

# Torys on Intellectual Property

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## Exclusive Protection of Pesticide Data at Risk in Canada

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Under the *Pest Control Products Act* (PCPA), which regulates pesticide products, a generic pesticide manufacturer may be able to rely on the data of any registrant provided that the manufacturer can establish that its product uses an active ingredient equivalent to that of the registered pesticide.

The PCPA requires that pesticide products be approved before they can be imported into, manufactured, sold or used in Canada. As part of the registration process, applicants must submit data to establish the acceptability of the health and environmental risks and the value of the pesticide product.

Health Canada's Pest Management Regulatory Agency (PMRA) is drafting regulations for classifying the protection status of data submitted by innovators. No date has been set for completing these regulations. The PMRA currently implements the relevant policies through regulatory directives and has released a directive aiming to implement data protection practices that are closely aligned with the current practices of the U.S. Environmental Protection Agency.<sup>1</sup> Any data protected under the old Product-Specific Registration policy currently remain unaffected by this newer data protection policy.

### Classification of the Protection Status of Data

Data submitted to the PMRA can be granted either protected or non-protected status. Protected data may include any data submitted by a registrant regarding a new active ingredient and any associated end-use or manufacturing concentrate as well as data regarding additional or amended registrations used for new formulations or for expanding or updating existing data. In addition, any data requested by the PMRA under the PCPA as a condition of registration or for incident reporting may be protected.

Data that have been granted protected status can be assigned either exclusive protection or compensable protection.

The innovator of data granted exclusive protection may voluntarily, but is not obliged to, enter into negotiations with a generic pesticide manufacturer to provide access to and receive compensation for the generic's reliance on the data.

To discuss these issues, please contact the authors.

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Currently, exclusive protection is given only to data that formed the basis for the registration of a new active ingredient and its associated end-use product or manufacturing concentrate, and lasts for 10 years from the date of registration, with a possible additional extension of 5 years in certain cases.

Compensable protection – currently given to all protected data not exclusively protected – lasts for a specific period, during which a generic pesticide manufacturer can rely on the data by compensating the innovator. The manufacturer and innovator would negotiate a commercial agreement regarding access and compensation. This includes any data that formed the basis for an additional or amended registration, including new formulations and data submitted for a re-evaluation of a registered pesticide. Compensable protection status lasts for 12 years from (i) the date of the application for expanded use or a change in formulation; (ii) the date of submission if it is submitted in response to a PMRA request under the PCPA; or (iii) the date that the data are cited in a re-evaluation. The length of the compensable protection period cannot be extended.

### **Compensation for Access to Protected Data**

An innovator cannot refuse access to data with compensable protection, unlike the case of exclusively protected data. The negotiation of access to data with compensable protection status is mandatory; if negotiations fail, the parties are required to go to binding arbitration to determine the amount of compensation the innovator will receive from the generic pesticide manufacturer for access to the data. Under this process, the Minister of Health will determine the terms and conditions of the agreement once the compensation value has been determined. In January 2008, the PMRA released a regulatory directive outlining the procedure for the negotiation/arbitration process.<sup>2</sup> As of the time of writing, no negotiations or arbitrations have occurred. **T**

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<sup>1</sup> DIR2007-03 titled “Protection of Proprietary Interests in Pesticide Data in Canada” on August 1, 2007.

<sup>2</sup> DIR2008-01 titled “Registering a New Source of Technical Grade Active Ingredient Under the Protection of Proprietary Interests in Pesticide Data Policy” on January 16, 2008.