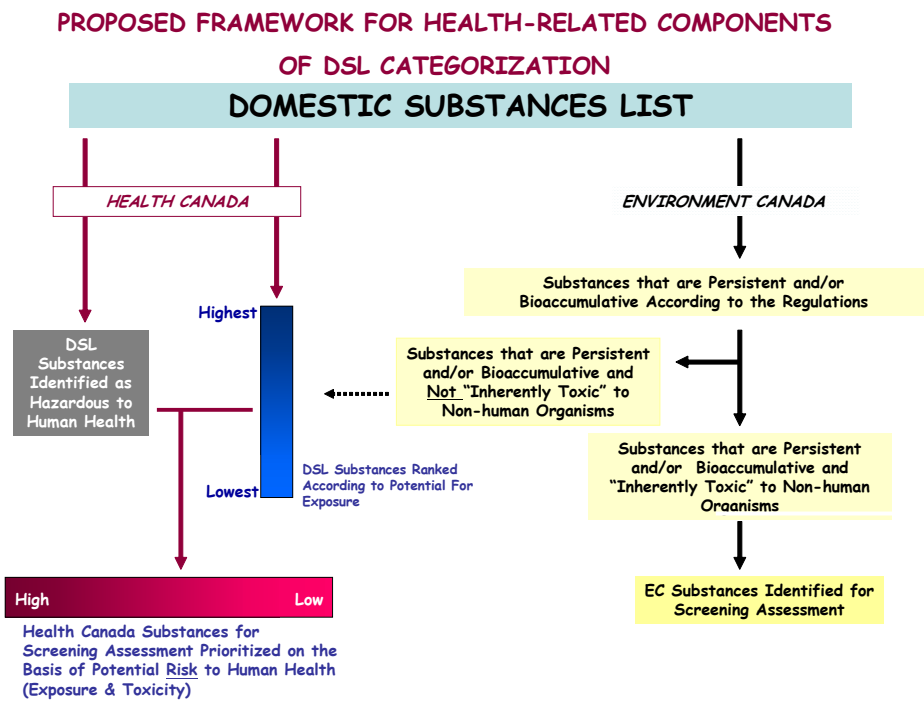


## Invitation to Provide Information on Substances Being Considered in Priority Setting for Health-Related Components of the Categorization of the Domestic Substances List under CEPA 1999<sup>1</sup>

### Introduction

This communication invites submission of information relevant to priority setting for the health-related components of categorization under the *Canadian Environmental Protection Act, 1999* (CEPA 1999). Categorization under CEPA 1999 requires the systematic consideration of all of the approximately 23,000 substances on the Domestic Substances List (DSL) prior to a legally mandated deadline of September 14, 2006 to set priorities for subsequent screening assessment (Government of Canada, 1999). The Minister of Health is identifying those substances on the DSL that pose the greatest potential for exposure of the general population in Canada (GPE) and those that are “inherently toxic” to humans.

The proposed approach to identify highest priorities from a human health perspective for DSL categorization is presented in the figure below and described in an additional communication entitled “Proposed Integrated Framework for Health-Related Components of Categorization of Substances on the Domestic Substances List under CEPA 1999” ([http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/publi-comment/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/publi-comment/index_e.html)). The draft maximal list is also being released in a companion communication entitled “Substances Prioritized for Additional Consideration in Categorization for Greatest Potential for Exposure and Inherently Toxic to Humans under CEPA 1999”. A full description of the proposed integrated approach and associated draft list of substances prioritized for screening assessment on the basis of potential risk to human health will be posted at the Existing Substances Division website in late 2004 (<http://www.hc-sc.gc.ca/exsd>).



<sup>1</sup> Information being invited for submission in relation to the environmental components of the program may be identified at [http://www.ec.gc.ca/substances/ese/eng/dsl/cat\\_index.cfm](http://www.ec.gc.ca/substances/ese/eng/dsl/cat_index.cfm)

In this framework, initially, a simple discriminating tool is applied to address potential for exposure for all 23,000 substances to set priorities. This identifies smaller numbers of substances considered to present the “greatest potential for exposure” (GPE - 849) and “intermediate potential for exposure” (IPE - 1779). The remainder of the substances on the DSL fall into the “lowest potential for exposure” (LPE). A simple discriminating tool is also applied to address hazard for all 23,000 substances. Additional tools of differing complexity will be applied to all (for GPE) or some (for IPE and LPE) of the substances in these various groups, to refine exposure prioritization and hazard identification, as well as to evaluate exposure-response.

The “Proposal for Priority Setting for Existing Substances on the Domestic Substances List under the Canadian Environmental Protection Act, 1999: Greatest Potential for Human Exposure” outlined the simple exposure tool which permitted relative ranking of all 23,000 substances on the basis of the limited information on quantities and use submitted in the compilation of the DSL

Information is welcome on the identity, use and/or toxicity on any substance prioritized for further consideration in subsequent stages of categorization in the proposal for the integrated framework to be released later this year. There is special interest, however, in early submission of specific information on a number of UVCBs and polymers in the GPE group and a small number of organic UVCBs in the IPE group. These substances are being identified at this time to provide sufficient time and opportunity for interested parties to submit information on a limited number of specified priorities relevant to their additional consideration prior to 2006 to more narrowly focus the content of the final categorization list.

Some of the work that the Department has been and is undertaking to additionally refine priorities is as follows:

- Identifying for potentially setting aside from further consideration, substances already assessed through the CEPA Priority Substances Program, or on the CEPA List of Toxic Substances.
- Individually examining the toxicity of GPE UVCBs and IPE organic UVCBs in order to determine whether they might potentially be set aside from further consideration in categorization, or as a basis for identification of specific information needs to make a decision.
- Individually examining the GPE polymers to determine whether they might potentially be set aside from the list of priorities for further consideration in categorization, or as a basis for identification of the information required for decision making.
- Developing a more complex exposure tool (ComET) that draws on additional information to additionally focus priorities with respect to potential for exposure.

Experience acquired over the past several years on these aspects has indicated that:

- For many UVCBs, priority setting for categorization for exposure and hazard to human health is complex and iterative and in many cases, required data are lacking from the public domain.
- Consistent with approaches in the New Substances/Chemical programs, basic information on the manufacture, processing and use patterns of polymers is required to evaluate potential exposure and hazard to human health.
- In the absence of more robust information, the complex exposure tool will incorporate many conservative professional judgments.

### **Data/Information Being Requested**

#### **UVCBs:**

Health Canada is soliciting submission of data/information in the following areas:

- Identification of generic sources of information on identity and use of UVCBs, (for example, International Cosmetic Ingredients (INCI) Dictionary, Naval Stores Production, Chemistry and Utilization, etc).
- Information on composition, physical/chemical properties, use and/or exposure of specified UVCBs.

### Background on Approach for UVCBs

For prioritized UVCBs, identifiable information on composition is being considered in addition to existing assessments of mammalian toxicity of a range of endpoints including cancer, genotoxicity, reproductive and developmental toxicity, repeated dose toxicity, etc. Where information on the toxicity of mixtures themselves is not available, initial consideration of hazard is based on the worst-case data for known constituents. The latter requires detailed descriptions of the chemical composition of the range of products that comply with the DSL name and CAS Registry Number. Also, to permit refinement of exposure estimates within the ComET tool for these UVCBs, information on current use, physical chemical properties, emissions or any monitoring data are also relevant

On the basis of a fairly extensive sample of the GPE UVCBs, readily identifiable published sources provide relatively poor insights into chemical composition. Without provision of this and related additional information, therefore, these substances will remain as priorities for screening assessment in 2006.

An example of relevant information on UVCBs is attached in Appendix 1.

### **Polymers:**

Health Canada is soliciting submission of data/information in the following areas:

- Information similar to that specified in New Substances Notification Regulations (NSNR) as to whether a polymer is only made under conditions that would meet low concern criteria, that is: compositional information, manufacturing scheme, molecular weight distribution, physical state, solubility data, etc. (Government of Canada 1994. New Substances Notification Regulations. SOR/94-260. Text available from <http://laws.justice.gc.ca/en/C-15.31/SOR-94-260/index.html>).
- Polymer use patterns and particle size for any airborne aerosols that might be generated relevant to exposure of the general population.

### Background on Approach for Polymers

For polymers, identification of priorities for additional consideration for human health should be consistent with those that would be identified by the New Substances Notification Regulations (NSNR).

For the 111 polymers on the GPE list, then, as per NSNR criteria, polymers which would meet the criteria of Schedule X of the NSNR (polyesters manufactured from a defined list of monomers) were identified initially. Then, in the absence of all the information required to make the full determinations under Schedule IX, polymers which contained no reactive functional groups of concern are being identified. Polymers with the potential presence of a functional group of human health versus environmental concern are then distinguished. Remaining polymers are then compared (based on monomers specified in the DSL name) with polymers that have undergone full review by the CEPA New Substances Program and which qualified for addition to the DSL.

For all polymers, however, additional information on manufacture, properties and uses, physical/chemical properties (including particle size for specified uses) or exposure is desirable to confirm that potential for inhalation through product or environmental exposure is minimal.

In the absence of submitted information, Health Canada will base its decision for categorization of polymers with respect to potential exposure or toxicity to human health on monomer properties and DSL use code information.

### **The Complex Exposure Tool (ComET):**

Submission of information in the following areas would increase the accuracy of exposure estimates being developed for all substances prioritized for further consideration on the basis of the integrated framework for greatest potential for exposure and “inherently toxic” to humans.

Generic:

- Use patterns for products.
- Extent of contact of product with skin and/or release to air or other media.

Substance Specific:

- More recent information on how the specified substances are used.
- If still relevant, more specific information on how the substance is used within the use code that was notified by industry during the DSL nomination process.
- Measured exposure data, or realistic worst-case simulations (e.g., percentage(s) in products, product-use frequency, and amount per use data).
- Documented input values to improve assumptions originally used in ComET (e.g., physical chemical properties, dermal penetration rates, etc).
- Documented emission data or release scenarios.

### Background on the Complex Exposure Tool (ComET)

ComET is a more complex tool being designed to provide upper bound quantitative estimates of combined consumer and multimedia environmental exposure for various durations and age groups, taking into account accessible information on use categories, representative (sentinel) product scenarios, physical/chemical properties, bioavailability and emissions. The tool will extend considerably identified scenarios for product categories to address the broad range of reported uses for the substances on the DSL prioritized for further consideration on the basis of highest potential exposure. The tool will also extend existing fugacity models to address environmental media of human exposure. To facilitate input into development of the tool, a peer consultation meeting is being organized (see <http://www.tera.org/peer/Exposure/ExposureWelcome.htm>).

### **Submission of Relevant Information**

Individual companies or consortia are invited to provide information of the nature specified above to permit additional refinement of the list of substances prioritized for additional consideration for categorization of greatest potential for exposure and “inherently toxic” to humans.

Relevant information in either hard copy or electronic format should be submitted by **September 16<sup>th</sup> 2005**, and should be forwarded to both Health Canada and Environment Canada simultaneously.

Electronic submissions are preferred, and should be sent to:

Health Canada ([ExSD@hc-sc.gc.ca](mailto:ExSD@hc-sc.gc.ca)) and Environment Canada ([DSL.SurveyCo@ec.gc.ca](mailto:DSL.SurveyCo@ec.gc.ca))

Information in hard copy format should be mailed to:

Existing Substances Division  
Environmental Contaminants Bureau  
Health Canada  
4<sup>th</sup> Floor, 269 Laurier Avenue West  
Address Locator: 4904A  
Ottawa, Ontario  
K1A 0K9

And

Environment Canada  
DSL Surveys Coordinator  
351 St. Joseph Blvd., 20th floor  
Gatineau, QC K1A 0H3  
CANADA

Health Canada will also continue to refine this list of priorities based on readily available information and evolving tools. However, those for which little information is identified prior to 2006 will be included on the list of priorities for screening in 2006 and relevant information gathering initiated as a basis to conduct the necessary screening level assessment.

Existing Substances Division  
Environmental Contaminants Bureau  
September 1, 2004

## Appendix 1

### Example of Relevant Data for Consideration of a UVCB

#### Tall oil rosin – 8052-10-6

The Registry Number applies to the third generic class of rosins, those obtained from the distillation of tall oil. These rosins are a by-product obtained in the form of soaps from alkaline extraction of wood during the kraft pulping process (Zinkel and Russell, 1989). The main components are the same C<sub>20</sub> rosin acids as previously described for the other two rosin classes.

Initial consideration of hazard would be reasonably based on the toxicity data identified in searches on the terms “tall oil rosin”, “rosin tall oil” and the Registry Number 8052-10-6, and the names and Registry Numbers of the major constituent acids and neutrals and determined by the worst case data set on each categorization endpoint on any tall oil rosin and on any of the major constituents.

“Rosin tall oil” (8052-10-6) was amongst the materials included in the Group Tolerable Daily Intake (TDI) of 1 mg/kg body weight assigned by the Scientific Committee on Food (SCF) in 1984 (EC, 1986) and “tall oil rosin” is a permitted indirect additive under section 178.3870 of the Code of Federal Regulations. In a more recent overview of SCF opinions on monomers and additives used in food contact applications (EC, 2003), “rosin tall oil” (8052-10-6) is included in a list of materials on which a TDI could not be determined but whose use [in food packaging] could continue.

#### Additional Relevant Data

Data on toxicity (published or unpublished) on specific Trade Name products relevant to this general class are desirable. Information on use, physical/chemical properties, emissions and/or monitoring is also relevant to determine potential for exposure by inhalation and to permit refinement of exposure estimates in ComET.

#### References

- EC (1986). European Commission. Reports of the Scientific Committee on Food. Seventeenth Series. Certain monomers and other starting substances to be used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs (Opinion expressed on 14 December 1984). [http://europa.eu.int/comm/food/fs/sc/scf/reports/scf\\_reports\\_17.pdf](http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_17.pdf)
- EC (2003). European Commission. “Synoptic document” Provisional list of monomers and additives notified to European Commission as substances which may be used in the manufacture of plastics intended to come into contact with foodstuffs (updated to 25 July 2003). SANCO D3/LR (2003) File:INT/SYNOPTIC DOCUMENT (07.2003). [http://europa.eu.int/comm/food/fs/sfp/food\\_contact/synoptic\\_doc\\_en.pdf](http://europa.eu.int/comm/food/fs/sfp/food_contact/synoptic_doc_en.pdf)
- Zinkel DF and Russell RL (1989). Naval Stores Production, Chemistry and Utilization. Pulp Chemicals Association.