Sent By Email, Facsimile and Courier

November 19, 2008

Mr. Mark Burgham
Executive Director,
Existing Substances Division
Environment Canada
351 St. Joseph Blvd.
Gatineau, Quebec K1A 0H3

Re: ***Canada Gazette*, Part I, Volume 142, Number 38, published September 20, 2008: Notice of Objection to and Request for the Appointment of a Board of Review in relation to the Proposed Order to add Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl] ethylamino]- 2-methylphenyl]methylene]- (CHPD) to Schedule 1 to the Canadian Environmental Protection Act, 1999**

Dear Mr. Burgham:

On September 20, 2008, the Governor in Council on the recommendation of the Minister of the Environment ("Minister") proposed an Order to add Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl] ethylamino]-2-methylphenyl]methylene]- (CHPD) to Schedule 1 to the Canadian Environmental Protection Act, 1999 (hereinafter referred to as the proposed Order) under the authority of subsection 90(1) of CEPA 1999. The Minister's recommendation is based on a finding that CHPD is "toxic" within the meaning of Section 94(a) of CEPA. The Minister has concluded that CHPD also meets the virtual elimination (VE) criteria set out in subsection 77(4) of CEPA 1999.

Pursuant to section 333 of CEPA, [LANXESS]* Corporation ("Petitioner") files a Notice of Objection and requests that a Board of Review be established under section 333 of *CEPA* to inquire into the nature and extent of the danger posed by CHPD.

Laws and policy procedures that must be followed during the creation of federal regulations include: CEPA 1999, the Cabinet Directive on Law-making; and the Government of Canada Regulatory Policy. We do not believe that these laws and procedures have been specifically followed with regard to the proposed Order.

The reasons for the objection and request for the appointment of a Board of Review are set out below.

I. An Inadequate Showing has Been Made that CHPD is Toxic within the Meaning of Section 64 of CEPA

*****The bracketed material in this document is considered confidential and protected from disclosure under Section 313 of the Canadian Environmental Protection Act (CEPA)

Pursuant to Section 64 of CEPA, the Minister must demonstrate in support of its recommendation to list a substance on Schedule 1, that the substance is toxic in that 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.

The CEPA definition of "toxic" requires both a demonstration of hazard and the actual or potential exposure to the environment in amounts sufficient to be of harm or constitute a danger. The Petitioner submits that the requisite demonstration of both hazard and exposure has not been made in the case of CHPD.

CHPD is in use throughout the world. No other government, regulatory body, or non-governmental organization has ever raised any concerns about CHPD. To the contrary, the use of CHPD in the main context in which it is used in Canada – as a colorant in food packaging material -- has been assessed by Health Canada and other governmental bodies and found to be safe. The CEPA assessment would be the first governmental review to identify CHPD as a substance of concern. Given the complete absence of regulatory scrutiny of CHPD anywhere else in the world, Petitioner submits that this conclusion by Environment Canada is facially suspect. One would expect that the Environment Canada conclusion would have been occasioned by some finding that CHPD has posed some problem, such as by its detection in environmental media in harmful amounts, or in the fatty tissue of mammals, or even by evidence of a "fish kill" during an accidental release of CHPD to a body of water. In point of fact, the CEPA assessment is the result of three factors: (1) modeling, which the Petitioner submits is inappropriate and flawed; (2) the refusal of the Environment Canada staff to accept actual data that contradict the results of the modeling; (3) the misguided application of the precautionary principle, and (4) the Petitioner's admitted, albeit justifiable, inability to submit all of the data needed to properly vindicate CHPD within the aggressive timeframes called for under the "CEPA Challenge."

Moreover, as explained below, there are virtually no releases of CHPD to the environment of Canada. As such, the use of the precautionary principle to protect against the potential for high releases of a substance not proven to be safe is not appropriate in this case.

A. **CHPD is Not Hazardous to the Environment**

With respect to the required demonstration of hazard, the finding by Environment Canada that CHPD is very toxic to aquatic organisms was made based on modeling data only. Actual data submitted by the Petitioner suggest CHPD is non-toxic to the environment. These actual data were not fairly considered in the final recommendation and were not presented to the CEPA Challenge Advisory Panel. The Petitioner submits

that the listing of a chemical in use throughout the world is a very serious matter. This should never be done on the basis of modeling data and should never be done when actual data has been submitted that suggests a non-toxic result. Part I of the Technical Comments that accompany this Notice of Objection and Request for Appointment of a Board of Review describes in great detail the failings of the Environment Canada assessment of the toxicity of CHPD, including the extraordinary amount of admitted uncertainty associated with the assessment, the defects apparent in Environment Canada's evaluation of the actual data, and the continued reliance on modeling even though it is clear that the models are not predictive of the true behavior of CHPD in the environment.

The implications of declaring CHPD as CEPA toxic, should it proceed, will be significant to the Petitioner's global market. The stigma of the toxic label will be impossible to recover from. Some jurisdictions, notably Japan, have a strong tendency to interpret these types of other-government results quite literally and will take action against the product in use in that country without regard to the merits.

Moreover, the Petitioner submits that should the Governor in Council approve this recommendation, it will set an unfortunate precedent for other substances in the Challenge process. CHPD is in the first batch of the Batch and Challenge process. Many more substances and assessments will follow. We believe that should CHPD be listed in Schedule 1 and be subjected to a V/E risk management plan, then the Government will have no choice but to also take these actions with other substances where no evidence other than modeling data suggest a toxic result; where modeling data is determined by the Government to be more reliable and valid than actual data submitted by the manufacturer; and where there are virtually no releases in the contexts and uses identified to be of concern. This type of precedent could have serious ramifications for all chemical importers and for all Canadian manufactures and exporters.

The mandatory Parliamentary Review of CEPA was completed recently. There was considerable discussion by participants and Parliamentarians on the toxic designation and the stigma attached to it. The conclusion reached was that the word should be maintained in order to retain the high listing threshold contemplated by the term and to keep the focus of CEPA as a risk-based statute. Parliamentarians concluded that peer-reviewed science must be strong in order for a listing to be valid. These factors are missing in the case of the proposed listing of CHPD.

B. **CHPD has Not been Shown to be Persistent or Bioaccumulative**

Part II of the attached Technical Comments explains that the determination that CHPD is persistent and bioaccumulative is based entirely on modeling, that out-dated models were used in the assessment, and that the use of the most recent versions of the models would have predicted a different outcome. Petitioner has proposed to conduct the actual testing that would put the question to rest and the protocols for such testing has been submitted to the Environment Canada staff for review and comment. The Petitioner believes that the decision on both the final order for listing of CHPD on Schedule 1 and the Virtual Elimination risk management recommendations be deferred until the proposed bioaccumulation tests are completed and the results are reviewed by Environment Canada.

C. There is No Actual or Potential Exposure of CHPD to the Environment that would be Sufficient to Constitute Harm or Danger

With respect to the actual or potential for exposure in harmful or dangerous amounts, it is important to understand that CHPD is not manufactured in Canada, total imports of the substance as such are no more than 300 kilograms (kg) per year, and there are only four (4) industrial sites in Canada that use the imported CHPD. Of the some 300 kg imported into Canada, the Environment Canada assessment indicates that releases are very small, less than 1% of the CHPD imported into Canada as such.

Most notably, the Proposed Risk Management Approach that Environment Canada has developed for CHPD concedes that:

- "Canadians do not need to be concerned because releases to the environment during use of plastic consumer products containing CHPD are expected to be extremely low."
- "Releases during the use of manufactured articles containing CHPD are expected to be extremely low."

As for releases from waste management of discarded plastic consumer products containing CHPD, estimated by Environment Canada to constitute 96% of the eventual disposition of the CHPD directly imported into Canada, the Proposed Risk Management Approach confirms:

- "Due to its non-volatility, CHPD is expected not to be found in landfill gas. With its high sorptivity and low biodegradation, it is likely that CHPD will sorb onto refuse and/or sediments and will not be found in leachate."
- It is also expected that CHPD will be transformed when the small fraction of solid waste is incinerated at temperatures at which municipal waste incinerators operate."
- "It is therefore expected that CHPD is not likely to be released to the environment from the waste sector."

The only potential releases that Environment Canada has identified are limited to some 0.5 kg from the 4 industrial sites that use CHPD and some additional 1.5 kg from the land application of sludge from waste water treatment (1.5 kg). As the Proposed Risk Management Approach states:

> "Exposure from CHPD is expected to be low. Releases from waste management facilities and the use of articles containing CHPD are not expected. The greatest potential for environmental exposure results from the estimated 1.5 kg of CHPD applied to land in the form of wastewater biosolids. This potential release would be spread across the provinces where CHPD is used and would not be concentrated in a single location. Additional environmental exposure could potentially result from the 0.5 kg of CHPD that is predicted to be released in effluent to surface water from wastewater treatment plants.

In point of fact, even the small releases (2 kg in total) that Environment Canada has estimated are incorrect and stem from inadequate efforts by Environment Canada to identify the true measure of the releases of CHPD to the environment in the context (water) and use (plastics manufacturing) identified by Environment Canada to be of concern. The Petitioner understands that Environment Canada was in direct contact with customers of CHPD but there is no indication that Environment Canada took that occasion to ask these customers about their handling practices. To the contrary, Customer surveys obtained by the Petitioner, and submitted to Environment Canada, indicate there are virtually no releases to the environment in these uses and contexts.

Petitioner would suggest that this is the first time to its knowledge that the exposure prong of the section 64 definition of toxic has been ignored.

II. The Proposed Order is Not Consistent with the Requirements of the Government of Canada Regulatory Policy 1999 ("Policy")

The Policy requires that:

- a problem or risk must be demonstrated;

- Federal government intervention is justified; and

- it must be demonstrated that regulation is the best alternative method of addressing the problem or risk.

There is no indication that any problem or risk exists with respect to the use of CHPD in Canada. On the contrary, the imports of CHPD are so limited, and the identified releases to the environment are so small, that all of the available information points to the absence of a problem or risk.

Although Petitioner submits that the modeled toxicity of CHPD to aquatic organisms has been definitively rebutted by actual data, we recognize there are still some outstanding questions about the bioaccumulation potential of CHPD. But, the proposed Federal government intervention is not justified simply because CHPD has not yet been proven to be absolutely safe, particularly in light of the stigma that would attach to CHPD worldwide were it to declared CEPA toxic and subjected to virtual elimination. As noted, the Petitioner has offered to conduct actual bioaccumulation testing and has submitted the protocols for such testing to Environment Canada. Precipitous Governmental intervention is entirely unnecessary and any decision-making should await the results of these tests. Given the planned testing, it can not fairly be said that declaring CHPD as CEPA toxic is the best alternative method of addressing the Government's concerns about CHPD.

III. Contrary to the Requirements of the Canada Regulatory Policy 1999, there has Not Been Appropriate Consultation in this Specific Case

The Policy requires that affected persons be consulted and that they have an opportunity to participate in developing or modifying regulations.

Although Environment Canada has issued numerous notices throughout the CEPA Challenge process, much of the consultation involved thousands of chemicals. There

were a number of miscommunications and misunderstandings between the various parties involved that prevented the Petitioner from understanding early on that CHPD was a priority to Environment Canada, and that prevented Petitioner from responding effectively in the timeframes specified under the CEPA Challenge. To explain, the Petitioner lists below these circumstances:

a. The December 9, 2006 Batch 1 Gazette notice specified that sufficient information had been provided on CHPD and CHPD was not included in the notice. The Petitioner took this to mean that CHPD was not of concern.

b. This "not of concern" perception was reinforced by the fact that on the Batch 1 Schedule form, CHPD was not listed.

c. In June 2007, Petitioner did sign and send production and customer data to Environment Canada. Further communication from Environment Canada after this time was not to the Petitioner but to a Canadian entity no longer associated with the Petitioner. Environment Canada directed these communications to the wrong entity despite the fact that Petitioner had advised the Agency in June 2007, that it wished to participate directly in the consultation.

d. There was a critically important notice period in the process that closed on August 2, 2007. Petitioner was not aware of this specific request for data on CHPD or the closing date of the notice period until September 7, 2007. Additionally, Environment Canada did not inform Petitioner of this request and notice period, despite the June 2007 communication to Environment Canada from Petitioner. However, Petitioner was able to submit a critical piece of data – an acute daphnia study - in October 2007. Subsequently, Environment Canada informed Petitioner that the information submitted in October was not reviewed or considered. This seemed to indicate to Petitioner that once again Environment Canada had no concerns.

e. In the fall of 2007 and into early 2008, Petitioner was still not sufficiently informed of the Batch and Challenge process and where CHPD stood in this process. As a result, Petitioner informed Environment Canada in comments submitted in March, 2008, that it was in the process of conducting a chronic daphnia study and would submit the results as soon as the study was complete.

f. In January, 2008, the Batch and Challenge Advisory Committee had been informed of the recommendation for listing of CHPD and V/E proposal based on models only. In July of 2008, Petitioner first learned of this January presentation to the Advisory Committee and that the Advisory Committee had expressed concerns about these decisions based on models only but suggested that the precautionary principle justified these actions. At the time, Environment Canada did not have information on actual releases from industrial facilities using CHPD and therefore the Advisory Committee did not have before it the exposure data that would have suggested that the precautionary principle did not need to be applied. As noted earlier, Customer surveys completed in August 2008 clearly indicate no releases in the contexts and uses of concern. Petitioner submits that the Advisory Committee conclusion may have been different had this information been presented to them.

g. Finally, Petitioner submitted extensive technical information of the risk assessment in connection with the July 4, 2008 Gazette notice announcing the Proposed Risk Management Approach, with a September 2, 2008 deadline for comment. Environment Canada refused to consider this technical information even though it could have had a

profound impact on the recommendation to list and V/E Order. Instead, the Minister signed a recommendation to list and V/E Order on September 3, 2008, a day before the federal election and a day after the close of the July 4, 2008 consultations.

Petitioner falls to understand the sense of urgency, or the need for a “rush to judgment”, that apparently has been adopted by Environment Canada throughout this consultation process. Petitioner considers that their technical comments submitted on September 2, 2008 would have had a material impact on the Ministerial Order. Petitioner submits that given Environment Canada’s refusal to consider the scientific merits, it is appropriate that a Board of Review be convened to do so.

IV. The Proposed Order is Contrary to the Cabinet Directive on Law-making

The Cabinet Directive on Law-making states that "Law should be used only when it is the most appropriate. When a legislative proposal is made to the cabinet, it is up to the sponsoring Minister to show that this principle has been met, and there are no other ways to achieve the policy objectives effectively". Petitioner submits for the reason set out above that the Minister has failed to demonstrate that the proposed Order is the most appropriate means to achieve the Minister’s objective under the CEPA Challenge. To the extent the goals of the CEPA Challenge are to prod industry to develop the data needed to defend their products, that goals has already been achieved by the data Petitioner has submitted and has proposed to submit. To the extent the goal is to engage in sound decision-making about the risks of chemicals in Canadian commerce, Petitioner submits that the goal would be better served by awaiting the results of the new testing that the Petitioner has proposed.

Conclusions

For the reasons set out above, and in the attached Technical Comments, Petitioner objects to the proposed Order and requests that a Board of Review be convened.

Respectfully Submitted,

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