Environment Canada and Health Canada responses to comments received regarding the *Canada Gazette*, Part I publication of the proposed *New Substances Notification Regulations (Chemicals and Polymers)*, the proposed *New Substances Notification Regulations (Organisms)*, the proposed *Regulations Amending the New Substances Fees Regulations* and the proposed *Regulations Repealing the New Substances Notification Regulations*

The Minister of the Environment published the proposed Regulations in Part I of the *Canada Gazette*, on October 30, 2004.

Stakeholders had 75 days to provide comments on the proposed Regulations. Written comments, questions and concerns on the proposed Regulations were received from private industry, industry associations and an environmental non-governmental organization. All comments received during this 75-day comment period have been considered in the preparation of the revised draft Regulations.

Note that the information contained in this document reflects the revised draft of the *New Substances Notification Regulations (Chemicals and Polymers)*, the *New Substances Notification Regulations (Organisms)*, the *Regulations Amending the New Substances Fees Regulations* and the *Regulations Repealing the New Substances Notification Regulations* that are still subject to change pending final approval. Once final approval is received, the Regulations will be published in Part II of the Canada Gazette. Publication is expected in summer 2005.

Consultation period: October 30, 2004 through January 14, 2005

Comments or questions	Environment Canada and Health Canada Responses
Policy issues:	
We think that the revision of the NSNR was a good opportunity to streamline the NSN process by enabling EC as the sole submission window for all NSN, including F&DA's currently submitted to HC. We experienced that the assessment correspondence resulting from submissions to both departments is performed by EC. For consistency, it would be advantageous for EC to be the single point of contact for all correspondence, including initial submission.	An Option Analysis is in process with regard to the regulatory framework for environmental assessment of the *Food and Drugs Act* substances. The option chosen will determine the notifications procedures over the long term. Environment Canada (EC) and Health Canada (HC) are open to examine again the current arrangement.
We need instruction via guidelines or explanatory notes on how to determine what means: "the chemical is present in products to which the public may be significantly exposed". We presume that a *de minimus* concentration could be determined for such products and below which public exposure would not "be significant". We recommend that EC and	The term "significant" is used in the Regulations to discriminate between different levels of exposure. EC and HC are of the opinion that a *de minimus* concentration would be very conservative and result in a majority of notifiers submitting the information required in subsections 7(1) or 11(1). Since the intent was to optimize the testing

HC review the need for using “significant exposure” in the regulation.	requirements while maintaining a high level of protection of the environment and human health, we support a case-by-case determination with regard to levels of exposure. When in doubt, we recommend that the notifier request a pre-notification consultation to clearly explain their exposure scenario. Further clarification on the meaning of “significantly exposed” will be provided in the revised *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers.*
We support the use of a sunrise system for regulating chemicals and polymers. This approach requires key test data at the lowest volumes possible to prevent the release of harmful substances. The principle of this system is gauged on hazard assessment as opposed to risk assessment and considers only the substance’s inherent toxicity and not the exposure. We recommend requesting data on toxicity, persistence, bioaccumulation, ozone depleting potential, global warming potential and endocrine disruption at as low volume as scientifically feasible.	This approach has been discussed throughout the last decade, including during the last CEPA review discussions. It was also presented during the Multistakeholder Consultations. However, the *Canadian Environmental Protection Act, 1999* (the Act) did not adopt a hazard-based approach; rather, a assessment of toxicity based on section 64 calls for a consideration of both intrinsic properties and exposure potential of the substance being assessed. The NSN Regulations are based on the intent of the Act, and therefore adopt the same approach. Moreover, implementing the sunrise system would not lead to an optimization of the resources for either industry or government. EC and HC believe that the quantity-trigger tiered approach in the proposed Regulations achieves protection of the environment and human health while reflecting the 76 consensus recommendations resulting from the Multistakeholder Consultations.
The paragraph 84(1)(*c*) of CEPA 1999 is ambiguous and there is a lack of transparency as to what is sufficient to trigger a suspicion of toxicity. Please clarify the authority of the regulators to require additional information when the prescribed information suggests a suspicion of toxicity, but is considered insufficient to adequately characterize the risk. If no clarification is made, please request additional tests in the schedule to ensure that sufficient data is available to demonstrate the risk. EC and HC should adopt the proposed interpretation stipulated in recommendation 3 of the *Final Report of the Multistakeholder Consultations*.	Suspicion of toxicity is based on expert judgement and is better treated on a case by case basis. Requiring further tests for all notifications to address situations that occur only for few notifications would not be cost effective. The departments will continue using these provisions as per its intended use, i.e. when the departments have concerns about the hazards of a substance but are unable to quantify the risks.
Transparency could be further improved by acquiring information on substances at as little as 20 kg/yr. It would allow a more exhaustive official record to be kept of all substances used in Canada. We would prefer to have test data to be collected, but simple listing of substances would promote transparency in the system. Such mechanism would be	REACH is currently proposing registration of chemicals (REACH does not address polymers) at 100kg/year the same as chemicals not listed on the Non-domestic Substances List (NDSL) under the NSNR. As agreed upon during the Multistakeholder Consultation, the 100 kg per year trigger was introduced in the Regulations as the entry level for

comparable to the registrations requirements proposed by the European Union under REACH, which requires the registration of all substances being used or manufactured in the EU.	non-NDSL chemicals.
By eliminating the need for test data for export-only substances, Canada appears to be espousing the not-in-my-backyard philosophy. This is unacceptable as many importing jurisdictions lack both legislative framework and resources to require toxicity data. We recommend subjecting 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 schedule for export-only substances.	EC and HC will conduct risk assessment on the substance on the basis of the information that they received. Analogue data can be used and modeling can be performed based on the structure information. The departments expect that the same level of environment and human health protection will be maintained with the new approach. Export-only substances and site-limited intermediate also need to satisfy the "contained" criteria in order to fall under section 5 and 6 of the Regulations. As defined, a maximum of 1 kg per day per site can be released in the aquatic environment after wastewater treatment. Substances with releases higher than 1 kg per day per site will not be eligible for notification under a Special Category, even though they are manufactured or imported for export-only. Canada is the only jurisdiction that requires notification of substances intended to be manufactured or imported for export-only purposes.
We support the requirement for exposure information relating to children, but we feel that child's health concerns should be more comprehensively addressed. We recommend expanding the data requirements relating to children's health to include neurotoxicological testing along with other hazardous endpoints.	EC and HC believe that the Regulations reflect the 76 consensus recommendations that came out of the Multistakeholder Consultations. Moreover, exposure scenarios based upon the collected information will be done during the assessment of the substance. Risk management measures can be taken if the substance is found to be potentially harmful for children.
NDSL schedules could and should be further strengthened to represent the same level of scrutiny and toxicity testing as for non-NDSL substances. We recommend requiring *in vivo* genotoxicity study, 28-day repeated-dose study and a teratogenicity at 1000 kg/year for both non-NDSL and NDSL substances. We also recommend requiring chronic toxicity tests for non-NDSL chemicals and polymers at 1000 kg/year and adding stronger indicator of chronic toxicity, such as toxicity tests of 90 days or 12 months.	This question was discussed during the Multistakeholder Consultations. EC and HC believe that the Regulations reflect the 76 consensus recommendations that came out of the Multistakeholder Consultations.
It is recommended EC review the needs or gaps and subsequent justification for the increased test requirements and align the proposed regulation with the current. Maintaining the requirements of the higher schedules as they are today will not decrease the protection to human health or the environment but continue the high quality standard delivered by the federal government to date.	As stated in recommendation 17 of the *Final Report of the Multistakeholder Consultations* and its associated response in the *Environment Canada/Health Canada Response to the Consultation Recommendation*, EC included the information and testing requirements as agreed during the consultation.

It was acknowledge by the government that there is no scientific justification for the current system of modifying data requirement based on monomer listing (see final report). However, the regulations contain drastically reduced data requirements for those polymers. Economic reasons should not affect this decision. The use of waivers on a case-by-case basis should be used instead. We recommend eliminating the separate regulatory stream for polymers with all monomers on the DSL of NDSL. Rather, these substances should be subject to the same data requirements as non-NDSL polymers.	A review of impacts by EC and HC determined that the environment and human health will remain protected, since data will likely be provided at a later date, if warranted. EC and HC recognize that there is an industry sector that is dependent upon creating new polymers with existing monomers, and that the existing provisions in the current NSN Regulations reflect this reality. Therefore, we believe that the Regulations reflect the 76 consensus recommendations that came out of the Multistakeholder Consultations.
Assessment period for NDSL sch. 4 is 30 days at a 1000kg while it is 5 days for non-NDSL sch. 4 at 100kg. Why would a NDSL schedule 4 assessment require so much more time to complete than one for a substance which is not NDSL-listed (given that the supporting information requirements are the same)? Both of them are 5 days for the current NSNR.	The NSN Multistakeholder Table adopted these assessment periods in recommendation 52 of the *Final Report of the Multistakeholder Consultations*. The trigger quantity for a NDSL chemical is 1000 kg/year versus 100 kg/year for a non-NDSL chemical, also a NDSL chemical will be eligible for DSL listing after only 2 tiers of notification; the 30 day assessment period at 1000kg will allow more time for creation and assessment of exposure scenarios which will contribute to protection of environment and human health.
It is recommended that the government allow a minimum of 90 days before entry into force after registration in the *Canada Gazette*, Part II. This will ensure compliance and more importantly, better protection of the environment and health of Canadians.	The Regulations will come into force 60 days after they are registered. The delay is to ensure a proper time for Industry and the Government to be adequately prepared for the coming into force of these Regulations. Also note that a revised draft of the Regulations, the NSNR (Organisms), the Regulations Amending the NSFR and the Regulations Repealing the NSNR will be posted on the internet along with this document prior to publication in the *Canada Gazette*, Part II.
We recommend that these Regulations be implemented as soon as possible. We also recommend that the “in force” date be effective as of the date the NSNR are published in the *Canada Gazette*, part II.	See the above response.
We think that fees should not be charged for the procurement of a general benefit and do not agree with EC stating that the NSNR are compliant with the *User Fee Act*. EC must give an opportunity to propose ideas to improve service, to conduct an impact assessment and to explain to clients how user fee is determined and identify the cost and revenue element of the user fee. EC must establish (1) an independent advisory panel to address complaint and (2) performance standards. How does EC intend to comply with Section 4(2) of the Act which requires EC to submit a proposal before Parliament with the following information:	Based on the recommendations from the Multistakeholder Consultation, EC and HC conducted a notifier’s survey in spring 2004. It was a good opportunity for stakeholders to illustrate what is working and what could be improved with respect to the service delivery. This survey was made by an independent party and followed the Treasury Board mandate for all government to improve the service delivery. The Final Report of the New Substances Program's Notifier Survey is available online at: http://www.ec.gc.ca/substances/nsb/download/nssurveyresults_e.pdf A report on the path forward of this survey will soon be available.

▪ What service, product, regulatory process, authorization, permit or licence the user fee is being proposed to cover ▪ The total amount that the regulating authority will collect in the first three fiscal years after introduction of the user fee and identifying the costs that the fee will cover ▪ Performance standard established ▪ Actual performance met Also commitment from EC that it will comply with Section 5, which mandates that the fees will be reduced when performance standard are not met.	Performance measurement indicators will be developed according to the results of the survey, to track improvements. Also, it was agreed at the beginning of the consultation that Cost Recovery as represented by the *New Substances Fees Regulations* (NSFR) was not part of the Consultation process; therefore, no changes were made to the structure of the NSFR. The *User Fee Act* was promulgated after the coming into force of the NSFR, and as such the provisions of the *User Fee Act* will only apply to the NSFR if the structure of the fees is revised (increasing or decreasing fees, adding fees for other services).
Administrative issues:	
A more comprehensive description of substances excluded or exempted from notification under the NSNR should be presented. These substances include: Mixtures, Hydrates, Manufactured Items/Goods, Wastes, Natural Substances, Transient Reaction Intermediates/Incidental Reaction Products, Impurities and Regulated Under Other Acts of Parliament.	These definitions are not included in the text of the Regulations, but further explanations will be provided in the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*.
Further clarified these: Amphoteric polymer, Export-only substances, Impurities and Water solubility versus Water Extractability	These definitions will be provided in the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*.
There is lack of transparency at numerous steps in the notification process (issuance of waivers, final conclusions reached by the government. There is also absence of transparency as to what actions will be taken by government if deadlines expire prior to completion of assessment. We recommend that the results of the assessment be posted for a 60 days public comment period.	As stated in the *EC/HC Response to the Consultation Recommendations*, EC and HC are committed to develop procedures for publication of summary assessment reports while respecting Confidential Business Information. Assessment templates were developed which include identification of third party information. Options have been discussed pertaining to the most effective approach for identifying third party information. Current plans are to pilot the publication of five summaries for substances destined for the Domestic Substances List (DSL). The pilot will provide information on the level of effort required to resource larger scale publication of assessment summaries. The Act does not contemplate a comment period for New Substances assessments.
Technical issues:	
There is a usual failure of the French version to specify whether the listed items of information are “anded” together, such that all have to be met, or “ored” apart, such that meeting any one of the listed items should be enough.	The French version of the Regulations follows French drafting conventions related to paragraphing.
Please clarify why there is a hatched box in the flowchart 2 and 3.	The hatched boxes were used in the Regulations to emphasize the

	potential additional information requirements set out in subsections 7(2) and 7(3) of the Regulations. If you take flowchart 2 as an example, there are 2 situations that can triggered submission of the additional information that is required 75 days before exceeding 50 000kg/yr, for a NDSL chemical. Subsection 7(2) is required if a substance is released to the aquatic environment in a quantity exceeding 3 kg per day, per site, averaged monthly and after wastewater treatment. Subsection 7(3) is required if the chemical is present in products to which the public may be significantly exposed. If the releases to the environment are below the above mentioned trigger and/or there is no significant public exposure, additional information is not required. An explanation was added to Schedule 12 of the Regulations.
The Regulatory Impact Analysis Statement (RIAS) fails to reference the role which animal testing would play in the ongoing refinement of the NSN program.	As stated in recommendations 25, 26 and 27 issued from the *Final Report of the Multistakeholder Consultations*, EC and HC are committed to minimize the use of animal testing. Wording has been added to the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers* to encourage the notifier to use *in vitro* and alternative methods to animal testing.
Transparency could be enhanced in the RIAS by including reference to the relationship between the Regulations and existing international data-sharing arrangements.	The RIAS was amended to incorporated references to international data-sharing arrangements.
The “change/notification test costs” do not accurately represent the current regulatory notification marketplace. The elimination of 2 physical/chemical tests with addition of 1 environmental fate and 1 acute ecotoxicity test results in a significantly greater impact than proposed. There appears to be rounding errors in the table.	We used EPA’s methodology and costing data to assess the affordability of changes in testing requirements. This approach provides a common basis for comparing the previous and revised testing requirements. Actual testing costs may be higher or lower depending on the circumstances. This approach does not capture savings realised by Industry from raising the trigger quantities, reducing the waiting time before substances are added to the NDSL and eliminating the cumulative and in possession requirements. The differences due to rounding have been noted in the text.
Please clarify that the pre-notification consultation (PNC) is an optional step in the notification process.	The text of the Regulations was amended as follow in this passage of Schedule 1 item 2: The new substances pre-notification consultation number if it has been assigned and if known. Also, further clarification will be provided in the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*.
It is questioned why any specific subgroup (children in schedule 5	This requirement can be answered by yes or no. No additional testing

subitem 8(f)) must be singled out for consideration, when others are not. Those groups are already given special consideration when risk assessment are prepared and submitted, this could create double assessment of information and thereby compounding safety factors.	is required if the substance is anticipated to be used in products intended for use by or for children. This information is required to create realistic exposure scenarios.
We noted that the regulatory text surrounding the 3kg/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.	This wording was not included in the text of the Regulations, but will be further explained in the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*.
Please identify that the substances are eligible for DSL listing upon completing the prescribed information and either exceeding 10 000kg/yr or commencing import/manufacture (NoMI). Section 18 of the Regulations appears inconsistent with the conditions for adding a polymer to the DSL through the NOEQ route.	Section 18 of the Regulations was amended to correct the inconsistency.
How users are to proceed when NDSL substances becomes listed on the DSL following notification pursuant to subsections. 7(1) or 11(1) and a user subsequently exceeds 50 000 kg/year and either high environmental release or significant human exposure?	Substances on the DSL are not subject to NSNR unless they are subject to a Significant New Activity (SNAc). SNAc is used where the potential for a substance to be toxic in applications other than those proposed by the notifier is unknown. The SNAc requires notification where the use falls outside the scope of the permitted activities.
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. In some cases (RRR polymer, NDSL substances which have not yet surpassed the 3kg/day/site or which are not currently present in consumer product where significant exposure are expected) the substances becomes eligible for DSL inclusion while there are still limitations imposed upon its use. It is proposed that a combination of SNAcs and/or "tags" be used to track substances after they have been DSL-Listed.	Flags are used on the DSL to identify Reduced Regulatory Requirement polymers and are subject to compliance monitoring and enforcement as are SNAcs. Further guidance on DSL flags and SNAc are provided in the *Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers*.
In the column 2 of schedule 1 of the NSFR, it should indicate that annual sales are less than or equal to $13 million.	This was noted and changed.

Date: May 20, 2005