Court File No. T-1071-16

FEDERAL COURT

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

Applicants

and

GOVERNOR IN COUNCIL, MINISTER OF HEALTH, SYNGENTA CANADA INC and ELANCO CANADA LIMITED

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. Durkin
(Registry Officer)

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APPLICATION

This is an application for judicial review:

- Challenging s. 14(1)(b) of the Pest Control Products Regulations, SOR/2006-124 (the "**Regulations**") as *ultra vires* the *Pest Control Products Act*, SC 2002, c 28 (the "**Act**"); and

- In the matter of the Pest Management Regulatory Agency's ("**PMRA**") course of conduct in successively registering, or amending the registrations of, certain pest control products under the Act, while failing to ensure it has the scientific information necessary to be reasonably certain that the products' environmental risks are acceptable.

The matter in respect of which review is sought – the *vires* of s. 14(1)(b) of the Regulations and the consequent validity of pest control products registered without public consultation, and the PMRA's unlawful course of conduct – covers the period from when the Act and Regulations came into force on June 28, 2006, to the present. The Governor in Council enacted the Regulations. 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 Thiamethoxam Technical Insecticide ("**Thiamethoxam Active**") and the agricultural end-use products containing Thiamethoxam Active (the "**Thiamethoxam end-use products**"). These products fall within the neonicotinoid class of pesticides.

Paragraph 14(1)(b) of the Regulations conflicts operationally with the Act. It precludes public consultation on decisions to register, or amend the registration of, pest control products, while the Act requires public consultation as a mandatory pre-condition to the exercise of such decision-making authority. The PMRA has successively registered or amended the registrations of Thiamethoxam Active and the Thiamethoxam end-use products without ever conducting public consultation required by the Act, in reliance on s. 14(1)(b) of the Regulations.

Subsection 8(4) of the Act requires the PMRA to deny an application to register, or amend the registration of, a pest control product where the PMRA 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, Thiamethoxam Active and the Thiamethoxam end-use products without the scientific information necessary to be reasonably certain that Thiamethoxam's environmental risks, in particular risks to pollinators, are acceptable.

The applicants make application for:

1A. An order declaring s. 14(1)(b) of the Regulations *ultra vires* the Act and of no force or effect.

1B. An order declaring that the PMRA has acted without jurisdiction in the matter of successively registering, or amending the registrations of, Thiamethoxam Active and the Thiamethoxam end-use products under the Act without ever conducting public consultation, in reliance on s. 14(1)(b) of the Regulations.

1C. An order declaring that the registrations of Thiamethoxam Active and the Thiamethoxam end-use products are invalid for having been made by the PMRA without jurisdiction.

1D. An order prohibiting the PMRA from renewing, amending, or otherwise extending the invalid registrations of Thiamethoxam Active and the Thiamethoxam end-use products.

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

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

4. Costs.

5. 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 Governor in Council enacted the Regulations.

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

6. Syngenta Canada Inc is the registrant of Thiamethoxam Active. Syngenta Canada Inc and Elanco Canada Limited are registrants of the Thiamethoxam end-use products.

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

The PMRA's objectives under the Act

8. 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.

9. 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.

10. 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

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

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

13. 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.

14. 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.

15. 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"

16. 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".

17. 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".

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

19. 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.

20. 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.

21. 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 Thiamethoxam Active and the Thiamethoxam end-use products

22. In or about November 2000, the PMRA first registered Thiamethoxam Active, along with two seed treatment end-use products, Helix Liquid Seed Treatment Insecticide ("**Helix Liquid**") and Helix Xtra Seed Treatment ("**Helix Xtra**"). 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.

23. The temporary registrations of Thiamethoxam Active, Helix Liquid, and Helix Xtra in 2000 were subject to the future submission of data on human health risks. The registrant supplied that required information on human health and, in 2003, applied to convert Thiamethoxam Active, Helix Liquid, and Helix Xtra from temporary to full registration.

24. While the PMRA was considering these conversion applications, two new Thiamethoxam based products were submitted for registration in or about August 2004: Actara 240SC Insecticide ("**Actara 240SC**") and Actara 25WG Insecticide ("**Actara 25WG**"). In evaluating these applications the PMRA became concerned about Thiamethoxam's risks to pollinators. The PMRA identified toxicity to pollinators as an important data gap in its understanding of Thiamethoxam's environmental risks.

25. On June 28, 2006, while the various applications dealing with Thiamethoxam Active and Thiamethoxam end-use products were being considered by the PMRA, the new Act and Regulations came into force.

26. On or about October 31, 2006, the PMRA registered Thiamethoxam Active and its end-use products Actara 240SC and Actara 25WG under the Act as "conditional registrations". The PMRA made these products' registrations subject to the future submission of information on Thiamethoxam's environmental risks, including a field study on toxicity to bees.

27. The outstanding information was due March 31, 2008 and the products' conditional registrations were made valid to December 31, 2008. The PMRA subsequently received and rejected a field study on toxicity to bees as invalid.

28. In or about 2008 the registrant applied to convert Thiamethoxam Active and a number of Thiamethoxam end-use products from conditional registrations to "full registrations". Neither the Act nor the Regulations use the term "full registration".

29. The PMRA denied the conversion applications on the basis of its concerns about Thiamethoxam's toxicity to bees and other non-target arthropods.

30. Instead the PMRA established new deadlines for the outstanding information and granted conditional registrations for Thiamethoxam Active and several Thiamethoxam end-use products, valid to December 31, 2013.

31. Between 2010 and 2013 the PMRA registered several new Thiamethoxam agricultural end-use products.

32. In or about 2013 the registrant applied to renew the conditional registration of Thiamethoxam Active for agricultural uses that was set to expire on December 31, 2013.

33. The PMRA decided this application by granting a renewal of Thiamethoxam Active's conditional registration. Thiamethoxam Active's conditional

registration is now set to expire on December 31, 2016. The PMRA stated that an "extension" of Thiamethoxam Active's conditional registration was necessary to provide more time for meeting the outstanding informational requirements regarding Thiamethoxam's environmental risks.

34. The PMRA similarly continued the conditional registrations of the Thiamethoxam end-use products until December 31, 2016.

35. There is no publicly available indication that the PMRA has received and considered the outstanding information on Thiamethoxam's environmental risks, specifically risks to pollinators, since it was first required in October 2006. In the decade between 2006 and 2016 the PMRA has allowed the number of Thiamethoxam end-use products, and their scope of use within the environment, to proliferate.

Paragraph 14(1)(b) of the Regulations

36. By purporting to exclude the application of the Act's mandatory public consultation requirements, paragraph 14(1)(b) of the Regulations is *ultra vires.* Public consultation is required prior to the PMRA's decision-making on an application to register or amend the registration of a pest control product. That requirement cannot be excluded by paragraph 14(1)(b) which operates subsequent to the PMRA's decision-making.

37. A regulatory provision that operationally conflicts with its enabling legislation is *ultra vires*.

38. Thiamethoxam Active and several Thiamethoxam end-use products have been registered under the Act since it came into force in 2006. Other Thiamethoxam end-use products have been registered since that time. The PMRA has never consulted the public on a decision to register or amend the registrations of these products, in reliance on s. 14(1)(b). The registrations of Thiamethoxam Active and the Thiamethoxam end-use products are therefore invalid.

The PMRA's course of conduct is unlawful

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

40. 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.

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

42. 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".

43. Over a period of approximately ten years the PMRA has registered and successively continued the registrations of Thiamethoxam Active and the Thiamethoxam end-use products without sufficient information to determine whether Thiamethoxam'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 Thiamethoxam Active and the Thiamethoxam end-use products.

44. 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.

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

Jurisdiction and Additional grounds

46. 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 Thiamethoxam Active and the Thiamethoxam end-use products.

Date: July 6, 2016

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