

# Changes to Regulatory Approval of Generic Pesticides

CETA leads to expanded scope of data available for generic registrations

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Amendments to the *Pest Control Products Act* (PCPA) and *Pest Control Products Regulations* (Regulations) have expanded the scope of data on which a follow-on applicant can rely for regulatory approval of generic pesticides, including crop protection products such as herbicides and fungicides.<sup>1</sup> The amendments come as a response to Canada's obligation under the Comprehensive Economic and Trade Agreement (CETA) to make rules aimed at avoiding duplicative animal testing.

## What You Need To Know

- **Broader scope of data available to support generic registration.** Generic applicants may now rely on test data from non-equivalent as well as equivalent products when seeking Health Canada approval. Although the goal was to reduce duplicative animal testing, the expansion to non-equivalent products is not limited to animal test data.
- **Term of data protection unaffected.** Despite the amendments, the duration of exclusive use data protection and compensatory data protection remains 10 years and 12 years, respectively.
- **Faster market entry for generics.** In addition to preventing unnecessary and duplicative animal testing, the amendments are expected to shorten the average time to market for generic pesticides.
- The amendments came into force on September 21 following the provisional application of CETA.

## Background

Under the PCPA, all pesticides to be sold in Canada must first be registered with Health Canada. Registration is achieved through a pre-market review to assess the potential risks a product poses to human health and the environment. Following registration, post-market reassessments are conducted every 15 years or in circumstances when Health Canada has reason to believe the risks associated with a product are unacceptable. Both pre-market and post-market reviews require an applicant/registrant to submit sufficient data in support of a registration, including the results of relevant animal testing.

Under the Regulations, data submitted by an applicant in respect of a new active ingredient never registered in Canada before benefits from 10 years of exclusive use data protection starting from the date of registration. During this period, follow-on generic applicants cannot rely on such data to support their own registrations, without the

registrant's permission. Furthermore, any data later submitted by the registrant to support an amendment to the registration, or to register a new end-use product containing the registered active ingredient, will enjoy 12 years of compensatory data protection. Compensatory data protection begins from the date of application and allows a generic to rely on previously submitted data provided compensation is paid to the registrant that first submitted the data. The amount of compensation payable in each case is determined by mandatory negotiation and binding arbitration as set out in the Regulations.

## Amendments

Pursuant to Article 20.30 of CETA, Canada is obligated to establish regulations aimed at avoiding duplicative testing on vertebrate animals.<sup>2</sup> Accordingly, the PCPA and Regulations were recently amended to allow follow-on applicants to rely on test data from both equivalent and non-equivalent products during pre-market and post-market review. According to guidance from the Pest Management Regulatory Agency, examples of the type of non-equivalent product data that may now be relied on include, chemical-specific studies of health risks associated with a particular activity to support non-equivalent products in respect of the same activity and toxicity studies to support non-equivalent products containing less potent chemicals from the same chemical group. Although the goal of these amendments was to reduce duplicative animal testing, the amendments are not limited to animal test data.

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<sup>1</sup> See: <http://gazette.gc.ca/rp-pr/p1/2017/2017-07-15/html/reg15-eng.php>.

<sup>2</sup> See: <http://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/20.aspx?lang=eng>.

*To discuss these issues, please contact the author(s).*

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