Biopesticides Registration Improvement Course

Joint Reviews

Martha Farkas
Registration Directorate
Pest Management Regulatory Agency
Health Canada

Driss Benmhend
U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticide and Pollution Prevention Division

Health Canada Santé Canada

Outline

- Definition
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- Background/Progress to Date
- Criteria for Eligibility
- Process
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Joint Reviews - Definition

- Formal process with negotiated timelines
- Workload is split among participating regulatory authorities
- Reviews of data are exchanged and peer-reviewed
- Goal is to reach a harmonized and simultaneous registration decision

Joint Reviews - Benefits

- More efficient registration process

- Evaluation of new pesticides (active ingredients and new uses) at the same time among participating countries (e.g., Canada, U.S.) while meeting country specific requirements

- Strengthens the regulatory process (e.g. peer-review process, best available science)

NOTE: Program is evolving and expanding as regulatory authorities/applicants build upon their experiences

Joint Reviews – Background / Progress to Date

- The Joint Review program was launched in 1996 as a NAFTA initiative, and applies to Conventional Chemical, Biopesticide, and Antimicrobial products
- The first biopesticide was registered under the NAFTA Joint Review program in 1999
- The Joint Review program has now expanded to include "Global" Joint Reviews (conventional chemicals only to date) and "Second Entry" Joint Reviews (e.g., use expansions)
- Progress to date wrt Biopesticide JRs (as of March 1, 2011):
  - Registered: 7 actives (+7 associated end-use products)
  - Under Review: 8 actives (+ associated end-use products)
  - Anticipated: 7 actives ingredients (+associated end-use products). Note: Preliminary discussions underway for first possible "global" joint review of a biopesticide

Joint Reviews – Criteria for Eligibility

1) Criteria for New Active Ingredients and Associated End-Use Products:
   - active ingredient cannot be registered in either country
   - complete database needs to be available at the time of application
   - proposed use pattern/formulation type is the same for countries involved
   - timeline for application (as well as marketing) is similar for countries involved

Joint Reviews – Criteria for Eligibility (cont'd)

b) Criteria for "Second Entry" Joint Reviews

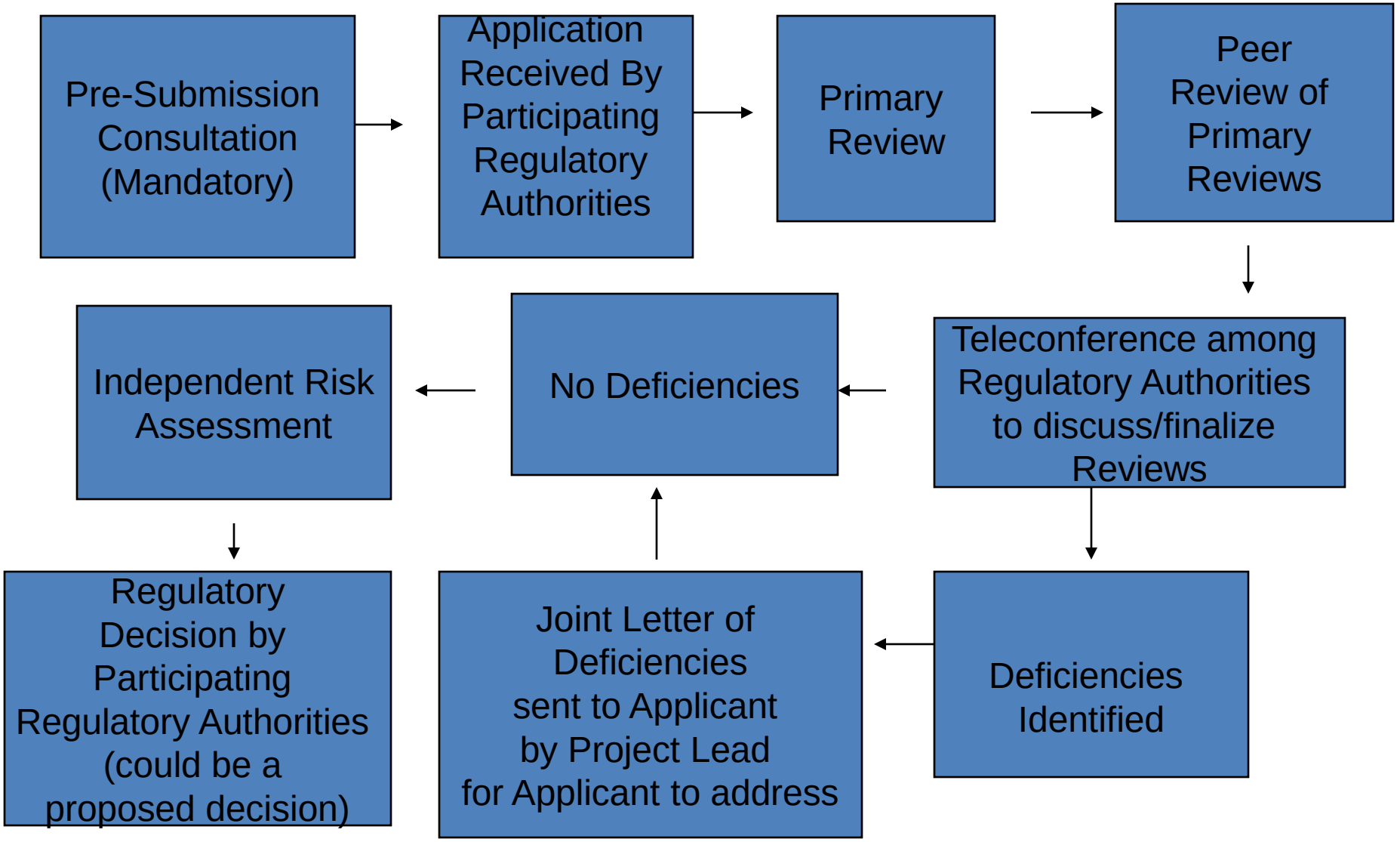
For each country involved:

- Active ingredient(s) must be registered
- There must be a complete database by modern standards on file for the active ingredient(s)
- Proposed uses (that are applicable to all countries) and formulations must be new
- Formulations should be the same among countries
- Timeline for application is the same
- For applications involving formulation changes, corresponding label uses should be the same.
- For new sources of registered active ingredients, the new source(s) of the active ingredient must be new / the same source(s).

Joint Reviews - Process

- Early pre-submission consultation between the applicant and the participating regulatory authorities is mandatory.
- A joint review pre-submission consultation is required to determine:
    - whether a joint review is possible
    - to establish joint data requirements for a specific product or the type of information required to support a data waiver
    - to establish the review time-lines
- A project lead is selected from the participating regulatory authorities
- A worksplit is decided by the participating regulatory authorities, and a project plan is developed for regulatory use which includes key milestones with associated timelines.

Joint Reviews – Process (cont'd)



Joint Reviews – Considerations

- NAFTA labels:
  - Initiative under the NAFTA Technical Working Group on Pesticides.
  - Allows for cross-border movement of approved products between Canada and the United States to the benefit of users, without compromising the integrity of the jurisdictional regulatory systems.
  - NAFTA label initiative can be considered for any pest control product registered in both Canada and the U.S. for which the formulation is equivalent in both jurisdictions.
  - To have a NAFTA labelled product, the product container needs to display an approved/joint American and Canadian primary panel (i.e., “base label”) with separate American and Canadian “Directions for Use”.
  - Pre-submission consultation process is an appropriate forum to initiate discussions regarding the NAFTA label option.

Joint Reviews - Challenges

- Pre-submission Consultation Phase:
  - To initiate the process, the applicant needs to:
    - contact participating regulatory authorities at the same time with the joint review proposal
    - submit the proposal at least 6 months to one year in advance of the anticipated application submission
- Application Submission:
  - Applications/data need to be submitted to participating regulatory authorities at the same time
  - Applicant needs to reply in a timely fashion to all identified deficiencies

References

- Joint Review of Biopesticides (i.e., Microbials and Biochemicals).
  - U.S. Site: http://www.epa.gov/oppfead1/international/naftatwg/projects/riskredu/microbial-update.pdf
  - Canadian Site: In the process of being translated for bilingual posting on Health Canada's website.

- Updated Procedures for the Joint Review of Biopesticides (i.e., Microbials and Biochemicals).
  - U.S. Site: http://www.epa.gov/oppfead1/international/naftatwg/index.html
  - Canadian Site: In the process of being translated for bilingual posting on Health Canada's website.

- NAFTA Label Guidance
  - U.S. Site: http://www.epa.gov/oppfead1/international/naftatwg/labels/implem-labels.htm
  - Canadian Site: http://www.hc-sc.gc.ca/cps-spc/pest/agri-commerce/import/nafta-alena-eng.php / http://www.hc-sc.gc.ca/cps-spc/pest/agri-commerce/import/nafta-alena-fra.php

Questions