

Response to comments received following release of the draft results of investigations and recommendations for various organotin substances

A Notice was published in the *Canada Gazette* Part I on April 21, 2007 indicating the availability of the Draft Follow-up to the 1993 Ecological Risk Assessment of Organotin Substances on Canada's Domestic Substances List, and inviting comments from interested parties for a period of 60 days.

Comments on the report were provided by:

1. Arkema Canada Inc.
2. Reagens Canada.
3. Learning Disabilities Association of Canada.

Comment	Response
<p><u>Organotin Stabilizers</u></p> <p>The submissions noted disagreement with a number of assumptions in the scenarios used to estimate release and ecological exposure to organotin stabilizers. These included estimates of maximum quantities used by individual facilities, fraction of the substances released to the environment, removal efficiencies of sewage treatment plants, and handling practices by the facilities and by third parties who recycle transport containers.</p> <p>A Vinyl Council of Canada (VCC) survey indicated that only one site in Canada using organotin stabilizers cleaned and reused empty containers and only one site in Canada disposed of rinsate to wastewater treatment. Typically, empty containers are sealed and sent to landfill or are sent to a recycler where any rinsate is disposed of as hazardous waste.</p> <p>The estimated rate of release of 0.4 kg/day from a large facility, corresponding to a release of 0.004% of the quantity of substance used, was excessive, and that given existing product stewardship policies and procedures in place at</p>	<p>Values that recognized the current stewardship practices of these facilities, but which are still conservative, were used to estimate the maximum exposure levels. Exposure scenarios are intended to address realistic worst case situations. As pointed out, there were still occurrences of facilities cleaning and reusing transport containers and releasing of rinsate to wastewater treatment at the time the VCC survey was conducted. It is recognized that actual releases from most facilities are likely to be less than the estimated levels.</p> <p>Recognizing that the estimated exposure concentrations indicated that stabilizers are not posing an ecological risk under current stewardship practices, use of more refined estimates was not warranted.</p>

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<p>facilities using organotin stabilizers, they are not entering the environment at all.</p> <p>The submission indicated that their calculation of release using more realistic yet highly conservative estimates resulted in an estimate of 0.02 kg/day.</p>	
<p><u>Tributyltins</u></p> <p>The submission states that the source of tributyltins measured in the Canadian environment has been determined to be its past use in anti-fouling paints, and this use has been banned.</p> <p>The submission expresses the belief that, with existing stewardship practices, tributyltin impurities from butyltin stabilizers are not entering the environment at all. Similarly, tributyltin residues from tetrabutyltin are also not entering the environment at all.</p> <p>Arkema Canada provides tributyltin oxide as a chemical intermediate to another company that produces another tributyltin substance, and Arkema Canada has determined that the other company has policies and procedures in place to prevent releases to the environment.</p> <p>Arkema Canada is willing to enter into a voluntary agreement with Environment Canada to confirm that it will not sell tributyltin oxide to companies that do not have adequate policies and procedures in place to prevent environmental release.</p> <p>Non-pesticidal tributyltin compounds are therefore not entering the environment and it is not appropriate to add them to Schedule I of CEPA 1999.</p>	<p>Tributyltin has been determined to meet the criteria for persistence and bioaccumulation according to the <i>Persistence and Bioaccumulation Regulations</i>. Given the continuing uses of tributyltin in Canadian commerce, as well as its high persistence and potential for bioaccumulation, it is considered that there is potential for its release at some stage of its life cycle, and that such releases could lead to harmful ecological effects.</p> <p>The approaches being taken with respect to tributyltin and tetrabutyltin are consistent with those being applied under the Challenge program of Canada's Chemicals Management Plan.</p>
<p><u>Tetrabutyltin</u></p> <p>The submission states that there is no</p>	<p>A realistic worst case scenario was used to</p>

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<p>justification for assumed releases of tetrabutyltin equivalent to those from tote shipping containers of 0.08% and that it ignores the regulatory regime in Canada to prevent releases to the environment.</p> <p>Tetrabutyltin has been notified under CEPA provisions as both a new and transitional substance. The company that notified it as a new substance is subject to Ministerial Conditions to prevent its release to the environment. Arkema Canada is the only company that notified tetrabutyltin as a transitional substance and is not subject to the Conditions, but voluntarily abides by their terms, and does not and will not sell the substance to companies that do not have adequate policies and procedures in place to prevent their release. Arkema Canada expresses a willingness to enter into a voluntary agreement to confirm that it will not sell tetrabutyltin to companies that do not have adequate policies and procedures in place to prevent its release.</p> <p>It is also noted that only one company in Canada consumes tetrabutyltin, that the company adheres to principles of Responsible Care, and that policies and procedures are in place to prevent release of the substance to the environment, regardless of the supplier of the substance.</p> <p>Reagens Canada indicates that it expressed to Environment Canada a willingness to voluntarily implement additional measures (such as an environmental emergencies plan for example) as a preferred alternative to the declaration of CEPA toxicity for tetrabutyltin, but states that the Department did not explore this possibility. Similar measures were used to prevent monobutyl and dibutyl compounds from entering the environment.</p>	<p>estimate release and exposure of tetrabutyltin. It is recognized that the estimated rate of release is likely greater than the actual rate.</p> <p>It is equally recognized that the distributor of tetrabutyltin indicates that it voluntarily applies stewardship practices consistent with existing Ministerial Conditions developed for new substances to prevent the release of the substance to the environment.</p> <p>However, tetrabutyltin is a precursor to tributyltin, which meets the criteria for persistence and bioaccumulation according to the <i>Persistence and Bioaccumulation Regulations</i>. Additionally, commercial tetrabutyltin is recognized to contain a substantial level of tributyltin. Therefore concerns and measures outlined for tributyltin also apply to tetrabutyltin.</p> <p>There were no transitional notifications of tetraoctyltin or trioctyltins. Therefore all notifiers of these substances are subject to the same regulatory actions specified in the Ministerial Conditions.</p>

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<p>Tetrabutyltin is not entering the environment and it is therefore not appropriate to add the substance to Schedule I of CEPA 1999.</p> <p>The submission states that a Ministerial Condition was considered sufficient to prevent release of the intermediate tetraoctyltin, which was notified as a new substance, and questions why this is not considered sufficient in the case of tetrabutyltin, for which the company voluntarily abides by the Ministerial Condition developed for it.</p>	
<p>The submissions noted that site visits by representatives of Environment Canada assured that the policies and procedures in place are adequate to prevent releases to the environment of organotin stabilizers and tributyltin and tetrabutyltin.</p>	<p>Representatives of Environment Canada's assessment programs visited a limited cross-section of facilities in order to increase familiarity with these operations. These visits were not audits and did not result in any official conclusions as to the adequacy of existing practices in preventing the release of organotin substances to the environment.</p>
<p>The submission recommends that Environment Canada conduct a formal study about the common disposition of empty containers from industrial manufacturing sites and the ultimate fate of container residues to improve upon release assumptions in future assessments.</p>	<p>Environment Canada notes this recommendation.</p>
<p>The submission indicated that dibutyltin is a developmental neurotoxicant and is neurotoxic <i>in vitro</i> and <i>in vivo</i> at levels that have been detected in human blood samples. Dimethyltins also produced neurotoxic effects. The risk assessment of organotins should be revised to reflect this new information and the risk management program should include mitigation policies for the additional organotins.</p>	<p>The document that was the subject of the Canada Gazette Notice and this comment period did not address human health issues. The Minister of Health completed a report on organotins in 2003, as a follow up to assessment of these substances due to their inclusion on the Priority Substances List. It was concluded that non-pesticidal organotin compounds do not present a danger to human life or health. Health Canada has subsequently considered the submitted data and determined that it would not impact on the overall conclusions of their assessment.</p>