NGO submission on proposed amendments to the New Substances Notification Regulations (Organisms)

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This submission has been endorsed by the following organizations:

Allergy & Environmental Illness Group (Prince Edward Island)

BC Pathways (British Columbia)

Canadian EarthCare Society (British Columbia)

Canadian Environmental Law Association (Ontario)

Canadian Health Coalition (Ontario)

Chemical Sensitivities Manitoba (Manitoba)

CHOKED (British Columbia)

Crooked Creek Conservancy Society of Athabasca (Alberta)

Eastern Co-operative Health Organization (ECHO) (Prince Edward Island)

Edmonton Friends of the North Environmental Society (Alberta)

Georgia Strait Alliance (British Columbia)

Greenpeace Canada

Inter-Church Uranium Committee Educational Co-operative (ICUCEC) (Saskatchewan)

New Brunswick Partners in Agriculture (New Brunswick)

Reach for Unbleached! (British Columbia)

Resource Efficient Agricultural Production (R.E.A.P.) - Canada (Quebec)

Saskatchewan Organic Directorate (Saskatchewan)

Sierra Club of Canada

Sierra Club of Canada, Prairie Chapter (Alberta)

STORM Coalition (Ontario)

The Ram's Horn (British Columbia)

Vegetarians of Alberta Association (Alberta)

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Executive Summary

The signatories listed above are submitting the following comments on the options proposed in the Discussion Document on the Review of the New Substances Notification Regulations (Organisms), as published on April 12, 2006.

In general, we support government's initiative to eliminate the research and development exemption which is currently found in section 2.4. Accordingly, we understand the need to introduce a new schedule to capture those organisms other than microorganisms which are currently exempt from notification. However, we have profound concerns around some aspects of government's proposals for the new schedule or schedules. Our concerns fall under the general headings of:

- notification requirements and substantial equivalence,
- testing and notification at the outset of research,
- eligibility for the Domestic Substance List,
- project-based notifications,
- containment and confinement guidelines,
- transparency,
- precaution, and
- enforcement and compliance.

Throughout the paper we make a number of recommendations, which are summarized below.

Recommendation #1: The exemption for research and development organisms should be removed.

Recommendation #2: Government should clarify whether the single new schedule introduced in option 1 would be open to organisms in basic containment.

Recommendation #3: Government should provide further information on the proposed content of the new schedule(s).

Recommendation #4: Comparisons with existing counterparts should only be treated as valid when equivalence can be demonstrated through scientific testing.

Recommendation #5: There should be an onus on the notifier to provide information on the extent and nature of the hazard posed.

Recommendation #6: When industry or a research facility first notifies an organism at the research and development stage, government should require sufficient information to inform itself of the risks posed to human health and the environment.

Recommendation #7: The organism should not be allowed to leave full containment unless evidence of its safety for human health and the environment is produced.

Recommendation #8: Government should require the notifier to justify the need to develop the new organism and explore the possible use of safe alternatives.

Recommendation #9: Notifiers should be obligated to update and correct data as their research projects proceed.

Recommendation #10: Government should coordinate with universities and funding institutions in developing the research and development notification protocol.

Recommendation #11: Organisms should not be added to the Domestic Substances List unless they have been notified under schedule 5.

Recommendation #12: Government should clarify whether the new project-based notification schedule would only be available to those organisms currently covered by the Research and Development (R&D) exemption.

Recommendation #13: Government should specify which organisms are notifiable under the proposed project-based notifications in option 3.

Recommendation #14: Government should provide scientific analysis of the risks posed by various waste treatment and disposal methodologies.

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Recommendation #18: Risk assessment outcomes should be peer reviewed by a panel of independent experts who report their findings in a public forum.

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Recommendation #28: Establish an Advocate Office to review assessment documentation and verify the appropriateness of CBI claims. Its role would be akin to a neutral ombudsperson.

Recommendation #29: Ensure that CBI information can be shared freely between all government departments which are in a position to inform the assessments of new organisms.

Recommendation #30: "The Panel recommends the precautionary regulatory assumption that, in general, new technologies should not be presumed safe unless there is a reliable scientific basis for considering them safe."

Recommendation #31: We support the following recommendation made by the Royal Society of Canada: "The Panel recommends that, where there are scientifically reasonable theoretical or empirical grounds establishing a *prima facie* case for the possibility of serious harms to human health, animal health or the environment, the fact that the best available test data are unable to establish with high confidence the existence or level of the risk should not be taken as a reason for withholding regulatory restraint on the product."

Recommendation #32: We support the following recommendation made by the Royal Society of Canada: “The Panel recommends that companies applying for permission to release a GM organism into the environment should be required to provide experimental data (using ecologically meaningful experimental protocols) on all aspects of potential environmental impact.”

Recommendation #33: There should be adequate resources dedicated to enforcement and compliance activities.

Recommendation #34: The party who bears the responsibility and liability should be the party to submit the notification.

Recommendation #35: A multi-stakeholder working group should be constituted as soon as possible to assist government in amending the regulations and developing the containment and confinement guidelines.

Recommendation #36: NGOs should be given equal representation to that of other sectors on the working group, and funding should be made available to support their participation.

Purpose in reviewing the Research and Development exemption

Section 2(4) of the New Substances Regulations (NSNR) (Organisms) reads as follows:

> These Regulations do not apply in respect of an organism, other than a micro-organism, that is a research and development organism and is imported to or manufactured in a facility from which there is no release into the environment of
> (*a*) the organism;
> (*b*) the genetic material of the organism; or
> (*c*) material from the organism involved in toxicity.

Government has expressed concerns about section 2(4) as it is currently formulated. In its document entitled "Potential Consequences"[1], government has noted many problems with the Research and Development (R&D) exemption. For example;

- Government is not aware of R&D activities taking place.
- The exemption provision lacks clarity, and experience has shown that the exemption criteria are not well understood. Thus, the exemption may be inconsistently applied.
- Lack of information makes it difficult for government to provide advice to companies in order to promote compliance.
- Government cannot verify compliance. Government cannot assess the appropriateness of the containment measures proposed, leading to a possible release into the environment.
- Government's ability to respond to accidental releases is limited.
- Government's ability to assess potential impacts on human health and the environment in a timely manner is hampered.
- A product of biotechnology may end up in the human and/or animal food system, with potential impacts on human health and the environment.
- There have been recent incidents where transgenic animal carcasses were improperly disposed of and ended up in the food chain.

We find these issues compelling, and agree that there is a serious need to remove the exemption for R&D organisms. Government is under a legal and moral duty to protect the Canadian public from organisms which could be harmful to their health or to the environment. Any regime designed to assess and manage these substances should ensure that government has the capability to verify compliance, assess risk, and enforce the law. However, government will remain unable to fulfil its responsibilities in respect of these organisms so long as it remains unaware of their use in this country.

[1] Environment Canada and Health Canada, "Potential Consequences"(November, 2005) [unpublished, this document is Attachment 9 in a package of materials prepared for information sessions on the New Substances Notification Regulations (Organisms) held in November, 2005] [hereinafter "Potential Consequences"].

Recommendation #1: The exemption for research and development organisms should be removed.

Government's proposal to include R&D organisms in the notification scheme through the addition of new schedule(s)

Currently, there is only one notification schedule (schedule 5) for all non-exempt organisms other than micro-organisms. Rather than requiring R&D organisms to also notify under this schedule, government is proposing to add one or more new schedules to the NSNR. Government's rationale is that requiring a full schedule 5 assessment for all organisms other than microorganisms may be unduly onerous, expensive, and time consuming. Government also states in its "Potential Consequences" document that "many activities may not need stringent containment to ensure the protection of human health and the environment."[2] The implication of this statement is that even those facilities which are unable to meet the "no release" R&D exemption criteria (and thus currently notify under schedule 5) should be allowed to submit a lesser notification package under certain circumstances.

Government has proposed three options for the new notification process. The first option is to add a single new schedule for organisms kept in containment, whether intended for R&D or not. The second option sees the creation of four new schedules for organisms kept in full containment, basic containment, experimental field trial release, and confined release. Again, these schedules would be open to both R&D and non-R&D organisms. The third option involves five new schedules: one for R&D "projects", as well as the four schedules listed under option 2. The schedule for R&D "projects" would "allow organisms belonging to the same species and used as part of a single R&D project to be notified and assessed on a project-by-project basis."[3] It is worth noting that these proposals do not only impact those R&D organisms which are currently exempt. Under each of the three options, some substances which are currently required to notify under the full schedule 5 would be allowed to submit a reduced notification package under one of the new schedules.

The exact information requirements to be included in the new schedule(s) remain undetermined. At this time, government has suggested that the core information requirements in the new schedules would be much less extensive than those found in schedule 5. As outlined in government's "Discussion Document", these core requirements would include general proposed use and potential uses; identification of the organism to the *species* level; description of the facility; anticipated annual quantity to be

[2] *Ibid*.
[3] Environment Canada and Health Canada, "Review of the New Substances Notification Regulations (Organisms) Discussion Document" (April 12, 2006) [unpublished, prepared for the workshop on the Research & Development Exemption provisions dealing with Organisms other than Micro-organisms held in Ottawa on June 15-16, 2006] [hereinafter "Discussion Document"] at 19.

imported or manufactured; expected modes of transport and storage; and contingency plans in case of release.[4]

Government has also proposed the development of containment and confinement guidelines, to assist notifiers in determining what measures are considered sufficient to qualify for the new notification stream(s).

Notification requirements and substantial equivalence

The three proposals, as a whole, raise a number of questions and concerns. The first question relates to the legitimacy of lesser notification requirements on the basis of partial containment or confinement. It is unclear whether the single new schedule introduced in option 1 would be open to organisms in basic containment. It would certainly be preferable to require full containment. Both option two and option three allow organisms in basic containment, confined release, and experimental field trial to notify under less rigorous notification schedules.

There is no indication that the new proposed schedules would include any information concerning:

- the identification of the organism to the strain level,
- phenotypic and genotypic changes,
- genetic stability,
- nature of any introduced genetic material,
- a description of the methods used to detect the organism,
- pathogenicity,
- toxicity,
- invasiveness,
- conditions required for its survival and growth,
- or the potential for dispersal of its traits by gene transfer.

Rather, the proposed schedules could contain minimal information requirements and provide little guidance on how the organism would interact with humans or the environment if accidentally released, or if intentionally released to a limited degree through experimental field trials, confined release, or basic containment. Accordingly, it remains unclear whether assessors would be able to determine with any level of confidence whether the level of containment or confinement was sufficient given the nature of the organism. It is difficult to comment on the adequacy of the three options given this uncertainty.

One possibility is that assessors might compare the newly notified organisms to related organisms on which there is more information available. This is a common risk assessment technique; assessors attempt to glean information about the substance by investigating a similar or parent substance which has already been released into the

[4] *Ibid*. at 32.

environment, either in Canada or elsewhere. This practice is similar to the use of "substantial equivalence" as a decision-making procedure.

The concept of "substantial equivalence" essentially suggests that when a genetically modified organism appears to be similar enough to its traditional counterpart, it may be treated in the same regulatory manner without the need for further assessment. However, this approach has been heavily criticized for its ambiguity and lack of scientific rigour. First, there's an inherent illogicality between the presence of a novel trait in the new organism and the designation of "equivalence".[5] Second, it is unclear how detailed an examination is required to order to establish "equivalence"; is equivalence based on superficial similarities sufficient, or is a more in-depth assessment of the novel trait required? Scientific methodology and the precautionary principle require the latter.

In examining this concept in the context of food biotechnology regulation in Canada, the Royal Society of Canada emphasized the need to *demonstrate* equivalence through scientific testing. It is therefore inappropriate to *assume* substantial equivalence as a decision procedure for facilitating approval of new substances without full assessment.[6] The Royal Society of Canada went on to suggest that the following protocol would be needed in order for "substantial equivalence" to provide a scientifically-valid safety standard:

> …[R]equires a scientific finding that the new food does not differ from its existing counterpart in any way other than the presence of the single new gene and its predicted phenotypic change. In every other way, phenotypically and in terms of its impacts on health and the environment, it will have been *demonstrated* to be identical to the existing food. Once this finding is made, the food can then be considered (i.e. "treated as") safe, in as much as the existing food is already considered safe, with the caveat that the phenotypic expression of the added novel gene(s) must also be *demonstrated* to have no negative health or safety impacts.[7] [Emphasis added]

The report of the Royal Society of Canada concluded that "the obvious approach to analysis of the consequences of the presence of the transgene is to employ direct testing for harmful outcomes."[8] Although these comments were made in the context of food biotechnology, they are equally applicable to the NSNR assessment regime. Certainly, it is clear that government would not have the requisite information to directly assess the harmful traits of the transgene in the proposed pared-down notification schedules. Accordingly, there is concern that government would not be able to determine whether anything less than full containment would introduce an unacceptable risk.

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[5] The Royal Society of Canada, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada" (Ottawa: The Royal Society of Canada, January 2001) at 181.
[6] *Ibid.* at 182.
[7] *Ibid.*
[8] *Ibid.* at 186.

The application of "substantial equivalence" types of judgements is also of concern with respect to substances that are subject to the full schedule 5 notification and assessment. There are several information requirements on schedule 5 which relate to the organism's behaviour after it has been released into the environment, such as:

- a description of the geographic distribution and habitat of the organism,
- the locations and situations where the organism has caused adverse ecological effects, and
- its interactions with other organisms in the environment.

By definition, organisms subject to the NSNR are new to Canada or are being used for a new purpose; if the former, they would not have been released into the environment at the time of notification. Accordingly, it would seem that the information necessary to address these requirements would have to be derived from either lab data extrapolations, records from other jurisdictions where the organism has been released, or through comparisons with a related or parent organism. The latter methodology closely parallels the use of "substantial equivalence" as a decision making tool. Given the recommendations of the Royal Society of Canada, we would hope that comparisons with parent organisms would only be deemed sufficient to demonstrate safety when accompanied with direct testing data from one of the other two sources. This recommendation is bolstered by our comments below on the precautionary principle and burden of proof.

Recommendation #2: Government should clarify whether the single new schedule introduced in option 1 would be open to organisms in basic containment.

Recommendation #3: Government should provide further information on the proposed content of the new schedule(s).

Recommendation #4: Comparisons with existing counterparts should only be treated as valid when equivalence can be demonstrated through scientific testing.

Testing and notification at the outset of research

There is clearly a need for test data to demonstrate the safety of an organism, as discussed in the section above on substantial equivalence. However, the notification of R&D organisms presents a challenge in this regard, for it is unclear how much data is available to researchers at the outset of their work. Indeed, there is enduring ambiguity around the question of when in the course of research an organism is considered to be "manufactured", thereby triggering notification under one of the proposed schemes. At the June workshop, some claimed that very little can be known at the outset about the new organisms which will be created throughout the course of an experiment. However, a presentation by Cecil Forsberg indicated that at the start of a new project, university animal research protocols may require researchers to indicate the possible consequences

to public health or wildlife should containment fail.[9] Additionally, it should be noted that the full schedule 5 data set is currently required prior to the manufacture of any research organisms which do not meet the strict containment criteria in the exemption.

Government's obligation to protect human health and the environment is not diminished in the face of data gaps and uncertainties. Rather, we would argue that it is heightened. The majority of organisms currently in use in Canada are still at the research phase, and hence the majority of risks are introduced at this stage. Government is best able to exercise precaution before the organism has been commercially developed and released. There should be an onus on the notifier to provide information on the extent and nature of the hazard posed; government should require extensive enough information at this early stage to inform itself of the risks posed to human health and the environment. If certain data requirements are inapplicable to an organism, waivers may still be granted as is currently the case. Organisms should not be allowed to leave full containment unless evidence of their safety is produced. Additionally, government should require the notifier to justify the need to develop the new organism and explore the possible use of safe alternatives.

Notifiers should also be obligated to update and correct data as their research projects proceed. This would help minimize sources of uncertainty, and facilitate the continuous improvement of the scientific understanding of organisms. It would also accommodate the need to change course partway through an experiment or explore unanticipated avenues.

The notification of R&D organisms may be further facilitated by careful coordination with universities and funding institutions which have established protocols in place. The goal is not to reduce government's information requirements to the lowest common denominator, but rather to develop synergies and avoid unnecessary duplication of effort.

Recommendation #5: There should be an onus on the notifier to provide information on the extent and nature of the hazard posed.

Recommendation #6: When industry or a research facility first notifies an organism at the research and development stage, government should require sufficient information to inform itself of the risks posed to human health and the environment.

Recommendation #7: The organism should not be allowed to leave full containment unless evidence of its safety for human health and the environment is produced.

Recommendation #8: Government should require the notifier to justify the need to develop the new organism and explore the possible use of safe alternatives.

[9] Cecil Forsberg, "University Perspectives" (workshop on the Research & Development Exemption provisions dealing with Organisms other than Micro-organisms, Ottawa, 15-16 June 2006) [unpublished] at slide #13.

Recommendation #9: Notifiers should be obligated to update and correct data as their research projects proceed.

Recommendation #10: Government should coordinate with universities and funding institutions in developing the research and development notification protocol.

Eligibility for the DSL

The three options presented by government fail to specify at what point in the process the organisms would qualify for addition to the Domestic Substances List (DSL). Presumably, this step would follow the last box on the flow chart entitled "Assessment outcome letter to notifier or SNAc" (Significant New Activity). It is unclear whether organisms could move directly from one of the new schedules onto the DSL, or whether they would need to be renotified under schedule 5 in order to be DSL-eligible. One employee of the New Substances Program has suggested that when organisms move from containment or confinement to full commercial use, they may not be required to renotify under schedule 5 but rather may be allowed onto the DSL with a SNAc notice. However, at the June workshop, Bernard Madé, Acting Director of the New Substances Branch, suggested that schedule 5 notification would be required prior to DSL listing.

This is a pivotal issue, and government's position should be formally clarified in writing in order to avoid confusion and provide certainty. We would oppose any approach which does not require the full schedule 5 notification before adding an organism to the DSL. The DSL should be reserved for organisms which have undergone a rigorous assessment (i.e. using schedule 5), and for which there is a strong understanding of the risks posed. If, after fully scrutinizing the organisms, government can confirm with a high degree of certainty that the organisms may be safely used for certain purposes but not for others, then the organism may be added to the DSL with a SNAc notice under section 106 of the *Canadian Environmental Protection Act, 1999* (CEPA). However, if government does not have a strong understanding of all of the risks posed by the organism, or if there are any data gaps, then the onus should be placed on industry to demonstrate the organism's safety prior to DSL-listing.

This is a fundamentally different proposition than routinely adding organisms to the DSL with SNAc notices, after collecting only minimal information under the new proposed schedules. The application of SNAcs should not be used as a substitute for more rigorous scientific assessments. The DSL represents organisms in commercial use in Canada; government will not have gathered enough information through the lesser schedules to determine organisms' commercial safety with any degree of certainty.

Recommendation #11: Organisms should not be added to the Domestic Substances List unless they have been notified under schedule 5.

Project-based notifications under option 3

Another worrisome component of government's Discussion Document is the proposal in option 3 to "allow organisms belonging to the same species and used as part of a single R&D project to be notified and assessed on a project-by-project basis." This approach deviates from the tradition of assessing new substances on a substance-by-substance basis, and introduces additional confusion into the assessment process. It is unclear whether this new project-based notification schedule would only be available to those organisms currently covered by the R&D exemption. On the one hand, the discussion document indicates that only fully contained R&D organisms would be eligible, but then suggests on the other hand that such organisms would currently be notifiable if the R&D exemption were not met. Clarification on this point is sought.

It is also unclear what type of assessment is envisioned under the "project-based" schedule. In the course of conducting R&D work, researchers may create several intermediate organisms through a sequence of genetic modifications. Some of these intermediate organisms may prove to be unviable and therefore not pursued, whereas others will ultimately develop into a final product. Under option 3, it appears that researchers are only required to notify the first organism in the sequence, and none of the intermediates. It is unclear whether the final product would also require notification, or if a change in the experimental protocols or the expiration of a time period would trigger a re-notification. There is concern that by drastically reducing the number of organisms within a project requiring notification, government assessors will fail to detect certain risks, such as those introduced by the final product (which, in turn, depend on the uses for which it is intended). Additionally, even if the final organism in the chain is notified, government will have less information available on which to base its decision, since it will not have details on the iterative process which led to the organism's development.

By pursuing this option, government risks unduly complicating an already confusing notification scheme. The entire new substances regulatory regime is premised upon the use of substance-by-substance assessments. Accordingly, risk management responses are often designed to apply to a single organism, and not to an entire project. This is an appropriate system, since each individual organism presents a distinct risk (i.e. in case of accidental release) even if it is only present at the intermediate stages of work. Funding applications are also sometimes organized on an organism-by-organism basis. Additionally, the existing timelines within which government must complete its assessments may be unsuitable for project-based assessments. Even if the timelines were extended to provide regulators with more time to assess multiple organisms, it would be difficult to predict how many organisms would be notified within any single project, and hence, how much time would be required.

Recommendation #12: Government should clarify whether the new project-based notification schedule would only be available to those organisms currently covered by the Research and Development (R&D) exemption.

Recommendation #13: Government should specify which organisms are notifiable under the proposed project-based notifications in option 3.

Development of containment and confinement guidelines

It is unfortunate that government is not in a position to provide further details around the proposed guidelines at this time, as their content would greatly impact the scientific supportability of the three notification proposals identified. If the containment and confinement guidelines lack rigour, there is little justification in allowing *any* organisms to circumvent the full requirements of schedule 5.

At the workshop on the review of the New Substances Notification Regulations (Organisms) held on June 15-16, 2006, it became clear that there is a dire need for guidance relating to containment and confinement protocols. There was disagreement and confusion among the industry and academic sectors regarding the type of containment which is currently required to qualify for the R&D exemption. In particular, it seemed apparent that few or none of the stakeholders present were appropriately containing the waste streams from new organisms, ie. through appropriate incineration methods. There was little understanding of the type of risks which other waste disposal methods, such as composting, could entail.

The widespread uncertainty regarding containment and confinement requirements not only justifies the need for guidelines, but also justifies the need to remove the R&D exemption. As long as government is unaware of the R&D activities which are taking place, it will be unable to educate researchers about appropriate containment measures and to ensure compliance. Additionally, it should not be left to the discretion of individual companies and institutions to decide what level of risk is posed by their containment arrangements. Rather, government should systematically research the various containment practices, particularly related to the disposal of wastes, and provide consistent direction to the regulated community. Government should also carefully consider how containment can be maintained during transport between and within facilities.

When drafting the guidelines, government should consider the plausibility of using a certification system for facilities at different levels of containment. Under such a system, it would be necessary for each facility dealing with a certain organism in a certain manner to have the requisite level of certification. If CEPA does not provide for this type of government oversight, consideration should be given to incorporating this recommendation into the review of CEPA which is currently underway.

At the June 15-16 workshop it was suggested that the guidelines may eventually be incorporated through regulation. We are strongly supportive of this recommendation, since it would allow government to treat the guidelines as enforceable measures.

Recommendation #14: Government should provide scientific analysis of the risks posed by various waste treatment and disposal methodologies.

Recommendation #15: Government should investigate the plausibility of using a certification system for facilities at different levels of containment.

Recommendation #16: Containment and confinement guidelines should be developed and incorporated through regulation.

Transparency

Transparency is paramount in respect of all CEPA processes, since the decisions made have direct ramifications for the environment and human health. Transparency is particularly necessary within the NSNR (Organisms) program, since there is a high level of public concern about organisms. This concern has been justified and amplified by past problems and accidental releases involving organisms under CEPA and under the other regulatory regimes. There is also a perceived conflict of interest in government acting as both assessor and primary funder of many biotechnology research and development activities.

Inclusion of R&D organisms in the regulatory scheme will greatly improve transparency, particularly if information pertaining to these substances is made publicly available. However, certain additional regulatory and procedural changes need to be made to achieve an appropriate level of transparency. These recommended changes include:

Recommendation #17: There should be an opportunity for public comment before final decisions are made,[10] and a formalized process to solicit independent peer review of notification packages.

Recommendation #18: Risk assessment outcomes should be peer reviewed by a panel of independent experts who report their findings in a public forum.[11]

Recommendation #19: The science in support of all assessment decisions should be publicly available via the internet. Research data from industry experiments should be made publicly available.[12]

Recommendation #20: Government assessors should publish their rationale for all decisions, including decisions to grant waiver requests, within a specified timeframe. The rationale should include explanations of how any public comments or objections were addressed.

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[10] The categorization of existing substances on the DSL currently provides for this type of public feedback. After conducting a screening level risk assessment, the Ministers are required to publish their proposed decision in the *Canada Gazette* for public comment.
[11] The Royal Society of Canada, *supra* note 5 at recommendation 9.3, pg xi.
[12] *Ibid.* at recommendation 6.8, pg xiv.

Recommendation #21: There should be an independent peer review of the data requirements to be included in the new schedule(s) and the containment / confinement guidelines.

Recommendation #22: The ENGO community should also be given an opportunity to provide input on the data requirements in the new schedule(s) and on the containment / confinement guidelines.

Recommendation #23: Government should specify what actions will be taken by assessors if deadlines expire prior to the completion of assessments.

Another overarching concern is the treatment of Confidential Business Information (CBI). Government does have an official policy regarding confidentiality claims,which is set out in its guidance materials. Under this policy, notifiers must meet six criteria (with substantiation provided), and sign a Certification Statement attesting to the accuracy of the claim.

However, when asked how confidential information is treated in practice, three different government employees provided three different answers. The final analysis would seem to suggest that *all* information received from a notifier is considered confidential unless the company provides explicit written consent for government to disclose it. Additionally, confidentiality is maintained between government agencies which have not signed information sharing agreements, so its possible that notification packages may not be shared in some cases where the same organism is notified to different agencies under two or more Acts. As a result, public access to information is jeopardized, and consistency in government decision-making processes is eroded. Certainly, it is difficult for both the public and the regulated community to understand and adhere to the CBI provisions when confusion exists within government itself. Both the CBI guidelines and government's internal practices are in serious need of revision, according to the following recommendations:

Recommendation #24: Regulations should be passed establishing a new set of mandatory criteria for claiming confidentiality, pursuant to multi-stakeholder input.

Recommendation #25: There should not be a greater level of confidentiality accorded to notification packages for research and development organisms.

Recommendation #26: Summaries of all notification packages with Confidential Business Information (CBI) claims should be made public prior to the final assessment decisions. The summaries should include a list of the information or studies submitted by industry in support of their applications.

Recommendation #27: Where confidentiality is claimed, the company's Chief Executive Officer (CEO) must attest to the fact that the confidentiality criteria have been met.

Recommendation #28: Establish an Advocate Office to review assessment documentation and verify the appropriateness of CBI claims. Its role would be akin to a neutral ombudsperson.

Recommendation #29: Ensure that CBI information can be shared freely between all government departments which are in a position to inform the assessments of new organisms.

Precautionary principle and burden of proof

The precautionary principle is well known in environmental policy discourse and is referenced four times in the text of CEPA itself.[13] The preamble of CEPA includes the following passage: "[w]hereas the Government of Canada is committed to implementing the precautionary principle that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

The exercise of precaution is particularly critical in the context of new organisms. If accidents occur or if risks are overlooked, the release of organisms can have disastrous consequences. Human health may be compromised on a vast scale, species of plants and animals may be jeopardized, and business sectors may be devastated by border closings and international sanctions. These costs are seldom accounted for in discussions and calculations of business "competitiveness".

There are several ways in which precaution can, and should, play an integral role in the regulation of new organisms. The above discussion on substantial equivalence includes a precautionary recommendation to require that any comparisons with parent organisms be empirically supported with test data. We also recommended that government exercise precaution by requiring industry to demonstrate an organism's safety before allowing it to leave full containment, and requiring full schedule 5 notification before placing an organism on the DSL.

There are several important recommendations in the report by the Royal Society of Canada which pertain to the use of precaution and the burden of proof. These recommendations are relevant and bear reiterating in the context of this discussion:

[13] See the preamble, s. 2(1)(a), s. 6(1.1), and s. 76.1.

Recommendation #30: "The Panel recommends the precautionary regulatory assumption that, in general, new technologies should not be presumed safe unless there is a reliable scientific basis for considering them safe"[14]

Recommendation #31: We support the following recommendation made by the Royal Society of Canada: "The Panel recommends that, where there are scientifically reasonable theoretical or empirical grounds establishing a *prima facie* case for the possibility of serious harms to human health, animal health or the environment, the fact that the best available test data are unable to establish with high confidence the existence or level of the risk should not be taken as a reason for withholding regulatory restraint on the product."[15]

Recommendation #32: We support the following recommendation made by the Royal Society of Canada: "The Panel recommends that companies applying for permission to release a GM organism into the environment should be required to provide experimental data (using ecologically meaningful experimental protocols) on all aspects of potential environmental impact."[16]

Pursuant to this last recommendation, we would argue that anything less than full containment constitutes a release into the environment. It is important to note that even full containment introduces the possibility of accidental release, and concerns over those R&D substances currently under full containment have prompted this regulatory review. Clearly, companies and research institutions should not be permitted to move outside of full containment unless they can demonstrate their new organisms' safety using experimental data.

Enforcement and Compliance

In order for the new regulatory scheme to serve its designed purpose, it will be necessary for government to actively pursue enforcement and compliance activities. Money and manpower will need to be explicitly earmarked for this effort. Particular attention should be paid to those high risk organisms which are supposedly being maintained at a high level of containment. It will also be important to verify that projects are still exhibiting the same level of risk at which they were notified.

Concerns around enforcement trigger concomitant concerns around liability. Currently, there is sometimes a disconnect between the party who notifies (i.e. the researcher) and the party who controls many of the lab conditions and bears part of the liability (i.e. the institution). Efforts should be made to ensure that the responsible party is the one who actually submits the notification package.

[14] The Royal Society of Canada, *supra* note 5 at recommendation 8.1, pg. x.
[15] *Ibid.* at recommendation 8.3, pg. x.
[16] *Ibid.* at recommendation 6.10, pg. xii.

Recommendation #33: There should be adequate resources dedicated to enforcement and compliance activities.

Recommendation #34: The party who bears the responsibility and liability should be the party to submit the notification.

Conclusion

We are generally supportive of the proposal to remove the exemption for R&D organisms which is contained in section 2(4) of the NSNR (Organisms). However, we have indicated several areas where clarifications on government's proposals are sought, and we have recommended a number of safeguards which must play an integral role in any new regulatory scheme. Precaution should be the guiding principle when dealing with new organisms, and there should be an onus placed on notifiers to justify the safety of their research. Additionally, at the R&D phase government should take the opportunity to question the need for the new organism and require the exploration of safe alternatives.

A key recommendation to emerge from the workshop was that a multi-stakeholder working group should be constituted to assist government in amending the regulations and developing the containment and confinement guidelines. We support this recommendation, with the caveat that non-governmental organizations (NGOs) should be given equal representation as other sectors. Funding should also be made available to support the participation of multiple NGO members. Given the highly technical nature of the issues, the participation of at least one alternate member should also be facilitated. The terms of reference for the working group should outline its objectives, the anticipated duration of its work, how decisions will be made, and how the results of its work will be communicated to the public and to the Ministers. The working group should be launched as soon as possible, so that the regulatory amendments can be published no later than summer 2008.

Recommendation #35: A multi-stakeholder working group should be constituted as soon as possible to assist government in amending the regulations and developing the containment and confinement guidelines.

Recommendation #36: NGOs should be given equal representation to that of other sectors on the working group, and funding should be made available to support their participation.