

A Response to the Proposed Toxic Substances Management Policy for Canada

Publication #252

ISBN# 978-1-77189-478-4

**Submitted to
Environment Canada**

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November 1994

VF:
CANADIAN ENVIRONMENTAL LAW
ASSOCIATION.
CANADIAN INSTITUTE FOR
CELA BRIEF NO.252; A re...RN14761

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Appendix 1

I. INTRODUCTION

Toxic contamination of the Canadian environment remains one of the most vital concerns of Canadians. There is increasing evidence that the problems emanating from toxic contamination are more insidious and their effects more far reaching than previously conceived. Urgent, strong, and comprehensive action is needed.

It is in light of this problem that the Canadian Environmental Law Association (CELA) and the Canadian Institute for Environmental Law and Policy (CIELAP) welcome the opportunity to comment on the proposed "Towards a Toxic Substances Management Policy for Canada" (hereinafter referred to as the TSMP). This document will first provide a context for the TSMP. Then it will review the definitions, thresholds and implementation issues related to the TSMP.

II. CONTEXT FOR TSMP

The proposed TSMP has not been developed in a vacuum. Indeed, it is fair to say that the TSMP emerged from a long history of efforts in various parts of the country to address the problem of toxic chemicals. Perhaps one of the most obvious roots of the TSMP pertains to the legal regime in the Great Lakes.

The Great Lakes Experience

In 1978, the Canadian and U.S. governments signed the Great Lakes Water Quality Agreement. Article II of that Agreement states that:

"The discharge of toxic substances in toxic amounts be prohibited and the discharge of any or all persistent toxic substances be virtually eliminated."

Annex 12 of that Agreement states that, when designing regulatory strategies to implement Article II, those strategies must be undertaken in the "philosophy of zero discharge."

In reviewing governments' progress in furthering this goal, the International Joint Commission (IJC) stated quite unequivocally its interpretation of these provisions:

"...it is clear to us that persistent toxic substances have caused widespread injury to the environment and to human health. As a society, we can no longer afford to tolerate their presence in our environment and in our bodies. Their use and presence in the Great Lakes environment are also inherently inconsistent with the Agreement's purpose and specific problems. Hence, if a chemical or group of

chemicals is persistent, toxic and bioaccumulative, we should immediately begin a process to eliminate it.¹

The recommendation has been echoed through the Commission's work, including a report of one of its advisory committees, the Virtual Elimination Task Force.²

Any policy emanating at the federal level must be consistent with, and contribute to, the implementation of the Great Lakes Water Quality Agreement.

Parliamentary Review of the Canadian Environmental Protection Act

A further context for the TSMP is the Parliamentary Review of the Canadian Environmental Protection Act (CEPA). The Act, which is the primary federal statute governing toxic chemicals, is undergoing this review by the Standing Committee on Environment and Sustainable Development. There has been a strong and consistent message from environmental and labour groups on the need for a pollution prevention approach that includes sunset and sunrise protocols to phase-out persistent toxic substances.³

This initiative is important as it is where the government's long term goals and approaches with respect to toxic substances will be determined. As such, any toxics management policy must be coordinated with, and preferably incorporated into, the reform of the Canadian Environmental Protection Act.

The Broader Context for Action

While no detailed review of the more recent literature and studies on the effects of toxic chemicals will be provided, it is clear that the implications of the literature and studies are significant. The recently released Dioxin Reassessment undertaken by the U.S. Environmental Protection Agency, for instance, implies that changes in hormone levels or other adverse health effects can occur in humans at or near levels of exposure to dioxin that are already experienced by members of the public. These trends indicate the need for strong, unequivocal action to protect the environment from toxic substances.

III. DEFINITIONS IN THE TSMP

Definition of "Virtual Elimination" - No Measurable Release

According to the proposed TSMP, substances that meet all four criteria will be placed on Track 1. The proposal then states that: "Track 1 substances will be virtually eliminated from the environment through management strategies that ensure no measurable release of the substance."⁴ The implication of this statement is that the

definition of virtual elimination is "no measurable release" into the environment.

This definition of virtual elimination must be rejected. There are a number of reasons why the proposed definition should be rejected.

*** It Is Inconsistent with the Concept of Pollution Prevention**

The proposed approach, which defines the goal of Track 1 as "no measurable release" allows a pollution control response rather than a pollution prevention response. Pollution prevention is defined as approaches that avoids or prevents the use and generation of toxic substances. Its strength is that it emphasizes changes in the industrial process through such techniques as raw product substitution, process reformulation, substitution, and other such techniques.

When the goal is defined as "no measurable release," legitimacy is given to continuing pollution control models that attempt to reduce emissions at the end-of-the-pipe. TSMP does not promote process change or other measures that avoid the use or generation of toxic chemicals. As such, the proposed TSMP reinforces present practices. It will not encourage innovation. It may lead industry to adopt more expensive, and ultimately less efficient, end-of-the-pipe measures. These investments will preempt other pollution prevention investments. In effect, these facilities will be held "hostage" to traditional pollution control technologies rather than pursuing pollution prevention strategies.

*** It Will Lead to Endless Debates as to the Definition of What is "No Measurable Release"**

Apart from the general concern, there are also practical problems with the "no measurable release" approach. Most importantly, who will define what is the "not measurable" limit? How will that limit be set? What happens if detection technology improves? The reality is that the determination of what is the "no measurable release limit" will be just as difficult, just as controversial and just as practically complex, as existing limits.

*** It is Inconsistent with the International Joint Commission's Definition of Virtual Elimination**

In its Seventh Biennial Report, the IJC re-iterated its previous approach and views, and states:

"we...want to continue attempts to manage persistent toxic substances after they have been produced or used, or ... eliminate and prevent their existence in the ecosystem in the first place, ... Since it seems impossible to eliminate discharges of these chemicals ..., a policy of

banning or sunsetting their manufacture, distribution, storage, use and disposal appears to be the only alternative.⁶

The Commission has rejected the "no detectable level" as an appropriate preventative approach. The federal government's approach, therefore, is contrary to the direction suggested by the IJC.

Recommendation No. 1:

The definition of "virtual elimination" as "no measurable release" should be rejected. Virtual elimination should be defined in a manner consistent with the definitions offered by the International Joint Commission and implemented through a national pollution prevention framework.

Reverse Onus

The use of the reverse onus concept in the proposed TSMP is an inappropriate use of the concept. The reverse onus concept is a component of the precautionary principle. The precautionary principle states that where there is uncertainty as to the environmental consequence of an activity, precaution should be exercised such that the activity does not proceed. The reverse onus is a mechanism whereby those undertaking such activities have the onus of establishing that the activity is safe.

In the TSMP, the reverse onus concept does not reverse any onus and place it on industry. It is really fashioned as an objection to the fact that a substance has been deemed to be persistent, bioaccumulative and toxic. As such, this section, if it is to be retained at all, should simply be deemed an objection. If this is a process for objections, then a clear procedure must be established to identify how objections should be undertaken, and timelines and thresholds should be established to make it clear when objections will be accepted or overruled.

Recommendation No. 2:

The reverse onus provision in the TSMP should be removed. If some process is to be included to challenge the decisions taken as to the hazard assessment, then clearly laid out rules and procedures should be articulated.

Definition of Environment

The definition for "environment" outlined in the proposed TSMP is limiting. It fails to include clearly the occupational environment. Occupational exposure is a major source or human exposure to toxic substances and should be considered in the TMP.

Recommendation No. 3:

The TSMP definition for "environment" should explicitly include the occupational environment.

Assessing Substances As a Class

One of the obvious deficiencies of the TSMP is that it takes a substance-by-substance approach rather than a class approach. Admittedly there is no accepted methodology for proceeding with class assessments. However, TSMP should include a commitment to work toward class assessments.

Recommendation No. 4:

The TSMP should include a commitment to developing a methodology for class assessments and then proceed by way of class assessments rather than substance-by-substance assessment.

The TSMP and the Canadian Environmental Protection Act

At present, the proposed TSMP does not explain how it is to be related to the Canadian Environmental Protection Act (CEPA). This is troublesome as there is a Parliamentary Review of CEPA currently being undertaken. The TSMP should be interpreted as a method to "fast-track" and take the most severe recourse to the most dangerous substances. In this context, the TSMP could provide a means to direct specific action at toxic, persistent and bioaccumulative substances. Indeed, the value of the TSMP may depend, in large part, to the extent to which it is incorporated into CEPA.

Recommendation No. 5:

The TSMP should become a part of CEPA as a means to fast-track and facilitate direct action against inherently dangerous substances.

IV. THRESHOLDS AND CRITERIA

Exclusion of Naturally Occurring Substances

The TSMP explicitly excludes elements and naturally occurring inorganic substances from the virtual elimination goal, thereby ignoring a large category of pollutants which have been shown to cause severe environmental and human health damage.

This exclusion is unique from the perspective of the efforts made by other jurisdictions

and scientific bodies to identify chemicals for virtual elimination. For example, the International Joint Commission and the Ontario Ministry of Environment and Energy (MOEE) have not made this distinction between substances. Their view is that no matter what the nature of a substance, if it is toxic, bioaccumulative and persistent, it should be phased-out and banned. The proposed TSMP does not follow this approach.

Moreover, the TSMP includes an "expert judgement" for those substances which have human-made and natural sources. That is, "expert judgement" will be applied to determine whether or not a substance is released in sufficient quantities by human-made sources in order to justify virtual elimination. This "expert judgement" is a significant step backwards. It allows an administrative judgement, with little or no accountability structures. What one "expert" says may be completely different than what another "expert" says. There is, for example, already a disagreement on whether toxic PAHs are included or not in the proposed TSMP.

Recommendation No. 6:

All substances, regardless of their nature, should be eliminated from human sources if they exceed the thresholds for toxicity and, persistence or bioaccumulation.

Persistence

The TSMP is based on levels of persistence far higher than those proposed by other jurisdictions, scientists, or independent bodies, including those used by Environment Canada for one of its voluntary programs [Accelerated Reduction/Elimination of Toxics (ARET)]. This has two very different implications.

First, Environment Canada would be administering programs based on a dissimilar scientific basis. However, there is a need for consistency in delivering governmental programs, especially since the proposed TSMP is national in scope and is urgently needed. Secondly, by allowing higher persistence levels, the proposed TSMP would allow toxic chemicals into the environment which will remain there for a long time. This would result in continued damage to human health and the environment.

Persistence is measured as the half-life of a substance in the various media in the environment (air, water, soil or sediment). The TSMP proposes a persistence (half-life) of 182 days in water. But all other scientific evidence says this is too high. In fact, TSMP quotes several scientific sources which propose a lower half-life. The IJC, MOEE, university scientists and even industry suggest a half-life of 56 days or less as a definition for persistence.⁶

It is surprising that the federal government would propose to use such a high level of persistence. It is especially surprising since the TSMP references scientific evidence

and then chooses to ignore it. It is also surprising since the federal government signed the Great Lakes Water Quality Agreement with the U.S., which specified persistence as a half-life of 56 days in water.

Recommendation No. 7:

The persistence criteria need to reflect, and be consistent with, scientific evidence. In particular, the half-life of a substance in surface water needs to be set at 56 days, and at 2 days in air.

Bioaccumulation

The proposed TSMP sets an unusually high level of bioaccumulation for a substance to follow the virtual elimination track. The TSMP indicates that a Bioconcentration Factor (BCF) of greater than 5,000 is the cutoff for substances to be virtually eliminated (if it also exceeds the persistence, toxicity and anthropogenic criteria).

However, all other scientific evidence used by the drafters of the TSMP recommends lower levels of bioconcentration. The MOEE and the ARET processes, for example, uses a BCF of greater than 500 as a cut-off for virtual elimination.

Recommendation No. 8:

The BCF should be lowered to at least 500, and preferably to 250.

Toxicity

In order for a substance to follow the virtual elimination track, it must be toxic as defined by the Canadian Environmental Protection Act (CEPA) or it must be 'CEPA-toxic equivalent.'

This definition of toxic has a number of serious problems, which have been described elsewhere in detail.⁷ 'Toxic' as defined by CEPA sets a very high threshold for action, the definition is reactive (i.e., significant damage has to have occurred before action is taken), and the definition assumes that there is enough information to know the quantities or concentrations of substances in the environment.

As a result of using this definition of toxicity, the federal government has recently found only 25 of 44 priority chemicals toxic. Moreover, the federal government found that, by using this definition of toxic, it could not determine whether 13 chemicals were toxic or not. The government cited "insufficient information" as the reason.

Recommendation No. 9:

For the TSMP to work effectively and in a preventative manner, it must be disconnected from the CEPA definition of toxicity. Rather than using the CEPA toxic approach, TSMP should use the hazard assessment developed by the MOEE (see Appendix 1 for the hazard assessment).

Combination of Criteria

For a substance to be virtually eliminated, the TSMP requires that a chemical must meet all the criteria: be predominantly anthropogenic, persistent, bioaccumulative and toxic. Thus, not only does the TSMP require very high thresholds, it also requires that a substance meet all these thresholds. This will allow the continued release of substances clearly damaging to human health and the environment.

Recommendation No. 10:

Substances emanating from human sources should be phased-out and banned if they are toxic and, bioaccumulative or persistent.

V. IMPLEMENTING THE TSMP

Existing Track 1 Substances

The stated goal of the proposed TSMP is the "virtual elimination" of environmental releases of Track 1 substances (toxic, persistent, bioaccumulative, and predominantly anthropogenic). Virtual elimination is defined as "no measurable release."

Given the serious environmental and human health effects associated with substances of this nature, this definition is inadequate as it would permit the use of Track 1 substances within closed-loop systems, or where it is available, end-of-pipe technology to reduce discharges below measurable levels. Even if the environment is defined to include the occupational environment, this approach does not address the possibility of upsets or accidental releases, or the possibility of cross-media transfers which inevitably arise with end-of-pipe pollution control technologies.⁹ It may also encourage firms to make investments in end-of-pipe technologies rather than seeking to develop substitutes or alternatives to the substances in question.⁹

Recommendation No. 11:

The intentional manufacturing or use of substances found to meet the Track 1 criteria should be banned through regulations made under CEPA. Exemptions from this rule should only be permitted under truly extraordinary and exceptional circumstances,

such as the substance being a cure for AIDS or Cancer. Exemptions should only be granted following a public review by a Board of Review at the conclusions of which a two-thirds majority of the Board recommends an exemption. In the event that a two-thirds majority of the Board does not recommend an exemption, the substance should be banned from manufacturing or use, with no further appeals. In the event that the Board recommends an exemption, the Minister should still have the option of banning the use or manufacturing of the substance. Any Track 1 substance given exceptional approval should still be required to be subject to a pollution prevention plan to eliminate the possibility of a release of the substance into the general or occupational environments. Intervenor funding for bona fide public interest intervenors in Board of Review Proceedings should be provided.¹⁰

Where Track 1 substances are created as by-products of the manufacturing or use of non-Track 1 substances, pollution prevention plans should be developed and implemented with respect to the Track 1 substances being created. These plans should provide for the elimination of release of the substance in question into the general or occupational environment. The manufacturing or use of non-Track 1 substances which result in the Track 1 by-products should be discouraged as a matter of public policy.

Existing Track 2 Substances

The proposed TSMP's treatment of Track 2 substances (toxic, but not bioaccumulative, persistent, and predominantly anthropogenic) is extremely disappointing. The proposed TSMP indicates that the federal government will "advocate," not require the life cycle, cradle-to-grave management of these substances (p.3) and "encourage," not require, pollution prevention in relation to them (p.3). Given the very stringent standard of proof which Environment Canada and Health Canada have set for the establishment of "toxicity" for the purposes of CEPA, substances found to be "toxic" for the purposes of CEPA, by definition are having, or have the potential to have, significant environmental or human health effects.

Recommendation No. 12:

The environmental release of such substances should not be permitted under the TSMP. Rather, pollution prevention plans should be required to be developed and implemented for non-Track 1 "CEPA toxic" (Track 2) substances. These pollution prevention plans should be required to provide for the elimination of release into the general and occupational environment of the Track 2 substances in question.

New Substances¹¹

The proposed TSMP would permit the use and manufacturing of Track 1 (toxic, persistent, and bioaccumulative) new substances provided that it could be

demonstrated that there would be no release of these new substances into the environment (virtual elimination). Given the potential environmental and human health effects of such substances, this approach should not be adopted.

Recommendation No. 13:

Track 1 New Substances

The intentional use or manufacturing of new substances which meet the Track 1 criteria should not be permitted, except under truly extraordinary and exceptional circumstances similar to those outlined for existing Track 1 substance. As with existing Track 1 substances exemptions should only be granted following a recommendation by a two-thirds majority of a Board of Review. In the event that a two-thirds majority of the Board does not recommend an exemption, the manufacturing or use of the substance should be prohibited, with no further appeals. If the Board recommends an exemption, the Minister should still have option of prohibiting the use or manufacturing of the substance.

Track 2 New Substances

Pollution prevention plans, providing for the virtual elimination from the general and occupational environment of new "CEPA toxic" Track 2 substances should be required prior to their use or manufacturing being permitted in Canada. This would be consistent with the treatment of existing Track 2 substances.

By-Products of New Substances

Current CEPA provisions do not permit new substance assessment of by-products of use of new substances. The deficiency should be addressed during the CEPA review.¹² If a Track 1 substance is created as an inevitable by-product of the use or manufacturing of a non-Track 1 or even non-"CEPA toxic" new substance, the use or manufacturing of new substance should be prohibited. Exemptions from this rule should only be permitted under exceptional circumstances as defined above. A pollution prevention plan to eliminate release to the general and occupational environments should be required to be developed and implemented if the by-product is a Track 2 substance.

VI. CONCLUSION

The government of Canada's release of a draft Toxic Substances Management Policy is an important first step in the development and implementation of a comprehensive policy and regulatory framework for such substances in Canada. Unfortunately, the proposed policy suffers from a number of serious weaknesses, and consequently

cannot be endorsed without major revisions.

CIELAP and CELA's major concerns regarding the proposed policy include the following:

- * the proposed definition of virtual elimination is inconsistent with the principles of pollution prevention and the definition set out by the IJC;
- * the definition of "environment" as outlined in the TSMP excludes occupational environment. The occupational environment should be explicitly included in this definition;
- * the criteria of "predominantly anthropogenic" appears to exclude elements and other naturally occurring substances known to have significant health and environmental effects, such as lead and mercury, from action under the proposed TSMP;
- * the proposed definition of persistence is inconsistent with the definition of persistence set out by other agencies, including the IJC, and the definition contained in the Great Lakes Water Quality Agreement. Persistence should be defined as having a half-life of 56 days in water and 2 days in air;
- * the proposed definition of bioaccumulation is too high and inconsistent with the definitions employed by other agencies. Bioaccumulation should be defined as a bioconcentration factor of at least 500, and preferably 250;
- * substances are required to be toxic, persistent and bioaccumulative to be placed on Track 1. A combination of toxicity and persistent, or toxicity and bioaccumulative should be sufficient to place a substance on Track 1;
- * the *deliberate* use and manufacturing of Track 1 substances would be permitted to continue. This approach is inconsistent with that proposed by the IJC for persistent toxic substances;
- * there is no commitment to action with respect to Track 2 substances except to encourage voluntary action by users and manufacturers of the substance in question. Pollution prevention plans to eliminate release to the general and occupational environments should be required for such substances; and
- * no clear procedures are provided for the "reverse onus" appeal process regarding Track 1 substances. Appeals should require a public hearing before a Board of Review, with provisions for intervenor funding for *bona fide* public interest intervenors.

CELA and CIELAP look forward to further opportunities to contribute to the development of this important policy by the government of Canada.

ENDNOTES

1. International Joint Commission, Sixth Biennial Report to the Governments of Canada and the United States (Ottawa - Washington, 1992), p. 4.
2. Report to the International Joint Commission, Report of the Virtual Elimination Task Force (Windsor, 1993).
3. See, for instance, the submission of a number of members of the Canadian Environmental Network Toxics Caucus, Reforming the Canadian Environmental Protection Act (September 1994), especially, Paul Muldoon, "Incorporating Pollution Prevention into Part II of CEPA: An Agenda for Reform."
4. Environment Canada, Towards a Toxic Substances Management Policy for Canada (Ottawa, September 1994), p. 2.
5. International Joint Commission, Seventh Biennial Report to the Governments of Canada and the United States (Ottawa-Washington, 1994), p. 26.
6. New Directions Group, Discussion Paper (1991).
7. See: P. Muldoon. "Incorporating Pollution Prevention into Part II of CEPA: An Agenda for Reform." in B. Mausberg, P. Muldoon, and M. Winfield [eds.], Reforming the Canadian Environmental Protection Act. (Ottawa: Canadian Environmental Network, 1994).
8. Canadian Institute for Environmental Law and Policy and National Wildlife Federation, Prescription for a Healthy Great Lakes: Report of the Program for Zero Discharge (Toronto and Ann Arbor: CIELAP and NWF, 1991), ch. 4.
9. R. Kemp, "An Economic Analysis of Cleaner Technology: Theory and Evidence," in K. Fischer and J. Schot, Environmental Strategies for Industry (Washington D.C.: Island Press, 1992), p. 281.
10. See M. Winfield, ed., Reforming the Canadian Environmental Protection Act: A Submission to the Standing Committee on Environment and Sustainable Development (Toronto: Canadian Institute for Environmental Law and Policy, September 1994 (CIELAP Brief 94/7)), Recommendation 27.
11. These Recommendations expand on Winfield, Reforming the Canadian Environmental Protection Act, Recommendations 12 and 13.
12. Winfield, Reforming CEPA, Recommendation 16.

Table 1.6: Ontario MOE Scoring System Summary Chart

Parameter Name	Endpoint & Units	Scoring Criteria					
		0	2	4	6	8	10
Environmental Persistence	t _{1/2} (days)	≤0	>10 to 50	>50 to 100	>100 to 1000	>1000	>1000
Procarcinogenic	DCF log L ₅₀	≤0 2.0	>20 to 500 >2.0 to 4.0	>500 to 15000 >4.0 to 6.0	>15000 >6.0		
Parameter Name	Endpoint & Units	0	2	4	6	8	10
Acute Lethality	oral LD ₅₀ mg/kg	>5000	>500-5000	>50-500	>5-50	>0.5-5	≤5
	dermal LD ₅₀ mg/kg	>5000	>500-5000	>50-500	>5-50	>0.5-5	≤5
	inhalation LD ₅₀ mg/m ³	>15000	>1500-15000	>150-1500	>15-150	>1.5-15	≤5
	aquatic LC ₅₀ mg/L	>1000	>100-1000	>10-100	>1-10	>0.1-1	≤1
Chronic/Subchronic Toxicity, Non-Mammals	aquatic EC ₁₀ mg/L	≥20	2-20	0.2-2	0.02-0.2	<0.02*	<0.02*
	MAEC mg/L	≥2	0.2-2	0.02-0.2	0.002-0.02	<0.002*	<0.002*
	NOAEC mg/L	≥0.2	0.02-0.2	0.002-0.02	0.0002-0.002	<0.0002*	<0.0002*
	terrestrial subchronic NOEL mg/kg/d	≥1000	100-1000	10-100	1-10	<1*	<1*
terrestrial subchronic NOEL mg/kg/d	≥500	50-500	5-50	0.5-5	<0.5*	<0.5*	
					*in one genus	*in different genus	
Chronic/Subchronic Toxicity, Plants	Water, mg/L						
	Air, mg/m ³						
	Soil, mg/kg						
	% Mass/Growth Reduction: SS (NOAEL)						
	water	>10	>1-10	>0.1-1	>0.01-0.1	0.001-0.01	<0.001
	air	>100	>10-100	>1-10	>0.1-1	0.01-0.1	<0.01
	soil	>100	>10-100	>1-10	>0.1-1	0.01-0.1	<0.01
	>50% (EC ₅₀)						
water	>100	>10-100	>1-10	>0.1-1	0.01-0.1	<0.01	
air	>1000	>100-1000	>10-100	>1-10	0.1-1	<0.1	
soil	>1000	>100-1000	>10-100	>1-10	0.1-1	<0.1	
>50%							
water	>1000	>100-1000	>10-100	>1-10	0.1-1	<0.1	
air	>10000	>1000-10000	>100-1000	>10-100	1-10	<1	
soil	>100000	>1000-10000	>100-1000	>10-100	1-10	<1	
Chronic/Subchronic Toxicity, Mammals**	oral NOEL mg/kg/day	>1000	>100-1000	>10-100	>1-10	>0.1-1	≤1
	inhalation NOEL mg/m ³	>3000	>300-3000	>30-300	>3-30	>0.3-3	≤3
Teratogenicity	mg/kg/day	no terata, or terata only at >1000	terata or developmental anomalies at >50-1000	terata or developmental anomalies at >10-50	terata or developmental anomalies at >1-10	terata at >0.1-1, without overt maternal toxicity	terata at ≤0.1 without overt maternal toxicity
Carcinogenicity	human and animal bioassay data	no tumours in adequate studies on at least two species, and does not interact with genetic material	tumours in only one animal species, negative results in others	causes benign tumours in more than one species, and does not interact with genetic material; promoter only, or causes cell transformation in tube only (negative evidence in vivo)	tumourigenic in bioassays at doses causing metabolic enzyme saturation, or associated with lesions that predispose to tumours. No interaction with genetic material	indirect-acting carcinogens, no interaction with genetic material	direct-acting carcinogens that interact with genetic material

** Note: The Chronic/Subchronic Toxicity, Mammals criteria are based on studies of ≥90 days duration. If only shorter-term subchronic studies are available, the data are modified as follows, for scoring purposes:

Study duration 28-89 days - multiply criteria by 10
 Study duration ≤28 days - multiply criteria by 100

- * the proposed definition of bioaccumulation is too high and inconsistent with the definitions employed by other agencies. Bioaccumulation should be defined as a bioconcentration factor of at least 500, and preferably 250;
- * substances are required to be toxic, persistent and bioaccumulative to be placed on Track 1. A combination of toxicity and persistent, or toxicity and bioaccumulative should be sufficient to place a substance on Track 1;
- * the deliberate use and manufacturing of Track 1 substances would be permitted to continue. This approach is inconsistent with that proposed by the IJC for persistent toxic substances;
- * there is no commitment to action with respect to Track 2 substances except to encourage voluntary action by users and manufacturers of the substance in question. Pollution prevention plans to eliminate release to the general and occupational environments should be required for such substances; and
- * no clear procedures are provided for the "reverse onus" appeal process regarding Track 1 substances. Appeals should require a public hearing before a Board of Review, with provisions for intervenor funding for bona fide public interest intervenors.

CIELAP and CELA look forward to further opportunities to contribute to the development of this important policy by the government of Canada.

Yours sincerely,

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