SUBMISSIONS ON THE PROPOSED NEW SUBSTANCES NOTIFICATION REGULATIONS (CHEMICALS AND POLYMERS)

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January 14, 2005

Bernard Madé
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Dear Mr. Madé:

Re: Submission on the New Substances Notification Regulations (Chemicals and Polymers)

The undersigned are submitting the following comments on the proposed New Substances Notification Regulations (Chemicals and Polymers), as published in the Canada Gazette Part 1 on October 30, 2004.

In general, we applaud the improvements which have been made to these Regulations, and we support many of the provisions in their current form. We are particularly pleased to note the addition of longer-term toxicity testing for certain NDSL substances, simpler schedules and regulatory text, useful explanatory tables and flowcharts, and an acknowledgement of children's unique health issues, to name a few. However, there remain opportunities to strengthen these Regulations by further entrenching the precautionary principle, expanding the scope of toxicity testing, improving transparency and public access to information, and prioritizing health and scientific concerns over economic ones. We hope that these comments will be given careful consideration as your department considers how to proceed with the development of these important Regulations.

The Sunrise System

We support the use of a sunrise system for regulating chemicals and polymers as a more precautionary method of assessing environmental and human health. The sunrise structure requires key test data at low volumes so as to prevent the release of harmful substances from the outset. The testing regime is also made more comprehensive through the addition of tests for ozone depleting potential and global warming potential.

The sunrise approach is premised on the fundamental principle that toxicity should be gauged by hazard assessments as opposed to risk assessments. The use of hazard assessments over risk assessments is appropriate where there exists scientific uncertainty regarding the danger posed by a substance or the effectiveness of control mechanisms. Hazard assessments involve only the

measure of a substance's inherent toxicity, and do not base management decisions on the notion of exposure. Risk assessments combine the dual determinations of inherent toxicity and exposure, thereby creating a model based on the relative probability of harm occurring. The "probability" element of this latter type of assessment is problematic because it allows for incremental releases of small quantities of potentially toxic substances. These releases are permitted on the assumption that harm is *unlikely* to occur; however, it is often difficult to determine *how* unlikely since there is a paucity of information about the substances' inherent characteristics. There may also be unanticipated factors which heighten the probability of harm, such as multiple sources, interactions with other substances, and exposure to particularly vulnerable populations.

It is worth noting section 2(1) of the proposed Regulations, which states that the purpose of the Regulations is for the Minister to determine "whether the chemical or polymer is toxic or capable of becoming toxic". Preventing the release of substances *capable of becoming toxic* is fundamentally different than preventing the release of substances with the *probability of becoming toxic*.

The sunrise system attempts to move away from the risk-based scheme to a hazard-based one by requiring assessments of human and environmental health impacts at as low a volume as is scientifically feasible. In this way, necessary restrictions can be placed on dangerous substances before they accumulate to the 1000 kg/yr or more likely the 10,000 kg/yr or 50,000 kg/yr thresholds, thereby preventing damage which could otherwise be caused at these volumes.

It is suggested that deviations from this common sense approach are motivated by economic, as opposed to scientific, rationales. Nonetheless, we recognize that the sunrise system is unlikely to be adopted in its entirety in today's economic climate. Indeed, we applaud the substantial progress which has been made in certain areas of the Regulations, such as the treatment of NDSL chemicals and polymers which previously received no longer-term toxicity testing. Having said this, the NDSL schedules for both chemicals and polymers could and should be further strengthened to reflect the same level of scrutiny and toxicity testing requirements as are being proposed for non-NDSL substances. This is warranted by virtue of the fact that information received from the U.S. EPA is far from comprehensive, that much of the information remains confidential, and that there are consequently large gaps in our scientific understanding of substances on both the TSCA Inventory and, ultimately, the NDSL.

The progress made with respect to NDSL substances was unfortunately not mirrored in the proposed schedules for non-NDSL chemicals and polymers, and we feel that the sunrise principles warrant particular application to these classes of substances. For example, it is alarming that key tests such as the *in vivo* genotoxicity study, the 28 day repeated-dose study, and a teratogenicity study are reserved for the 10,000 kg/year threshold.

Additionally, although we support the requirement for exposure information relating to "whether it [the substance] is anticipated to be used in products intended for use by or for children"[1], we feel that children's health concerns should be more comprehensively addressed. This data requirement, as currently proposed, is simply not adequate as it fails to articulate what action the government will undertake if a substance is found to include properties harmful to children. Children may experience different health effects at different concentrations than adults. Children may also be impacted by substances through unique routes of exposure, a fact which should be fully recognized by the assessment process. It is thus essential that the minimum data set for new substances include an assessment of the neurotoxicological effects on children as well as other hazardous properties. There is a danger that substances from the TSCA Inventory will enter the NDSL and ultimately be placed on the DSL without assessors ever scrutinizing their effects on children.

- **Recommendation: Require data on toxicity, persistence, bio-accumulation, ozone depleting potential, global warming potential, and endocrine disruption at as low a volume as is scientifically feasible. Specifically, require an *in vivo* genotoxicity study, a 28 day repeated-dose study, and a teratogenicity study at 1000 kg/yr for both non-NDSL and NDSL substances.**
- **Recommendation: Expand the specific data requirements relating to children's health to specifically include neurotoxicological testing, along with other hazardous endpoints.**

Chronic Toxicity

The most alarming deviation of the proposed Regulations from the sunrise system is in the area of chronic toxicity testing. There is only one prescribed test which is capable of providing an indication of chronic toxicity: the 28 day repeated-dose mammalian toxicity test: This test is only required for non-NDSL Chemicals and Polymers at 10,000 kg/year, and for NDSL Chemicals and Polymers at 50,000 kg/yr *if* such substances are additionally released to the aquatic environment in excess of 3 kg/day/site or if the substances are present in products where significant public exposures are anticipated. Standard tests for sub-chronic toxicity (ie. 90-day) and chronic toxicity (ie. 12 months) are not prescribed at any volume, for any type of substance, prior to DSL eligibility.

The lack of chronic toxicity test data in the proposed Regulations is extremely worrisome, particularly with respect to the schedules for non-NDSL substances. It is recognized that, although the NDSL schedules as currently proposed are far from ideal in many respects, they mark a significant improvement over the existing regulatory framework which at no point requires the 28 day repeated-dose test for NDSL substances prior to placing them on the DSL. Having said

[1] Schedule 5, s. 8(f). Similar wording is found in schedule 3, s. 15(i) and schedule 9, s. 13(c).

this, it would, of course, be preferable to require the 28 day repeated-dose mammalian toxicity test for *all* NDSL substances prior to their addition to the DSL.

Without more comprehensive test data on chronic toxicity, government officials are forced to base their regulatory decisions on less accurate and informative methods. For instance, they may turn to databases, surrogate information, mathematical extrapolations, or models such as QSAR [Quantitative Structure-Activity Relationship]. However, it is generally acknowledged that test data is significantly better at predicting chronic toxicity than QSAR data, and other methods, such as mathematical extrapolations, often necessitate the use of large uncertainty factors.

These alternative methods are particularly problematic when assessing those substances, such as dioxin, which have dramatically different short-term and long-term effects. Such substances may have multiple mechanisms of action, or may not exhibit any effects at all during the short duration of acute toxicity studies.

Accordingly, it is imperative that government require the 28 day repeated-dose mammalian toxicity test, *at a minimum*, prior to the 1000 kg/yr cut-off. The proposed schedules are inadequate to provide an accurate assessment of substances' long-term effects. By delegating such testing requirements to the 10,000 kg/yr or 50,000 kg/yr thresholds, there is the possibility of human and animal populations suffering harm from the unknown hazards posed by chronically toxic substances. Additionally, we urge government to consider the addition of stronger indicators of chronic toxicity to the testing regime, such as toxicity tests of 90 day or 12 month duration.

- **Recommendation: Require chronic toxicity tests for non-NDSL chemicals and polymers at 1000 kg/yr.**
- **Recommendation: Add stronger indicators of chronic toxicity, such as toxicity tests of 90 day or 12 month duration.**

Ability to Require Additional Information

One of the key recommendations to emerge from the multistakeholder consultation on the NSNR involves the ability of government to use section 84(1)(c) or some more expansive mechanism to request additional information from notifiers when there exists a *suspicion* of toxicity.

Section 84(1) stipulates that:

> Where the Ministers have assessed any information under section 83 and they suspect that a substance is toxic or capable of becoming toxic, the Minister may, before the expiry of the period for assessing the information,

(a) permit any person to manufacture of import the substance, subject to any conditions the Ministers may specify;
(b) prohibit any person from manufacturing or importing the substance; or
(c) request any person to provide any additional information or submit the results of any testing that the Ministers consider necessary for the purpose of assessing whether the substance is toxic or capable of becoming toxic.

Although the wording appears unambiguous, in the absence of further guidance, the authority conferred by section 84(1)(c) involves considerable discretion on the part of government. There is a lack of transparency as to what would be sufficient to trigger a suspicion of toxicity. For instance, is the same level of suspicion required for all of the management options provided for by section 84? Or could one level of suspicion be sufficient to trigger a request for more information yet not enough to warrant a prohibition?

It seems clear that this provision is currently underutilized, perhaps due to these uncertainties in its interpretation. As of 2001, section 84(1)(c) had only been invoked by government on one occasion. The multistakeholder consultations resulted in a consensus recommendation that section 84(1)(c) be broadly interpreted to allow supplementary tests to be added, or the standard tests to be conducted at lower volume thresholds. The suspicion trigger for subsection (c) would not necessarily be as high as that required for subsections (a) or (b); examples of appropriate circumstances in which to invoke subsection (c) included "the presence of enough data to raise a suspicion of toxicity, but insufficient information to adequately characterize the substance, or the presence of structural features associated with adverse effects, combined with the possibility of exposure."[2]

The existence and prudent exercise of such a power is key to the precautionary application of the NSNR regime as a whole, and could potentially help to alleviate many environmental and health concerns. For instance, one would hope that regulators would request additional long-term toxicity tests when they are unable to rule out the possibility that a substance causes chronic toxicity. The critical importance of this recommendation was illustrated by the Final Report of the Multistakeholder Consultations:

> The Table emphasizes that the ability of Environment Canada and Health Canada to utilize section 84 in this manner will be crucial to the successful implementation of the main recommendations in this report. The development of a clear government guidance document that will facilitate this mechanism, therefore, must be given highest priority.[3]

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[2] Canada, Environment Canada and Health Canada, *Consultations on the CEPA New Substances Notification Regulations and New Substances Program: Final Report of the Multistakeholder Consultations* (Ottawa: Environment Canada, 2002) [hereinafter *Final Report*] at 13.
[3] *Ibid.*

In light of these strong words and government's subsequent commitment to provide further guidance by summer 2003, it is discouraging that Environment Canada and Health Canada reported that no progress had been made in their document "Report on Progress: Implementing the Consultation Recommendations for Period Ending October 2003."

We anxiously await feedback as to the implementation of this recommendation. Government's ability and impetus to request additional information in a precautionary manner is critical to the effectiveness of these Regulations as a whole. If section 84(1)(c) were not ultimately applied in the manner envisaged, we would recommend that much more extensive tests be prescribed in the schedules, and waivers subsequently granted where appropriate. Additionally, there could be prescribed classes of substances which automatically warranted additional tests or DSL disqualification based on their intrinsic characteristics, in much the same way certain classes of substances currently receive exemptions from the standard scheme.

- **Recommendation: There should be immediate clarification regarding the authority of regulators to require additional information when the prescribed information suggests a suspicion of toxicity, but is considered insufficient to adequately characterize the risk. In the absence of this clarification, additional tests should be prescribed in the schedules to ensure that sufficient data is available to demonstrate that the substance poses no risk to human health and the environment.**
- **Recommendation: In the meantime, Environment Canada and Health Canada should adopt the proposed interpretation of section 84 and should develop a guidance document that describes how authorities under section 84 (and/or other mechanisms) can be accessed and used to obtain additional information (beyond that prescribed in the notification scheme) required to complete the assessment (Table Recommendation #3).**
- **Recommendation: The NS Program should revise its internal procedures to ensure that, whenever warranted, additional data are requested at earlier stages in the assessment process (Table Recommendation #37),**

Export Only Substances

There is a growing pressure in Canada and around the world to harmonize data requirements so as to facilitate international sales of commercially viable chemicals and polymers. However, there is an unfortunate and ironic concurrent trend towards reducing the testing requirements for those substances destined solely for the international market. Export only substances are substances that are manufactured or imported for export only. There is only a skeleton set of data requirements proposed for this class of substances, and all of the testing

requirements in the existing regime have been eliminated. Namely, notifiers are no longer required to provide data from hydrolysis, ready biodegradation, and acute mammalian toxicity tests. As a result, the proposed Regulations do not include any test data for export only substances.

This raises serious ethical questions about Canada's obligation to the international market. Admittedly, there are jurisdictional limitations which prevent the federal government from sharing data with importing countries unless controls have been imposed, however, this state of affairs is in constant flux as international agreements and protocols are continually negotiated and refined. By eliminating the need for test data, Canada appears to be espousing the not-in-my-backyard philosophy which allows problem substances to be effortlessly exported to countries which may or may not have the scientific, economic, or administrative capacity to scrutinize such substances for health and safety concerns. This is unacceptable as many importing jurisdictions lack both the legislative framework and the resources necessary to require toxicity data. Additionally, it is unlikely that Canada will ever have cause to impose controls on these substances in light of the minimal information requirements which will be imposed. Finally, there is a concern about the adequate protection of workers who are required to handle these substances without fully understanding the dangers they present.

The counter-argument is an economic one; it is said that if Canada's standards are overly onerous as compared to those in other jurisdictions, chemical producers will move their businesses elsewhere and thereby evade higher testing requirements in any event. However, there is a danger of succumbing to the allure of being the lowest common denominator in the race towards international harmonization.

- **Recommendation: Subject export-only substances to the same level of scrutiny as those destined for the domestic market. At a minimum, reinsert the testing requirements which are currently included on the schedules for export only substances.**

Polymers with All Monomers on the DSL or NDSL

This area of the Regulations is perhaps the one most heavily influenced by economic as opposed to health and environmental considerations. Prior to the completion of the NSNR stakeholder consultations, "it was the view of Environment Canada and Health Canada that there is no scientific justification for the current system of modifying data requirement based on whether or not monomers are listed on the DSL or NDSL."[4] However, despite this strong statement, the proposed Regulations nonetheless contain drastically reduced data requirements for this class of polymer.

[4] *Ibid.* at 39.

The rationale for this concession was clearly acknowledged by government: "Environment Canada and Health Canada recognize that there is an industry sector that is dependant upon creating new polymers with existing monomers, and that a niche for this activity has been created by existing provisions in the current NSN Regulations."[5] We would argue that this is an invalid justification to rely upon when drafting regulations with the stated purpose of determining whether substances are toxic or capable of becoming toxic. Not only does this scheme depart from a hazard-based philosophy, it fails to even adhere to risk assessment principles.

A more precautionary approach would be to require the full spectrum of non-NDSL polymer data requirements, unless notifiers could justify the use of waivers on a case-by-case basis. Section 81(8) of CEPA specifically provides that the Minister may waive information requirements where such information is not needed in order to determine whether the substance is toxic or capable of becoming toxic. Additionally, there is already a category (with a corresponding reduced set of data requirements) for those polymers which qualify as Reduced Regulatory Requirement Polymers due to the lesser threat which they pose. These provisions would seem to provide ample opportunities for polymer manufacturers and importers to receive more lenient regulatory treatment whenever warranted.

On a final note, there is some confusion regarding section 18(2)(e) of the proposed Regulations. This section stipulates that the prescribed information for a polymer, all of whose reactants are on the DSL or NDSL, is specified in schedules 9 and 10. This appears to be inconsistent with s. 11(2) and (3) of the Regulations, as well as page 38 of the Final Report of the Multistakeholder Consultations. In each of these latter instances, it would seem that such polymers are subject to additional requirements upon reaching 50,000 kg/yr, if they are also released to the aquatic environment in excess of 3 kg/day/site or if they are present in products to which the public may be significantly exposed. Section 11(2) does not differentiate between NDSL polymers and non-NDSL polymers with all reactants on the DSL or NDSL in this respect; it is unclear why section 18(2)(e) would be inconsistent with this framework. We would strongly oppose a system wherein those polymers with all reactants on the DSL or NDSL were not subject to any testing requirements beyond those found in schedules 9 and 10.

- **Recommendation: Eliminate the separate regulatory stream for polymers with all monomers on the DSL or NDSL. Rather, these substances should be subject to the same data requirements as non-NDSL polymers.**

[5] *Ibid.*

The Need for "Flags" to be Attached to Certain Substances on the DSL

There is currently no adequate mechanism with which to monitor and enforce the appropriate use of substances after they have been placed on the DSL. This is particularly relevant for Reduced Regulatory Requirement Polymers, NDSL Chemicals and Polymers which have not yet surpassed the threshold volume of 3 kg/day/site[6] averaged over one month, and NDSL Chemicals and Polymers which are not currently present in consumer products where significant exposures are expected. In each of these cases, the substance becomes eligible for DSL inclusion while there are still limitations imposed upon its use.

As discussed above, Reduced Regulatory Requirement Polymers are allowed to enter the DSL after a perfunctory data analysis due to the fact that they pose little risk in their present form. However, the question remains: how will government ensure that such polymers are not modified into less benign varieties after being posted to the DSL? In its "Report on Progress: Implementing the Consultation Recommendations for Period ending October 2003," government claims to have developed a mechanism for identifying and tracking such polymers once they enter the DSL. Since no further Advisory Notes have been released to demonstrate the effectiveness of the proposed mechanism, we are unable to comment on its adequacy to protect against unmonitored modifications of polymers listed on the DSL.

Similarly, NDSL Chemicals and Polymers are allowed onto the DSL without submitting a 28 day repeated-dose mammalian toxicity study, an *in vitro* gene mutation study, or an *in vitro* chromosomal aberration study so long as they 1) are not likely to have releases of more than 3 kg per day per site, and 2) are not likely to be present in consumer products where significant exposures are expected. Again, it is unclear how daily volumes and the commercial uses will be monitored after the substances are added to the DSL.

It has been proposed that a combination of SNAcs and/or "tags" be used to track substances after they have been DSL-listed. The New Substances Program Operational Policies Manual contains a brief discussion of the use of SNAcs as a mechanism for tracking these types of substances both before and after inclusion on the DSL. While the use of SNAcs for this purpose is theoretically plausible, in reality SNAcs were neither designed for this function, nor have they been utilized in this manner previously. They are intended for application on a case-by-case basis, whereas in this instance entire classes of substances will require further monitoring after their addition to the DSL. Additionally, the provisions contained in SNAcs are triggered by *significant* changes in use patterns. Although the inclusion of a substance in a new consumer product may constitute such a

[6] As an aside, we noted that the regulatory text surrounding the 3 kg/day/site cut-off fails to reference the added stipulation that the volume should be calculated "including envisioned future uses by multiple users and/or a variety of applications" as set out in the *Final Report*. It is hoped that this caveat will be clearly established in any applicable guidelines which are subsequently published.

significant event, it is unlikely that the exceedance of 3kg/day/site would be sufficient. Finally, in order to apply the SNAc provisions, the Minister must suspect that the significant new activity may result in the substance becoming toxic. This threshold will curtail the ability of government to routinely request the additional test data; the onus will be on government to demonstrate that a valid suspicion exists.

For these reasons SNAcs or other, more tailored mechanisms will have to be fortified before we can reach any level of comfort with the proposed regulatory treatment of these classes of substances.

Transparency

Transparency issues are problematic throughout the New Substances Notification regime. The proposed amendments do not go far enough to address these matters. There is a lack of transparency at numerous steps in the notification process, including the issuance of waivers to notifiers for specific test data, and the final conclusions reached by government departments. In light of the new and (in many cases) reduced assessment periods, there is also an absence of transparency regarding what actions will be taken by government if deadlines expire prior to the completion of assessments. This is unacceptable and should be reevaluated in the context of CEPA requirements. Transparency could be improved by adopting the approach used for assessing existing substances, whereby the results of the assessment are posted and 60 days of public comment prescribed in the Act. Currently, the only notice provided by government with respect to new substances is the Canada Gazette Notice announcement of additions to the DSL, prohibitions, or restrictions placed on specific substances.

It is to the benefit of Canadians to know which substances are being used, manufactured, and imported in this country. Transparency could be further improved by acquiring information on substances at as little as 20 kg/yr., as is currently required under the NSN Regulations. The ability of government to collect and review data at this low volume is particularly relevant to those substances which exhibit dangerous properties at extremely low volumes. Additionally, it allows a more exhaustive official record to be kept of all substances in use in Canada. While we prefer to have toxicity, bioaccumulation, persistence, and other test data available for substances even at these low volumes, the simple listing of substances promotes transparency in the system. Such a mechanism would be comparable to the registration requirements proposed in the European Union's policy on toxic substances called Registration, Evaluation and Authorization of Chemicals (REACH), which requires the registration of *all* substances being used or manufactured in the EU. However, there is an obvious difference in that the NSN Regulations only apply to new substances.

The Regulatory Impact Analysis Statement also lacks transparency in that it fails to reference the role which animal testing would play in the ongoing refinement of the NSN program.

Finally, transparency could be enhanced if additional text were included in the Regulatory Impact Analysis Statement which made direct reference to the relationship between the proposed Regulations and existing international data-sharing arrangements. For example, this section lacks an explanation of the effects these proposed amendments may have upon initiatives such as the Four Corners Agreement. Page 3041 of the Canada Gazette Part 1, October 30, 2004, under the section entitled "Benefits to notifiers and the Government of Canada", may be an appropriate area in which to include this explanation.

- **Recommendation: Transparency should be an integral component of the New Substances Notification process, with clear indications of where public comments can be sought.**

In conclusion, although we are generally pleased with the improvements proposed for the New Substances Notification Regulations, there are several areas which we feel merit further consideration. Thank you for considering our submissions on these matters, and we would be happy to respond to questions or engage in further discussion about any of these topics in the future.

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