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Canada Proposes to Allow Inspection of Confidential Test Data for Post-Market Reviews

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On June 14, 2019, Canada's Pest Management Regulatory Agency (PMRA) began a public consultation on Discussion Document DIS2019-01, "Consultation on Inspecting Confidential Test Data for Post-market Reviews in the Reading Room." Before a pesticide can be registered for use in Canada, PMRA states that it reviews the available scientific test data to determine whether there are concerns for human health or safety, or the environment, when the product is used according to the label. Some of the data reviewed by the PMRA scientists include confidential test data on:

- Toxicology related to human health;
- Bystander and occupational exposure;
- Food residue trials;
- Environmental toxicology and fate;
- Product efficacy, crop tolerance, and benefits of the product; and
- Other scientific data or studies submitted to, or considered by the PMRA.

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According to PMRA, the purpose of the consultation document is to seek input on a proposal to expand access to confidential test data by inviting interested members of the public to inspect these data at the proposed decision stage for post-market reviews such as re-evaluations and special reviews. Currently, PMRA prepares confidential test data for public inspection only after it makes a final decision. PMRA proposes to allow interested parties seeking to understand the scientific basis for a proposed re-evaluation or special review decision to inspect the data used by PMRA earlier in the process. PMRA states that by viewing these data earlier, comments submitted through the existing consultation process may be more well-informed.

PMRA notes that the proposed change would still require the inspection of confidential test data to take place at its National Head Office in Ottawa, Ontario. PMRA states that it is aware that this could be burdensome and is investigating alternative approaches for the future that may allow the inspection of data through other means, such as satellite reading rooms or secure portals. Publication of the consultation document began a 60-day comment period.

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