

SUMMARY OF PUBLIC COMMENTS RECEIVED REGARDING THE GOVERNMENT OF CANADA ASSESSMENT “FOLLOW-UP REPORT ON CHLORINATED PARAFFINS”

An announcement of the follow-up assessment on chlorinated paraffins was published in the Canada Gazette on June 11, 2005, for a 60-day public comment period. Comments were received from industries and industry associations; no comments were received from non-governmental organizations, members of the public, or academia.

Comments have been received from:

1. The Canadian Vehicle Manufacturers' Association (CVMA)
2. The Industry Coordinating Group (ICG) for CEPA
3. The Chlorinated Paraffins Industry Association (CPIA).

Comments covered the following topics: general comments on the assessment and risk management process, physical-chemical properties, exposure, effects, bioaccumulation, conservatism, application factors, and weight of evidence.

Tables containing detailed comments, relating to human health and ecological issues, and the responses to them, have been prepared and are available on request. A summary is provided below.

Comments

Comments have been submitted with respect to policy or process, including those provided below.

- It was suggested that completion of the risk assessment be delayed since: (i) more time is required for international collaboration; (ii) we should wait for the European Union/United Kingdom (EU/UK) conclusions on medium and long chain chlorinated paraffins to be published; (iii) the current science is inadequate and more studies are planned.
- It was recognized that the toxicity of short chain chlorinated paraffins is well documented; however, it was suggested that there are issues with the science for medium and long chain chlorinated paraffins and therefore the conclusion that these substances meet the criterion set out under paragraph 64(a) of the *Canadian Environmental Protection Act, 1999* is premature.
- It was suggested that the assessment be split by chain length since most of the uncertainty in the assessment relates to data for medium and long chain chlorinated paraffins.
- Comments requesting clarification or providing suggestions for the appropriate risk management of chlorinated paraffins were received.

- It was suggested that CAS numbers should be listed in the Gazette notice rather than general classification of chemicals.
- It was suggested that details of the Environment Canada industry survey should be available for public review.
- It was suggested that more emphasis be placed on the US EPA risk assessment.

Comments have been submitted which addressed a number of technical issues, including those provided below.

- The use of non-Canadian and outdated data in the estimation of exposure and effects was questioned. It was suggested that there is an over reliance on EU/UK reports which are still in draft form.
- The use of what were believed to be overly-protective values for exposure and effects was questioned. In addition specific aspects of these calculations were criticized including: (i) the assumption of a 20 cm plow depth; and (ii) the assumption of no dilution for discharges to surface water.
- The use of an extra application factor of 10 for persistent and bioaccumulative substances was questioned.
- It was felt that the presence of short chain chlorinated paraffins in remote regions should not be the basis for concluding long range transport without investigating local sources.
- The validity of sediment analysis studies for interpreting persistence and long range transport was questioned, as were the quality assurance/quality control (QA/QC) measures. In addition, it was suggested that natural production of chlorinated paraffins could confound sediment interpretation.
- The validity of determining persistence of medium and long chain chlorinated paraffins based on modelling their behavior in air was questioned.
- The back-calculation method for determining persistence in sediment was questioned.
- The weight-of-evidence in support of bioaccumulation and persistence was questioned.
- It was suggested that further critical evaluation of scientific studies for toxicity was required.
- It was proposed that tumours of the liver, kidney and thyroid in laboratory animals exposed to short chain chlorinated paraffins were induced by

modes of action which were not relevant to human health. An assessment by the European Commission (2000) was cited in support of this claim. Additionally, thirteen reports were submitted in support.

- It was noted that there was a paucity of information on long chain chlorinated paraffins, especially with respect to concentrations in environmental media to which humans might be exposed.

Summary of Response to the Public Comments on the Ecological Risk Assessment Approach

All comments from the public comment period were carefully tabulated, reviewed, and addressed. The following presents a brief description of the response to the topics outlined above and the ecological risk assessment approach used.

- The EU/UK reports were consulted in the preparation of the assessment. The assessment was developed based on the most current science available and in close consultation with risk assessors from the EU/UK and with leading scientific researchers. Given the long period of time that has been available to produce new scientific studies, completion of the assessment will not be further delayed for studies that are not currently completed.
- Long chain chlorinated paraffins were divided into 3 sub-categories based on comments, differences in physical chemistry, and to be more in line with other international assessments. The subdivisions are: C₁₈₋₂₀ liquid, C_{>20} liquid, and C_{>20} solid long chain chlorinated paraffins.
- Based on a thorough scientific review of experimental and modelled data, there is sufficient information to conclude that short and medium chain chlorinated paraffins and liquid C₁₈₋₂₀ long chain chlorinated paraffins are persistent, bioaccumulative and meet the criterion set out under paragraph 64(a) of the *Canadian Environmental Protection Act, 1999*. However, based on the limited information available the conclusions for liquid and solid C_{>20} long chain chlorinated paraffins have been revised to state that they do not meet the criterion set out under paragraph 64(a) of the *Canadian Environmental Protection Act, 1999*.
- A risk management approach for chlorinated paraffins is being prepared and consultations will be held with affected stakeholders following publication of the final ecological screening assessment report in 2008.
- Due to the complexity of the class, and the heterogeneous nature of mixtures resulting from the production of chlorinated paraffins, an exhaustive listing of CAS numbers is not feasible. However, a list of representative CAS numbers is available upon request.

- As a standard procedure, information collected during the industry survey is not disclosed to the public since it contains confidential business information.
- As a standard practice, Canadian data will be used for the assessment if it is relevant and available. In case of insufficient or no Canadian data, data from other countries will be examined for its relevance and used in the assessment if it is judged to relate to conditions similar to those found in Canada. The UK sewage treatment plant data has been retained in the assessment; however, the data collected around a US chlorinated paraffins manufacturing facility is no longer relevant to Canada due to the age of the study and the recent closure of the only Canadian chlorinated paraffins manufacturing facility. The data collected near the currently closed chlorinated paraffins manufacturing facility in Canada was also determined to be outdated. These data have been removed from the risk quotient calculations.
- The standard approach in assessments is to use data that is representative of the high-end of actual exposures. As such, the risk determined is both realistic and protective of the environment. The data is selected for use in the assessment on the basis of its relevance to Canadian conditions as opposed to geographic location, although preference is given to Canadian data over data from other countries. A thorough review of all published data was completed prior to the assessment and only acceptable data was used in the assessment process. The validity of the assumptions implicit in modelled data was also carefully examined. However, the following assumptions have been changed to be consistent with international assessment practices:
 - The plow depth in exposure calculations has been changed from 10 cm to 20 cm, which is consistent with EU/UK assessment practices. The assumption of no biodegradation and a 10 year time frame for sewage sludge applications to soil have not been changed and are consistent with EU/UK practices.
 - Given that the EU/UK use a dilution factor of 10 in estimating aquatic exposure for substances discharged from sewage treatment plants to watercourses, the assessment has been revised to include a dilution factor of 10 where appropriate.
- The extra application factor of 10 for persistent and bioaccumulative (P&B) substances has been removed from the assessment. Text has been added to note that risk quotients (as currently calculated) may underestimate the risk of P&B substances to the environment.
- While there is insufficient information to assess the contribution of local sources to short chain chlorinated paraffins concentrations in the Arctic, the majority of “local sources” suggested in the comments received are a substantial distance from the lake sediment sites studied. Other evidence of long range transport includes short chain chlorinated paraffins

- congeners patterns measured in Arctic sediment that are indicative of industrial emissions that have been subject to long range transport.
- The US EPA 1993 assessment contains outdated information and considers only releases to water, whereas sediment and soil are the primary media of concern for chlorinated paraffins. As such, more emphasis was placed on EU/UK assessments that are published or being developed.
 - The QA/QC protocol for the sediment data was determined to be of high quality. There is also no published information to suggest that highly chlorinated alkanes can be produced by natural processes.
 - The text has been revised to reflect the limitations of air persistence models, given that medium and long chain chlorinated paraffins have low partitioning to air.
 - While the back-calculation method for determining the half-life of a chemical in sediment does not provide a discrete value, it can provide an answer as to whether a chemical's half-life is significantly greater than the 1-year criterion specified in the persistence and bioaccumulation regulations.
 - Both empirical and modelled data are presented that demonstrate that short and medium chain chlorinated paraffins and liquid C₁₈₋₂₀ long chain chlorinated paraffins meet the criteria for bioaccumulative and persistent substances. Based on the limited data available, the assessment has been revised to indicate that liquid and solid C_{>20} long chain chlorinated paraffins do not meet the criteria for bioaccumulation. Modeled BAF results have been added to the revised assessment.

Summary of the Response to the Public Comments on the Human Health Assessment

All comments from the public comment period were carefully tabulated, reviewed, and addressed. The following presents a brief description of the response to the topics outlined.

- Re: relevance of tumours to humans. The European Commission report had been available to Health Canada at the time of the follow-up assessment. That report noted that: "There was no agreement on the significance of the tumours nor their relevance to man between Member States. The issue was subsequently referred to the Specialised Experts. In their view only three were considered significant and of these two were considered not to be relevant to man. In their view, there was insufficient evidence to conclude that the kidney tumours were a male rat specific event and consequently the concern for humans could not be ruled out." In addition, the estimates of daily intake of short chain chlorinated

paraffins were within the range of the tolerable daily intake derived by the International Programme on Chemical Safety. The submitted reports (most are unpublished) regarding the analysis of mode of action were not evaluated in details as short chain chlorinated paraffins are considered to meet the criterion under paragraph 64(c) of the *Canadian Environmental Protection Act, 1999* based on non-cancer endpoints and, additionally, they met the criterion under paragraph 64(a) of the Act.

- The paucity of data for long chain chlorinated paraffins was identified as an uncertainty in the assessment. However, since long chain chlorinated paraffins containing up to 20 carbon atoms (in addition to short and medium chain chlorinated paraffins) are targeted for Virtual Elimination, further research is not considered to be a priority.