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PROPOSED RISK MANAGEMENT APPROACH

for

Ethanol, 2-chloro-, phosphate (3:1)
or
Tris (2-chloroethyl) phosphate (TCEP)

Chemical Abstracts Service Registry Number (CAS RN):
115-96-8

Environment Canada
Health Canada

August 2009

Canada

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This proposed risk management approach document builds on the previously released risk management scope document for Ethanol, 2-chloro-, phosphate (3:1), and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

1. ISSUE

1.1 Categorization and the Challenge to Industry and Other Interested Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the Domestic Substances List (DSL). Categorization involves identifying those substances on the DSL that a) are considered to be persistent (P) and/or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations*, and "inherently toxic" (iT) to humans or other organisms; or b) present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets the definition of "toxic" set out in section 64 of the Act.

In December 2006, the Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comment, profiles of batches containing 15 to 30 high-priority substances. New batches are released for comment every three months.

In addition, the information-gathering authority in section 71 of CEPA 1999 is being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge will be used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance Ethanol, 2-chloro-, phosphate (3:1), Chemical Abstracts Service Registry Number (CAS RN)[1] 115-96-8, referred to throughout this document as "TCEP," is included in Batch 5 of the Challenge under the Chemicals Management Plan.

[1] CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior written permission of the American Chemical Society.

1.2 Final Screening Assessment Report Conclusion for Ethanol, 2-chloro-, phosphate (3:1)

A notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for Ethanol, 2-chloro-, phosphate (3:1) on August 22, 2009, under subsection 77(6) of CEPA 1999.

Based on the information presented in this screening assessment, it is concluded that TCEP is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

On the basis of carcinogenicity of TCEP, for which there may be a probability of harm at any level of exposure, as well as the potential inadequacy of the margins between estimated exposures to TCEP and critical effect levels, it is concluded that TCEP is a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

It is therefore concluded that TCEP does not meet the criteria in paragraphs 64(*a*) and 64(*b*) of CEPA 1999, but it does meet the criterion in paragraph 64 (*c*) of CEPA 1999. Additionally, TCEP meets the criteria for persistence but does not meet the criteria for bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999.

For further information on the final screening assessment report conclusion for TCEP, refer to the final screening assessment report, available at http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_5_e.html.

1.3 Proposed Measure

As a result of a screening assessment of a substance under section 74 of CEPA 1999, the substance may be found to meet one or more of the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act. Under certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances or to recommend the implementation of virtual elimination (or both). In this case, the Ministers proposed to recommend the addition of TCEP to the List of Toxic Substances in Schedule 1. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

The final screening assessment report did not conclude that TCEP meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, TCEP will not be subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach, to prevent or minimize its release into the environment.

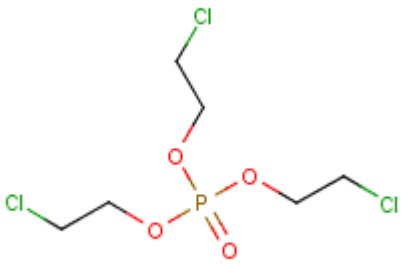
2. BACKGROUND

2.1 Substance Information

TCEP is part of the chemical grouping discrete organics and the chemical sub-grouping alkyl phosphate esters.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular weight for TCEP.

Table 1. Substance identity of TCEP

Chemical Abstracts Service Registry Number (CAS RN)	115-96-8
DSL name	Ethanol, 2-chloro-, phosphate (3:1)
Inventory names[2]	*Ethanol, 2-chloro-, phosphate* (PICCS) *Ethanol, 2-chloro-, phosphate (3:1)* (AICS, ASIA-PAC, ENCS, PICCS, SWISS, TSCA) *Tris(2-chloroethyl) phosphate* (EINECS, PICCS) *Tri(2-chloroethyl)phosphate* (ECL)
Other names	*3CF; Amgard TCEP; CEF; Celluflex CEF; CLP; Disflamoll TCA; Fyrol CEF; Fyrol CF; Genomoll P; Niax 3CF; Niax Flame; NSC 3213; Retardant 3CF; TCEP; Tri(β-chloroethyl) phosphate; Tri(2-chloroethyl) phosphate; Tri(chloroethyl) phosphate; Tris(β-chloroethyl) phosphate; Tris(2-chloroethyl) orthophosphate; Tris(chloroethyl) phosphate*
Chemical group	Discrete organics
Chemical subgroup	Alkyl phosphate esters
Chemical formula	$C_6H_{12}Cl_3O_4P$
Chemical structure	
SMILES	O=P(OCCCl)(OCCCl)OCCCl
Molecular weight	285.49 g/mol

[2] **Source:** National Chemical Inventories (NCI) 2008: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Combined Inventories from the Asia-Pacific Region); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); PICCS (Philippine Inventory of Chemicals and Chemical Substances); SWISS (Inventory of Notified New Substances; Giftliste 1); TSCA (Toxic Substances Control Act Chemical Substance Inventory).

3. WHY WE NEED ACTION

3.1 Characterization of Risk

Based principally on the weight-of-evidence assessment of the European Commission (1996, 1999), an important effect of TCEP exposure is carcinogenicity. Due to the mixed results in the limited *in vivo* and *in vitro* genotoxicity assays in mammalian cells and the range of tumours observed in multiple species of experimental animals for which the modes of induction have not been elucidated, it cannot be precluded that TCEP induces tumours via a mode of action involving direct interaction with genetic material.

With respect to non-cancer effects, the lowest-observed-(adverse)-effect level, or LO(A)EL, for short-term and subchronic exposures was 44 mg/ kg-bw per day based on increased relative liver and kidney weights in a 16-week oral rat study. Renal tubular hyperplasia along with renal tubule and thyroid tumours were also observed at TCEP concentrations of 44 mg/kg-bw per day, the lowest dose tested, in the 2-year study in rats.

Reproductive toxicity has also been observed in several oral studies in rats and mice and in inhalation studies in mice. The oral LOAEL for reproductive effects was 700 mg/kg-bw/day in mice; however, the oral reproductive LOAEL for rats could not be determined due to insufficient information to enable characterization of dose-response in the critical analyses (rats were administered TCEP levels of 0, 22, 88, or 175 mg/kg-bw per day). In the only study in which the toxicity of repeated inhalation exposure to TCEP was examined, testicular toxicity was noted in mice at 0.5 mg/m^3 or more for 4 months.

Comparison of the critical effect level for repeated dosing via the oral route (i.e., 44 mg/kg-bw per day, at which non-cancer effects and significant increases in tumours were observed) and the upper-bounding estimate of daily intake of TCEP by the general population via environmental media in Canada (0.5 µg/kg-bw per day) results in a large margin of exposure of approximately 88 000. If the upper-bounding estimate of dermal exposure to household dust is considered, the resulting margin of exposure would be in the same order of magnitude. Comparison of the only identified effect level for reproductive effects via inhalation (0.5 mg/m^3) and the conservative upper-bounding exposure estimate via inhalation for TCEP in indoor air in private dwellings (0.38 $\mu g/m^3$), results in a margin of exposure of approximately 1 300, while comparison with the average indoor air concentration in these homes (0.02 $\mu g/m^3$), results in a margin of exposure of 25 000. However, based on available data, general population exposures via inhalation of indoor air from schools, daycare centres, offices, transportation vehicles and other locations may be higher and would result in lower margins of exposure than those presented for residential settings. Exposure to TCEP may also occur through the use of consumer products. Based on product scenario modelling, the highest consumer product exposure estimates were based on infants (0 to 6 months) and toddlers (6 months to 4 years old) mouthing polyurethane foam containing TCEP at a concentration equivalent to TCEP's water solubility and resulted in a daily estimated exposure of 0.04 mg/kg-bw per day for infants and 0.02 mg/kg-bw per day for toddlers. Comparison of these conservative estimates with the critical effect level for oral exposure (44 mg/kg-bw per day) results in margins of exposure of 1 100 for infants and 2 200 for toddlers (who may have greater accessibility than infants).

The conservative approach was used in deriving conclusions of the screening assessment including due consideration of the uncertainties and overestimates for both the toxicological and exposure results respectively.

3.2 Exposure of Children

The predominant sources of exposure to TCEP occur from indoor air and dust. Children may be exposed through contact with contaminated house dust via the inhalation of TCEP emitted from electronics (especially televisions). These exposures are secondary to the mouthing of polyurethane foam cushioning by children. In the European Union's draft assessment on TCEP, children mouthing a foam toy had the highest exposure estimates. The toy in question has since been recalled and removed from the European Union marketplace. It is unknown whether or not TCEP is found in children's toys in the Canadian marketplace. While exposures from TCEP through food sources may occur, it is considered a minor contribution to overall exposure.

4. CURRENT USES AND INDUSTRIAL SECTORS

Based on a survey conducted under section 71 of CEPA 1999, no Canadian companies reported manufacturing TCEP in a quantity greater than or equal to the 100-kg reporting threshold in 2006. However, results from the same survey and from voluntary data submitted by industry indicate that the total quantity of TCEP imported into Canada in 2006 was in the range of 100 000 to 1 000 000 kg (Environment Canada 2008a, 2008b).

According to uses reported under section 71, TCEP was used as an additive flame retardant in polyurethane foams used in automotive cushioning applications (Environment Canada 2008a, 2008b). TCEP may also be found as a component of industrial roofing construction products (Plastics Technology 2009) and as a flame-retardant plasticizer (Marklund et al. 2005). It has known uses in adhesives.

Globally, TCEP is used primarily as a plasticizer and viscosity regulator with flame-retardant properties for polyurethanes, polyester resins, polyacrylates, polyvinyl chloride, cellulose derivatives and other polymers (IARC 1990; EURAR 2006). TCEP has been used in both rigid and flexible polyurethane foams found in roofing insulation and upholstered furniture. TCEP has also been used in the textile industry (e.g., back-coatings for carpets); in the manufacture of cars, railway cars and aircraft; in polyvinyl chloride compounds; in flame-resistant paints and varnishes, epoxy, phenolic and amino resins; in wood resin composites such as particleboards; and in adhesives and lacquers (IARC 1990; IPCS 1998; EURAR 2006; OECD 2006). Flame retardants are also used for aeronautical purposes to surpress fires in aircraft (American Fire Safety Council 2005).

In the European Union, TCEP was historically used in the production of rigid and flexible polyurethane foams and systems, but such usage has been on the decline since the 1980s and has primarily been substituted by other flame retardants (IPCS 1998; EURAR 2006). TCEP is not recommended for use as a flame retardant in fabrics meant for apparel (IARC 1990; IPCS 1998).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

Information reported under section 71 of CEPA 1999 indicated that 7 kg of TCEP were released into water sanitary sewer systems in 2006 (Environment Canada 2008a). TCEP has also been found in some municipally supplied sources of Canadian drinking water (Canada 2009).

Releases of TCEP are not currently reportable under the National Pollutant Release Inventory (NPRI 2006) or the U.S. Toxics Release Inventory (TRI 2006).

TCEP may be released during formulation and processing mainly into wastewater and, to a lesser extent, exhaust gases (OECD 2006). Consumers may also release TCEP into the environment during use of products containing the substance and when disposing these products in landfills. Significant leaching from landfills is possible as a result of TCEP's high water solubility (OECD 2006). TCEP has been found in various water systems and landfill leachate (Ishikawa et al. 1985; Yasuhara 1994; Scott et al. 1996; IPCS 1998; Yasuhara et al. 1999; Fries and Püttmann 2003; Andresen et al. 2004).

5.2 Exposure Sources

TCEP does not occur naturally in the environment. This substance is produced by reacting phosphorus oxychloride with ethylene oxide and requires subsequent purification (IARC 1990; IPCS 1998).

The predominant sources of exposure to TCEP occur from indoor air and dust, which is secondary to releases of TCEP from products and materials used in the home and which may include polyurethane foam (PUF) in furniture; electronic products (e.g., televisions and computers); adhesives; non-apparel textiles; upholstery; the back-coating of carpets; rubber and plastics; and paints and varnishes.

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

No Canadian risk management actions specifically related to TCEP were identified. Provincially, the Province of British Columbia has standards for rural, urban and industrial soil levels, including a standard for drinking water.

6.2 Existing International Risk Management

TCEP is a California proposition 65 listed chemical and may also be found on the U.S. EPA's *Toxic Substances Control Act* (TSCA) section 8(b) chemical inventory.

TCEP is listed on the environmental hazard list of the Nordic Council of Ministers as being dangerous to the environment.

TCEP has been identified as an OECD HPV (High Production Volume) chemical (OECD 2003) and as a U.S. HPV chemical (US EPA 1990).

Australia's State of Queensland Public Health Regulation, "2005 Schedule 3B Queensland Consolidated Regulations," has a standard of 1 g/L TCEP in recycled water supplied for drinking purposes.

Germany proposed indoor air guideline I for TCEP of 0.005 mg/m^3 or 5 $\mu g/m^3$(Sagunski and Rosskamp 2002).

Germany proposed indoor air guideline II for TCEP of 0.05 mg/m^3 or 50 $\mu g/m^3$(Sagunski and Rosskamp 2002).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

All commercial TCEP is produced by the reaction of phosphorus oxychloride with ethylene oxide followed by purification.

Production of TCEP has been in decline over the past two decades, as its use in rigid and flexible polyurethane foams and systems has been substituted by other flame retardants.

In Europe, TCEP, CAS RN 115-96-8, is no longer being manufactured for use in foam applications and has been replaced by Tris (1-chloro-2-propyl) phosphate (TCPP), CAS RN 13674-84-5. TCPP is a mixture of four isomers. In Canada, TCPP has not yet been evaluated in an assessment to determine whether it meets the criteria under section 64 of CEPA 1999. TCPP is a medium-priority substance for assessment under the Chemicals Management Plan.

The European Union draft risk assessment reports that TCEP is no longer produced in Europe (referring to countries before EU enlargement on May 1, 2004) and that processing has been reduced. TCEP and TCEP-related products, however, are still marketed in the European Union (EURAR 2006).

Despite no production of TCEP in the European Union for 2001–2002, three companies reported importing approximately 1150 tonnes of TCEP into the EU, partially from Russia and Poland. In

the context of the European Union risk assessment, Russia and Poland are considered to be outside the EU. As 143 tonnes were subsequently exported, the total EU tonnage is estimated at 1007 tonnes per annum. This value is used in the calculation of environmental exposure in the European Union risk assessment (EURAR 2006).

In 2005, Germany—the European Union country that reports on risk assessment—had received voluntary data from a new EU member state reporting production of 300–500 tonnes for 2004. It was further communicated that exports were about 300–400 tonnes in 2004. Despite this data, the EU risk assessment still views the total EU tonnage of 1007 tonnes per year as the key value (EURAR 2006).

7.2 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

8. PROPOSED OBJECTIVES

8.1 Human Health Objective

The proposed human health objective for TCEP is to reduce exposures to TCEP to the extent practicable, as it cannot be precluded based on the currently available evidence that it is not a non-threshold carcinogen.

8.2 Risk Management Objective

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s). The proposed risk management objective for TCEP is to reduce exposures to TCEP by eliminating it from products in the home.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Approach

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*,[3] and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management approach was selected using a consistent approach, and took into consideration the information that was received through the Challenge and other information available at the time.

The predominant sources of exposure to TCEP occur from indoor air and dust, which is secondary to releases of TCEP from products and materials used in the home and which may include polyurethane foam (PUF) in furniture; electronic products (e.g., televisions and computers); adhesives; non-apparel textiles; upholstery; the back-coating of carpets; rubber and plastics; and paints and varnishes. The risk management being considered is to prohibit the use of TCEP in these products and materials. The final extent of this prohibition will be determined upon further consultation and discussion with stakeholders.

9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions, including prohibition, in relation to TCEP will be published in the *Canada Gazette,* Part I, no later than September 2011, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope for TCEP, which summarized the proposed risk management under consideration at that time, was published on February 21, 2009. Industry and other interested stakeholders were invited to submit comments on the risk management scope during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

Comments on the risk management approach will be considered after October 21, 2009, once the 60-day comment period has closed.

The primary stakeholders include

- the flexible and rigid polyurethane foam manufacturing industry;
- Canadian Vehicle Manufacturers Association;
- the aircraft manufacturing industry;
- upholstered furniture manufacturers;

[3] Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal."

- electronic manufacturers;
- Canadian Toy Association and the Children's Safety Association of Canada;
- non-governmental organizations; and
- all interested parties, including Health Canada and Environment Canada

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach	August 22, 2009 to October 21, 2009
Response to comments on the risk management approach	At time of publication of proposed instrument
Consultation on the draft regulation or instrument	Fall-winter 2009
Publication of the proposed regulation or instrument	No later than August 2011
Formal public comment period on the proposed regulation or instrument	No later than fall 2011
Publication of the final regulation or instrument	No later than February 2013

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to October 21, 2009, since the risk management of TCEP will be moving forward after this date. During the development of regulations, instrument(s) and/or tool(s), there will be opportunities for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division
Gatineau QC K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 819-953-7155
Email: Existing.Substances.Existantes@ec.gc.ca

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