US ERA 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

EPA Organic Labeling



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Overview for EPA's Organic Labeling Program

- EPA's Organic Labeling Program exists to assist USDA's National Organic Program.
- The terms of EPA's program are laid out in Pesticide Registration (PR) Notice 2003-1.
- EPA's organic labeling is processed by a work group. Allowed claims are verification of a pesticide's allowability under the NOP.



Resources for your subject

• Online CFR for USDA (7 CFR Part 205):

http://ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&tpl=/ecfrbrowse/Title07/7cfr205 main 02.tpl

- Guidance for EPA's Labeling Program (PR Notice 2003-1): http://www.epa.gov/PR_Notices/pr2003-1.pdf
- USDA's NOP website: http://www.ams.usda.gov/AMSv1.0/nop



Commonly Seen Problems / Issues

- Incomplete submissions –applications to add organic claims should contain a manufacturing process and a complete compositional accounting.
- Inadequately vetting inputs EPA reassessed ingredients, unaccounted for inerts in MPs, non-compliant proprietary mixes, ingredient spec sheets that don't add up to 100%.
- Not taking use sites into consideration.
- Assuming an OMRI claim does not require full EPA review.



Solutions for Improving Applications

Better Communicate Standards for Review

- Product Chemistry: EPA and USDA want details on all inputs. How are oils extracted? Are the ingredients naturally-occurring (i.e. are they biochemical or biochemical-like)? Are the minerals mined? Are natural ingredients synthetically produced? Does the broth or the reagent get consumed?
- CSF Requirements: Provide all active CSFs, a statement voiding other CSFs, a complete list of suppliers, MSDS/spec sheets from each of those suppliers accounting for 100% of the composition.
- Check National List Requirements: Have applicants cross-check application with USDA National List requirements.
- Check PR Notrice and LRM Requirements: Take the time to assure use sites and NOP language comport with PR Notice 2003-1 and the LRM.
- Full Diligence on OMRI Applications: An OMRI claim on a label is an EPA NOP claim and requires full review.



Uncertainties

- There are many gray areas in the NOP. To resolve uncertainties:
 - Use the online resources available on USDA and EPA's NOP websites. You will find copies of rules, policy letters, standards of review, contact info. etc...
 - There are many channels for resolving disagreement and misunderstanding regarding EPA NOP claims. EPA will consider unique circumstances. EPA decisions may be subject to USDA re-review. The NOSB provides ultimate recourse.
 - Call or write for guidance:

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