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The Case for Establishing a Board of Review for Resolving Environmental Issues: The Science Court in Canada

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ABSTRACT

Technology and scientific advancements are accelerating changes in society at a pace that is challenging the abilities of government regulatory agencies and legal courts to understand the benefits and costs of these changes to humans, wildlife, and their environments. The social, economic, and political facets of concern, such as the potential effects of chemicals, complicate the preparation of regulatory standards and practices intended to safeguard the public. Court judges and attorneys and, in some cases, lay juries are tasked with interpreting the data and implications underlying these new advancements, often without the technical background necessary to understand complex subjects and subsequently make informed decisions. Here, we describe the scientific-quasi-judicial process adopted in Canada under the *Canadian Environmental Protection Act*, *1999*, which could serve as a model for resolving conflicts between regulatory agencies and the regulated community. An example and process and lessons learned from the first Board of Review, which was for decamethylcyclopentasiloxane (D5; CAS# 541-02-06), are provided. Notable among these lessons are: 1) the need to apply state-of-the-science insights into the regulatory process, 2) to encourage agencies to continuously review and update their assessment processes, criteria, and models, and 3) provide these processes in guidance documents that are transparent and available to all stakeholders and generally foster closer cooperation between regulators, the academic community, industry, and nongovernment organizations (NGOs). *Integr Environ Assess Manag* 2016;12:572–579. © 2015 SETAC

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INTRODUCTION

As technological advances, especially in synthesis and use of chemicals, result in more and more uses of chemicals that provide significant benefits to quality of lives of humans, there are increased risks of releases, intentional and unintentional, to the environment.

Chemicals have "Janus characteristics"; on the one hand they are beneficial, whereas on the other, they can pose risks. Historical examples are numerous and range from the insecticide, DDT, through the industrial chemicals, PCBs to chlorofluorocarbons. When accidents occur or technologies go wrong and humans or the environment are harmed, the issue is rapidly transformed from a scientific issue of fates and effects and quantifying injuries to one of assigning blame and paying for damages. This process involves economics, sociology, and political science, and can often become quite contentious. In such an environment, it is common for "experts" to become advocates for the various parties, and the subsequent decisions often have little to do with the underlying science or even benefits to the greater society. For instance, in the United States, various special interest groups, (nongovernment organizations [NGOs]) have taken it on themselves to influence public policies by bringing lawsuits against industries, public institutions, and government agencies such as Environment Canada (EC) and the US Environmental Protection Agency (USEPA). There are social, economic, and political facets to any controversy about potential effects of chemicals on wildlife or humans. These can complicate preparation of reports or interpretation of results of tests requested for regulatory purposes. These issues are then vetted by judges and attorneys and, in some cases, juries, selected from the lay public at large. Data underlying these issues can be scientifically complex, which makes it difficult for the

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nontechnical layperson to understand the subtle details, and to make rational, evidence-based decisions. Even individuals highly trained in economics, political science, and steeped in the law find it difficult to understand concepts such as equilibrium partitioning, trophic magnification, fugacity, and chemical activity.

As a result of the complexity of the information, it has become difficult for courts and regulatory agencies to fulfill their mandates and come to reasonable decisions, based solely on facts and the science. The outcome is often protracted decision making, confused or partial rulings, or delays associated with requests for additional information. From society's vantage point, uncertainty from the absence of clear judicial or regulatory guidance might be interpreted as tacit approval of proposed uses of new products and activities. It also can inspire conservatism and invoke restraints founded on the "Precautionary Principle" (Government of Canada 2001). In either case, society is unable to balance perceived and actual risks and benefits. To this end, court judges in Canada and at the global level, such as at the International Court of Justice, now rely on a special technical advisor or advisors, generally trained in a specific field of science or engineering, to assist them in understanding technical details involved with issues of chemicals in the environment. For the Board of Review (BoR) used as an example here, there were 3 "judges," all with special, detailed, technical, and scientific knowledge. However, even in situations such as this, it is evident that the formal judicial process is not the most effective venue in which to fully adjudicate complex issues related to chemicals and the environment.

Governments have taken steps to address technical issues. In 1865, the US Congress enacted legislation to form the National Academy of Sciences (NAS). The NAS undertakes reviews of socially relevant, technical issues to provide scientific advice to elected officials who might not have sufficient technical knowledge in specific fields of scientific endeavor. Convened committees of the NAS are balanced to provide a diversity of experience and opinions, and an open declaration of biases and potential conflicts of interests are provided. The end result of the consultation with Congress or an agency of the Executive branch is either a confidential report in the case of strategic issues, a publication in a peer-reviewed journal, and in some cases, a book published by the National Academy Press (NAP).

In a second approach, for some controversial issues, the USEPA relies on reports from its Science Advisory Board (SAB), established by the US Congress in 1978 (USEPA 2014a). In the case of chemicals used in agriculture and regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the USEPA has a Science Advisory Panel (SAP) (USEPA 2014b) The USEPA SAB and SAP have "chartered" or permanent members that are appointed for a specific term. In addition to these individuals who have specific expertise and chair the committees assessing specific issues, ad hoc members are also appointed to specific committees to add additional expertise and perspective.

Although NAS and USEPA panels have been effective in resolving some technical issues, they cannot address all issues involving specific situations that are brought before civil courts. In this article, we describe our experience of use of a board of review, in essence a "court of science" that was implemented in Canada under Canadian Environmental Protection Act (CEPA; CEPA 1999) to enquire into controversial decisions involving the environment, with the specific example of decisions of Environment Canada relating to decamethylcyclopentasiloxane (D5; CAS# 541-02-06).

CANADA'S BOARD OF REVIEW PROCESS

The authorizing legislation that provides for the Minister of Health and the Minister of the Environment to convene a BoR, anticipated situations where there would be disagreements, based on technical issues, between regulators and the regulated community. It was recognized that these issues would be controversial but also highly technical in nature.

Because the BoR, used as an example here, was the first conducted under CEPA (1999), the members had to develop all of the policies and procedures under which the BoR was conducted. The specifics of the issue and the deliberations of the BoR are detailed in the report (Siloxane D5 Board of Review 2011). Here, we present some information about the policies and procedures that were developed by the BoR to discharge its mandate. Some of the information considered by the BoR during their deliberations consisted of confidential business information (CBI), which cannot be published. In addition, the specific recommendations made by the BoR to the Minister of the Environment were advisory in nature and the final decision on the manner in which to proceed was solely that of the Minister. In addition, the report of the BoR was equivalent to a judgment in a court of law, and the deliberations of the board and reasoning behind the opinions of the BoR cannot be discussed. The report of the BoR is the only record of the opinions of Board, and these cannot be further elaborated or dissected. Because of these constraints, this article focused on processes and general observations but not the technical details on which the decision was made. These details are further discussed in a recent series of articles published in *Environmental Toxicology and Chemistry* (Fairbrother et al. 2015; Gobas et al. 2015; Mackay 2015; Mackay et al. 2015).

EXAMPLE: THE SILOXANE D5 BOARD OF REVIEW

Genesis of the Siloxane D5 BoR

Several countries have legislation that requires assessment of substances used in commerce. The Canadian Environmental Protection Act (CEPA 1999) requires that the Minister of the Environment and the Minister of Health conduct screening assessments of substances that have met the categorization criteria as set out in section 74 of CEPA to determine whether these substances present or may present a risk to the environment or human health. Based on a screening assessment, the Ministers can propose: 1) to take no further action, 2) to add the substance to the Priority Substances List (PSL) for further assessment, or 3) recommend that the substance be added to the List of Toxic Substances in Schedule 1 of CEPA and, where applicable, implement the virtual elimination (ban the use) of the substance in Canada.

Prior to undertaking a screening assessment, the user industries and other interested stakeholders are "challenged" to submit information to inform assessments of risks posed by the substance. For D5, this challenge was published in the *Canada Gazette*, on May 12, 2007. After receiving additional information in response to the challenge, a final screening assessment (EC and HC 2008a) of D5 was conducted by the Departments of Health and Environment and published in November of 2008 and concluded that, based on the available information, D5 was entering the environment in a quantity or

concentration or under conditions that may have an immediate or long-term harmful effect on the environment or its biological diversity. As a result of that determination, the Minister of Health and Minister of the Environment recommended that D5 be added to the Toxic Substances List in Schedule 1 of CEPA, 1999. This decision was based on the potential for harm in the environment, because no concerns for humans were identified.

One of the affected industry stakeholders, the Silicones Environmental, Health, and Safety Council of North America (SEHSC) filed a Notice of Objection on July 10, 2009 and requested that a BoR be established to enquire into the nature and extent of the danger posed by octamethylcyclotetrasiloxane (D4) and D5. The SEHSC claimed that the Screening Assessments for these substances were not conducted in a manner that was consistent with the best available science and that errors were made in the approach used by government officials when assessing them. Furthermore, the SEHSC stated that new scientific information was available to demonstrate that D4 and D5 did not meet the criteria for toxicity and that new risk assessments should be undertaken.

Taking into account that new scientific information relevant to D5 had been made available since the final Screening Assessment, on August 21, 2010, the Minister of the Environment published Notice of his intention to establish a BoR to review D5. The request for a BoR for D4 was denied because no new evidence was provided by industry.

Establishing the Siloxane D5 BoR

The Siloxane D5 BoR was established in 2010. The Minister of the Environment appointed Professor John P. Giesy, PhD, FRSC, Fellow Society of Environmental Toxicology and Chemistry (SETAC) as Chair, and Professor Keith Solomon, PhD, Fellow Academy of Toxicological Sciences (ATS) and Fellow SETAC, and Professor Sam Kacew, PhD, Fellow ATS, as members of the BoR. Gerry Stobo and Steven Kennedy served as legal counsel to the BoR. The Minister directed the BoR to prepare and submit a report, together with recommendations, and the evidence that was considered, on or before March 31, 2011.

The BoR was established as an independent, scientific review panel, the mandate of which was to review the extensive body of science, conduct a quasi-judicial process and prepare a comprehensive report, with recommendations, to the Minister of the Environment. Pursuant to the CEPA (1999), the BoR had the powers vested in a commissioner under the *Inquiries Act* meaning that they could subpoena witnesses and compel witnesses to testify. Furthermore, the BoR was required to conduct a process that respected the laws of procedural fairness to ensure that parties were given an adequate opportunity to present their case and respond to cases of opposing parties. That is, the BoR was granted complete independence and significant powers. The BoR was supported by a full-time secretariat and a paralegal assistant. Because the BoR was dealing in matters of law and the members had no formal training in the law, the services of independent counsel were invaluable. The BoR was given the discretion to interview and select what they considered to be the most appropriate legal counsel and 2 attorneys were retained. Here, we provide information on the policies and procedures that were implemented by the BoR to conduct the review and we discuss possible future applications of this approach.

Procedures followed by the BoR

The BoR needed to establish procedures and protocols for conducting the review. After reviewing the mass of available scientific information, and noting that the parties were in the process of completing other studies relevant to the issues under consideration, and taking into account the need to provide parties with an adequate opportunity to present their case, the BoR notified the Minister of the Environment that it could not complete the BoR process within the originally prescribed timeframe and requested an extension. The Report of the BoR was delivered to the Minister of the Environment on October 20, 2011, just over 1 y from the time the BoR was established, and 2.5 y from the time the Screening Assessments were published by Environment Canada and Health Canada.

In a departure from a traditional court or quasi-judicial hearing procedures where witnesses are examined by their respective and opposing counsel first, the BoR decided to have members of the Board examine the witnesses before counsel was given the opportunity to "cross-examine" witnesses called by the opposing party. Following the receipt of oral testimony, counsels for the parties were given the opportunity to make closing arguments and respond to questions from the BoR. In effect, this proceeding was a "court of science."

The BoR needed to ensure that all interested parties were allowed to participate in the review. In response to a public notice, the BoR received and granted 2 requests for intervener status; one from the Canadian Cosmetic, Toiletry and Fragrance Association (CCTFA) and the other from a coalition consisting of the Canadian Environmental Law Association, the International Institute of Concern for Public Health, Chemical Sensitivities Manitoba, and the Crooked Creek Conservancy Society of Athabasca (the Coalition). Because it was aware that new scientific information relating to D5 would be available, the BoR and the parties agreed that new information be received before the end of 2010. This information was added to the extensive body of scientific information already available.

Determination of scope and mandate of the BoR

As the BoR undertook its review, an issue arose with respect to the scope of its mandate. In particular, it was suggested that the BoR consider the nature and extent of danger posed by D5 to human health in addition to considerations related to the environment or its biological diversity. To understand the position of parties, the BoR asked all parties for their views. After considering the submissions received from all parties, on November 16, 2010 the BoR issued a ruling in which it stated that its mandate was to focus on the nature and extent of the danger posed by D5 to the environment, and it would not render an opinion on the potential effects of D5 on health of humans. This decision was also influenced by the fact that Health Canada decided that D5 did not represent an imminent threat to health of humans and would not support a decision of virtual elimination. This decision was accepted by all parties.

In the steps leading up to the hearings, all parties, except the Coalition, provided new scientific information and analysis, which were not available to Environment Canada when the Screening Assessment was completed. All of that information, in addition to the information taken into account by government officials during the final Screening Assessment, was filed with the BoR and made available to the parties. In addition, written submissions were received from all parties.

Parties were also given the opportunity to pose interrogatory questions to opposing parties. Written answers to those interrogatories were provided to the BoR and were, similarly, made available to all parties. As a result, before the hearing began, parties and the BoR had a comprehensive and extensive record relating to D5. In the view of the BoR, the range and quality of scientific information presented was sufficient for it to conduct a meaningful inquiry into the nature and extent of the danger to the environment posed by D5 and reach a robust opinion.

Based on comments provided by Environment Canada and the SEHSC and CCTFA, the BoR agreed with both parties that its mandate was to conduct an independent de novo scientific assessment of the relevant and available science relating to D5 and the potential adverse effects posed by this chemical to the environment. The BoR also agreed with counsel for Environment Canada that its mandate was not to conduct this review in the manner of an appeal of the Screening Assessment. However, the BoR concluded that it should not ignore the analysis and conclusions expressed in the final Screening Assessment, because these provided the context and foundation upon which this review was based. The BoR agreed that it was not to pronounce on whether D5 is "CEPA-toxic" (i.e., whether the compound was "toxic" according to section 64 of CEPA (1999), nor was it within the mandate of the BoR to determine whether or not D5 should be added to Schedule 1 as a toxic substance. Those decisions were entirely within the purview of the Minister of the Environment.

Hearings were conducted from April 26 to May 6, 2011, and final arguments were heard on May 26, 2011. Testimony was received from witnesses called by Environment Canada and the SEHSC and CCTFA, all of whom were qualified as experts in various scientific disciplines. Additionally, the BoR called one witness, Dr. Steve Dungey, from the United Kingdom Environment Agency.

The meaning of "danger" to the environment

A key question that needed to be resolved by the BoR was how to answer the question in the notice from the Minister as to whether D5 presented a "danger to the environment." In conducting its de novo scientific assessment of the nature and extent of the danger posed by D5 to the environment, the BoR considered how the term "danger" should be interpreted. It therefore fell to the BoR to interpret the meaning of that term in the context of the notice issued by the Minister of the Environment. The following sections are taken directly from the report (Siloxane D5 Board of Review 2011) and are repeated here because this was a key question.

The term "danger" is found in paragraphs 64(b) and (c) of CEPA, (1999) but what constitutes "danger" is not defined in CEPA or in the *Persistence and Bioaccumulation Regulations* (Government of Canada 2000). The BoR noted that paragraphs (b) and (c) contrasted slightly with paragraph 64(a) which refers to "harmful effect." Section 64 reads:

> "... a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that
>
> (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
> (b) constitute or may constitute a danger to the environment on which life depends; or
> (c) constitute or may constitute a danger in Canada to human life or health" [emphasis added].

In analyzing this issue, the BoR worked closely with its legal counsel and was able to draw on guidance offered by the Supreme Court of Canada in *R. v. Hydro-Québec*, (SCC 1997) when it interpreted the 1985 (now repealed) version of *Canadian Environmental Protection Act*, R.S.C. 1985 (Section 11), which used the word "danger" in a similar context.

The minority of the Court noted that there was no definition of the terms "danger" or "harmful effect" in Section 11. The Court reframed the essence of that section by stating that toxicity would be shown:

> "If a substance...poses or may pose a risk [emphasis added] to human life or health, or to the environment upon which human health depends, or to any aspect of the environment itself...;"

Taking this into account, the BoR interpreted its mandate to mean that it was to enquire into the nature and extent of the risk posed, if any, by D5 to the environment and to determine whether detrimental effects were caused, or might be caused. In other words, the BoR was mandated to conduct what was, in essence, a de novo assessment of risks posed by D5, taking into account all of the available, relevant, scientific information about D5.

When conducting the de novo risk assessment, the BoR concluded that best scientific practice required that it take into account information about the "intrinsic" physical and chemical properties of the substance along with its uses, releases, dissipation, transformation and degradation, pathways of exposures, toxicity, and effects. Additionally, the BoR determined that the review should be rooted in real-world terms, taking into account the quantities or concentrations and conditions under which D5 is used or, based on the best information available, the likely future volumes or uses. This approach permitted the BoR to consider the current patterns and methods of use as well as potential changes in use and concentrations in the future and these would affect the nature and extent of the risk of D5 in the environment.

The role of precaution applied by the BoR

In conducting its review, the BoR was reminded by all parties of the importance and role of the Precautionary Principle provided for in paragraph 2(1)(a) of CEPA (1999). The BoR understood the importance of, and need for, precaution when assessing the impact a chemical may have on human health or the environment. However, the BoR noted that it was also important to understand the proper application of the precautionary principle and the precautionary approach to risk assessment. When conducting a risk assessment, evaluators appropriately rely on the Precautionary Approach to the extent warranted. Consequently, where data gaps exist, or in cases where data are equivocal or unreliable, evaluators rightfully rely on a conservative or precautionary approach, using reasonable worst-case assumptions and uncertainty factors, when analyzing information or modeling. This approach ensures an appropriate degree of caution and protection.

In this case, however, the BoR had credible and trustworthy scientific information to consider and did not need to rely solely on the precautionary principle in the same way as required by those conducting the Screening Assessment. The BoR also recognized that the precautionary principle comes into play in management decisions, that is, when regulators determine what measures, if any, they should impose when a chemical of concern has been identified following a risk assessment.

Use of models and tools for assessing environmental fate and distribution of D5

When a chemical is being evaluated and there are limited empirical measurements of concentrations in the environment, predictive models can be used to estimate releases to the environment, as well as its fate and distribution after release. Although D5 had been in use for over 30 years, there was limited information on concentrations measured in, or effects on, the environment. Consequently, models featured prominently in the Screening Assessment conducted by government officials.

The BoR carefully reviewed the models and tools applied in the Screening Assessment (EC and HC 2008b) and subsequent modifications made to them and to their input parameters. The BoR concluded that these models and tools had several limitations and potential inaccuracies. The BoR was of the view that those shortcomings resulted in inaccurate predictions of environmental fates. Consequently, the interpretations based on these models and tools were of limited utility to the review conducted by the BoR. Once empirical monitoring data were available, the BoR gave greater weight to measured values than the initial estimates made by use of the MegaFlush model (EC 2009) and MassFlow tool (EC 2008).

PERSISTENCE, BIOACCUMULATION, AND TROPHIC MAGNIFICATION OF D5 IN THE ENVIRONMENT

In its deliberations, the BoR addressed interpretation of "intrinsic" properties of D5 in relation to primary determinants of risk to the environment, which were determined to be persistence, bioaccumulation, and toxicity (P, B, and T). Only key points are highlighted below as more detail is provided in the Report of the BoR. However, these points are important in that they can inform the characterization of the PBT properties of other chemicals.

Although persistence might contribute to potential for a substance to be a danger, it is not necessarily an indicator of danger in and of itself. There are many natural and synthetic substances that are persistent but do not cause harm or danger to the environment, such as natural organic matter and long-chain alkanes. The BoR recognized that, although a chemical might meet thresholds for persistence pursuant to the Regulations (Section 3 to 5; Government of Canada 2000), it would only be a danger to the environment if its persistence results in exposures that cause adverse effects in the environment. Consequently, persistence must be accompanied by accumulation in one or more compartments of the environment (or organisms) to the point that these exposures exceed the dose or threshold concentration that causes an adverse effect. Whether this occurs or not depends on other intrinsic properties of the chemical and its environment. In its report (Siloxane D5 Board of Review 2011), the BoR discussed how these properties interact with persistence and whether this results in danger to the environment.

The BoR recognized that when determining potential for a chemical to produce adverse effects, it is important to assess whether organisms are likely to be exposed to the chemical. One aspect of the assessment of potential exposure was to estimate the potential for the compound to enter into organisms by examining the bioconcentration factor (BCF), bioaccumulation factor (BAF), biota sediment application factor (BSAF), and/or trophic magnification factor (TMF). Several approaches could have been taken, depending on the information available and the tier of the risk assessment. Accumulation factors can be measured under controlled laboratory conditions, estimated from field exposures, or predicted by models.

The BoR recognized that accumulation of a substance from the matrix or food in an assay, or test, for toxicity (acute or chronic) inherently considers BCF or BMF, as well as the relevance of the concentrations that accumulate in an organism, even if these are not measured. If toxicity was not observed in a long-term assay, then accumulation by an organism as a result of that exposure would not produce adverse effects. Therefore, the exposure tested in the assay represented a de minimis risk. In essence, accumulation in and of itself is not necessarily harmful. It is only harmful when the accumulation results in a dose to the organism that exceeds its threshold of toxicity, or that of its predators.

CONCLUSIONS OF THE BOARD OF REVIEW

The conclusions of the BoR are quoted directly from the report (Siloxane D5 Board of Review 2011) and were the following:

- The evidence presented to the Board demonstrated that Siloxane D5 exceeded the regulatory threshold for persistence. However, Siloxane D5 did not exceed the thresholds established in the Regulations for bioaccumulation.
- Siloxane D5 does not biomagnify through the food chain, although it can be accumulated into organisms from environmental matrices or food. That is, concentrations of Siloxane D5 do not increase in predators relative to their prey.
- There is no evidence to demonstrate that Siloxane D5 is toxic to any organisms tested up to the limit of solubility in any environmental matrix. The Board is of the opinion that Siloxane D5 will not accumulate to sufficiently great concentrations to cause adverse effects in organisms in air, water, soils, or sediments.
- Consequently, taking into account the intrinsic properties of Siloxane D5 and all of the available scientific information, the Board concluded that Siloxane D5 does not pose a danger to the environment. Furthermore, the Board concluded that, based on the information before it, the projected future uses of Siloxane D5 will not pose a danger to the environment.

Strengths and uncertainties

Risk assessments will, by their very nature, contain some measure of uncertainty. New data provided by Environment Canada and the SEHSC and CCTFA enabled the BoR to conduct a more refined assessment. The BoR recognized that the probabilistic nature of risk is such that absolute certainty of safety or of danger is not possible. The additional data on toxicity and concentrations in the environment allowed for more reliable characterization of these 2 critical inputs to the assessment of risk. However, the BoR acknowledged that some

uncertainties remained. Although the physical-chemical properties of D5 strongly suggested that its only mechanism of toxicity was via general narcosis and physical interference with membranes, it may interact with unknown receptors or transport proteins or other chemicals present in the environment (mixtures effect). The lack of effect in mammals and all other organisms, even at high doses above the threshold for solubility, supports a conclusion that narcosis is the mechanism of action for D5. This may not be true for classes of organisms other than those tested, but the BoR considered this to be unlikely considering the similarities between species with respect to membranes, structures, and receptors.

LESSONS LEARNED

During the course of this review, the BoR was made aware of several matters about which it offered comments. These comments were intended to offer guidance only to government and industry officials respecting the framework within, and the conduct of, assessments of risk.

Persistence and Bioaccumulation Regulations

The BoR encouraged the Federal Departments to regularly review, and update as appropriate, the *Persistence and Bioaccumulation Regulations* (Government of Canada 2000). As evidenced by the new information that the BoR was able to consider in the proceedings relating to D5, advancements in sampling, measurement, and analysis provide an expanding frontier of techniques available to determine whether substances pose a danger to the environment (or human health). The Regulations should be reviewed periodically to ensure that they reflect current scientific standards and methodologies for assessment of risks.

The BoR also was of the opinion that a guidance document should be issued by the Departments describing how parameters such as persistence, bioaccumulation, and intrinsic properties are examined in a risk assessment. Such a document should be developed in consultation with stakeholders and would provide a clear understanding of how the Departments interpret the Regulations and would guide the conduct of science needed to address these requirements.

Availability and transparency of the models

The BoR recognized that models can be used to estimate releases to the environment, as well as their fate and distribution after release. Models can be of particular assistance when a chemical is being evaluated and there are limited empirical measurements of concentrations in the environment. Environment Canada relied heavily upon the output of models to inform the Screening Assessment for D5.

In the scientific community, it is generally accepted practice that models should be fully specified and, to the extent possible, transparent, that is, the algorithms are fully described and the source code is accessible. Furthermore, all input data provided to the model and the output generated should generally be made available, subject to considerations respecting confidential information. When inputs to a model do include confidential information, government officials should attempt to find ways that the model and its inputs can be disclosed without revealing confidential information. In addition, the model should be validated against measured data for the substance or for similar substances to those being tested.

The BoR encouraged Environment Canada to update its models regularly and to seek the input of subject matter experts both within and outside the government to ensure the integrity of their models and to ensure that both users and stakeholders are aware of models' strengths and weaknesses.

Conduct of Screening Assessments

It was not within the mandate of the BoR to pronounce on the process followed by government and industry in the Screening Assessment. However, the BoR did have some observations:

- It is appropriate for government officials to adopt a conservative or precautionary approach to ensure the protection of the environment and human health in the absence of a comprehensive data set and analysis.
- The BoR strongly encouraged industry and interested stakeholders to work diligently with government officials when screening assessments are being conducted to fill data gaps and provide relevant commentary and analysis.

In respect of the latter observation, a number of articles on D5 and related siloxanes have been published in the literature since the BoR provided its opinions and report. Many of these articles relate to studies done by Environment Canada (Velicogna et al. 2012; Alaee et al. 2013; Norwood et al. 2013; Parrott et al. 2013; Wang, Norwood et al. 2013; Wang, Steer et al. 2013), by industry (Xu and Kropscott 2012, 2013, 2014; Gouin et al. 2013; Kim et al. 2013; Mackay et al. 2013, 2014; Montemayor et al. 2013; van Egmond et al. 2013; Woodburn et al. 2013; Xu and Wania 2013; Kozerski et al. 2014; Seston et al. 2014; Xu et al. 2014), and others (Borgå, Fjeld et al. 2012; Borgå, Kidd et al. 2012; Burkhard et al. 2012a, 2012b, 2013; Conder et al. 2012; Redman et al. 2012; Borgå et al. 2013; Kierkegaard et al. 2013a, 2013b; Kierkegaard and McLachlan 2013; Krogseth et al. 2013; MacLeod et al. 2013; Hong et al. 2014; McGoldrick et al. 2014). That this considerable quantity of information has become available to the public adds to the general understanding of the physical, environmental, chemical, and biological properties of the cyclic siloxanes and moves science and regulation forward.

Procedural lessons

The process of the BoR was unique in that it was a hybrid of science and law. This presented challenges to the scientists on the Board and to the lawyers and counsel for the parties in terms of understanding each other's expertise. However, by good will and effective communication among the Board and the other parties, this was resolved to mutual benefit. All company reports and studies were made available to the BoR. Because of the judicial nature of the proceedings, these could have been subpoenaed; however, this was not necessary and all information was transparently available to the BoR and the parties involved. In a departure from the traditional passive role of judges in a court of law, the BoR took an active role in the questioning of expert witnesses and did this before the lawyers conducted their cross examinations. The process was more formal than most scientific discussions but the verbatim transcripts were helpful during the drafting of the final report and ensured greater accuracy than the typical minutes of scientific meetings. The BoR used a document management system called Ringtail® that provided excellent search capability and allowed presentation of documents to all parties during the hearings as well as access by the BoR at other times. This increased the transparency of the deliberations.

There are alternatives to the procedures followed by the BoR. The traditional panels and advisory groups convened by agencies such as NAS, the USEPA, the Royal Society of Canada, and SETAC can play an invaluable role by assessing the state of the science in prescribed subject areas such as analyses of exposure to substances in the environment, emerging technologies, and extraction of natural resources (e.g., oil sands or shale petroleum). These procedures provide evaluations of the state of knowledge and needs for information but lack legal weight. In contrast, the mechanism of the BoR might be most effective in addressing specific chemicals that bring both benefit and risks. Examples are D5, disinfectants, and neonicotinoids. An interesting alternative is the "hot tub" process used in Australia to reduce the influence of partisanship of experts, minimize disagreements, enhance procedural efficiency, and improve access to justice (Edmond 2009). Basically, the hot tub is the provision of concurrent evidence, a less formal process than legal evidence, where experts can make extended statements, comment on, and even test opposing opinions. This is done in a single colloquium setting where the experts provide testimony and field questions from the judge, counselors, and each other. No process is perfect but the concept of hot tubbing has been promoted as "providing significant improvements in the presentation and evaluation of scientific expert testimony" (Yarnall 2009) and brings together the advantages of aspects of traditional panels into the legal arena.

In conclusion, we have sought to provide state-of-the-science commentary and interpretation of the criteria of persistence, bioaccumulation and toxicity as applied in screening assessments of chemicals. We have stressed the need for regulatory agencies to continuously review and update their assessment processes and criteria and provide these processes in guidance documents that are available to all stakeholders. When using models it is highly desirable to review models, seek validation by monitoring where possible and provide updates to stakeholders on the assumptions of the model and perceived weaknesses of the model in the form of guidance documents. It is desirable to encourage closer cooperation between regulators and industry so that current insights into chemical properties, usage, fate, prevailing environmental concentrations, intrinsic toxicity, and effects are used to inform the assessment. It is hoped that lessons learned from this BoR of Review will be of more general and lasting value in situations where environmental science interacts with governmental regulatory processes.

Declaration of funding support, remuneration, ethics considerations, and security

The plaintiffs in the proceedings of the BoR of Review were a consortium of industries referred to as the Silicones Environmental, Health and Safety Council of North America (SEHSC). The defendant was Environment Canada. Costs associated with conducting the BoR of Review were paid by Environment Canada, which was represented by the Department of Justice of Canada. The BoR had a single point of contact with Environment Canada and operated outside of the normal chain of command such that there was no communication between the BoR and Environment Canada. The BoR operated at "arm's length" and never felt any pressure, political or otherwise, to do anything but assess the science and prepare an unbiased opinion relative to the "charge" given by the Minister. The BoR chose to not award costs to the plaintiffs. Members of the BoR were compensated for their time through a contract with Environment Canada. Travel and lodging were paid for BoR members who lived outside of Ottawa. The members of the BoR had to obtain the appropriate security clearances from the government of Canada so they could handle classified and or confidential business information. Members of the BoR informed their home institutions (employers) of their intent to participate in the BoR and received permission to do so. The members of the BoR were appointed by and served at the pleasure of the Minister of the Environment of Canada. The Chair was also selected by the Minister of the Environment. The BoR reported their findings via a public report in both official languages of Canada, English and French, to the Minister of the Environment for his use in making a decision. Prior to entering into contracts with the members of the BoR, each was vetted to determine if they had any conflicts of interest or known, publically stated biases and none were found. Public proceedings and communications between the BoR and the parties were conducted in a manner similar to a civil court in Canada. All proceedings were conducted under the laws of Canada and specifically to the regulations promulgated in the Canadian Environmental Protection Act of 1999. All materials used by the BoR during their deliberations were secured during the tenure of the BoR and then returned to the government of Canada at the end of the proceedings.

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