

A large, faint watermark of the United States Environmental Protection Agency (EPA) logo is centered in the background. The logo consists of a circular seal with the words "UNITED STATES ENVIRONMENTAL PROTECTION AGENCY" around the perimeter and a central emblem featuring a stylized flower or plant.

# ***Regulating Antibiotic Use on Crops***

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## *Antibiotics as Pesticides*

- Antibiotics used on crops are pesticides under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act)
  - EPA required to determine that pesticides are not expected to cause unreasonable adverse effects to human health or the environment
- EPA assesses potential development of antibiotic resistance as an adverse effect under FIFRA



## *Regulating Antibiotics as Pesticides*

- FIFRA requires EPA to consider the costs and benefits before registering a pesticide
  - For antibiotic pesticides, benefits can be high
  - Data limitations can create some uncertainty about the potential for resistance to develop
- Risk analysis is different, benefits analysis same as for other types of pesticides



## *Benefits of Antibiotics on Crops*

- Bacterial pest pressure appears to be increasing on agricultural crops (much as it is on human health)
  - Number of antibiotic pesticides registered for use on crops is limited (three active ingredients)
- Uses may be critical to maintaining health of a single year's harvest or even viability of the industry (e.g., citrus greening)



## *How Risk Assessments of Antibiotics Differs from Conventional Pesticides*

- Conventional pesticide assessments evaluate
  - Human and ecological health, environmental fate and effects, and benefits review (use patterns and pests, alternatives, and comparative performance)
- Antibiotic assessments also evaluate:
  - Potential for resistance, including a specific isolate study based on the active ingredient, a qualitative analysis, and consultation with FDA/CDC/USDA



## *Assessing for Resistance*

- Goal: to reduce the potential for resistance, while allowing availability of antibiotics to protect plant and crop health
- Risk-reduction techniques may mitigate risks
  - More targeted application technique => lower risk
  - Resistance mitigation on a case-by-case basis, depending on crop and antibiotic
- Agricultural practices may also reduce the need for antibiotics on crops



## *Assessing for Resistance*

- Science of resistance contains many unknowns – changing all the time
  - Quantitative risk assessment is not possible
- EPA uses qualitative assessment, adapted from FDA's Guidance for Industry #152
- Results from three categories integrated into overall conclusion of Low, Medium or High
  - Potential of the proposed use to contribute to antibiotic resistance in human pathogens



## *Assessing the Risk: A Collaboration*

- CDC, FDA, USDA consulted in risk assessment and management phases
  - Consulted on adapted process, predevelopment
  - EPA shares results, soliciting further comments
  - Risk mitigation/monitoring options discussed
- Options for refining the risk assessment through special studies or other means
- EPA first began consulting with CDC on antibiotic pesticides in 2005





## *Registration Limitations*

- EPA sometimes requires users or registrants to submit monitoring data
  - May show whether the use is likely to convey resistance or may detect any cross-resistance
- EPA may also issue a time-limited registration
  - Resistance issues in plant pathogenic bacteria may not be known immediately after application
- Cooperation and collaboration with federal partners is expected to continue



## *Conclusions*

- EPA uses a robust, science-based process to evaluate potential resistance developing from agricultural use of antibiotics
- Federal partners provide up-to-date input from internationally recognized experts into the pesticide risk assessment
- Science will continue evolving
  - EPA will continue to adjust its assessment and decision processes accordingly