Federal Court  Cour fédérale

Date: 20151222

Docket: T-2114-13

Citation: 2015 FC 1412

Ottawa, Ontario, December 22, 2015

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

ECOLOGY ACTION CENTRE AND LIVING OCEANS SOCIETY

Applicants

and

MINISTER OF THE ENVIRONMENT, MINISTER OF HEALTH AND AQUABOUNTY CANADA INC.

Respondents

JUDGMENT AND REASONS

Introduction

[1] The application before the Court involves two Ministerial decisions concerning a genetically engineered Atlantic salmon (*Salmo salar*) containing a single copy of the opAFP-GHc2 transgene at the EO-1α locus, known as the AquAdvantage Salmon [AAS].

[2] Genetically modified food is controversial; however, this application solely concerns two decisions made by the respondent Ministers of the Environment and Health [collectively the Ministers]. The issue is not whether the Ministers were right, but whether their decisions were reasonable and made in conformity with the relevant legislation.

[3] For the reasons that follow, I find that the Ministers' decisions were reasonable and were made in the manner prescribed by the *Canadian Environmental Protection Act, 1999*, SC 1999, c 33 [CEPA]. Accordingly, this application must be dismissed.

The Parties

[4] The applicants are registered non-profit societies committed to the public interest in marine environment protection. The respondents accept that they are public interest litigants and have standing to bring this application.

[5] The Ministers have responsibilities under CEPA and specifically in relation to the issues before the Court under Part 6 thereof entitled *Animate Products of Biotechnology*. Also relevant to this application and the challenges brought by the applicants are the regulations issued with respect to Part 6, the *New Substances Notification Regulations (Organisms)*, SOR/2005-248 [NSN Regs].

[6] The respondent, AquaBounty Canada Inc. [AquaBounty] is a biotechnology company that developed and owns the rights to AAS. It claims that AAS grow to market size significantly more rapidly than wild or farmed salmon. It operates a "secure land-based experimental/research

hatchery" in Souris, Prince Edward Island [the PEI Facility]. AquaBounty proposes to produce sterile, all female AAS eggs on a commercial scale at the PEI Facility, which will be exported to a contained, land-based, grow-out facility in Panama. In order to do so, AquaBounty was required to make an application under Part 6 of CEPA. The decisions under review result from that application.

The Application

[7] The applicants make two general submissions:

1. That the Minister of the Environment failed to comply with the requirements of CEPA when on November 23, 2013, she published in the *Canada Gazette* a Significant New Activity Notice [SNAc Notice] in respect of AAS; and

2. That the Ministers failed to obtain and assess legally required information for the toxicity assessment they conducted under section 108 of CEPA.

[8] I propose to first set out the regulatory framework in CEPA and the NSN Regs that are at play. I shall then outline the relevant facts and the specific issues raised by the applicants. Lastly, I will analyze the parties' positions on those issues and the reasons for the conclusions I have reached.

The Regulatory Framework for Living Organisms

[9] Part 6 of CEPA sets out a regulatory framework for the assessment and approval of animate products of biotechnology [living organisms]. The full text of Part 6 is attached as

Annex A. This framework revolves around a list maintained by the Minister of the Environment called the Domestic Substances List [DSL].

[10] If a living organism is not on the DSL, it cannot be manufactured or imported unless certain prescribed information has been provided to the Minister of the Environment [a New Substances Notification or Notification] by the person wishing to do so [the Notifier], and the period for assessing that information has expired: CEPA, subsection 106(1). The living organism must be assessed as to whether it is toxic or capable of becoming toxic: CEPA subsection 108(1). Section 64 of CEPA specifies that, for the purposes of Part 6,

> …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.

An organism that meets or is capable of meeting the definition in section 64 of CEPA is described as being CEPA-toxic.

[11] In the case of AAS, section 4 of the NSN Regs specifies that the Notifier must provide the information set out in Schedule 5 of the NSN Regs. Schedule 5 includes, in paragraph 3(b), information with respect to "the intended and potential uses of the organism, and the potential locations of introduction" and, in paragraph 5(a), "the data from a test conducted to determine its pathogenicity, toxicity or invasiveness." The prescribed information set out in Schedule 5 must

be provided at least 120 days before the Notifier manufactures or imports the organism: NSN Regs, paragraph 5(d).

[12] The Notifier may request the Ministers to waive any of the information requirements imposed by Schedule 5, and the Ministers may do so if one of the three conditions set out in subsection 106(8) apply; namely if:

> (a) in the opinion of the Ministers, the information is not needed in order to determine whether the living organism is toxic or capable of becoming toxic;
>
> (b) a living organism is to be used for a prescribed purpose or manufactured at a location where, in the opinion of the Ministers, the person requesting the waiver is able to contain the living organism so as to satisfactorily protect the environment and human health; or
>
> (c) it is not, in the opinion of the Ministers, practicable or feasible to obtain the test data necessary to generate the information.

[13] If a waiver is granted, then subsection 106(9) of CEPA provides that the Minister of the Environment "shall publish in the Canada Gazette a notice stating the name of any person to whom a waiver is granted and the type of information to which it relates."

[14] Moreover, if a waiver is granted under subsection 106(8)(b) because the Ministers are of the opinion that the Notifier "is able to contain the living organism so as to satisfactorily protect the environment and human health," then subsection 106(10) of CEPA stipulates, in relevant part, that "the person to whom the waiver is granted shall not use, manufacture or import the living organism unless it is … at the location specified in the request for the waiver…."

[15] Paragraph 6(d) of the NSN Regs provides that, for the purposes of the toxicity assessment conducted by the Ministers under subsection 108 of CEPA "the Ministers must assess the information" provided pursuant to Schedule 5 of the NSN Regs within "120 days after receiving the information."

[16] Although the Ministers have sole legislative authority to assess whether an organism is CEPA-toxic, their departments have entered into a memorandum of understanding with the Department of Fisheries and Oceans [DFO] whereby DFO provides advice on the toxicity of any fish that are subject to assessment.

[17] Following the Ministers' assessment, CEPA provides the Minister of the Environment with four options. She:

1. may, before the expiry of the assessment period, permit any person to manufacture or import the living organism on conditions where she suspects the living organism is toxic or capable of becoming toxic: CEPA, paragraph 109(1)(a);

2. may, before the expiry of the assessment period, prohibit any person from manufacturing or importing the living organism where she suspects the living organism is toxic or capable of becoming toxic: CEPA, paragraph 109(1)(b);

3. may, within 90 days after the expiry of the assessment period, permit the manufacture or importation of the organism, but require a further toxicity assessment if a person proposes to engage in a "significant new activity" that may

result in the living organism becoming toxic: CEPA, subsections 110(1) and 106(4); or

4. shall, with 120 days after several conditions are met, permit any person to manufacture or import the organism by adding it to the DSL: CEPA, subsection 112(1).

[18] Section 104 of CEPA defines a "significant new activity" as including any activity that, in the opinion of the Ministers, results or may result in the entry or release of the living organism into the environment in a quantity or concentration, or in a manner and circumstances, that are significantly greater, or significantly different, than that which has previously occurred.

[19] If the Ministers suspect that a significant new activity may result in the living organism becoming toxic, then the Minister of the Environment may publish a SNAc Notice in the *Canada Gazette* within 90 days of the end of the assessment period: CEPA, subsection 110(1). Once the SNAc Notice is published, no person may use the organism for a significant new activity that is indicated in the notice unless that person has provided the Minister of the Environment with the prescribed information (i.e. the information listed in Schedule 5 of the NSN Regs) and the period for assessing that information has expired: CEPA, subsections 110(3) and 106(4).

The Facts

[20] There is no dispute on the facts. For ease of reference, the facts are set out chronologically.

[21] On April 29, 2013, AquaBounty submitted a New Substances Notification with respect to AAS. In its Notification, AquaBounty declared its intent to manufacture sterile all-female AAS eggs at its contained PEI Facility and export up to 100,000 eggs annually for grow-out and processing in Panama. The processed fish would then be sold as food in approved retail markets. AquaBounty's Notification included a request for a waiver of the requirement to submit "the data from a test conducted to determine [AAS's] pathogenicity, toxicity or invasiveness." Filing the Notification triggered the 120 day assessment period provided for in section 108 of CEPA, such that the assessment period would end on August 27, 2013.

[22] On August 13, 2013, DFO provided the Minister of the Environment with its assessment of AAS entitled *Summary of the Environmental and Indirect Human Health Risk Assessment of AquAdvantage Salmon* [the DFO Report]. The DFO Report concluded that, for the specific use scenario that had been notified, AAS was not CEPA-toxic or capable of becoming CEPA-toxic:

> **1 - Indirect Human Health Risk**
> The finding of negligible for the exposure assessment with reasonable certainty and low for the indirect health hazard assessment with reasonable certainty resulted in a risk assessment outcome of low with reasonable certainty and a conclusion of not "CEPA toxic".
>
> **2 - Environmental Risk**
> The finding of negligible for the exposure assessment with reasonable certainty and high for the environmental hazard assessment with reasonable uncertainty resulted in a risk assessment outcome of low with reasonable certainty and a conclusion of not "CEPA toxic".

[23] The DFO Report also indicated that DFO did not object to AquaBounty's waiver request. It considered that the information sought to be waived was unnecessary because AquaBounty would be operating in a contained facility:

> Given the use scenario and that the information provided in support of the waiver request was considered sufficient to demonstrate that the organism will be contained so as to satisfactorily protect the environment and human health, data on invasiveness as specified in paragraph 5(a) of Schedule 5 of the *New Substances Notification Regulations (Organisms)* is not needed to determine whether the organism is toxic as defined under section 64 of CEPA 1999. [emphasis added]

[24] DFO also recommended that the Minister of the Environment issue a SNAc Notice that would require further assessment of any use of AAS beyond that proposed by AquaBounty at its PEI Facility or export of AAS other than to AquaBounty's facility in Panama:

> The emphasis that has been placed on containment to prevent exposure to the Canadian environment and in particular on physical containment of AAS, makes it imperative that the use scenario proposed by AquaBounty be maintained including all physical, biological, geographical and operational containment measures. Therefore, any activities outside of the well-defined parameters that have been described in the notification may be considered a significant new activity and could require a Significant New Activity Notice.

[25] On August 19, 2013, the Minister of the Environment granted the waiver that AquaBounty had requested.

[26] On August 27, 2013, the assessment period ended. The Ministers agreed with DFO that the manufacture and use of AAS proposed by AquaBounty is not CEPA-toxic or capable of becoming CEPA-toxic. The Ministers also agreed with DFO that a SNAc Notice should be issued but differed from DFO on its scope.

[27] As noted above, DFO wanted the SNAc Notice to indicate that a "significant new activity" would be defined, in part, as an activity at a location other than the PEI Facility and for export other than to Panama. However, the Ministers ultimately accepted the different recommendation of their own officials in a report entitled *Record of Decision and Rationale (RDR): Control Measures for New Organisms* [RDR]. In that report, the officials took a more functional approach to defining a significant new activity. They took the view that "the existing activity is not defined by its location but rather by the containment measures put in place in Canada to prevent any release of the live fish into the Canadian environment" and that restricting export to a particular location was probably unenforceable.

[28] On November 23, 2013, the Minister of the Environment published a SNAc Notice in the *Canada Gazette* in relation to AAS. As proposed by her officials, the SNAc Notice was broader than that recommended by DFO. It defined a "significant new activity" as any activity other than the uses of AAS proposed by AquaBounty within a "contained facility" or the grow-out of female triploid AAS within a "contained facility," provided that they are euthanized before leaving the facility:

> 1. In relation to the living organism identified as genetically engineered Atlantic salmon (Salmo salar) containing a single copy of the opAFP-GHc2 transgene at the EO-1α locus, a significant new activity is any activity other than:
>
> (a) the use of any non-triploid [i.e. offspring producing] living organism within a contained facility:
>
> (i) as a research and development organism, or
>
> (ii) for producing triploid [i.e. sterile], all-female living organism;
>
> (b) the use of the male, triploid living organism within a contained facility as a research and development organism;

(c) the use of the female, triploid living organism within a contained facility:

(i) as a research and development organism, or

(ii) for grow-out where it is euthanized before leaving the contained facility; or

(d) the export of the female, triploid living organism at the eyed-egg stage. [emphasis added]

The Issues

[29] The applicants submit that there are eight questions to be addressed:

1. What is the standard of review?

2. Did the Ministers err in purporting to conclude a section 108 assessment of AAS by failing to collect and assess information regarding potential uses of the organism and potential locations of introduction?

3. Did the Ministers unlawfully conclude a section 108 assessment of AAS prior to granting a waiver of information requirements for toxicity and invasiveness data and publishing notice of such a waiver in the Gazette?

4. Did the Minister of the Environment err in publishing the SNAc Notice prior to the expiry of the assessment period?

5. Did the Minister of the Environment, through the publication of the SNAc Notice, unlawfully permit uses of AAS contrary to subsection 106(10)?

6. Did the Minister of the Environment, through the publication of the SNAc Notice, unreasonably permit uses of AAS that were not considered as part of the section 108 assessment?

7. Do the applicants have standing to bring this application?

8. What is the appropriate remedy?

[30] In light of the concession of the respondents that the applicants have public interest standing, item (vii) does not need to be addressed. In light of the result, item (viii) does not need to be addressed.

[31] Fundamentally, the applicants challenge two decisions: (1) the decision made pursuant to section 108 of CEPA, assessing the information on AAS provided pursuant to section 106; and (2) the decision to publish the SNAc Notice.

The Standard of Review

[32] The applicants submit that, although no jurisprudence has determined the standard of review applicable to the specific decisions at issue in this case, courts have determined that "the discharge of mandatory Ministerial obligations under CEPA is reviewable on [the] standard of correctness:" *Great Lakes United v Canada (Minister of the Environment)*, 2009 FC 408, [2010] 2 FCR 515 [*Great Lakes*].

[33] The applicants submit that the impugned decisions involved the discharge of mandatory Ministerial obligations. They note that subsection 106(9) of CEPA states that the Minister of the Environment "shall publish in the Canada Gazette" a notice of a waiver of any information requirements [emphasis added]. Similarly, subsection 108(1) of CEPA states that the Ministers "shall…assess" the prescribed information in order to determine whether an organism is toxic or capable of becoming toxic [emphasis added]. Their submission, briefly stated, is that because the validity of the impugned decisions turns on whether the Ministers discharged these obligations, their decisions are to be reviewed on a standard of correctness.

[34] The applicants cite three decisions in support of their submission that the applicable standard is correctness. They cite *Great Lakes* at paragraphs 237-240 for the proposition that "[a] failure to comply with a statutory requirement is an error of law subject to a standard of correctness." They cite *Canada (Minister of Citizenship and Immigration) v Kandola*, 2014 FCA 85 [*Kandola*] at paragraphs 42-43 for the proposition that, when it comes to a "pure question of statutory construction embodying no discretionary element" the Minister "cannot claim to have any expertise over and above" that of the Court. Lastly, they cite *Save Halkett Bay Marine Park Society v Canada (Environment)*, 2015 FC 302 [*Halkett Bay Marine*] in which the Court applied *Kandola* in the context of a review of the Minister of the Environment's decision to grant a permit authorizing the sinking of a ship in order to turn it into an artificial reef. In *Halkett Bay Marine* the applicant claimed that the Minister of the Environment was not authorized to permit the sinking because the ship contained banned substances in its hull, known as TBTs. The Court held that, to the extent that the Minister's decision turned on issues of statutory interpretation, her interpretation was subject to a correctness standard of review. It stated at para 54 that:

> The purely legal component concerns subsection 127(1) of the Vessel Pollution Regulations and certain provisions in the CEPA, which the Society states establish an outright ban on TBTs. This Court's review of whether those provisions in fact establish an outright ban on TBTs in Canada that rendered the issuance of the Permit contrary to law is conducted on a correctness standard. This is because this is "a pure question of statutory construction embodying no discretionary element," the Minister "cannot claim to have any expertise over and above" that of the Court in respect of such questions, and there is no privative clause in the CEPA (*Canada (Citizenship and Immigration) v Kandola*, 2014 FCA 85 (CanLII), at para 43). Moreover, insofar as the Vessel Pollution Regulations are concerned, they were passed pursuant to the CSA, above, which is not the Minister's "home statute" and no evidence was adduced to demonstrate that she has any particular familiarity

> with that statute (*Agraira v Canada (Public Safety and Emergency Preparedness*), 2013 SCC 36 (CanLII), at para 50).

[35] I am not persuaded that these authorities mandate a correctness standard in the present case. A review of the points in dispute reveals that many of them are not "pure" questions of law; rather, they involve issues of mixed fact and law, such as whether the Ministers considered all relevant factors when coming to their decisions. Second, to the extent that the Ministers' decisions could be said to turn on "pure" questions of law (such as when a waiver becomes effective under subsection 106(8), when it has to be granted, and what the word "location" means in subsection 106(10)) these are "nuts and bolts" questions of statutory interpretation that are confined to a particular context within the Ministers' home (or closely connected) statutes. They therefore warrant a degree of deference: *McLean v British Columbia (Securities Commission)*, 2013 SCC 67, [2013] 3 SCR 895 at paragraph 28 [*McLean*].

[36] This case involves the review of routine decisions made within a complex regulatory framework. In this context, I think that it is important to emphasize, as the Supreme Court did in *McLean* at paragraph 31, that "courts 'may not be as well qualified as a given agency to provide interpretations of that agency's constitutive statute that make sense given the broad policy context within which that agency must work'" (citing *National Corn Growers Assn. v Canada (Import Tribunal)*, [1990] 2 SCR 1324). The Ministers have adopted an interpretation of CEPA in light of their day-to-day experience administering the Act. They have expertise "over and above" that of the Court. Their interpretation must not be unreasonable but, as long as that threshold is met, this Court should defer.

[37] Applying a reasonableness standard to the issues in dispute, they may be summarized as follows: (1) was the Ministers' decision that AAS is not CEPA-toxic reasonable; and (2) was the Minister of the Environment's publication of the SNAc Notice reasonable?

The Toxicity Assessment

[38] The applicants make three submissions with respect to the Ministers' toxicity assessment.

A. Potential Uses and Locations

[39] The applicants say that the Ministers erred in failing to consider information with respect to "the…potential uses of [AAS]" and "potential locations of introduction," information for which no waiver was sought or given. They point to subsection 108(1) of CEPA, which provides that "the Ministers shall … assess information provided under subsection 106(1) [being the prescribed information in Schedule 5 of the NSN Regs]." Paragraph 3(b) of Schedule 5 states that "the intended and potential uses of the organism, and the potential locations of introduction" are to be provided by a Notifier. The applicants submit that the Ministers failed to assess potential uses and locations of AAS; instead, they only assessed AquaBounty's proposed use and location. They point to the DFO Report which states: "The risk assessment is conducted on AquaBounty's proposed use scenario to grow AAS under the containment conditions specified in the regulatory submission for the PEI and Panamanian facilities."

[40] I suspect that the reason for the applicants' concern here is that they believe that the Ministers' alleged failure to consider potential uses and locations resulted in an assessment that was too narrow to encompass the range of possible uses and locations that the Minister of the Environment ultimately approved in the SNAc Notice. The applicants may believe that others

can now rely on the SNAc Notice and engage in "potentially" toxic endeavours that have not been adequately assessed. If that is their concern, then it is misplaced as shall be seen below.

[41] In any event, I agree with the respondents that the Ministers did consider information with respect to the potential uses and locations of introduction of AAS. All parties accept that the Ministers relied on the DFO Report. As the applicants note, the report did state that DFO's assessment was based on the use scenario proposed by AquaBounty. However, the report goes on to observe that:

> Changes to the proposed use scenario or to the proposed containment measures may result in the entry or release of AAS into the environment in a quantity, manner or circumstances significantly different to the potential exposure of AAS assessed in the current risk assessment. Given the potential hazard of AAS to the environment and associated uncertainty, including potential invasiveness, any significant new activity may result in an altered exposure and consequently in a different risk assessment conclusion than provided in this report.

[42] As a result, DFO recommended that the Minister of the Environment issue a SNAc Notice that would require further assessment of any use of AAS beyond that specifically proposed by AquaBounty.

[43] In addition to the DFO Report, the Ministers relied on the RDR, which was prepared by officials at Environment and Health Canada. Under the heading "Control Measure(s) Rationale: Scientific Rationale" that report states:

> • Within a contained facility, as proposed by the notifier, there is no environmental exposure and therefore a conclusion of CEPA Toxic was not reached.

> • Should a new activity result in environmental exposure, the available data as provided by the notifier or as available in the public domain, is insufficient to determine whether or not the organism poses any hazards that will result in an environmental risk particularly given the uncertainty regarding the survival or persistence of the organism in the environment.
>
> • Given this level of uncertainty, a significant new activity (SNAc) notice is therefore recommended in order to ensure that any potential activities outside of a contained facility undergo further evaluation. [emphasis added]

[44] Contrary to the applicants' submission that the above-quoted statement in the DFO Report shows that the Ministers did not consider other potential uses of AAS or locations of introduction, it shows that they did. That statement, and the similar statement in the RDR, shows that the Ministers did consider the potential uses of AAS and reached some conclusions with respect to them. They concluded that they did not have enough information to determine whether some potential uses could result in AAS becoming toxic. They also concluded that other potential uses, such as uses outside of the PEI Facility but within a contained facility, could be approved based on the information provided. As a result, the Minister of the Environment issued a SNAc Notice that permitted potential uses of AAS that the Ministers determined would not result in toxicity, while requiring additional assessment for other uses.

[45] The applicants further submit that "[b]ecause there was no information before the Ministers on potential uses or locations of introduction beyond the use scenario identified by AquaBounty, they could not have fulfilled their statutory duty to give consideration to such information." Again, I disagree. First, as noted above, the Ministers did consider, and were even able to make an assessment of, some potential uses and locations of introduction based on the information provided by AquaBounty. Second, it would not be reasonable to interpret the NSN

Regs to require that AquaBounty submit, or the Ministers assess, information about speculative potential uses that are unrelated to AquaBounty's actual intended use. An assessment based on speculative potential uses would be unlikely to yield reliable conclusions about toxicity. Furthermore, the purpose of a SNAc Notice is to avoid the need for such speculation; it allows the Ministers to permit uses that they have found to be non-toxic, while subjecting significantly new uses to additional assessment, if and when they are concretely proposed.

[46] In my view, the requirement to provide information with respect to potential uses and locations of introduction is intended to ensure that Notifiers provide information about how an organism might be used, and where it might be introduced, as a result of the Notifiers' intended use. This reading is supported by the Government of Canada's *Guidelines for the Notification and Testing of New Substances: Organisms* [the Guidelines], which state that:

> A description of the intended and potential uses of the organism or product containing the organism should be provided. Potential locations of introduction includes identification, in general terms, of the ecozone (identified on the map referred to in the definition of "ecozone" a reduced version of which is given in Appendix 2) and types of habitat (e.g. aquatic, terrestrial) where the organism could be predicted to be used. [emphasis added]

According to the Guidelines, the potential locations of introduction of AAS are those that could be predicted in general terms. These locations are presumably predicted based on AquaBounty's intended use of AAS. Therefore, what is required is not information about where AAS might be introduced in all possible worlds, but where it might be introduced given AquaBounty's intended use. This information was provided. The DFO Report explicitly considers whether AAS might escape into the Bay of Fortune estuary in PEI, or into the watershed near AquaBounty's facility in Panama. These are the potential locations of introduction. DFO considered them at length.

B. Validity of Waiver

[47] The applicants submit secondly that the Ministers erred in failing to consider "the data from a test conducted to determine [AAS's] pathogenicity, toxicity or invasiveness" because the Minister of the Environment's waiver of this requirement was invalid.

[48] The applicants submit that a waiver is effective only when notice of it has been published in the *Canada Gazette*. They say that the purpose of publication is to ensure accountability, which cannot be achieved if a notice is allowed to be published months, or even years, after the waiver is granted. They also rely on the wording of subsection 106(9) of CEPA; namely, that "[t]he Minister shall publish…a notice stating the name of any person to whom a waiver is granted…" [emphasis added]. They submit that Parliament's use of the word "is" suggests that a waiver "is" granted upon publication of the notice. If Parliament had intended that a waiver could be granted before a notice is published, then it could have used the words "was" or "has been" to convey that intent.

[49] The applicants say that the Minister of the Environment cannot wait as long as she wants before publishing notice of a waiver she has granted. I agree that the Minister cannot wait as long as she wants because unnecessary and unreasonable delay would subvert the will of Parliament. The 1999 Committee debate suggests that the publication requirement was included to afford some degree of transparency and accountability, including political accountability, to the public. For example, in that debate, Ms. Paddy Torsney, the Parliamentary Secretary to the Minister of the Environment, stated that the notice of waiver "would in fact ensure that there is publication, that information is available, and that ministers of the Crown remain accountable to

the public through the House and other mechanisms. So to suggest that without this paragraph somehow things are going to be done in obscurity is not accurate". This goal, of ensuring transparency and accountability, is undermined when a notice is published too long after the assessment period has ended.

[50] However, I cannot agree with the applicants that the Minister waited too long in this case when she delayed publishing the notice of waiver for almost six months. While publication must take place within a reasonable time following the grant of the waiver, failing which *mandamus* may lie to order it, there is no statutory requirement that these events must occur at the exact same time or even in close proximity. Even if the goal of publication is that of promoting accountability, it will be met regardless of whether the notice is published precisely when the waiver is granted, or within a reasonable time thereafter. I am unable to conclude that the delay in this case was unreasonable as there is no evidence to suggest that these applicants were thwarted in bringing their concerns to the public or court, nor is it sufficient to find that the will of Parliament was subverted.

[51] I also do not think that Parliament's use of the word "is" necessitates a finding that a waiver is only granted once notice is published. There is authority for an interpretation of "is" that includes a reference to past events. As the Court stated in *R v Letkeman*, [1983] SJ No 1045 (SKQB) at para 7, "[w]hile the word 'is' most often will refer to the present, it can have a grammatically correct past signification, as in the sense of 'has been': see, Black's Law Dictionary (5th ed.), p 745" and see also *Village Gate Resorts Ltd v Moore*, (1997), 47 BCLR (3d) 153 (BCCA) at paras 35-37.

[52] It is also noteworthy in this regard that the grant and notice of a waiver are dealt with by distinct provisions of CEPA, subsections 106(8) and (9), respectively. If Parliament had intended that a notice itself would bring about the legal effect of waiving an information requirement, it could have conveyed its intention in a single, explicit, provision that links the notice to its legal effect. This is what was done in subsection 106(4). According to that subsection, "[w]here…the Minister publishes a notice in the Canada Gazette indicating that this subsection applies with respect to the living organism, no person shall use the living organism for a significant new activity that is indicated in the notice…"

[53] Finally, during the Standing Committee on Environment and Sustainable Development's review of the waiver requirement in 1999, members of the committee conveyed their understanding that a notice of waiver is published after the waiver itself is granted. For example, Mr. Rick Laliberte described the notice requirement as an "after-the-fact publishing of a waiver that has been made."

[54] These factors suggest that the grant and notice of a waiver need not be simultaneous. The notice may follow the grant of a waiver and the Minister's six month delay does not impact the validity of the grant or the date when the waiver was granted.

C. Timing of Waiver

[55] The applicants' third submission is that the Minister of the Environment erred in failing to grant the waiver before the start of the toxicity assessment.

[56] The applicants point out that, according to paragraph 6(d) of the NSN Regs, the Ministers' toxicity assessment runs for "120 days after receiving the information referred to in Schedule 5." They submit that, until a waiver of an information requirement is granted, all of the Schedule 5 information is still required. Therefore, they say, the 120 day period can only start to run after all waivers have been granted, and all of the other prescribed information has been provided.

[57] The applicants' submission may reflect a reasonable interpretation of the NSN Regs. However, the question is not whether their interpretation is reasonable, but whether the Ministers' interpretation is unreasonable. According to the Ministers' interpretation, the assessment period begins to run when the required information has been provided or, if any information has not been provided, when a waiver has been requested with respect to it. This approach has the advantage of allowing the Ministers to proceed with an assessment without having to wait until all waiver requests have been dealt with. It also has the disadvantage of creating a possibility that the Ministers will proceed with an assessment in the face of a pending waiver request, only to have that request refused, giving rise to the need for additional assessment. This disadvantage is recognized and addressed in the Guidelines, which state in section 5 that:

> A waiver request must be submitted in writing as part of a notification package and should include a well-documented rationale to support it. Rejection of a waiver request will delay the assessment (see section 9.1 of these Guidelines). To avoid delays, it is recommended that notifies discuss the proposed waiver request with appropriate officials at Environment Canada and Health Canada before submitting the notification (see Section 6 of these Guidelines). [emphasis added]

[58] The question then is whether the Ministers' interpretation is consistent with the terms of CEPA and its associated regulations. In order to answer this question, we must look to the text of this legislation and, in particular, paragraph 6(d) of the NSN Regs, which states that the Ministers' toxicity assessment runs for "120 days after receiving the information referred to in Schedule 5." The important thing to note about this provision is that it simply does not address how a waiver request, and a corresponding failure to provide all of the information referred to in Schedule 5, affects the running of the assessment period. Instead, it simply states that the assessment period will begin to run once the information in Schedule 5 is received. Therefore, on a parochial and strictly literal reading of the provision, the assessment period cannot begin to run even after a waiver is granted, because the information that is waived will still be "information referred to in Schedule 5" and will still be outstanding. Recognizing this difficulty, the applicants suggest that, when read in context, paragraph 6(d) really means that the assessment period will begin to run when the Ministers have received the "information referred to in Schedule 5" or a waiver has been granted in respect of any information that they have not received. The Ministers, on the other hand, maintain that the assessment period will begin to run when they have received the "information referred to in Schedule 5" or have received a request for a waiver with respect to any information that they have not received, and that request is ultimately granted. Neither of these contextual elaborations upon the meaning of paragraph 6(d) is explicit in the NSN Regs. However, it is clear that some elaboration is required to make that paragraph consistent with the reality of waivers. I cannot say that the Ministers' interpretation is unreasonable. In fact, it seems more practical and arguably more reasonable than the applicants' proposed interpretation because, until some assessment of the prescribed information has been done, it will be impossible to determine whether the requested waiver ought to be granted or not.

It makes little sense to do one assessment for that purpose and then re-do the assessment for the purpose of determining toxicity.

D. Right of Public Participation

[59] Pervading the applicants' submissions with respect to the waiver is the view that a notice of waiver is intended to, and does, provide an opportunity for public participation in a toxicity assessment. While not strictly necessary to dispose of the challenge to the toxicity determination I wish to address that view, as I disagree that such an opportunity exists in the manner they describe.

[60] First, as the respondents note, the Standing Committee on Environment and Sustainable Development considered a proposed amendment to CEPA in 1999 that would have required public comment before a waiver could be issued. The Committee rejected this amendment on the ground that it would create undue delay in the issuance of waivers. Given that public participation in the waiver process was specifically considered, and rejected by the Committee in 1999, it should not be read into CEPA today.

[61] Second, according to subsection 106(9) of CEPA, a published notice of waiver need only state the name of the person to whom the waiver is granted and the type of information to which it relates. As the applicants themselves complain at paragraph 67 of their memorandum, this format "makes it impossible to discern what substances or organisms [the notices] relate to or how long [those substances or organisms] may have been present in Canada." While such minimal information may provide a modicum of transparency, it is implausible to think that it

gives rise to any participatory rights. This point was explicitly acknowledged during the 1999 Committee meeting, when a member remarked that a notice of waiver "just identifies the name of the person and the type of information to which it relates. It certainly doesn't allow for public comment."

[62] Finally, I agree with the respondents that, had Parliament intended to allow public participation in toxicity assessments, it would have explicitly said so, as it does in several other areas of CEPA, including section 332, which sets out a notice and comment process for every order or regulation made under the Act.

[63] Toxicity assessments are not simple and quick processes. A select group of experts is chosen to review a complex Notification and report with recommendations. Publishing the full Notification and soliciting public comments, which would then also have to be considered, would make it virtually certain that no decision would be made within the 120 day period Parliament provided.

The SNAc Notice

[64] The applicants make two submissions that the Minister of the Environment's SNAc Notice is overbroad. First, they submit that, because subsection 106(10) of CEPA restricts AquaBounty to using AAS "at the location specified in [its] request for [a] waiver" (i.e. its PEI Facility) the SNAc Notice is overbroad insofar as it permits the use of AAS at any "contained facility." Second, the applicants submit that the SNAc Notice is unlawful because it permits the

commercial grow-out of AAS in Canada, even though this scenario was not considered in the Ministers' assessment.

1. Overbroad Definition of "Location"

[65] Subsection 106(10) of CEPA states that, where the Minister of the Environment has waived an information requirement under paragraph 106(8)(b), "the person to whom the waiver is granted shall not use, manufacture or import the living organism unless it is…at the location specified in the request for the waiver…" The applicants submit that, in this case, the "location specified in the request for the waiver" is AquaBounty's PEI Facility. They therefore submit that the terms of the SNAc Notice are inconsistent with subsection 106(10) because they permit the use of AAS in any "contained facility," rather than the PEI Facility in particular.

[66] The respondents submit that there is no inconsistency between the scope of the restrictions in the SNAc Notice and those in subsection 106(10). They submit that, in issuing the SNAc Notice that she did, the Minister of the Environment implicitly held that the word "location" in subsection 106(10) of CEPA should be construed broadly so as to include any location that is functionally equivalent to AquaBounty's PEI Facility (i.e. any "contained facility"). In this way, the scope of the SNAc Notice is the same as the scope of subsection 106(10): both restrict the use of AAS to a "contained facility."

[67] I agree with the applicants that subsection 106(10) restricts AquaBounty to using AAS at its PEI Facility. I therefore do not accept the respondents' interpretation of "location" in that

subsection. That interpretation is simply not supported by the plain meaning of the provision and the relevant sections of CEPA.

[68] As noted above, subsection 106(10) of CEPA stipulates, in relevant part, that "[w]here the Minister waives any of the requirements for information under paragraph (8)(b), the person to whom the waiver is granted shall not use, manufacture or import the living organism unless it is … at the location specified in the request for the waiver" [emphasis added].

[69] The Court was not provided with AquaBounty's request for waiver or its Notification. Therefore, the Court does not have direct evidence of what location was specified in that request. However, paragraph 8(1)(d) of the NSN Regs does state that "any information to be provided to the Minister under these Regulations must include … the civic address of the site of manufacture … of the organism." The Guidelines provide at page 87 that "[i]f the notified organism is to be manufactured in Canada, provide the manufacturer and the location of the manufacturing site(s)." And the form contained therein at page 108 indicates that the "Proposed Site of Manufacture in Canada" is to be indicated by street, city, and Province. Finally, when the DFO Report considered, and made a recommendation with respect to, AquaBounty's request for a waiver, it did so on the basis that the "location" in question was AquaBounty's PEI Facility. It is therefore clear that the "location specified in the request for the waiver" was the address of the PEI Facility. It is not reasonably open to the Minister, when interpreting subsection 106(10), to interpret "location" more broadly or ascribe a different meaning to it than the precise location an applicant specifies in its request for a waiver. In any case, there is no evidence that the Minister adopted such an interpretation.

[70] In my view, there is only one reasonable interpretation of subsection 106(10) on the facts before the Court. AquaBounty requested and was granted a waiver from providing "the data from a test conducted to determine [AAS's] pathogenicity, toxicity or invasiveness." The waiver was granted because the Ministers were of the opinion that AquaBounty was "able to contain the living organism so as to satisfactorily protect the environment and human health:" CEPA, paragraph 106(8)(b). That decision was made with specific reference to the PEI Facility identified and described in the application. Accordingly, AquaBounty, having received the waiver, "shall not use, manufacture or import living organism unless it is … at the location specified in the request for the waiver:" CEPA, subsection 106(10).

[71] The applicants submit that, once this Court concludes that subsection 106(10) restricts AquaBounty to the use of AAS at its PEI Facility, it must also conclude that the SNAc Notice is inconsistent with subsection 106(10) and, therefore, is unreasonable. As noted above, the applicants emphasize that the uses permitted by the SNAc Notice are broader than the uses permitted by subsection 106(10). In particular, while subsection 106(10) restricts AquaBounty to using AAS at its PEI Facility in particular, the SNAc Notice permits any person to use AAS at any contained facility. The applicants submit that allowing the SNAc Notice to stand would lead to the absurd result that, although AquaBounty would be restricted to using AAS at its PEI Facility in particular, other persons would be able to use it at any "contained facility."

[72] The parties appear to agree that it would be absurd to interpret CEPA in a manner that would restrict AquaBounty's use of AAS more than that of other persons, whose uses have not been assessed at all. Where the parties differ is in their proposed solution to this alleged

absurdity. The applicants would resolve the tension between subsection 106(10) and the SNAc Notice by "getting rid" of the SNAc Notice; they submit that the SNAc Notice is unreasonably broad, and should be quashed on that basis. AquaBounty, on the other hand, would resolve the tension by "getting rid" of subsection 106(10); it submits that, when a SNAc Notice is issued, the restrictions in the Notice supersede and replace the restrictions in subsection 106(10), thereby placing AquaBounty on equal footing with all others. I accept neither view. In order to understand why, it is necessary to consider the relationship between a SNAc Notice that engages subsection 106(4) of CEPA and the application required under subsection 106(1).

[73] I asked the parties at the hearing whether subsection 106(1) continues to apply even though AquaBounty has submitted a Notification under that subsection and a SNAc Notice has been issued. In particular, I asked whether all persons wishing to manufacture AAS in Canada, including AquaBounty if it wishes to manufacture AAS at a different location, will be required to submit a new Notification under subsection 106(1). It was my impression that all parties were of the view that no such Notification would be required. I do not agree.

[74] Part 6 of CEPA refers to three ways of dealing with living organisms: manufacture, importation, and use.

[75] The Notification and assessment process provided for in subsection 106(1) of CEPA is directed only to manufacture and importation – not use. It is quite specific in stating that "[w]here a living organism is not on the Domestic Substances List … no person shall manufacture or import the living organism unless … the prescribed information … has been

provided by that person to the Minister … and … the period for assessing the information … has expired" [emphasis added].

[76] On the other hand, a SNAc Notice issued under subsection 110(1) of CEPA is directed only to use – not manufacture and importation. This can be seen in subsection 106(4), which provides that "where a living organism is not specified on the Domestic Substances List and the Minister publishes a notice in the Canada Gazette indicating that this subsection applies with respect to the living organism, no person shall use the living organism for a significant new activity that is indicated in the notice unless … the person has provided the Minister with the prescribed information … and … the period for assessing the information … has expired" [emphasis added].

[77] This difference in focus between subsection 106(1) (manufacture and importation) and subsection 106(4) (use) means that, even though a SNAc Notice was issued that permits use at a contained facility, any person seeking to manufacture or import AAS must still file a Notification under subsection 106(1). This includes even AquaBounty who, because it received a waiver under paragraph 106(8)(b), is limited by subsection 106(10) to using and manufacturing AAS at its PEI Facility, and so cannot manufacture elsewhere without undergoing further assessment.

[78] To summarize, the impact of Part 6 of CEPA on AquaBounty is the following. Having filed a Notification and been provided with the requested waiver, and the assessment period having passed, it can "manufacture" and "use" AAS (provided it is not a use that is a significant new activity) only at the PEI Facility. If it wishes to manufacture AAS at a different location, or

import AAS, then it must file a new Notification under subsection 106(1). If it wishes to use AAS for a significant new activity, then it must file a Notification under subsection 106(4).

[79] The impact of Part 6 of CEPA on persons other than AquaBounty is that they must file a Notification under subsection 106(1) in order to be permitted to manufacture or import AAS and, if they are proposing a use that is a significant new activity, they must file a Notification under subsection 106(4).

[80] What impact does this interpretation have on the alleged absurdity outlined above? It causes it to disappear. In particular, it demonstrates that AquaBounty is not placed in an unequal position by the operation of subsection 106(10). Like AquaBounty, all persons are required to submit a Notification if they wish to manufacture or import AAS. As part of their Notification, they can request a waiver. If, like AquaBounty, they request a waiver pursuant to subsection 106(8)(b), then their use, manufacture, and import of AAS will be limited to the location specified in their request for a waiver, pursuant to subsection 106(10). If, on the other hand, they do not request a waiver, then their use will only be constrained by the scope of the SNAc Notice. In this way, AquaBounty is placed on equal footing with everyone else. There is therefore no absurdity, nor any unreasonableness, in the Minister issuing a SNAc Notice that permits a wider range of uses of AAS than that permitted by subsection 106(10). The applicants' objection dissolves.

2. Overbroad Definition of Permitted Uses

[81] I agree with the applicants that "commercial grow-out in Canada was not assessed as part of the DFO Risk Assessment." However, DFO did assess the risks posed by commercial grow-out in Panama. I agree with the submission of AquaBounty that, when the Certified Tribunal Record is read as a whole, it is clear that the Minister of the Environment's functional approach to the SNAc Notice led her to conclude that "the containment measures required by the AAS SNAc Notice will work equally well regardless of whether the AAS are being grown out for research, reproduction or commercial grow-out." Adult AAS leaving the contained facility in Canada are required to have been euthanized. There is no evidence in the record that euthanized AAS are a danger to the environment. Moreover, they cannot be used for human consumption unless approved by Health Canada, which, if called upon to issue an approval, would examine risk to human health. Accordingly, I am not persuaded that the scope of the SNAc Notice was overly broad and unreasonable.

Disposition and Costs

[82] For these reasons, this application must be dismissed. The applicants as public interest litigants submit that they ought not to have costs visited upon them and they asked for and were granted an opportunity after these reasons issued to make written submissions on costs. If the parties are unable to reach an agreement on costs, the applicants shall serve and file their written submissions (not exceeding 5 pages) within 3 weeks of the date of the Judgment, and the respondents shall service and file their responses (not exceeding 5 pages) within 2 weeks thereafter.

JUDGMENT

THIS COURT'S JUDGMENT is that the application is dismissed, and in accordance with these Reasons, costs are reserved.

"Russel W. Zinn"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

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