

CHLORINATED PARAFFINS

INDUSTRY ASSOCIATION

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November 19, 2008

Executive Director
Existing Substances Division
Environment Canada
Gatineau, Quebec K1A 0H3

VIA EMAIL: Existing.Substances.Existantes@ec.gc.ca

RE: Proposed Order to Add Chlorinated Paraffins to Schedule 1 of the Canadian Environmental Protection Act (CEPA), 1999 (Canada Gazette, Part I, September 20, 2008)

Dear Minister of Environment:

The Chlorinated Paraffins Industry Association (CPIA¹) submits these comments in response to the September 20, 2008, notice in *Canada Gazette*, Part I, regarding Environment Canada's (EC) Proposed Order to add Chlorinated Paraffins (CPs) to the List of Toxic Substances in Schedule 1 of the Canadian Environmental Protection Act (CEPA), 1999 (the "Proposed Order"). The CPIA further submits a Notice of Objection and hereby requests pursuant to section 333 of CEPA, that the Minister convene a Board of Review to assess the proposed action and the appropriateness of proceeding with the CEPA Toxic designations for all CPs.

These comments and Notice of Objection are based on an extensive evaluation of the August 30, 2008 Follow-up Canadian CP Risk Assessment. As the attached comments will document, there does not appear to be an objective justification to support the proposed CEPA Toxic designations. CPIA's objection is based on many factors which can succinctly be characterized as follows:

- There should be a sound technical basis justifying a CEPA Toxic determination, particularly given that Canada has called for a "prohibition regulation" on all uses of CPs. By Canada's own admission, there is "low" to "minimal" confidence in the data and analysis relied on in the assessment.
- Concerns for human health effects are largely the result of an unrealistic, worst case assumption that food in Canada is contaminated with CPs, even though there are essentially no real market basket data from Canada. Instead, Canada uses a

¹ The Chlorinated Paraffins Industry Association (CPIA) represents manufacturers of chlorinated paraffins from around the world.

study published in 1980 from the United Kingdom (UK) and assumed that Canadian food is contaminated at the analytical limits from the UK study even though in many instances, the UK study did not measure detectable levels of CPs. Additionally, there are much more reliable data such as a recent study from Japan.

- The age group that Canada asserts has the highest exposure to CPs are infants under the age of six months that are not formula fed. The exposure estimate for this subpopulation is not based on human breast milk or baby formula data, which are the primary foods ingested by infants 0-6 months. Canada is relying on the Nutritional Canada Survey (NCS) which indicates that dairy foods are the largest source of nutrition for infants 0-6 months. The NCS includes baby formula under the category of dairy and clearly this is what infants are primarily ingesting if they are not ingesting human milk.² However, in the case of LCCPs, the Risk Assessment uses a single sample of cheese, analyzed in the late 1970s in the UK, to represent all dairy exposures to these infants. This estimate is used despite the clear guidance from Health Canada that “estimation of total daily intake for Priority Substances is generally based on the assumption that a typical infant is exclusively breastfed up to 6 months of age, after which foods are consumed in the quantities determined in the NCS.” (EHD 1998)
- Even with these unrealistic dietary assumptions and exposure estimates for infants, in the case of LCCPs there are no exposures for any age group above the conservative health benchmark (which includes a safety factor of 1000). For SCCPs and MCCPs a similar worst case assumptions are made.
- The Follow-up Assessment relies on some portions of national and international assessments such as the ones conducted by the UK and European Union (EU) but then without any explanation, ignores other portions of those same assessments. For example, in the case of the quantitative portion of the SCCPs Assessment, Canada emphasized the review conducted in 1996 by the IPCS but did not consider the risk assessment put forth by the European Union, which concluded that SCCPs were not a concern for human exposure. It is curious that Canada used the outdated data from the UK on food contamination but then arrived at a completely different decision than the UK/EU over human health concerns. While the EU did adopt a Marketing and Use restriction for metalworking fluids and leather treatment, the concerns that drove these restrictions were aquatic toxicity and not human health.
- For environmental effects, Canada also relied on unrealistic worst-case assumptions and even then, the quantitative analysis by and large does not support the CEPA Toxic designations. Most of the Risk Quotients (RQs) derived are

² While nutrition surveys and guidelines indicate that it is typical to introduce solid foods between the ages of 4 and 6 months, these are typically simple cereals and pureed vegetables – not cheese, potato crisps, jams, and other foods included in the exposure assessment by Campbell (1980).

significantly less than 1. In only two scenarios involving MCCPs, does the assessment even suggest a concern for environmental effects and in these instances, the RQs are only slightly greater 2. As described further in these comments, had Canada used more realistic worst case assumptions, the RQs in all cases would have been less than 1.

- Canada neglected to review several important studies that the CPIA submitted in 2005 as part of its comments on the draft Follow-up Assessment. Additionally, the Canadian assessment does not factor in several important relatively new studies on CPs, some of which were in fact conducted in Canada.
- No consideration appears to have been given to the potential societal impacts of a CEPA Toxic designation.

In addition to the lack of supporting evidence, the proposal does not clearly define the specific substances covered. This is evidenced by the stated inability to ascribe CAS numbers to the listing. The CPIA fails to understand this difficulty given that the affected compounds are presumably those that are on the Domestic Substance List. If Canada proceeds with the listing, it is incumbent on Canada to clearly identify the specific compounds covered.

The CPIA would welcome the opportunity of further discussing this matter with the appropriate officials. Please do not hesitate to contact me if I can provide any clarification.

Sincerely,

Robert J. Fensterheim
Executive Director