in petrol in recognition of the concerns common to all industrialised countries about the adverse effects on public health attributed to the emission of lead in the exhaust gas of vehicles.

Council Directive 78/611/EEC of 29 June 1978 on the approximation of the laws of the Member States concerning the lead content of petrol was adopted with a view to limiting the elemental lead level to a maximum of 0.40 g/L. In 1985 (Council Directive 85/210/EEC of 20 March 1985) and 1987 (Council Directive 87/416/EEC of 21 July 1987), the maximum permitted elemental lead level was reduced to 0.15 g/L and Member States allowed to ban leaded petrol altogether.

It is well known that lead is a toxic compound which accumulates in organisms thus causing severe damage, in particular to unborn life. Humans are exposed directly through inhalation of lead emitted into the air, which also acts to transport lead into other human exposure media, including dust, soil, food and water. Since the beginning of the 1970s, it has been recognised that the combustion of alkyllead additives in motor fuels accounts for the major part of all lead emissions and that lead blood levels increase with traffic density. At the same time, it became evident that lead concentrations steadily increased in various environmental compartments such as air and soil in close connection with the increase of motor vehicle traffic.

Blood lead sampling is one of the methods most widely used to assess human risk from exposure to lead. In 1977, the European Community adopted Council Directive 77/312/EEC of 29 March 1977 on biological screening of the population for lead. In each Member State, 50 or more blood lead samples had to be analysed per million inhabitants. In 1982 (Council Directive 82/884/EEC of 3 December 1982), a limit value was set at 2 $\mu g/m^3$ of lead in the ambient air in terms of annual average.

In several Member States where blood analyses were carried out in the 70s and the 80s, it was shown that the decreases in air concentration due to restrictions on leaded fuel was related to the diminution in blood lead concentration levels. For example,

- In Belgium, the average blood lead levels for various segments of the population steadily declined during the 1980s. The decline has been, in part, attributed to the reduction in the permissible level of lead in petrol.
- In Finland, average blood lead levels decreased from 11 µg/dL to 2.8 µg/dL in the period 1975-1992. In Helsinki, the average blood lead level of children decreased from 4.6 to 3.0 µg/dL between 1983 and 1988; in the same period, car exhaust emissions of lead decreased by 75 % in the capital area.
- In Germany, various studies indicate that average blood lead levels in school children and adults declined since 1975. The reductions are believed to be a result of the decrease of lead in air, attributed to the phasing out of lead in petrol. Germany provided. See annex 1 summarising indicative examples of such studies.
- In Sweden, average blood lead levels of children living near smelters or in rural or urban environments have been declining since 1978, to below 5 µg/dl in 1988. Average blood lead levels for the general population in Stockholm also fell to below 6 µg/dl by 1984. The reduction in the permissible level of lead in petrol was considered as one of the important factors contributing to the decline in blood lead levels. (See Annex 2 for an example of such studies).
- In United Kingdom, the average blood lead concentrations for children, as well as adult females and males, also declined steadily during the mid-1980s, with the average levels being well below the 25 µg/dL level of concern. According to the UK Department of the Environment, the reduction in the permissible level of lead in petrol during 1985 appeared to contribute slightly to the decrease of lead in the body burden of children.

Reference to the relevant documentation

- OCDE/GD(93)67 Risk reduction monograph No. 1 Lead background and national experience with reducing risk organisation for economic co-operation and development Paris 1993. (available at www.oecd.org-pdf-M00034000-M00034181.pdf)
- German Ministry of Interior: Die Bliebelastung des Menschen und ihre Bedeutung für die Gesundheit – Umweltbrief Nr. 15, 19-39, Bonn 1976. (copy attached).

2.4	**Reasons for the final regulatory action**	
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	☒ **Yes** ❑ **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	
	TML has been assessed to be very acutely toxic by inhalation, in contact with skin and if swallowed. It may cause harm to the unborn child, and a possible risk of impaired fertility has been identified. In addition, TML is eliminated only very slowly and there is a danger of cumulative effects. Occupational exposure to alkyllead compounds, either by inhalation or by absorption through the skin, poses particular risks. Overexposure of the general population to alkyllead may also occur during car tank refill. Moreover, the combustion of alkyllead additive in motor fuels accounted for the major part of all lead emissions, which is also known to produce adverse effects on the health of the general population.	
	Reference to the relevant documentation	
	OCDE/GD(93)67 Risk reduction monograph No. 1 Lead background and national experience with reducing risk organisation for economic co-operation and development Paris 1993. International Programme on Chemical Safety, 1977. Environmental Health Criteria No.3: Lead. IPCS/ WHO, Geneva. (available at: http://www.inchem.org/documents/ehc/ehc/ehc003.htm).	
	Expected effect of the final regulatory action	
	Prevention of the above listed health effects for workers and the general public.	

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	❑ **Yes** ☒ **No**
	If yes, give summary of the known hazards and risks to the environment	
	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**	☒ **Industrial**
	Use or uses prohibited by the final regulatory action	
	All uses as an anti- knock agent in vehicles.	
	Use or uses that remain allowed	
	The latest regulatory action provided for certain limited derogations. Member States may be allowed to continue to permit the marketing of leaded petrol containing not more than 0.15 g/L lead within their territory until 1 January 2005, provided that it can be demonstrated that a ban would result in severe socio-economic problems or would not lead to overall environmental or health benefits. Member States may also allow a derogation for small quantities of leaded petrol containing not more than 0.15 g/L lead, up to a maximum of 0.5% of total sales, for collectors' old cars. The lead content of petrol for aircraft is not covered by the regulatory action.	
2.5.2	**Final regulatory action has been taken for the chemical category**	❑ **Pesticide**
	Formulation(s) and use or uses prohibited by the final regulatory action	
	Not relevant.	

	Formulation(s) and use or uses that remain allowed
	Not relevant.

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (kT)	**Year**
Produced	50.30*	1993
	37.90*	1998
Imported	Not available.	
Exported	During the 90s, most of the European production was exported to countries outside EC.	
Used	8.12*	1995

* Total lead additives (*i.e.* TEL and TML) in EC (Source: TNO (2001), for European Commission, "Risk to health and the environment related to the use of lead in products").

2.6	**Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions**
	General health problems in all states where the substance is used. Protection of workers and the general public.

2.7	**Other relevant information that may cover:**
2.7.1	**Assessment of socio-economic effects of the final regulatory action**
2.7.2	**Information on alternatives and their relative risks**
2.7.3	**Relevant additional information**

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium
Telephone	+322 299 48 60
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E-mail address	klaus.berend@cec.eu.int
Designated National Authority	
Institution	DG Environment European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium

Name of person in charge	Klaus BEREND
Position of person in charge	Administrator
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Date, signature of DNA and official seal: _____