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CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

## Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999

P.C. 2011-742 June 23, 2011

Whereas, pursuant to subsection 332(1) ([see footnote a](#)) of the *Canadian Environmental Protection Act, 1999* ([see footnote b](#)), the Minister of the Environment published in the *Canada Gazette*, Part I, on October 3, 2009, a copy of the proposed *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999*, substantially in the form set out in the annexed Order, and persons were given an opportunity to file comments with respect to the proposed Order or to file a notice of objection requesting that a board of review be established and stating the reasons for the objection;

And whereas, pursuant to subsection 90(1) of that Act, the Governor in Council is satisfied that the substances set out in the annexed Order are toxic substances;

Therefore, His Excellency the Governor General in Council, on the recommendation of the Minister of the Environment and the Minister of Health, pursuant to subsection 90(1) of the *Canadian Environmental Protection Act, 1999* ([see footnote c](#)), hereby makes the annexed *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999*.

### ORDER ADDING TOXIC SUBSTANCES TO SCHEDULE 1 TO THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

#### AMENDMENT

1. Schedule 1 to the *Canadian Environmental Protection Act, 1999* ([see footnote 1](#)) is amended by adding the following in numerical order:

113. Tributyltins, which contain the grouping  $(C_4H_9)_3Sn$

114. Tetrabutyltins, which have the molecular formula  $(C_4H_9)_4Sn$

#### COMING INTO FORCE

2. This Order comes into force on the day on which it is registered.

#### REGULATORY IMPACT ANALYSIS STATEMENT

*(This statement is not part of the Order.)*

#### **Issue and objectives**

Canadians depend on chemical substances that are used in the manufacturing of hundreds of goods, from medicines to computers, fabrics and fuels. Unfortunately, some chemical substances can negatively affect human health and the environment when entering the environment in a certain quantity or concentration or under certain conditions. Scientific assessments of the impact of human and environmental exposure have determined that a number of these substances constitute or may constitute a danger to human health and/or the environment or its biological diversity under the criteria set out under section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

The *Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999* (hereinafter referred to as the Order), made pursuant to subsection 90(1) of CEPA 1999, adds tributyltins

and tetrabutyltins, two classes of organotin substances, to the List of Toxic Substances in Schedule 1 to CEPA 1999.

This addition enables the development of instruments including regulations for these substances under CEPA 1999. The Ministers may choose to develop regulatory or non-regulatory instruments to manage environmental risks posed by these substances.

## ***Description and rationale***

### Background

Organotins are primarily used as stabilizers of polyvinyl chloride (PVC), a type of plastic, and in pesticidal formulations. Organotins are also used as additives for stabilizing lubricating oils, hydrogen peroxide and polyolefins. Based on the most recent data available, some organotins (including tributyltins and tetrabutyltins) are currently in use in Canada.

“Non-pesticidal organotin compounds” were assessed under the Priority Substances List (PSL) in 1993 and were concluded not to be toxic to the environment. At that time, there was insufficient information available to conclude on the risk to human health. Subsequently, Health Canada completed, in May 2003, a PSL follow-up report on organotins, which concluded that non-pesticidal organotins did not constitute a danger to human health as set out in paragraph 64(c) of CEPA 1999.

Between August 1994 and March 2000, the Minister of the Environment received notifications for nine “new” organotin substances pursuant to subsection 26(2) of the *Canadian Environmental Protection Act* ([see footnote 2](#)), or subsection 81(1) of the *Canadian Environmental Protection Act, 1999*. These new and transitional substances were assessed via the New Substances Program to determine whether they are toxic or capable of becoming toxic under the criteria set out under section 64 of CEPA 1999, that is to say whether the substance is entering or may enter 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;
- constitute or may constitute a danger to the environment on which life depends; or
- constitute or may constitute a danger in Canada to human life or health.

The assessment report, under the New Substances Program, concluded that these nine substances notified as “new” are suspected to meet the criterion set out in paragraph 64(a) of CEPA 1999.

Furthermore, the Existing Substances Program conducted a follow-up ecological assessment, under section 68 of the *Canadian Environmental Protection Act, 1999*, to determine if the conclusions reached for the nine organotins notified as new substances would also apply to other organotins substances on Canada’s *Domestic Substances List*.

The follow-up ecological assessment conducted on non-pesticidal organotins covered the following classes: monomethyltins, monobutyltins, monoocetylins, dimethyltins, dibutyltins, dioctyltins, tributyltins, triphenyltins, tetraphenyltin and tetrabutyltins (the latter two are precursors to triphenyltin and tributyltins, respectively).

The follow-up ecological assessment, under the Existing Substances Program, concluded that

- mono- and dimethyltins, butyltins and octyltins, as well as fluorotriphenyltin (triphenyltins) and tetraphenyltin, do not meet the criteria set out in section 64 of CEPA 1999; and
- tributyltins and tetrabutyltins meet the criterion under paragraph 64(a) of CEPA 1999; and
- tributyltins meet the criteria for persistence and bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations*.

Non-pesticidal tributyltins are not used in Canada; however, they may be found as an impurity in tetrabutyltin (up to 20%) and in mono- and dibutyltin compounds (less than 1%). Mono- and dibutyltins are primarily used in Canada as tin stabilizers in polyvinyl chloride (PVC) processing, but are also used in lesser amounts for coatings for glass and as catalysts. Tetrabutyltin is used as a raw material for the production of monobutyltins and dibutyltins compounds in Canada.

Internationally, the European Union (EU) has adopted a decision to prohibit, as of July 1, 2010, the use of tri-organotin compounds in articles, or part thereof, where the concentration is greater than the

equivalent of 0.1% by weight of tin. Additionally, the International Maritime Organization (IMO) has adopted an International Convention on the Control of Harmful Anti-fouling Systems on Ships, which came into force in September 2008. The Convention prohibits the use of harmful organotins, including tributyltins, in anti-fouling paints used on ships and establishes a mechanism to prevent the potential future use of other harmful substances in anti-fouling systems. No risk management actions for tetrabutyltin have been proposed by other countries at this time.

Environmental releases of organotins are expected to occur mostly to water.

Tributyltins are harmful to many aquatic organisms at low concentrations. They are present in the environment as a result of human activity. They have been shown to impose male sexual characteristics on females of some marine invertebrates and appear to have the potential to induce sex reversal in some marine fish. Estimated and measured concentrations of tributyltins in some locations in Canada are high enough to cause adverse effects in sensitive organisms.

Tetrabutyltins can be harmful to sensitive aquatic organisms at low concentrations. There is further concern for these substances because they can break down to tributyltins. In addition, commercial grades of tetrabutyltins contain up to 20% of tributyltins as an impurity.

Tributyltins and tetrabutyltins are predominantly anthropogenic and were found to be entering, or have the possibility of 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. Therefore, tributyltins and tetrabutyltins are added to Schedule 1 to CEPA 1999.

In addition, the available data regarding persistence and bioaccumulation indicates that tributyltins meet the criteria set out in the *Persistence and Bioaccumulation Regulations*, under CEPA 1999. Tributyltins thus meet the criteria for Track 1 substances, as defined in the *Toxic Substances Management Policy*.

The full assessment report may be obtained from the Chemical Substances Web site at [www.chemicalsubstances.gc.ca](http://www.chemicalsubstances.gc.ca) or from the Program Development and Engagement Division, Environment Canada, Gatineau, Quebec K1A 0H3; 819-953-7155 (fax); or by email at [substances@ec.gc.ca](mailto:substances@ec.gc.ca).

### **Alternatives**

The following measures can be applied after an assessment is conducted under CEPA 1999:

- Adding the substance to the Priority Substances List for further assessment (when additional information is required to determine whether or not a substance meets the criteria in section 64);
- Taking no further action in respect of the substance; or
- Recommending that the substance be added to the List of Toxic Substances in Schedule 1 and, where applicable, recommending the implementation of virtual elimination.

It has been concluded in the final follow-up assessment report that tributyltins and tetrabutyltins are entering, or may enter, 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. Tributyltins and tetrabutyltins pose a risk to the environment and meet the criteria under section 64 of CEPA 1999. Adding these substances to Schedule 1, which will enable the development of proposed regulations or other risk management instruments, is therefore the best option.

Additionally, the presence of tributyltins in the environment results primarily from human activity and they meet the persistence and bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations*. Therefore, tributyltins meet the criteria for Track 1 substances, as defined in the Government of Canada's *Toxic Substances Management Policy*.

### **Benefits and costs**

Adding these substances to Schedule 1 enables the Ministers to develop a proposed regulation or other instruments to manage ecological risks posed by these substances. The Ministers may also choose to develop non-regulatory instruments to manage these risks. The Ministers will assess costs and benefits and consult with the public and other stakeholders during the development of these risk management proposals.

### **Consultation**

On April 21, 2007, the Ministers published for a 60-day public comment period in the *Canada Gazette*,

Part I, a summary of the results of the follow-up ecological assessment on organotins and a statement indicating the measures they propose to take for some organotins, based on scientific considerations. Prior to this publication, the CEPA National Advisory Committee (NAC) was informed of the release of the follow-up ecological assessment on organotins and the public comment period mentioned above. No comments were received from CEPA NAC.

During the 60-day public comment period, submissions from two industry stakeholders were received on the scientific assessment. Responses to the comments were provided and are summarized below. The full response to comments document is available on the Chemical Substances Web site at [www.chemicalsubstances.gc.ca](http://www.chemicalsubstances.gc.ca).

Technical comments on the assessment report were submitted by stakeholders and were carefully reviewed. The text of the assessment report was revised based on these comments. However, these revisions did not have an impact on the proposed conclusions of the assessment.

Industry stakeholders stated that voluntary and regulatory product stewardship policies and procedures are followed by both sellers and users to prevent releases of non-pesticidal tributyltins and tetrabutyltins to the environment. They therefore believe that these substances are not entering the environment and that it is not appropriate to add them to Schedule 1 of the *Canadian Environmental Protection Act, 1999*.

In its assessment, Environment Canada uses information that takes into account the current stewardship practices of facilities using organotin stabilizers. Environment Canada noted that with these effective stewardship practices in effect, releases of these substances would be minimized to levels that would not be expected to harm aquatic organisms. Because of the unique concerns relating to persistent and bioaccumulative substances, the assessment of such substances must be performed using a preventative, proactive approach, to ensure that harm does not occur. Therefore, Environment Canada indicates that there is still potential for release of tributyltins at some stage of their life cycle, and that such releases could lead to harmful ecological effects because these substances have the potential to remain in the environment for long periods of time, that releases of extremely small amounts of persistent and bioaccumulative substances may lead to relatively high concentration in organisms and that highly persistent and bioaccumulative substances have the potential to biomagnify through the food chain, resulting in especially high internal exposures for top predators. These concerns also apply to tetrabutyltins as they are precursors to tributyltins.

Finally, the approaches being taken with respect to tributyltins and tetrabutyltins are consistent with those that are being applied under the Challenge program of Canada's Chemicals Management Plan.

#### *Consultation following publication of the proposed Order in the Canada Gazette, Part I*

The proposed Order was published in the *Canada Gazette*, Part I, on October 3, 2009, for a 60-day public comment period. No comments were received during that period.

#### **Implementation, enforcement and service standards**

The Order adds the two above-mentioned classes of substances to Schedule 1 to CEPA 1999. An appropriate assessment of implementation, compliance and enforcement will be undertaken during the development of a proposed regulation or control instrument(s) respecting preventive or control actions for these substances.

#### **Contacts**

David Morin  
Executive Director  
Program Development and Engagement Division  
Environment Canada  
Gatineau, Quebec  
K1A 0H3  
Substances Management Information Line:  
1-800-567-1999 (toll free in Canada)  
819-953-7156 (outside of Canada)  
Fax: 819-953-7155  
Email: [substances@ec.gc.ca](mailto:substances@ec.gc.ca)

Tina Green

Director  
Risk Management Bureau  
Health Canada  
Ottawa, Ontario  
K1A 0K9  
Telephone: 613-948-2585  
Fax: 613-952-8857  
Email: tina.green@hc-sc.gc.ca

[Footnote a](#)

S.C. 2004, c. 15, s. 31

[Footnote b](#)

S.C. 1999, c. 33

[Footnote c](#)

S.C. 1999, c. 33

[Footnote 1](#)

S.C. 1999, c. 33

[Footnote 2](#)

The *Canadian Environmental Protection Act* is now repealed and replaced by the *Canadian Environmental Protection Act, 1999*.

**NOTICE:**

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with extensible hypertext markup language (XHTML 1.0 Strict).

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