
**Canada's PMRA and United States' EPA
Harmonized
Product Chemistry Templates**

June 2, 2016

Presentation Outline

- Background
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 - What are the harmonized templates
 - Why develop harmonized templates
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Background

- During a US/Canada product chemistry workshop held in November 2011, EPA and PMRA noticed harmonization on many, but not all, data/guideline requirements for product-specific data. These differences, as products were reviewed by the respective countries, often created issues during the joint review process.
- Project created under the United States-Canada Regulatory Cooperation Council (RCC) Work Plan on Crop Protection (Action Item 3:“Address Obstacles to Joint Registration”)
- Currently part of RCC Work Plan under Joint Template for Product Chemistry Reviews (<http://trade.gov/rcc/documents/b2-pmra-epa-wp-assessment-template.pdf>)

Objective - Project

- Develop a single product chemistry template per product / application
 - Created by applicant and submitted to regulatory authority
 - Used by reviewer and modified as appropriate, based on review of supporting data
 - Shared with other regulatory authorities (if applicable)
- Outcome
 - Streamline the OECD Tier II summaries for product chemistry data
 - Use of templates will enhance all product chemistry evaluations including workshare and secondary review of joint actions

Objective - Webinar

- Present progress to date
- Encourage use of templates by applicants

What are the Harmonized Templates?

- New Product Chemistry Templates
 - Hybrid of NAFTA and OECD requirements / data identifiers
 - Integrate the best of both formats to benefit applicants, reviewers and potentially other regulators wishing to make use of the reviews
- A new way of submitting product chemistry characteristics/data in a harmonized format
 - Data in the templates will address all of EPA's and PMRA's product chemistry guidelines. Agency data requirements (e.g. GLP requirements) have not changed.
 - When there is a guideline / data requirement difference between EPA and PMRA, the template indicates this and directs the applicant on how to respond
- No additional data is required. The product chemistry templates simply reorganize how the data is submitted.

Why Develop Harmonized Templates?

- Build on the OECD-format documentation
 - Existing OECD format for pesticide review
 - Tier II summaries generated by registrants (dossier)
 - Regulators generate final evaluation (monograph)
 - Challenges associated with OECD format for product chemistry reviewers
 - Reliance on four volumes rather than one
 - Inclusion of multiple products rather than one
 - Structure lends itself to organizational challenges and redundancies
 - PMRA and EPA – product-specific regulatory systems
 - Better suited to a single-document evaluation
 - Templates are a hybrid of NAFTA-template and OECD requirements / data identifiers
 - One template for technical-grade products and another for formulated (e.g., end-use) products

Why Develop Harmonized Templates?

- Submitting the product chemistry data in the harmonized templates to both countries will allow both Agencies to more efficiently review the product chemistry requirements and provide secondary concurrence, as well as reducing the propagation of errors via rekeying data.
- PMRA and EPA worked together in designing the format of the templates, in an effort to make them streamlined and informative for both industry and regulators.

Expected Outcomes

➤ Efficiency

- Summarized product chemistry data would be in one template vs. four volumes
- Better alignment with EPA and PMRA regulatory systems, based on one product per application / review
- Each regulatory authority receives the same template
 - Facilitates discussion of reviews/concerns in joint reviews and workshares

➤ Consistency

- In the past, differences in approach led to challenges in the joint review process
- Use of the new harmonized template with associated guidance is anticipated to enhance exchangeability of reviews

Demo of Technical-Grade Product Template

Demo of Formulated (End-Use) Product Template

Next Steps

- Short term:
 - Call for the registrant community to use the templates for PMRA and EPA submissions.
 - Provide feedback based on use experience
- Long term:
 - Full scale adoption of templates for all applications