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1
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Emergency Exemptions –
Section 18 Petitions

- Emergency exemptions from registration: 4 Types – Crisis, Specific, Public Health and Quarantine.
- EPA now required to establish a temporary tolerance (FQPA)
- States have authority to issue crisis exemptions for 15 days unless followed by a specific, quarantine or public health petition.
- EPA issues the other 3.
- See 40 CFR 166 and EPA guideline requirements.

2
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TYPES OF EXEMPTIONS

- Specific (S): (non-routine emergency situations)
- Crisis (C): (immediate response to a pest problem)
- Quarantine (Q): (protection of the U.S. and its territories)
- Public Health (PH): (risk to human health)

3

EMERGENCY EXEMPTIONS

- EPA performs multidisciplinary risk assessments
- EPA will not approve a request if the pesticide use may cause unreasonable adverse effects or if emergency criteria are not met
- Under FQPA, EPA must establish time-limited tolerances for emergency uses
- EPA must find that there is reasonable certainty that no harm will result from aggregate and cumulative exposure by humans
- EPA consults with FDA, USDA and CDC on requests that have bactericides/antimicrobials or antibiotics as the pesticide(s) of choice.

4

EXEMPTION REQUESTS

- FIFRA Section 18 authorizes EPA to allow states to use a pesticide for an unregistered use for a limited time if EPA determines that emergency conditions exist
- States, USDA, and USDI can request exemptions
- EPA attempts to make decisions on requests within 50 calendar days

5

CITRUS: SPECIFIC EXEMPTION REQUEST

- The Registrants:
 - AgroSource, Inc.
 - NuFarm Americas, Inc.
- The Products:
 - FireWall™ 50 WP
 - FireLine™ 17 WP
 - Mycoshield®

6
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CITRUS: SPECIFIC EXEMPTION REQUEST CONT'D

- The Pest Vector:
- Asian Citrus Psyllid (ACP) (*Diaphorina citri* Kuwayama)

- The Disease:
- Huanglongbing (HLB) (*Candidatus Liberibacter asiaticus*)

7
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CITRUS: SPECIFIC EXEMPTION REQUEST CONT'D

- The Active Ingredients:
- Streptomycin Sulfate - 65.8%
- Oxytetracycline Hydrochloride – 18.3%
- Oxytetracycline Calcium Complex – 31.5%

8
3/23/2016

SPECIFIC EXEMPTION CHRONOLOGY

- December 4, 2015: Commissioner Putnam submits a specific exemption to EPA for review and approval.
- March 2, 2016: Division Director Rackley schedules a conference call with EPA for updates on the pending request.
- March 4, 2016: Commissioner Putnam issues a crisis declaration for use of the 3 antimicrobial products.

CRISIS DECLARATION CHRONOLOGY

- March 4, 2016 thru March 22, 2016: Pesticide registrants distribute their products for citrus growers to purchase and apply. TPR/FFVA, CRDF, UF, FDACS and registrant field specialists assist in providing answers to grower questions.

Why This Exemption Is Unusual

- Two pesticide registrants
- Three product formulations
- Two active ingredients
- Two sets of field efficacy trials
- Two sets of field residue trials
- Two sets of risk reports
- The potential for extensive field resistance monitoring in a huge crop group

11
3/23/2016

WHAT NOW.....?

- Applications of these three (3) antimicrobial products will continue (federal law) until EPA rules on the 2015 specific exemption request.
- If approved, the citrus industry will have one (1) year of uninterrupted use.
- Recertification for 2017-2018 is possible if results are promising after one year of use.

FINALLY, WE HOPE.....

-to improve tree health and suppress the effects of Huanglongbing (HLB) disease season-long/year-round on infected citrus trees !!!!!

13
3/23/2016

QUESTIONS?

14
3/23/2016