



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

Submission Pitfalls of Biopesticide Applications at U.S. EPA - BPPD

Mike Mendelsohn, Regulatory Action Leader

Members of the RAL Coffee Club

Biopesticides and Pollution Prevention Division (BPPD)

Labeling Issues

- ◆ Label Changes Not Highlighted
- ◆ Label Ingredient Statement Does Not Match CSF
- ◆ Product Name on Label Does Not Match CSF
- ◆ Graphic Description on Draft Labels (Helpful)



Confidential Statement of Formula (CSF) Issues

- ◆ CSF with Original Signature Not Sent
- ◆ Manufacturing Use Product Used in End-Use Product Needs to Parenthetically Note the Pure Active Ingredient; e.g. 50% Pure
10 lbs = 5 lbs Pure in End-Use Product



Confidential Statement of Formula (CSF) Issues Continued

- ◆ CSF for Microbial Does Not Include Viability Measure, e.g., CFU/g
- ◆ CSF for Microbial Lacks Nationally Recognized Culture Collection Number
- ◆ CSF Lists Source as Commodity Rather than Specific Source



Forms & Administrative Issues

- ◆ Incomplete Data Matrix - Narrative Describing How Data is Satisfied Helpful
- ◆ Missing Forms; e.g., Formulator=s Exemption and Data Compensation
- ◆ Formatting 86-5 Deficiencies; e.g., GLP Statements and Study Director=s Signature
- ◆ Duplicate Data Submission Rather than Citation



Forms & Administrative Issues Continued

- ◆ Signatures and Dates Missing Where Needed
- ◆ Packaging Information is Missing on Application Form
- ◆ Written Request for Time Extension Not Submitted



Data Issues

- ◆ Scientific Rationale for Data Waiver Requests Missing
- ◆ Inappropriate Test Material (TGAI vs. EP) and Test Levels
- ◆ QA/QC Data Lacking for Microbial Products
- ◆ No Pre-Submission Meeting
- ◆ Citations Without Copies of Literature

