

bpia

Biopesticide Industry Alliance



Biopesticide Industry Alliance Inc.

For more information, contact:

Bill Stoneman
Executive Director
(202) 536-4602

bstoneman@biopesticideindustryalliance.org

<http://biopesticideindustryalliance.org>





TECHNOLOGY SCIENCES GROUP, INC

AMY PLATO ROBERTS | SENIOR REGULATORY CONSULTANT

TEL: 202.684.2784 | FAX: 530.757.1299 | EMAIL:

AROBERTS@TSGUSA.COM | SKYPE: AROBERTSTSG

VISIT US AT WWW.TSGUSA.COM

BPIA's Mission Summarized

To increase the awareness of Biopesticides as effective products, realize further improvements to the regulatory process and provide valuable networking opportunities for members and affiliates.



BPIA's Goal

Our goal is to be the leading source of reliable information for biopesticides and to improve product stewardship, performance and factual promotion.



BPIA's Goal

As a business association we plan to grow guided by these common objectives:

- To communicate the benefits of biopesticides technologies as effective products.
- To promote industry standards ensuring that our products are highly respected, consistently of high quality and performance, reliable and widely used.
- To continue to develop strong working relationships with the authorities entrusted with regulating pesticides and to expand our position with these authorities and a dependable resource



How much will it cost and how long will it take to register this biopesticide at EPA (US) and PMRA (Canada)?



Theoretically, less than a conventional pesticide

Specific Biopesticide Regulatory Issues in North America

- Timeliness as related to market needs, timing and the needs of developers and investors.
- Very late notice of data deficiencies or issues.
- Unprecedented new data requirements with late notice in the review timelines.
- Less staff and less resources in the regulatory agencies = slower review process. Need for process improvements to ease the burden in the event more resources are not possible.



Specific Biopesticide Regulatory Issues in North America

Other EPA-specific issues:

- Potential issues with tolerance exemptions on some a.i.s that have very high toxic endpoints.
- EPA trend in the Biopesticide Division for making risk based decisions, not risk-benefit based decisions.
- Very slow and low priority reviews of “FAST TRACK” amendments. PRIA (fee for service) actions always takes the time and is highest priority.



Key Milestones

- Biochemical Classification - EPA
- Presubmission Meeting – Registrant/EPA
- Submission preparation - Registrant
 - Studies
 - Waivers
 - Assemble submission
- Submission target date - Registrant
- Front-End Screen – EPA
- 45/60 Day Technical Screen - EPA
- Science reviews - EPA
- PRIA Date – mandated by law; predetermined by action
 - Determines fee
 - Decision date, not a guarantee of decision or that all data supplied satisfies requirements



Specific Biopesticide Regulatory Issues in North America

USDA National Organic Program issues:

- Recommendation of the NOSB to the NOP for full review of all the former 4b inerts for their fit to the national organic standards – previously/currently allowed in biopesticides
- Occasional inconsistency in review of biopesticides by third party reviewers to the organic standards
- Potential for the USDA NOP to revisit review of the former 4a list of inerts of minimal concern (now 25b inerts).



Specific Biopesticide Regulatory Issues in North America

USDA-APHIS issues (relates to microbials only):

- Inconsistent application of APHIS permits (PPQ 526) for importation and movement of registered microbial pesticides

Domestic strains produced outside the USA
EPA registered foreign microbial strains for importation to the USA



Thank you!

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BIOPESTICIDE INDUSTRY ALLIANCE

