Court File No. T-1070-16

FEDERAL COURT

DAVID SUZUKI FOUNDATION, FRIENDS OF THE EARTH CANADA, ONTARIO NATURE, and WILDERNESS COMMITTEE

Applicants

and

MINISTER OF HEALTH, SUMITOMO CHEMICAL COMPANY LIMITED, BAYER CROPSCIENCE INC and VALENT CANADA INC

Respondents

NOTICE OF APPLICATION

TO THE RESPONDENTS:

A PROCEEDING HAS BEEN COMMENCED by the applicants. The relief claimed by the applicants appears on the following pages.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the applicants. The applicants request that this application be heard at *Toronto, Ontario*.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor acting for you must prepare a notice of appearance in Form 305 prescribed by the Federal Courts Rules and serve it on the applicants' solicitors WITHIN 10 DAYS after being served with this notice of application.

Copies of the Federal Courts Rules information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

Date: July 6, 2016

Issued by: J. Outram
(Registry Officer)

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APPLICATION

This is an application for judicial review in the matter of the Pest Management Regulatory Agency's ("**PMRA**") course of conduct:

- successively registering, or amending the registrations of, certain pest control products under the *Pest Control Products Act*, SC 2002, c 28 (the "**Act**"), while failing to ensure it has the scientific information necessary to be reasonably certain that the products' environmental risks are acceptable; and
- unlawfully extending the validity periods of certain pest control products.

The matter in respect of which judicial review is sought – the PMRA's unlawful course of conduct – covers the period from when the Act came into force on June 28, 2006, to the present. The PMRA is the Minister of Health's delegate, exercising all her powers under the Act. The pest control products dealt with in the matter are the active ingredient Clothianidin Technical Insecticide ("**Clothianidin Active**") and the agricultural end-use products containing Clothianidin Active (the "**Clothianidin end-use products**"). These products fall within the neonicotinoid class of pesticides.

Subsection 8(4) of the Act requires the Minister to deny an application to register, or amend the registration of, a pest control product where the Minister does not consider the product's environmental risks to be acceptable. Subsection 2(2) of the Act provides that the environmental risks of a product are acceptable if there is reasonable certainty that no harm to the environment will result from exposure to, or use of, the product. The PMRA has successively registered, or amended the registrations of, Clothianidin Active and the Clothianidin end-use products without the scientific information necessary to be reasonably certain that Clothianidin's environmental risks, in particular risks to pollinators, are acceptable.

Where a pest control product is deemed to be a "conditional registration", subsection 14(5) of the Pest Control Products Regulations, SOR/2006-124 (the "**Regulations**"), prohibits extension of the product's validity period subject to two narrow exceptions. Clothianidin Active and the Clothianidin end-use products are "conditional

registrations". On the face of the public record the PMRA has unlawfully extended the validity periods of Clothianidin Active and the Clothianidin end-use products.

The applicants make application for:

1A. An order declaring unlawful the PMRA's course of conduct in the matter of successively registering, or amending the registrations of, Clothianidin Active and the Clothianidin end-use products under the Act while failing to ensure it has the scientific information necessary to be reasonably certain that Clothianidin's environmental risks are acceptable.

1B. An order declaring unlawful the PMRA's course of conduct in the matter of extending the validity periods of Clothianidin Active and the Clothianidin end-use products.

1C. An order declaring that the registrations of Clothianidin Active and the Clothianidin end-use products are invalid.

2. An order that this application be heard together with a closely related application filed by the applicants on July 6, 2016.

3. Costs.

4. Such further and other relief as this Court deems just.

The grounds for the application are:

The Parties and Related Proceedings

1. David Suzuki Foundation, Friends of the Earth Canada, Ontario Nature, and Wilderness Committee (collectively the "**Applicants**") are public interest litigants. The Applicants are non-governmental organizations working to reduce the risks to Canadians and Canada's environment from harmful pesticides.

2. The Applicants have genuine interests in protecting Canadians and Canada's environment from the risk of harm due to pesticides. They have no personal, proprietary or pecuniary interests in the outcome of this application.

3. The Applicants have genuine interests in the administration of the Act, and in the PMRA's compliance with the Act's standards for environmental protection.

4. The Minister of Health is responsible for administering the Act. The Minister has delegated this responsibility to the PMRA.

5. Sumitomo Chemical Company, Limited is the registrant of Clothianidin Active. Bayer CropScience Inc and Valent Canada Inc are registrants of the Clothianidin end-use products.

6. On July 6, 2016, the Applicants filed a closely related application for judicial review with respect to the registrations of the active ingredient Thiamethoxam Technical Insecticide and the agricultural end-use products containing Thiamethoxam.

The PMRA's objectives under the Act

7. The PMRA's "primary objective" in administering the Act is to prevent unacceptable risks to people and the environment from the use of pest control products.

8. The health or environmental risks of a pest control product are acceptable under the Act 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.

9. The PMRA is also required to encourage public awareness in relation to pest control products by informing the public, and by facilitating public access to relevant information and public participation in the decision-making process.

Registration of pest control products under the Act

10. A pest control product cannot be used in Canada unless it is validly registered under the Act.

11. End-use products that controls pest and the "active ingredients" within those end-use products are both "pest control products" under the Act.

12. Upon receiving an application to register or amend the registration of a pest control product the PMRA conducts any evaluations it considers necessary with respect to the health or environmental risks or the value of the pest control product. It is the applicant's burden to persuade the PMRA that the health and environmental risks and the value of a pest control product are acceptable.

13. The PMRA is required to consult the public before granting or denying an application to register or amend the registration of a pest control product if:

    a) the product is or contains an unregistered active ingredient; or

    b) the Minister considers that registration or amendment of the registration may result in significantly increased health or environmental risks.

14. After the required evaluations and consultations have been completed the PMRA decides the application. If the PMRA considers the pest control product's health or environmental risks, or its value, to be unacceptable, the PMRA shall deny the application. If it considers the product's risks and value to be acceptable, it shall grant the application.

Requiring "additional information" and "conditional registration"

15. The PMRA may, by delivering a notice in writing under subsection 12(1) of the Act, require a registrant of a pest control product to provide "additional information" on the product's health or environmental risks, or its value. This notice is known as a "Section 12 Notice".

16. According to the Regulations, if a Section 12 Notice is delivered to the registrant of a pest control product when the PMRA registers or amends the registration of the pest control product under the Act, the registration becomes a "conditional registration".

17. Neither the Act nor the Regulations define a "conditional registration".

18. The Regulations provide that certain key provisions of the Act do not apply to a pest control product that is a conditional registration:

    a) the public's right to be consulted before the PMRA decides to register or amend the registration of a pest control product;

    b) the public's right to object after the PMRA decides to register or amend the registration of a pest control product; and

    c) the public's right to access information provided by an applicant or registrant to the PMRA in support of an application to register or amend the registration of a pest control product.

19. The registration of a pest control product that is a conditional registration is valid for up to three years. This validity period cannot be extended except in two circumstances: where the registrant complies with the requirements of the Section 12 Notice for that product or where necessary to allow for consultation required by the Act.

20. The Regulations allow the PMRA to renew a pest control product's conditional registration upon expiration. The registrant must apply for renewal. Upon application for renewal the Act's scheme for registration decisions applies – the PMRA must undertake required evaluations of the product's health and environmental risks, and its value, as well as consultations with the public.

Registration history of Clothianidin Active and the Clothianidin end-use products

21. In or about December 2003, the PMRA first registered Clothianidin Active, along with Poncho 600 Seed Treatment Insecticide, a seed treatment end-use product. These pest control products were registered as "temporary registrations" under the old Pest Control Products Regulations, CRC, c 1253, and *Pest Control Products Act*, RSC 1985, c P-9.

22. The PMRA was concerned about Clothianidin's toxic effects on bees. Consequently, the PMRA made these pest control products' temporary registrations subject to the future submission of information on Clothianidin's environmental risks, including a field study on chronic toxicity to bees.

23. When the new Act and Regulations came into force on June 28, 2006, requirements in the products' temporary registrations to submit information on Clothianidin's environmental risks remained outstanding. At some point after June 28, 2006, the PMRA registered Clothianidin Active, and the Clothianidin end-use products that were temporary registrations under the old regime, as "conditional registrations" under the new Act and Regulations.

24. Outstanding information on Clothianidin's environmental risks, including the field study addressing chronic toxicity to bees, was required by June 1, 2008, pursuant to Section 12 Notices. The products' conditional registrations were made valid to December 31, 2008. The PMRA subsequently received and rejected a field study submitted on toxicity to bees as invalid.

25. Between 2007 and 2009 the registrants of Clothianidin Active and the Clothianidin end-use products applied to convert the pest control products from conditional registrations to "full registrations". Neither the Act nor the Regulations use the term "full registration".

26. The PMRA denied these applications because it had "insufficient" scientific information on Clothianidin's environmental risks. Specifically, the PMRA had not received a valid field study on Clothianidin's chronic toxicity risks to bees.

27. Instead the PMRA established new deadlines for the outstanding information and granted conditional registrations for Clothianidin Active and the Clothianidin end-use products until December 31, 2012 or December 31, 2013, depending on the product.

28. Subsequently the PMRA has successively continued the registrations of Clothianidin Active and the Clothianidin end-use products, and registered new Clothianidin end-use products, all without sufficient information on Clothianidin's environmental risks, in particular risks to pollinators.

29. The PMRA has conceded that the lack of a field study on Clothianidin's chronic toxicity risks "represents a critical data gap in the risk assessment of Clothianidin". The PMRA has also added new requirements to submit information relevant to Clothianidin's environmental risks.

30. The most recent validity periods for the conditional registrations of Clothianidin Active and some Clothianidin end-use products expired December 31, 2015. The most recent validity periods for the conditional registrations for other Clothianidin end-use products expired December 31, 2013.

31. Nonetheless, the PMRA purports to have extended the conditional registration validity periods of Clothianidin Active and the Clothianidin end-use products until December 31, 2017.

32. There is no publicly available indication that the PMRA has received and considered the outstanding information on Clothianidin's environmental risks, specifically risks to pollinators, since it was first required in 2003. In the thirteen years between 2003 and 2016 the PMRA has allowed the number of Clothianidin end-use products, and their scope of use within the environment, to proliferate.

The PMRA's course of conduct is unlawful

33. The PMRA's course of conduct in registering and successively continuing the registrations of Clothianidin Active and the Clothianidin end-use products without sufficient information to determine whether Clothianidin's environmental risks are acceptable is unlawful.

34. The Act requires the PMRA to determine whether a pest control product's environmental risks are acceptable before granting or denying an application to register, or amend the registration of, that product.

35. The Act provides that an applicant has the burden of persuading the PMRA that a pest control product's environmental risks are acceptable.

36. The Act states that a pest control product's environmental risks are acceptable if there is "reasonable certainty that no harm to … the environment will result from exposure to or use of the product".

37. Over a period of approximately thirteen years the PMRA has registered and successively continued the registrations of Clothianidin Active and the Clothianidin end-use products without sufficient information to determine whether Clothianidin's environmental risks are acceptable. In the circumstances, the PMRA cannot be reasonably certain that no harm to the environment will result from exposure to or use of Clothianidin Active and the Clothianidin end-use products.

38. Further, the PMRA's ongoing failure to ensure that these products are safe undermines the PMRA's primary objective of preventing unacceptable risks to human health and the environment from the use of pest control products.

39. The PMRA purports to have extended the conditional registration validity periods of Clothianidin Active and the Clothianidin end-use products until December 31, 2017 without basis in the Act or the Regulations.

40. The PMRA's regulatory management of Clothianidin Active and the Clothianidin end-use products constitutes an unlawful course of conduct under the Act and Regulations.

Jurisdiction and Additional grounds

41. The Federal Court has jurisdiction to hear this application for judicial review of the matter described above, and to grant the relief sought, pursuant to sections 18 and 18.1 of the *Federal Courts* Act, RSC 1985, c F-7. In addition the Applicants rely on the *Federal Courts Rules*, the Act, the Regulations and such additional grounds as counsel may identify.

This Application will be supported by the following material:

1. An affidavit of Elaine MacDonald, to be served.

2. An affidavit from a representative of each applicant, to be served:

    a. Faisal Moola, David Suzuki Foundation

    b. Beatrice Olivastri, Friends of the Earth Canada

    c. Caroline Shultz, Ontario Nature

    d. Gwen Barlee, Wilderness Committee

3. Material requested pursuant to Rule 317 and produced to the Applicants and to the Court pursuant to Rule 318 of the *Federal Courts Rules*.

4. Such further and additional materials as counsel may advise and the Court may allow.

Rule 317 request

The Applicants request that the Minister send a certified copy of the following material not in the Applicants' possession, but in the possession of the Minister, or the PMRA as the Minister's delegate, to the Applicants and to the Registry:

1. All documents in the possession of the Minister, or the PMRA as the Minister's delegate, related to the ongoing practice of registering or continuing the registration of Clothianidin Active and the Clothianidin end-use products.

Date: July 6, 2016

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