Federal Court  Cour fédérale

Date: 20111121

Docket: T-1604-09

Citation: 2011 FC 1322

Ottawa, Ontario, November 21, 2011

PRESENT: The Honourable Mr. Justice Kelen

BETWEEN:

JOSETTE WIER

Applicant

and

THE MINISTER OF HEALTH

Respondent

REASONS FOR JUDGMENT AND JUDGMENT

[1] This is an application for judicial review of a decision, dated August 24, 2009, of the Minister of Health (the Minister), to not initiate a "special review" of the health or environmental risks of certain pest control products under section 17 of the *Pest Control Products Act*, S.C. 2002, c. 28 (the Act).

[2] Under the Act, any person may request a “special review” of the health or environmental risks of a registered pesticide, which the Minister “shall” perform unless there is reasonable certainty that no harm will result from exposure to the pesticide.

[3] The applicant, Josette Wier, did not file an affidavit or attend the hearings. In response to a question from the Court as to the identity of the applicant, counsel for the applicant stated that Josette Wier was an “environmental researcher” in Smithers, BC (a town in north-central British Columbia). The applicant was a medical doctor in France but is not qualified to practice medicine in Canada.

FACTS

The Applicant’s Section 17 Request

[4] In a 29-page letter dated May 25, 2009, together with a binder of medical and scientific studies, the applicant (through her counsel) made a request to the Minister to initiate a “special review” of the registered pesticide glyphosate containing polyoxyethylene tallow amines (POEA) (the pesticide). Counsel advised the Court that the pesticide is aerially sprayed in forests near where the applicant lives, and that she is concerned about the health and environmental risks of this pesticide.

[5] Glyphosate is a herbicide (a “weed-killer”) registered under the Act for many uses and in many locations, including killing weeds in forests which would otherwise smother re-plantings; in agriculture on food and fibre crops; in gardens for flowers and other ornamentals; and on turf or grass. This pesticide is one of the most popular and widely used pesticides. It was first registered for use in 1976 and sold under the trade name “Roundup”. As of 2009, there were 192 glyphosate-used products registered for a variety of uses in Canada.

[6] POEA are formulants added to glyphosate products. They allow the glyphosate products to spread more evenly on the waxy surface of leaves. As of September 2009, there were 137 glyphosate products containing POEA registered for use in Canada. Two of the most common glyphosate herbicides containing POEAs registered for use in Canada are “Vision”, the trade name of a product produced by Monsanto and used in the forest industry, and “Vantage”, the trade name of a product produced by DowAgro for the same use.

The 17(1) Request

[7] The applicant made distinct requests under three subsections of section 17 of the Act. In her subsection 17(1) request, the applicant stated that there is “significant new evidence” which provides reasonable grounds to believe that glyphosate herbicides containing POEA pose unacceptable risks to health or to the environment. In particular, the applicant identified the following evidence, which she stated provide cause for the Minister to initiate a special review under section 17(1) of the Act:

a. Three studies –dated 2009, 2007, and 2005 – that demonstrated risks to human embryonic and placental cells posed by glyphosate in concentrations much lower than those found with farm and agricultural use: N. Benachour and G.E. Seralini, (2009) “Glyphosate Formulations induce Apoptosis and Necrosis in Human Umbilical, Embryonic and Placental Cells”, *Chem. Res. Toxicol* 2009, 22, 97-105; Benachour et al. “Time and dose-dependent effects of Roundup on human embryonic and placental cells” *Arch. Environ. Contam. Toxicol.* 2007 Jul, 53(1): 126-33; and Richard et al., (2005) “Differential Effects of Glyphosate and Roundup on Human Placental Cells and Aromatase”, *Environ. Health Perspect.* 113: 716-720.

b. The applicant also cited two studies – dated 2001 and 2003 – that the applicant submitted corroborated the finding of increased risk of miscarriage from exposure to glyphosate in humans and animals.

c. Two studies – dated 2001 and 2002 – that were case studies of men who had Non-Hodgkin’s Lymphoma and that linked the disease to the mens’ exposure to pesticides: Hardell et al. “Exposure to pesticides as a risk factor for Non-Hodgkin’s Lymphoma and hairy cell leukemia: pooled analysis for two Swedish case-control studies” *Leuk. Lymphoma* 2002 May, 43(5): 1043-9; and Roos et al., “Integrative

assessment of multiple pesticides as risk factors for Non-Hodgkin's Lymphoma among men", *Occup. Environ. Med* 2003 September, 60(9): E11.

d. A 2008 study conducted by the British Columbia Ministry of the Environment concluding that there is evidence that POEA has toxic effects on amphibians (such as frogs), that there are "knowledge gaps" hindering an "effective and realistic assessment" of the impacts of glyphosate on amphibians, and that there has been no assessment of the whether using surfactants with lower toxicity than POEA would be effective: B.C. Ministry of the Environment, (2008) "Literature review of impacts of glyphosate herbicide on amphibians: What risks can the silvicultural use of this herbicide pose for amphibians in B.C.?" (the BC Literature Review).

e. The applicant submitted that amphibians are a sensitive indicator species, and cited two 1999 studies, two 2001 studies, and two 2002 studies for the proposition that pesticides and POEA surfactant in particular have contributed to amphibian population declines.

f. A 2005 study finding that glyphosate-based pesticides impeded the hatching process for sea urchin embryos: Marc J., et al. "A glyphosate-based pesticide impinges on transcription", *Toxicol. Appl. Pharmacol*., 2005 Feb. 15, 203(1): 1-8.

[8] The applicant stated that the evidence in the studies was "new" because it post-dated the registration of the "Vision" and "Vantage" herbicides. The applicant stated that the health and environmental risks identified in the studies above were not known or considered when Vision and Vantage were registered for use in Canada.

[9] The applicant stated that the evidence in the studies was "significant" because it presented scientific, peer-reviewed, published data indicating that the pesticide has human health and environmental risks in Canada that were not considered when it was registered.

[10] The applicant submitted in her request that the evidence "challenges the scientific validity of the previous evaluations" that led to the registration of the glyphosate herbicides containing POEA.

[11] At the hearing before the Court, counsel for the applicant conceded that the evidence does not demonstrate a "health risk" to humans or animals from the pesticide in issue. Accordingly, that part of the applicant's request was withdrawn. Also at the hearing, counsel from the applicant

withdrew the applicant's reliance on eleven of the twelve studies submitted in support of the request. The only documentary evidence relied upon by the applicant at the hearing was document "d" above, The BC Literature Review on the impact of the pesticide in issue on amphibians in silvicultural (forest cultivation) use. Accordingly the original section 17(1) request to the respondent was substantially narrowed at the hearing.

The Section 17(2) Request

[12] In her request for special review, the applicant further submitted that there were grounds for a special review under section 17(2) of the Act, which requires the Minister to initiate a special review of a registered pest control product where a member country of the Organization for Economic Co-operation and Development (OECD) has prohibited all uses of its active ingredient.

[13] The applicant stated that Australia, a member country of the OECD, had prohibited the use of glyphosate herbicides containing POEA surfactants in aquatic habitats because it is unreasonably toxic to amphibians. The applicant included an Australian document, dated June 1996, in support of this claim: "Special Review of Glyphosate", NRA Special Review Series 96.1.

[14] At the hearing, counsel for the applicant withdrew this section 17(2) request because the applicant's original understanding of the situation in Australia was mistaken.

The Section 17(3) Request

[15] Finally, the applicant submitted that there were grounds for a special review under section 17(3) of the Act, which requires the Minister to initiate a special review where there is information from a federal or provincial government that gives the Minister reasonable grounds to believe that the product's health or environmental risks are unacceptable. The applicant referred to the BC Literature Review, above, to support this submission. The applicant submitted that the "summary of

glyphosate impacts on amphibians" contained in the BC Literature Review contained information regarding the impact of glyphosate on amphibians that had not previously been considered by the Minister. The Court notes that BC has its own provincial legislation to ban pesticides, and BC has not banned the pesticide.

[16] At the hearing, counsel for the Applicant also withdrew the section 17(3) request.

The Precautionary Principle

[17] In her request, the applicant referred to the "precautionary principle", which the Supreme Court of Canada defined in *114957 Canada Ltée (Spraytech, Société d'arrosage) v. Hudson (Town)*, 2001 SCC 40, at paragraph 31, quoting from paragraph 7 of the Bergen Ministerial Declaration on Sustainable Development (1990):

> In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation

[18] The precautionary principle has now been legislated in section 20(2) of the Act which states 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 adverse health impact or environmental degradation.

[19] The applicant submitted that, environmental protection is a "fundamental value" in Canadian society, and that the precautionary principle requires the Minister to review the "new evidence" relating to toxicity of the pesticide to amphibians in ephemeral wetlands.

[20] The applicant submitted that the studies enclosed in her request demonstrated that the current registrations for glyphosate herbicides containing POEA are not based on the precautionary principle. She stated that there are reasonable grounds for finding the health or environmental risks posed by the glyphosate herbicides containing POEA are unacceptable.

The BC Literature Review

[21] The BC Literature Review on the impacts of the pesticide in silvicultural use on amphibians is the only evidence relied upon at the hearing by the applicant for this request. It is a report from the British Columbia Ministry of Environment dated June, 2008. It reviews over 100 research papers and studies. It concludes that the pesticide in issue has a toxic effect in amphibians. The restrictions on the use of the pesticide in silviculture require that sensitive areas around water are protected by a buffer zone where the pesticide cannot be used. However, the report states in the executive summary:

> In B.C. these requirements apply to large and moderate-sized wetlands and streams and are intended to protect aquatic organisms from impacts of glyphosate herbicides. Although most water bodies and many riparian areas are afforded protection, glyphosate may be sprayed over dry creeks as well as over certain types of temporary, isolated ponds that are habitats frequently used by amphibians.

The BC Literature Review states at page 10 that the over spraying of wetlands could result in the loss of certain foods that tadpoles graze on. In the summary, at page 31 of the BC Literature Review, the conclusion is that there is a harmful effect to tadpoles and "late-stage anuran embryos" from the pesticide. Under the heading "Knowledge Gaps" the BC report states at page 32:

> There is sufficient research to suggest that glyphosate herbicides use could pose a risk to amphibians and that its use needs to be re-evaluated…However, almost no research has been conducted to

> assess the impact on amphibians from silvicultural use of glyphosate herbicides in B.C.

It continues at page 33 to state:

> More research is essential to determine the impact of glyphosate use on amphibian populations using these habitats [i.e. the ephemeral wetlands].

Risk Analysis Conducted by Regulatory Agency in Response to the Applicant's Request

[22] The Minister has delegated responsibility for evaluating requests for special review to the Pest Management Regulatory Agency at Health Canada (the Regulatory Agency), which is an agency of experts at Health Canada charged with administering the Act and its Regulations. The Regulatory Agency has developed a process for reviewing and responding to requests for special review. In essence, this process involves three steps:

a. risk assessments by teams of scientists,

b. review by the "Science Operations Committee" of the Regulatory Agency, and

c. review and final decision by the "Science Management Committee" of the Regulatory Agency.

First Step in the Analysis of the Request by the Regulatory Agency

[23] Upon receipt of the applicant's request for a special review, the Regulatory Agency assigned the request to three teams of scientists for review:

a. the Environmental Assessment Directorate,

b. the Health Evaluation Directorate, and

c. the Chemistry Section of Compliance, Laboratory Services and Regional Operations.

[24] The scientists were asked to address the following four questions:

1. Do the data provided give reasonable grounds to believe that the environmental/health risks of the products are unacceptable (and justify a special review, as per subsection 17(1) of the PCPA) or managed via a normal re-evaluation?

2. Are the data provided credible (scientifically valid)?

3. Are the studies new or have they been reviewed by the PMRA previously?

4. Does it appear that the risks are associated with glyphosate only, POEA only or their combination?

[24] The findings of each of the three groups were set out in separate memoranda. No group found that the risk posed by the products under review warranted initiating a special review.

[25] The Environmental Assessment Directorate reviewed the two documents related to toxicity of glyphosate to amphibians (the Australian report and the BC Literature Review). Its findings are set out in its memorandum dated July 10, 2009, "EAD's evaluation of the application for a special review of glyphosate herbicides containing polyethoxylated tallow amines (POEA)" which stated in response to questions 1 and 3:

> **Question 1: Do the data provided give reasonable grounds to believe that the environment risks of products are unacceptable (and justify a special review, as per subsection 17(1) of the PCPA) or managed via normal re-evaluation?**
>
> - The studies cited in the two review documents indicate that glyphosate formulations are toxic to amphibians and other aquatic organisms. The PMRA was aware of this information.
>
> - There is, however, controversy as to the effects of glyphosate formulations on amphibians in small ephemeral wetlands following realistic conditions of applications of glyphosate formulations.
>
> - The lack of field studies hinders effective and realistic assessments of the risk to amphibians from the use of glyphosate formulations.
>
> - To address this uncertainty, a two-year study is being conducted (research authorization requests 2009-0879 and

2009-0593) to provide critical information to fill in knowledge gaps regarding:

- data on glyphosate levels in small wetlands following use under forestry and agriculture settings; and
- effects of glyphosate formulations on amphibians in small wetlands representative of those in agricultural and forestry sectors.

- The re-evaluation of glyphosate is anticipated to occur early in the next cycle of re-evaluation. By then, the results of the above-mentioned two-year research study would be considered.

……

Question 3: Are the studies new or have they been reviewed by PMRA previously?

- The PMRA was aware of the information presented in the two review documents.
- The literature review from the British Columbia Ministry of the Environment cites publications from 1974 to 2006 on the effects of glyphosate formulations on amphibians. The PMRA commented on, and attended a conference call to discuss, this literature review prior to its publication in 2008. The PMRA has not directly reviewed the majority of the studies cited in the document.
- The special review document by Australia (1996) cites studies published from 1974 to 1995 on the toxicity of glyphosate and/or surfactants on various species of aquatic organisms. Several of the same studies were used in our assessment of the pre-harvest use of glyphosate in 1991 (R91-01).

(Bold emphasis in original document)

[26] The Environmental Assessment Directorate's memorandum does not contain an explicit conclusion regarding the acceptability of the risk posed by glyphosate substances. In response to question 1, the Environmental Assessment Directorate stated that the studies confirm that

glyphosate formulations are toxic to amphibians and other aquatic organisms, but that there is uncertainty in the effects that they have in realistic, as opposed to engineered, scenarios.

[27] The respondent's affiant in this application for judicial review, Dr. Peter Delorme, is the Director of Product Assessment within the Environmental Assessment Directorate of the Regulatory Agency. He deposed that the memorandum, which was intended for internal use at the Regulatory Agency's discussions prior to making the decision, in effect concluded that the risks were not unacceptable. First, as stated in the memorandum, the Environmental Assessment Directorate concluded that the risks identified had already been addressed. In particular, the study referred to above (R91-01), was a discussion document written by the Regulatory Agency in 1991. It states that glyphosate products containing POEAs are toxic to aquatic organisms, but suggests ~~mitigation~~ measures to mitigate the risks. Also, as discussed in the memorandum, Health Canada was in fact involved in the BC Literature Review prior to its publication, and itself consulted many of the studies relied on by the Australian review.

[28] Second, Dr. Delorme stated that the memorandum demonstrated that the Directorate felt that the risk was not unacceptable because of the nature of evaluations.

[29] In the Affidavit, Dr. Delorme deposed that recent field studies by the Canadian Forestry Service, Natural Resources Canada showed that the pesticide in issue had no significant adverse effects on amphibians under the actual use conditions (see paragraph 67 of his Affidavit). He further deposed that there will be additional field study research related to the environmental effects of this pesticide on amphibians and stated that results from this research are expected to be available within the next one to two years. At the time of his cross-examination, the preliminary results from the field studies were known. However this information was not available at the time of the decision

under review, and the applicant objected to its introduction. This Court has therefore disregarded this new evidence not before the decision-maker.

Second Step in the Analysis of the Request by the Regulatory Agency

[30] The second stage of review of the applicant's request was undertaken by the "Science Operations Committee." The Science Operations Committee is a committee of senior managers from each directorate. The Science Operations Committee receives a briefing note that is prepared by scientific staff of Health Canada and is circulated in advance of their meeting. The scientific staff also participated at the meeting to answer technical questions that may arise.

[31] The Science Operation Committee briefing note dated July 15, 2009 stated under the heading "Environmental Risk Assessment":

> **E. ENVIRONMENTAL RISK ASSESSMENT (based on two provided publications)**
>
> - The toxicity of glyphosate formulations to aquatic organisms including amphibians is recognized. Most of the toxicity studies indicate that the toxicity of glyphosate formulations to aquatic organisms is mainly attributed to the surfactant, POEA.
> - There is controversy as to the effects of glyphosate formulations on amphibians in small ephemeral wetlands following application of glyphosate formulations. This uncertainty currently hinders effective and realistic assessments of the risk to amphibians from the use of glyphosate formulations.
> - A two-year study is currently underway that will provide critical information to fill in knowledge gaps regarding:
>   - **a.** Field data on glyphosate levels in small wetlands following use under forestry and agricultural settings; and
>   - **b.** Effects of glyphosate formulations on amphibians in small wetlands representative of those in agricultural and forestry sectors.
>
> (Bold emphasis in original document)

Third Step in the Analysis of the Request by the Regulatory Agency

[32] Following its meeting, the Science Operations Committee makes recommendations that are then forwarded to the "Science Management Committee". The Science Management Committee is chaired by the Chief Registrar and includes all of the Health Canada Regulatory Agency's Directors General. They receive the Science Operations Committee recommendations in a briefing note that, like the briefing note prepared for the Science Operations Committee, is prepared by scientific staff.

[33] In this case, the Science Management Committee briefing note, dated July 30, 2009, recommended that a special review not be initiated, but that the scheduled re-evaluation of glyphosate be expanded to include a risk assessment of POEA/glyphosate combinations:

> **B. Considerations**
>
> - There is some uncertainty as to the effects of glyphosate formulations on amphibians in small ephemeral wetlands. A field based study by a group of university researchers with collaboration of Environment Canada scientists was initiatied in 2009,which may help to resolve uncertainties. However, the final results of those studies are anticipated until 2011 or later…
>
> **C. Recommendations**
>
> - SOC recommended proceeding with the scheduled re-evaluation of glyphosate with the inclusion of a risk assessment of POEA/glyphosate combinations rather than initiating a special review (option #1 of the SOC briefing note)
>
> (Bold emphasis in original document)

[34] In appropriate cases, the Science Management Committee may recommend further investigations be conducted. In this case, the Science Management Committee decided that a special

review did not need to be initiated, but it decided to include a POEA risk assessment in the scheduled re-evaluation. Its decision, dated July 30, 2009, was reflected in the minutes of the meeting which read as follows:

> SMC agreed to not initiate a special review; proceed with the scheduled re-evaluation of glyphosate and include a risk assessment of POEA/glyphosate combinations.

A Draft Letter from the Regulatory Agency in Response to the Special Review Request by the Applicant

[35] The evidence before the Court showed that a draft letter was prepared, in response to the applicant's request. The letter originally contained two paragraphs which were later deleted. The first deleted paragraph recognized the controversy as to the effects of the pesticide in issue on amphibians in small ephemeral wetlands. The original words in the draft letter stated:

> There is controversy as to the effects of glyphosate formulations on amphibians in small ephemeral wetlands following the application of glyphosate formulations.
>
> This uncertainty currently hinders effective and realistic assessments of the risk to amphibians from the use of glyphosate formulations.

[36] This deletion was made by Dr. Delorme. The reason for the deletion can be seen in a comment about the draft letter by another member of the EAD, Janine Glacier. She wrote about the draft letter:

> Field studies by CFS under operational (and realistic) conditions provide the most useful information to address the concern about amphibians. I don't believe that the uncertainty "hinders effective or realistic assessment". Quite the contrary, there is a large amount of information available that enables an effective and realistic assessment.

The Decision Under Review

[37] By letter dated August 24, 2009 the Regulatory Agency declined the applicant's request to initiate a special review. The Regulatory Agency explained the process by which such requests are assessed – namely, by a team of scientists who recommend whether to initiate a special review based on their assessments of the merit of the scientific evidence presented in the request and whether the evidence changes existing risk assessment or risk mitigation measures, and whether there may be other mechanisms, such as re-evaluation that would be better suited to responding to the identified risks.

[38] The letter listed the evidence submitted by the applicant: six documents related to health risks, two documents related to environmental risks, two court decisions, an annex from the UN Human Rights Council, and a media article reporting on the results of a study included in the above.

[39] With regard to the health concerns, the Regulatory Agency stated that the overall conclusion of the evidence presented is that POEA formulants make glyphosate-containing products more toxic than those without the added POEA. But the letter states that all of the studies presented by the applicant were performed *in vitro* using cell cultures. In contrast, the letter states that the Regulatory Agency considers *in vivo* studies, which are conducted in more realistic settings, to be more indicative of the risks:

> Although information from *in vitro* studies is considered in the overall assessment of a product, *in vivo* studies by various routes (oral, dermal, inhalation) are more representative of the hazard potential. PMRA assessments such as those that were conducted for glyphosate products containing POEA are based primarily on *in vivo* studies.

[40] The letter further stated that the data presented in one study, "An exploratory analysis of the effect of pesticide exposure on the risk of spontaneous abortion in an Ontario farm population,"

were not convincing, due to the nature of the study itself, which included "unvalidated self-reported exposure information and lack of control for potentially important confounding factors such as maternal age."

[41] As stated above, the applicant did not challenge this health risk finding before the Court.

[42] With regard to the environmental risks raised by the applicant, the Regulatory Agency recognized the danger posed to aquatic organisms:

> In response to environmental concerns (documents 1 and 8), the PMRA recognizes the toxicity of glyphosate formulations to aquatic organisms and that the toxicity of those formulations is at least in part attributable to the surfactant, POEA.

[43] The Regulatory Agency stated, however, that no registered uses of glyphosate allow for direct application to water. The Regulatory Agency further concluded that existing measures are effective at protecting amphibians:

> Based on the currently available toxicity data, it is expected that the existing mitigation measures on labels, that limit drift into aquatic systems from agricultural uses, will be protective of amphibians in small ephemeral wetlands. Labels for forestry uses also indicate that appropriate buffer zones should be maintained for the protection of aquatic species.
>
> There is insufficient new evidence of unacceptable risk to amphibians in the submitted information to support a special review of environmental effects. The upcoming re-evaluation of glyphosate will include consideration of amphibians and of the surfactant POEA.

[44] The Regulatory Agency concluded that the applicant had failed to bring enough new evidence of unacceptable risk to amphibians to support a special review. While the letter mentioned existing mitigation measures for forestry uses of the pesticide, it did not address the risk raised by the BC Literature Review – namely, the risk to amphibians in ephemeral wetlands when the

pesticide is aerially sprayed in clear cut areas, which are not currently covered by the existing mitigations measures.

[45] The Regulatory Agency noted further that an upcoming re-evaluation of glyphosate would include “consideration of amphibians and of the surfactant POEA.”

[46] With regard to the applicant’s claims under section 17(2) of the Act, the Regulatory Agency found that Australia does not prohibit all uses of glyphosate, but rather has restricted uses allowing for direct application to water. The Regulatory Agency repeated that no such uses are approved in Canada. With regard to the applicant’s arguments under section 17(3), the Regulatory Agency stated that the literature review published by the government of British Columbia did not give grounds for a special review for the reasons stated with regard to section 17(1). The applicant did not challenge these two parts of the decision.

[47] As for the precautionary principle, the Regulatory Agency stated that the entire process by which products are registered under the Act incorporates the precautionary principle:

> The PMRA wishes to assure you that the approach, which the PCPA prescribes for PMRA regulatory activities, is inherently precautionary. This applies to all product registrations, including glyphosate herbicides containing POEA. The Act places the onus on industry to conduct extensive scientific testing that will enable the PMRA to thoroughly evaluate a pesticide and consider its acceptability. PMRA evaluators use conservative assumptions in assessing health and environmental risks and when prescribing protective measures such as conditions of registration. A pesticide is only registered for use or sale in Canada if the rigorous scientific assessment process provides reasonable certainty that no harm to human health, future generations or the environment will result when the product is used according to label instructions.
>
> The very high standard of “acceptable risk” imposed by the Act in a pre-market approval regulatory system is designed to prevent pest control products from posing the types of threat of harm identified in

> the Rio Declaration. However, Section 20 of the Act does make provision for the use that particular precautionary approach on an interim basis if, in the course of a re-evaluation or special review, it is determined to be appropriate pending completion of the process. Once the re-evaluation or special review is completed, if it is determined that the product no longer meets the acceptable risks or value standard the registration must be amended or cancelled, as the case may be, in accordance with subsection 21(2).

[48] The Regulatory Agency found that the current risk mitigation measures in place for the impugned pesticides "are appropriate until a re-evaluation of glyphosate-containing products is considered." The Regulatory Agency found that the applicant's evidence did not provide reasonable grounds for finding unacceptable health or environmental risks.

[49] The Regulatory Agency informed the applicant that a re-evaluation of glyphosate was anticipated in the near future. The re-evaluation would be conducted jointly with the United States Environmental Protection Agency. The US Environmental Protection Agency had published its initial workplan for that project on July 22, 2009, and acknowledged that the US would be working cooperatively with the Regulatory Agency. It informed the applicant that there is a public request for data involved in that process, and that the applicant could re-submit her information at that time.

[50] The decision repeatedly referred to the re-evaluation under section 16 suggesting that a special review under section 17 was therefore not necessary. The decision stated as follows:

> On page 1: "…If risk concerns are recognized, the PMRA also considers whether there are other mechanisms, such as re-evaluation that may be better suited to responding to the risk concerns than a special review."
>
> On page 2: "There is insufficient new evidence of unacceptable risk to amphibians in the submitted information to support a special review of environmental effects. The upcoming re-evaluation of glyphosate will include consideration of amphibians and of the surfactant POEA."

> On page 4: “The PMRA has determined that the current risk mitigation measures in place for glyphosate (including no registered uses for direct application to water and other risk mitigation measures to minimise non-target exposures from spray drift)” are appropriate until a re-evaluation of glyphosate-containing products is conducted.”
>
> On page 4: “Based on the overall assessment of your request, the PMRA has determined that the information submitted does not meet the requirements to invoke a special review. However, the PMRA will address concerns around the potential environmental risks associated with POEA in the broader re-evaluation of all glyphosate products. While this may entail additional work due to the broader scope, this will lead to a more complete consideration of the concerns.”
>
> On page 4: “The PMRA anticipates that the re-evaluation of glyphosate will be officially announced within the year and will include particular consideration of glyphosate products containing POEA.”
>
> On page 4: “One of the initial steps of the re-evaluation will be a public request for data to address specific topics. We appreciate your interest in the regulation of pesticides and would encourage you to submit any additional information regarding glyphosate at that time.”

LEGISLATION

[51] The Minister’s objectives in administering the *Pest Control Products Act*, S.C. 2002, c. 28, are set out in section 4:

4.(1) In the administration of this Act, the Minister’s primary objective is to prevent unacceptable risks to people and the environment from the use of pest control products.	4.(1) Pour l’application de la présente loi, le ministre a comme objectif premier de prévenir les risques inacceptables pour les personnes et l’environnement que présente l’utilisation des produits antiparasitaires.
(2) Consistent with, and in furtherance of, the primary objective, the Minister shall	(2) À cet égard, le ministre doit :

(a) support sustainable development designed to enable the needs of the present to be met without compromising the ability of future generations to meet their own needs;

a) promouvoir le développement durable, soit un développement qui permet de répondre aux besoins du présent sans compromettre la possibilité pour les générations futures de satisfaire les leurs;

(b) seek to minimize health and environmental risks posed by pest control products and encourage the development and implementation of innovative, sustainable pest management strategies by facilitating access to pest control products that pose lower risks and by other appropriate measures;

b) tenter de réduire au minimum les risques sanitaires et environnementaux que présentent les produits antiparasitaires et d'encourager le développement et la mise en oeuvre de stratégies de lutte antiparasitaire durables et innovatrices — en facilitant l'accès à des produits antiparasitaires à risque réduit — et d'autres mesures indiquées;

(c) encourage public awareness in relation to pest control products by informing the public, facilitating public access to relevant information and public participation in the decision-making process; and

c) sensibiliser le public aux produits antiparasitaires en l'informant, en favorisant son accès aux renseignements pertinents et en encourageant sa participation au processus de prise de décision;

(d) ensure that only those pest control products that are determined to be of acceptable value are approved for use in Canada.

d) veiller à ce que seuls les produits antiparasitaires dont la valeur a été déterminée comme acceptable soient approuvés pour utilisation au Canada.

4.1 For greater certainty, protection and consideration

4.1 Il est entendu que la protection et la considération

afforded to children in this Act shall also extend to future generations.	que la présente loi accorde aux enfants s'étendent aux générations futures.

[52] The Act defines "environmental risk" and "pest" in section 2(1):

"environmental risk", in respect of a pest control product, means the possibility of harm to the environment, including its biological diversity, resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.	« risque environnemental » Risque de dommage à l'environnement, notamment à sa diversité biologique, résultant de l'exposition au produit antiparasitaire ou de l'utilisation de celui-ci, compte tenu des conditions d'homologation proposées ou fixées.
"pest" means an animal, a plant or other organism that is injurious, noxious or troublesome, whether directly or indirectly, and an injurious, noxious or troublesome condition or organic function of an animal, a plant or other organism.	« parasite » Animal, plante ou autre organisme qui est, directement ou non, nuisible, nocif ou gênant, ainsi que toute fonction organique ou condition nuisible, nocive ou gênante d'un animal, d'une plante ou d'un autre organisme.

[53] The definition of a "pest control product" is also established in section 2(1) of the Act:

"pest control product" means	« produit antiparasitaire »
(a) a product, an organism or a substance, including a product, an organism or a substance derived through biotechnology, that consists of its active ingredient, formulants and contaminants, and that is manufactured, represented, distributed or used as a means for directly or	a) Produit, substance ou organisme — notamment ceux résultant de la biotechnologie — constitué d'un principe actif ainsi que de formulants et de contaminants et fabriqué, présenté, distribué ou utilisé comme moyen de lutte direct ou indirect

indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects;	contre les parasites par destruction, attraction ou répulsion, ou encore par atténuation ou prévention de leurs effets nuisibles, nocifs ou gênants;
(b) an active ingredient that is used to manufacture anything described in paragraph (a); or	b) tout principe actif servant à la fabrication de ces éléments;
(c) any other thing that is prescribed to be a pest control product.	c) toute chose désignée comme tel par règlement.

[54] The definition of what constitutes an “acceptable risk” is set out in section 2(2):

2.(2) For the purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.	2. (2) Pour l’application de la présente loi, les risques sanitaires ou environnementaux d’un produit antiparasitaire sont acceptables s’il existe une certitude raisonnable qu’aucun dommage à la santé humaine, aux générations futures ou à l’environnement ne résultera de l’exposition au produit ou de l’utilisation de celui-ci, compte tenu des conditions d’homologation proposées ou fixées.

[55] The Act prohibits the use of unregistered pest control products in section 6(1):

6. (1) No person shall manufacture, possess, handle, store, transport, import, distribute or use a pest control product that is not registered under this Act, except as otherwise authorized under subsection 21(5) or 41(1), any of sections 53 to 59 or the	6. (1) Sauf dans les cas autorisés par les paragraphes 21(5) et 41(1), les articles 53 à 59 et les règlements, il est interdit de fabriquer, de posséder, de manipuler, de stocker, de transporter, d’importer, de distribuer ou d’utiliser un produit

regulations.	antiparasitaire non homologué en vertu de la présente loi.

[56] Section 6(5) prohibits the misuse of pest control products:

6. (5) No person shall handle, store, transport, use or dispose of a pest control product in a way that is inconsistent with	6. (5) No person shall handle, store, transport, use or dispose of a pest control product in a way that is inconsistent with
(a) the regulations; or	(a) the regulations; or
(b) if the product is registered, the directions on the label recorded in the Register, subject to the regulations.	(b) if the product is registered, the directions on the label recorded in the Register, subject to the regulations.

[57] The penalties for committing the above offences are stated in section 6(9):

6. (9) A person who contravenes any provision of this section is guilty of an offence and liable	6. (9) Quiconque contrevient à toute disposition du présent article commet une infraction et encourt, sur déclaration de culpabilité :
(a) on summary conviction, to a fine of not more than $200,000 or to imprisonment for a term of not more than six months, or to both; or	a) par procédure sommaire, une amende maximale de 200 000 $ et un emprisonnement maximal de six mois, ou l’une de ces peines;
(b) on conviction on indictment, to a fine of not more than $500,000 or to imprisonment for a term of not more than three years, or to both.	b) par mise en accusation, une amende maximale de 500 000 $ et un emprisonnement maximal de trois ans, ou l’une de ces peines.

[58] Section 16(1) gives the Minister discretion to initiate a re-evaluation under the Act, subject to the requirements in section 16(2):

16. (1) The Minister may initiate the re-evaluation of a registered pest control product	16. (1) Le ministre peut procéder à la réévaluation d’un produit antiparasitaire

if the Minister considers that, since the product was registered, there has been a change in the information required, or the procedures used, for the evaluation of the health or environmental risks or the value of pest control products of the same class or kind.

homologué s'il estime que, depuis son homologation, il y a eu un changement en ce qui touche les renseignements exigés ou la procédure à suivre pour l'évaluation de la valeur des produits de même catégorie ou de même nature ou des risques sanitaires ou environnementaux qu'ils présentent.

(2) Without limiting the generality of subsection (1),

(2) Sans que soit limitée la portée générale du paragraphe (1) :

(a) if a decision of a type referred to in paragraph 28(1)(a) or (b) was made in relation to a pest control product on or after April 1, 1995, the Minister shall initiate a re-evaluation of that product no later than one year after 15 years have elapsed since the most recent decision of that type; and

a) lorsqu'une décision sur l'homologation d'un produit antiparasitaire, du même type que celle visée aux alinéas 28(1)a) ou b), est prise le 1er avril 1995 ou après cette date, le ministre procède à une réévaluation du produit au plus tard un an après la période de quinze ans écoulée depuis la plus récente décision de ce type;

(b) if the most recent decision of a type referred to in paragraph 28(1)(a) or (b) was made in relation to a pest control product before April 1, 1995, the Minister shall initiate a re-evaluation of that product no later than April 1, 2005 or the date that is one year after 15 years have elapsed since that decision, whichever date is later.

b) lorsque la plus récente décision sur l'homologation d'un produit antiparasitaire, du même type que celle visée aux alinéas 28(1)a) ou b), a été prise avant le 1er avril 1995, le ministre procède à une réévaluation du produit au plus tard le 1er avril 2005 ou, si cette date est postérieure, la date qui suit d'un an la période de quinze ans écoulée depuis la décision.

[59] The requirement that the Minister conduct a special review in certain circumstances is contained in section 17 of the Act:

17. (1) The Minister shall initiate a special review of the registration of a pest control product if the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.	17. (1) Le ministre procède à l'examen spécial de l'homologation du produit antiparasitaire lorsqu'il a des motifs raisonnables de croire que la valeur du produit ou les risques sanitaires ou environnementaux qu'il présente sont inacceptables.
(2) Without limiting the generality of subsection (1), when a member country of the Organisation for Economic Co-operation and Development prohibits all uses of an active ingredient for health or environmental reasons, the Minister shall initiate a special review of registered pest control products containing that active ingredient.	(2) Sans que soit limitée la portée générale du paragraphe (1), lorsqu'un pays membre de l'Organisation de coopération et de développement économiques interdit l'utilisation d'un principe actif pour des raisons sanitaires ou environnementales, le ministre procède à l'examen spécial des produits antiparasitaires homologués contenant ce principe actif.
(3) Without limiting the generality of subsection (1), the Minister shall initiate a special review of the registration of a pest control product if a federal or provincial government department or agency has provided information to the Minister that relates to the health or environmental risks or the value of the product and if, after considering the information provided, the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value	(3) Sans que soit limitée la portée générale du paragraphe (1), le ministre procède à l'examen spécial de l'homologation du produit antiparasitaire lorsqu'un ministère ou organisme public fédéral ou provincial lui fournit les renseignements relatifs aux risques sanitaires ou environnementaux ou à la valeur du produit visé et, à la suite de l'étude de ces renseignements, le ministre a des motifs raisonnables de croire que la valeur du produit ou les risques sanitaires ou environnementaux qu'il

is, unacceptable.	présente sont inacceptables.
(4) Any person may request a special review of the registration of a pest control product by making a request to the Minister in the form and manner directed by the Minister.	(4) Toute personne peut faire une demande d'examen spécial au ministre, en la forme et de la façon qu'il précise.
(5) Within a reasonable time after receiving a request, the Minister shall decide whether to initiate a special review and shall respond to the request with written reasons for the decision.	(5) Dans un délai raisonnable suivant la réception de la demande, le ministre décide s'il procède ou non à l'examen et communique à son auteur sa décision en la motivant par écrit.

ISSUES

[60] The applicant raises the following issues on this judicial review application:

1. Did the Minister err by only considering "new evidence", and by failing to consider the entire body of evidence relevant to the existence of an environmental risk, including information that he had prior to the applicant's request?

2. Did the Minister err by concluding that a mandatory special review under section 17 is not required if he intends to engage in a periodic review under section 16 of the Act in the near future?

3. Did the Minister err in interpreting the evidentiary threshold required to initiate a special review under section 17?

4. Did the Minister err in his interpretation of his statutory obligation to apply the precautionary principle?

5. Was the Minister's finding, that glyphosate herbicides containing POEA do not present an unacceptable risk, unreasonable?

[61] The respondent raises a sixth issue: whether relief should be granted. Although an earlier motion to strike the application as moot was dismissed, the respondent submits that the applicant is not entitled to relief because there is little or no practical value to her of such relief, and refusing to grant the relief is in the public interest. This is because a re-evaluation pursuant to section 16 of the

Act was commenced in November 2009. Thus, were the Minister to reconsider his decision and order a special review under section 17, the respondent submits this would simply replicate the work that has already begun pursuant to section 16.

STANDARD OF REVIEW

[62] In *New Brunswick (Board of Management) v. Dunsmuir*, 2008 SCC 9, the Supreme Court of Canada held at paragraph 62 that the first step in conducting a standard of review analysis is to "ascertain whether the jurisprudence has already determined in a satisfactory manner the degree of (deference) to be accorded with regard to a particular category of question": see also *Khosa v. Canada (Minister of Citizenship & Immigration)*, 2009 SCC 12, per Justice Binnie at paragraph 53.

[63] This application seeks to review a decision of the Minister under section 17 of the Act. The provision requires the Minister to initiate a special review where he finds reasonable grounds for believing that health or environmental risks associated with a product use are unacceptable.

[64] Neither party has pointed the Court to a case in which the standard of review of a Minister's decision under this section of the Act was considered. The respondent did, however, rely on a 1994 decision of the Federal Court of Appeal, *Pulp, Paper and Woodworkers of Canada Local 8 v. Canada (Minister of Agriculture, Pesticides Directorate)* (F.C.A.), [1994] F.C.J. No. 1067 (Q.L.), reviewing a decision of the Minister to register a product under the former version of the Act. The case is useful insofar as it discusses the scope of a Minister's discretion under the Act.

[65] In *Pulp, Paper and Woodworkers of Canada*, the Court of Appeal considered an appeal from a Federal Court decision granting the applicant a writ of certiorari to quash a decision by the Minister to register a pesticide as a controlled product. The legislation at issue was similar to that applicable in this case. There, the Minister had discretion, under section 18 of the former Act, to

refuse to register a product when the Minister felt that he did not have enough information to assess or evaluate the product, or felt that the use of the product would lead to an unacceptable risk of harm to public health. The Court of Appeal stated the following with regard to the standard a court should use in reviewing a Minister's decision in these circumstances (references omitted):

> ¶25. It follows, from section 18, that once the necessary information is before the Minister, a court of law has no jurisdiction to question the sufficiency of that information. The trial judge was, therefore, in error when he proceeded to analyze the lack of depth of Ralph's [Mr. C.D. Ralph, the Product Management Division of the Pesticides Directorate of the Department of Agriculture and Minister's delegate] evaluation and research since it was clear from the affidavit that Ralph had addressed his mind to the nature and quality of the information he had received. The trial judge certainly went too far when he concluded that "[e]ven if the Minister addressed his mind to the appropriate question and found that the information supplied in relation to the application for registration of Busan 30WB was sufficient to enable the control product to be assessed and evaluated, the Minister nevertheless exceeded his authority in exercising his discretion to cause Busan 30WB to be registered because the sufficiency decision was patently in error". In the case of *Re Maple Lodge Farms Ltd. and Government of Canada*, McIntyre J., for the Supreme Court of Canada, made it very clear that:
>
> > ... It is, as well, a clearly-established rule that the courts should not interfere with the exercise of a discretion by a statutory authority merely because the court might have exercised the discretion in a different manner had it been charged with that responsibility.

[66] Subsequent jurisprudence has reinforced this approach. Thus, the Court will evaluate the Minister's interpretations of the legal standards applicable to him on a standard of correctness, but once the Minister has correctly interpreted his duties, his exercise of discretion in performing those duties will be reviewed on a standard of reasonableness: see also, *Dunsmuir*, above, at paragraphs 47, 49-50, and 53.

[67] Issues 1 and 5 raised by the applicant challenge the Minister's evaluation of the evidence and application of the evidence to the law. These are reviewable on a standard of reasonableness.

[68] The remaining issues concern the Minister's interpretation of the legal requirements of the Act. These are not areas within the Minister's specialized area of expertise and there is no privative clause that suggests a more deferential standard should apply to the Minister's legal interpretations. As such, they are to be reviewed on a standard of correctness: see *Dunsmuir* at paragraph 55.

ANALYSIS

Statutory Framework of the Pest Control Products Act

[69] The Act's objectives are stated in section 4. Subsection 4(1) states that the Minister's "primary" objective in administering the Act is to "prevent unacceptable risks to people and the environment from the use of pest control products."

[70] Companies seeking to sell a pest control product in Canada must submit an application for registration to the Regulatory Agency, which is an agency of experts that the Minister has charged with administering the Act and Regulations. The Regulatory Agency has a detailed process of review and analysis that it undertakes prior to making its decision regarding the registration of a pesticide.

[71] A pesticide's registration under the Act includes a number of details, including conditions relating to the manufacture, use, composition, labelling of the product, and the period for which the registration is valid. Products are registered for specific uses, and if registrants want to expand a product's registered uses, they must re-apply to the Regulatory Agency and provide any additional required data.

[72] Once a pesticide is registered, its registration is maintained subject to additional evaluations that may be undertaken by the Minister. There are two ways in which such evaluations occur. First, “re-evaluations” pursuant to section 16 of the Act are conducted periodically (such as every 15 years) or where the Minister believes that evaluation procedures or information requirements for the pesticide’s registration have changed since the product was registered.

[73] Second, “special reviews” pursuant to section 17 of the Act must be initiated where the Minister “has reasonable grounds to believe that the health or environmental risks of the pesticide are, or its value is, unacceptable”; where “a member country of the Organisation for Economic Co-operation and Development prohibits all uses of an active ingredient for health or environmental reasons”; or where a federal or provincial government has alerted the Minister to information that the Minister thinks provide reasonable grounds for finding that the risks to health or the environment are unacceptable.

[74] Any person may make a request that the Minister initiate a special review of the safety of a particular pesticide under subsection 17(4) of the Act. This ensures that any individual in Canada worried about the safety of a pesticide can have its safety examined by the scientific experts.

[75] The Minister has an obligation to initiate a review under section 17(1), if the Minister has reasonable grounds to believe that the health or environmental risks of the pesticide are unacceptable, or the value of the pesticide is unacceptable. As provided in section 4 of the Act, the Minister’s primary objective is to prevent unacceptable risks to people and the environment from the use of pest control products.

[76] In determining whether a product poses an unacceptable risk under section 17, the Regulatory Agency has a review process, described above in paragraph 21.

The Court's Analysis of the Request for Special Review in this Case

[77] The request for a special review of glyphosate herbicides containing POEA was contained in a 29 page letter dated May 25, 2009 together with a binder of studies referred to in the letter. The grounds for a special review were "the enclosed significant new evidence which establishes reasonable grounds to believe the health or environmental risks" of the pesticide in issue are unacceptable.

[78] The letter referred to several medical studies which the letter said raise reasonable grounds to believe that the health risks of the pesticides are unacceptable, "because they adversely affect human reproduction and development; cause endocrine disruption and may cause cancer". At the hearing of this application for judicial review, the applicant abandoned these "health risks" as a ground for review. Accordingly the applicant did not challenge the respondent's decision that there was not evidence to support a special review of health effects of the pesticide in issue.

[79] Another ground for the review was "new evidence of toxicity to amphibians", in particular the silvicultural use of this pesticide. The decision under review recognized the toxicity of the pesticide to aquatic organisms including amphibians. This evidence was known to the respondent and it was for this reason that there are as a result mitigation measures existed, namely labels restricting the use of the pesticide to, inter alia:

1. "avoid direct applications to any body of water",
2. "avoid drifting of spray on to any body of water or other non-target areas",
3. "Specified buffer zones should be observed", and
4. "avoid the drift hazard when aerially treating silvicultural sites by ensuring that appropriate buffer zones are maintained"

[80] The applicant did not challenge this part of the decision, i.e. avoiding bodies of water mitigates the toxicity to amphibians. Accordingly, the main reasons allegedly submitted for the need for a special review in the 29 page letter with attached studies were not maintained at the hearing before the Court. Rather, at the hearing, the applicant relied on one narrow aspect in one of the studies submitted with the request. This aspect is referred to in two places in the 29 page letter.

[81] The only aspect of the request for review relied on by the applicant at the hearing is referred to in two places in the 29 page letter: the possible environmental risk to amphibians in ephemeral wetlands from the silvicultural use of the pesticide. Accordingly, the only basis for the request for special review which is still in contention by the applicant relies upon the BC Literature Review which states in its Executive Summary…

> …There is insufficient information on the levels of glyphosate contamination in small ephemeral wetlands, which are favoured habitats of amphibians, and which may be exposed to direct over spraying with herbicide under current use guidelines…

[82] These ephemeral wetlands are transitory wetlands which come and go in the clear cut areas where the forest has been replanted. The BC Literature Review states that:

> Glyphosate herbicides are applied once during the silvicultural cycle (50 – 80 years), primarily during summer and early fall (July – September), but applications are repeated if further weed suppression is required.

The concern raised by the BC Report is that there is insufficient information on the levels of this pesticide in these transitory wetlands which are used by frogs and salamanders. The BC Literature Review concludes that these knowledge gaps need to be addressed.

[83] Accordingly, this 29 page request was virtually withdrawn by counsel for the applicant at the hearings and only proceeded on the alleged environmental risk to amphibians in small transitory wetlands in the forest.

<u>Issue 1</u>: Did the Minister err by only considering "new evidence", and by failing to consider the entire body of evidence relevant to the existence of an environmental risk, including information that he had prior to the applicant's request?

[84] The applicant submits that the Minister had a duty to consider all evidence in the Minister's possession regarding potential risks posed by POEA-containing glyphosate products that had arisen since the Minister's last evaluation of the products. The applicant submits that by framing one of the four questions as "Are the studies new or have they been reviewed by the PMRA previously?" the Minister excluded from consideration those studies that had been reviewed already by the Regulatory Agency after the registration of the product, and so had not been subject to risk analysis under review.

[85] The applicant submits that even if scientists at the Regulatory Agency were aware of developments in the literature, the Minister had an obligation to formally consider that evidence as a possible basis for a special review. In particular, the applicant submits that the fact that the Regulatory Agency had been consulted on, and discussed, the BC Literature Review did not give it grounds to escape evaluating this report in terms of the risks that it raised.

[86] The respondent submits that the Regulatory Agency did consider all of the information in its possession, including that which was not included in the applicant's request materials. Furthermore, the respondent submits that the language chosen by the Minister was chosen in part to reflect the applicant's own characterization of her evidence as "new" because it post-dated the products' registration.

[87] The Court agrees with the applicant that the Minister had an obligation to consider all of the evidence in determining whether there are reasonable grounds for finding a risk unacceptable. The Act specifies neither that the evidence presented in the request for a special review be significant nor new – this was language chosen by the applicant as grounds for initiating the special review.

[88] The Court agrees with the respondent, however, that the Minister understood her duty. The reports submitted by the scientists indicate that they were evaluating the applicant's evidence in light of their existing knowledge, which included all of the evidence in their possession. The Minister's conclusion was not that the evidence had already been considered and therefore did not present reasonable grounds for believing there to be an unacceptable risk, but that the evidence did not raise any concerns that there was an unacceptable risk. That is, the Minister's concern with the novelty of the evidence was properly focused on whether the evidence changed any of the analysis that had already been undertaken at the time that the pesticides were registered.

Issue 2: Did the Minister err by concluding that a mandatory special review under section 17 is not required if she intends to engage in a re-evaluation under section 16 of the Act at some point in the future?

[89] The applicant submits that the Minister is not entitled to find that a special review is not necessary because a re-evaluation is planned. The applicant submits that the Minister's discretion under section 17 is limited to determining whether there are reasonable grounds to believe that there is an unacceptable risk. If the Minister so finds, the Minister "shall" initiate a special review. The applicant submits that the Minister has no discretion to substitute a future re-evaluation in such circumstances.

[90] The respondent submits that the Minister did not refuse the applicant's request because a re-evaluation was to be undertaken. Rather, the Minister refused the applicant's request because the

Minister found that there were not reasonable grounds to believe that the products pose an unacceptable environmental risk. This decision was based on an evaluation of all of the evidence and the findings of the Regulatory Agency's scientists. The respondent notes that the following key factors played into the Minister's decision:

1. The Regulatory Agency was aware of the toxicity of glyphosate end-use products containing POEA and had put in place mitigation measures to address concerns about harm to aquatic species in agricultural settings, especially by preventing the direct application of the products to water. The applicant's information did not alter the Regulatory Agency's assessments in this regard.

2. In particular, what evidence the applicant submitted that may have changed the risk assessment was found to be not convincing because it was done in a laboratory setting as opposed to in more realistic settings. Field studies showed no significant adverse effects under actual use conditions.

3. Mitigation measures were already in place to protect organisms that are significantly sensitive to the application of glyphosate end-use products like amphibians.

[92] The decision did not explicitly address the alleged risk of the pesticide to amphibians in ephemeral wetlands, which are aerially sprayed in silviculture. However, the letter did repeatedly (six times) refer to the re-evaluation of the pesticide under section 16 suggesting that a special review under section 17 was therefore not necessary. The decision stated:

1. …there are other mechanisms, such as re-evaluations that may be better suited to responding to the risk concerns that a special review.

2. …The upcoming re-evaluation of glyphosate will include the consideration of amphibians and of the surfactant POEA.

3. …mitigation measures…are appropriate until a re-evaluation is conducted.

4. …The PMRA will address concerns…in the broader re-evaluation…this will lead to a more complete consideration of the concerns.

5. …the re-evaluation of glyphosate will be officially announced within the year and will include particular consideration of glyphosate products containing POEA.

6. …a public request for data to address specific topics…encourage you to submit any additional information regarding glyphosate at that time.

From these six references in the decision, the Court can only conclude that the respondent fettered her discretion under section 17 because a section 16 re-evaluation of the same environmental risks was planned. The Court concludes that the Minister erred in law by misinterpreting the mandatory wording of section 7 which requires that a "special review" be conducted regardless of whether a section 16 re-evaluation is planned or is underway.

Issue 3: Did the Minister err in interpreting the evidentiary threshold required to initiate a special review under section 17?

[93] The applicant submits that the Minister applied a wrong test to the determination of whether to initiate a special review. The applicant submits that the Minister required the applicant to establish an unacceptable risk, rather than requiring only that the applicant establish "reasonable grounds to believe that there may be a possibility of a risk to the environment."

[94] The respondent submits that the four questions used by the Regulatory Agency were derived from the "Criteria for a special review" developed by the Regulatory Agency in 2007. According to these criteria, a special review is not required if the active ingredient is under re-evaluation; the risk concern is imminent in nature so that immediate regulatory action will be taken instead; the concern can be addressed more quickly through other existing mechanisms, the Regulatory Agency has done an assessment addressing the concern; or the information does not change the current risk assessment.

[95] The respondent submits that these criteria are consistent with the Act because they are specifically designed to further the Act's purpose of protecting Canadians. The respondent submits that this purpose is furthered when the Regulatory Agency is able to draw on a number of possible responses to potential dangers. In some cases, for example, where risk is imminent, immediate regulatory action will further the aims of the Act better than a special review. In others, for example, where a re-evaluation is underway, a special review will be superfluous and simply take resources from more efficient uses.

[96] Finally, the respondent submits that the Minister has the authority under section 20(1) of the Act to immediately cancel or amend a product registration during the course of a re-evaluation or a special review if the Minister has reasonable grounds to believe that such a step is necessary to protect human health or safety or the environment.

[97] With regard to the proper test that the Minister must use to determine whether to initiate a special review under section 17(1) of the Act, the Court finds that "reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable" means the Minister has compelling and credible evidence that gives rise to a serious possibility that the pesticide may cause an unacceptable health or environmental risk. From another statutory perspective, in accordance with the definition of an "acceptable" risk in subsection 2(2) of the Act, the Minister is reasonably certain that the pesticide will cause no harm to human health or the environment taking into account its conditions of use. "Reasonable grounds" was explained by the Supreme Court of Canada in *Mugesera v. Canada (Minister of Citizenship and Immigration)*, 2005 SCC 40, at paragraph 114:

> ¶114 The first issue raised by s. 19(1)(j) of the Immigration Act is the meaning of the evidentiary standard that there be "reasonable grounds to believe" that a

> person has committed a crime against humanity. The FCA has found, and we agree, that the "reasonable grounds to believe" standard requires something more than mere suspicion, but less than the standard applicable in civil matters of proof on the balance of probabilities: *Sivakumar v. Canada (Minister of Employment and Immigration)*, [1994] 1 F.C. 433 (C.A.), at p. 445; *Chiau v. Canada (Minister of Citizenship and Immigration)*, [2001] 2 F.C. 297 (C.A.), at para. 60. In essence, reasonable grounds will exist where there is an objective basis for the belief which is based on compelling and credible information: *Sabour v. Canada (Minister of Citizenship & Immigration)* (2000), 9 Imm. L.R. (3d) 61 (F.C.T.D.).

[98] Based on the record before the Court upon which this decision was made, there is conflicting evidence that the pesticide in issue presents an acceptable risk to amphibians in ephemeral wetlands which are aerially sprayed with the pesticide in silviculture. The briefing notes for the Science Operations Committee and the Science Management Committee and the draft letter all recognize that there is an uncertainty about whether the pesticide will harm amphibians in this environment. The Regulatory Agency recognizes that the pesticide is toxic to amphibians in bodies of water and for this reason the pesticide cannot be sprayed over or close to bodies of water. On the other hand, Dr. Delorme and an official at the Environmental Risk Directorate were of the opinion that the field studies done by the Canadian Forestry Service showed that there was no environmental risk to amphibians in ephemeral wetlands as a result of the pesticide. However, there were no reports of these field studies or any other documentary evidence in the record before the decision-maker in this case. Accordingly the Court finds that the Minister did err in interpreting the evidentiary threshold required to initiate a special review under section 17 of the Act with respect to one small aspect of the request.

[99] The Minister's decision to engage in a re-evaluation of glyphosate products under section 16 of the Act demonstrates a concern with keeping product registrations current. Section 16 permits the Minister to initiate a re-evaluation where the Minister considers that procedures for evaluating products, or the information required to register them, has changed since a product was registered.

The re-evaluation therefore allows the Minister to keep registrations current. The fact that the Minister chose to initiate a re-evaluation is therefore not evidence that the Minister believed that there were reasonable grounds for finding the risks posed by glyphosate products are unacceptable.

Issue 4: Did the Minister err in his interpretation of his statutory obligation to apply the precautionary principle?

[100] Section 20(2) of the Act states 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 adverse health impact or environmental degradation." The applicant submits that this section should apply to the Minister's determinations under section 17 of the Act.

[101] With opinions within the Regulatory Agency on both sides of the question as to whether the pesticide presents an unacceptable environmental risk to amphibians in ephemeral wetlands, the precautionary principle would require that the Minister initiate a special review into that issue.

Issue 5: Was the Minister's finding that glyphosate herbicides containing POEA do not present an unacceptable risk, unreasonable?

[102] The applicant submits that the findings of the BC Literature Review, the report of the Regulatory Agency's own scientists from the Environmental Assessment Directorate, and the Minister's own statement of risk in its decision, demonstrate that the Minister's decision is unreasonable.

[103] In *Pulp, Paper and Woodworkers of Canada*, above, the Court of Appeal stated the degree of deference to be given to the Minister in her determinations of risks under the Act. In that case, the Court stated the following, as quoted above:

> It follows, from section 18, that once the necessary information is before the Minister, a court of law has no jurisdiction to question the sufficiency of that information.

[104] As stated above, the Minister's decision will be reasonable where it is based on the evidence, is justified, transparent and intelligible, and where it falls within the range of acceptable outcomes.

[105] In this case, there was evidence on both sides of the issue. The evidence relied upon my Dr. Delorme that the Canadian Forestry Service had done field studies which showed there was not an environmental risk to amphibians from this pesticide in ephemeral wetlands was not consistent with the briefing notes prepared by the scientists in the Regulatory Agency, was not consistent with the BC Literature Review and was not consistent with the recognition by the Minister that a re-evaluation of the environmental risk of the pesticide to amphibians in ephemeral wetlands was necessary.

[106] Moreover, the decision is not transparent or intelligible, because the decision does not expressly address the narrow environmental risk at issue in this case. The Court recognizes that the 29 page letter requesting the special review barely referred to this narrow risk and instead emphasized a health risk and other issues. Accordingly, it is understandable that the decision did not expressly address this narrow risk. At the same time, since this application seeks review on this narrow ground, the Court must concede that the decision is not transparent or intelligible with respect to this risk. It would have been preferable if the letter had referred to the Canadian Forestry Service field studies and had specifically addressed the risk. Accordingly, the Court agrees with the applicant that the Minister's decision is not transparent or intelligible with respect to the narrow risk at issue before the Court, and that the evidence with respect to this risk is not properly documented in the record such that it could be relied upon as the basis for the decision.

Issue 6: Should the Court Grant Relief?

[107] The respondent submits that even if the Court agrees that the Minister erred, the Court should decline to refer the matter back to the Minister because there will be little, if any, practical value to the applicant since the section 16 re-evaluation of the pesticide is underway. The Court does not agree. If the criteria for a special review under section 17 have been met, Parliament mandates that the Minister shall conduct the special review. The special review can co-exist with the section 16 re-evaluation of the pesticide. The special review will be narrower than the comprehensive re-evaluation being conducted in the conjunction with the United States. For this reason, the special review will be targeted and possibly quicker. The applicant is entitled to a proper analysis as to whether the pesticide in issue presents an environmental risk to amphibians inhabiting ephemeral wetlands which are subject to the aerial spraying of the pesticide in silviculture. The evidence alluded to is that the two year field studies have just been completed and that the studies may present new evidence upon which the Minister can make a transparent and intelligible decision under section 17 of the Act.

CONCLUSION

[108] For these reasons, this application for judicial review will be allowed with costs and the matter referred back to the Minister for reconsideration.

COSTS

[109] The applicant is a public interest litigant concerned that the registered pesticide “glyphosate containing POEA” presents a health and environmental risk and asks the Minister of Health under the Act to initiate a “special review”. While this application for judicial review is allowed, the Court notes that most of the grounds for the applicant’s request for the special review were abandoned before this Court at the hearing of the application. At the same time the application did raise

complex and important issues. For these reasons, the Court will exercise its discretion under Rule 400 of the *Federal Courts Rules* over the amount and allocation of costs in considering the factors set out in subsection 3 of Rule 400. Costs awarded to the applicant will be calculated under Tariff B, Column III at the mid-point number of units allowed under that column.

JUDGMENT

THIS COURT'S JUDGMENT is that:

1. This application for judicial review is allowed with costs.

2. The decision of the Minister of Health, dated August 24, 2009 not to initiate a "special review" is set aside, and the matter is referred back to the Minister for reconsideration in accordance with these reasons for judgment.

"Michael A. Kelen"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1604-09
STYLE OF CAUSE:	JOSETTE WIER v. THE MINISTER OF HEALTH
PLACE OF HEARING:	Vancouver, British Columbia
DATE OF HEARING:	August 23 and 24, 2011
REASONS FOR JUDGMENT AND JUDGMENT:	KELEN J.
DATED:	November 21, 2011

APPEARANCES:

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