

US EPA ARCHIVE DOCUMENT



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas
Le groupe de travail technique de l'ALENA sur les pesticides

Biopesticides Registration Improvement Course

“BRIC”

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Potomac Yards South



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Biopesticide and Pollution Prevention Division



Goal of BRIC

US, Canadian, & Mexican Authorities:

- Described Biological Pesticide Registration Processes
- Described Common Problems in Registration Applications (Administrative & Data Submissions)
- Provided Advice for **Improvements**
- Discussed Electronic Data & Label Submission
- Discussed Experience & Benefits of NAFTA Joint Reviews (PMRA & EPA Only)

Agenda & Presentations

<http://www.epa.gov/pesticides/biopesticides/nafta-bric/agenda.pdf>



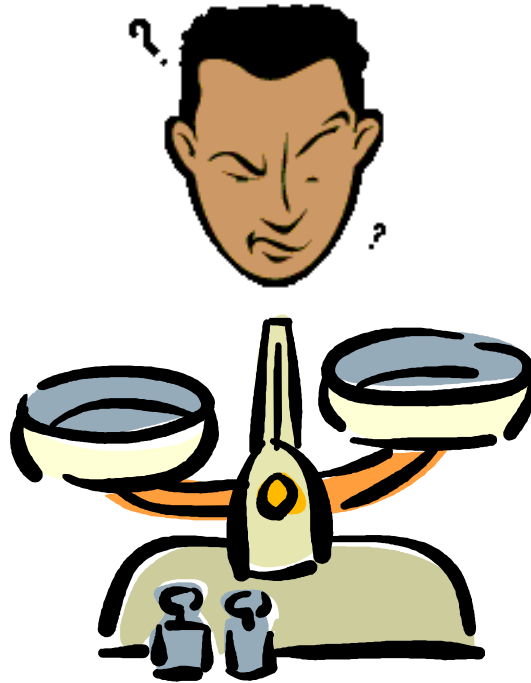
Common Issues

- **Administrative documents incomplete, missing**
 - ✓ Signatures/dates missing, incorrect agent
 - ✓ 86-5 Format Failure
- **Data requirements not fully addressed**
 - ✓ Inappropriate, unsupported data waivers
 - ✓ Cited/submitted data for “similar” AI
 - ✓ Equivalence to AI not demonstrated
 - ✓ CSF Incomplete or Inaccurate
 - ✓ Alternative Data Cited, Not Provided
 - ✓ Literature “Bombs” or “Dumps”



Common Issues

Guideline
Studies?



Waivers,
Alternate
Data?

↑ CO\$T

↓ Risk of Renegotiation,
Not Grant, Denial

↓ CO\$T

↑ Risk of Renegotiation,
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Solutions

- Pre-submission Meetings are *Beneficial*
- Address All Data Requirements & Justify Waivers *Individually*
- Read Guidelines for *Each* Data Requirement
- Alternative Data
 - ✓ Equivalence of test material to proposed product/ai
 - ✓ Explain how it satisfies data requirement
 - ✓ Submit literature or study, not just citations



Solutions

- **Make Sure ALL Forms are Included, Filled Out**
 - ✓ **Signatures = Agent of Record**
 - ✓ **Contact Information**
 - ✓ **Dates**

- **Data Volumes (Including Waivers) in PR Notice 86-5 Format**
 - ✓ **Confidentiality & GLP Statements**



Solutions

- Submit Applications *Well in Advance* of Use Season
- Allow *Extra Time* to Address Problems Identified During EPA's Review
- Allow *Extra Time* for State Registrations



BRIC - CCRB - CAAB

“Free” Advice

It's Better to **Ask Before Submitting**
an Application

Deficiencies Cost **Time**

and **Money** ...

So, tell me ... HOW many negotiations have you had with EPA?





BPPD's Process Improvements

- **Application received**
- **PIA Completeness Screen - 21 days**
- **Action forwarded to BPPD**
- **Submission Readiness Team (SRT)**
 - ✓ **Administrative Documents**
 - ✓ **Data, Waivers**
- **Fail - 75 Day Letter - Application does *not* move to next phase!**





BPPD's Process Improvements

- **Pre-Submission Meetings:**
 - ✓ **Focus on Common Problem Areas**
 - ✓ **Provide “Road Map” & Registration “Tool Kit” (on Disk?)**
- **Encourage Pre-Submission Follow-Up**
 - ✓ **Ask Questions During Package Preparation - Before Submitting Applications**