

# EPA vs. FDA: Regulatory War of the Worlds Over Antimicrobials in Food Processing Substances

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October 10, 2007

# History

- Due to a drafting error, the Food Quality Protection Act (FQPA), enacted in 1996, transferred jurisdiction for antimicrobial food contact uses, which historically had been regulated as food additives by FDA under FFDCA §409 to EPA under FFDCA §408.
- In 1998, the Antimicrobial Regulation Technical Corrections Act (ARTCA) partially restored FDA jurisdiction for food contact antimicrobial pesticides while also continuing EPA's regulatory authority for these same compounds.

# Current State of Affairs

- The current regulatory world for substances used in food processing plants is a highly complex scheme of both separate and shared responsibility between EPA and FDA.
- Compliance requires careful analysis.

# EPA - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

- Pesticides are regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §136(a) et seq.
- “Pesticide” means “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” FIFRA §2(u)(1).

# EPA - FIFRA

- “Pest” means “(1) any insect, rodent, nematodes, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (**except viruses, bacteria, or other micro-organisms on or in living man or living animals**).”

FIFRA §2(t).

# EPA - FIFRA

- Pests are further defined in EPA's regulations as "[a]ny fungus, bacterium, virus, or other microorganisms, except for those on or in living man or other living animals and those on **or in processed food or processed animal feed, beverages, drugs (as defined in FFDCA § 201(g)(1)) and cosmetics (as defined in FFDCA §201(i)).** 40 CFR §152.5(d).

# FDA – Federal Food, Drug, and Cosmetic Act (FFDCA)

- FFDCA regulates residues of substances in food.
- Section 409, administered by FDA, regulates “food additives,” substances which result or may reasonably be expected to result in becoming a component of food.

# EPA – Federal Food, Drug, and Cosmetic Act (FFDCA)

- Pesticide chemical residues are not regulated as food additives.
- Section 408, administered by EPA, regulates “pesticide chemical residues” in food.



# Joint Regulation

Some antimicrobial uses are regulated by FDA as food additives under FFDCA §409 *and* regulated by EPA as pesticides under FIFRA:

- ❑ Antimicrobials used as preservatives in articles with food contact with no intended ongoing effect on the articles or on the articles' food contact surfaces ("Exempt" treated articles).
- ❑ "Exempt" treated articles that may fall under this category include lubricants or cleaners used in food processing facilities in which a preservative is used to **"protect the treated article or substance itself."** 40 CFR §152.25(a) and EPA PR Notice 2000-1.

# Joint Regulation

Some antimicrobial uses are regulated by FDA as food additives under FFDCA §409 and regulated by EPA as pesticides under FIFRA:

- ❑ Antimicrobials applied in or on food packaging.

# Joint Regulation

Some antimicrobial uses are regulated by FDA as food additives under FFDCFA §409 *and* regulated by EPA as pesticides under FIFRA:

- Antimicrobials applied in water contacting food in facilities where food processing occurs for which claims to reduce microbial count in the water are made.

## EPA - Regulated as pesticides and subject to tolerances under FFDCA §408

- Antimicrobials applied on raw agricultural commodities (no processing) in the field or in facilities where no other processing occurs (e.g., packing houses).

## EPA - Regulated as pesticides and subject to tolerances under FFDCA §408

- Antimicrobials used on permanent and semi-permanent surfaces (e.g., hard surface sanitizers and disinfectants).
  - Pesticide registration under FIFRA and a tolerance or tolerance exemption under FFDCA §408.

## EPA - Regulated as pesticides and subject to tolerances under FFDCA §408

- Antimicrobials used in treated articles in which the article claims to have a pesticidal effect on the surface of the article.
  - “Non-exempt” treated article.
  - Pesticide registration under FIFRA and a tolerance or tolerance exemption under FFDCA §408.

# EPA – Approval Process

- FIFRA registration.
- Tolerance petition under §408.

# FDA – Approval Process

- Food contact notification; or
- Food additive petition; or
- GRAS (Generally Recognized as Safe).



# EPA and FDA Review Process

- Both agencies evaluate similar endpoints, but they do it in different ways.
- Generally, EPA requires more data than FDA, including:
  - 90-day dog
  - Reproductive toxicity
  - \$750,000 or more for these two studies

# Enforcement

- EPA
  - Civil penalties.
  - Criminal penalties.
- FDA
  - Food becomes adulterated.
  - Voluntary or mandatory recalls.

# Example 1: Lubricant in Food Processing Plant

- Best Ever Lubricant contains antimicrobial technology that protects against microbial agents causing odors and deterioration.
  - Regulated by FDA under FFDCA §409 as a food additive.
  - Regulated by EPA under FIFRA (pesticide registration required for antimicrobial).
    - FIFRA registration will require data for food contact.
  - Best Ever Lubricant falls under EPA's treated article exemption (40 C.F.R. §152.25(a)) and does not require registration.

## Example 2: Lubricant in Food Processing Plant

- Super Duper Lubricant with new proprietary antimicrobial technology protects against a variety of microbial agents including molds and gram-positive and gram-negative bacteria. It's especially effective against Listeria, E coli, and Salmonella.
  - Regulated by EPA under FFDCA §408 (tolerance or tolerance exemption) and FIFRA (pesticide registration for both antimicrobial and Super Duper Lubricant).
  - Claims go beyond “exempt” treated article claims, so registration required. EPA’s PR Notice 2000-1 discusses acceptable treated article claims, available at [http://www.epa.gov/PR\\_Notices/pr2000-1.pdf](http://www.epa.gov/PR_Notices/pr2000-1.pdf).
  - Public health claims are made. Therefore efficacy data must be supplied using EPA approved protocols.

## Example 3: Hard Surface Sanitizer in Food Processing Plant

- Jiffy Clean is a concentrated cleaner-disinfectant and no-rinse sanitizer for use in food processing plants. Jiffy Clean is effective against Salmonella, Staphylococcus and Pseudomonas.
  - This product is a pesticide that also cleans.
  - Regulated by EPA under FFDCA §408 (tolerance or tolerance exemption) and FIFRA (pesticide registration for Jiffy Clean).
  - Efficacy data must be submitted to EPA and accepted.

# Summary

<b>Antimicrobial Uses</b>	<b>FDA FFDCA §409</b>	<b>EPA - FIFRA Registration</b>	<b>EPA –Tolerance Exemption Under FFDCA §408</b>
To preserve water contacting food where food processing occurs	X	X	
To sanitize processed food in a food processing plant	X		
Raw agricultural commodities		X	X
Preservatives in articles with food contact (exempt treated articles)	X	X	
Food packaging preservatives	X	X	
Permanent and semi-permanent surfaces		X	X
Antimicrobial treated articles (non-exempt) (e.g., lubricant that sanitizes surfaces or claims to kill public health organisms)		X	X

# Summary

- Antimicrobials used in lubricants and hard surface cleaners must be registered with EPA.
- If a substance is GRAS (e.g., ascorbic acid), FIFRA registration still is required.
- Registration of the antimicrobial will require EPA food contact data.

# Summary

- Any lubricant or cleaner must itself be registered if it makes active claims of pesticidal activity, e.g., going beyond claims that the lubricant is protected against degradation.
- Under FFDCA §409, any lubricant that claims to prevent growth of “public health organisms” falls outside the “treated article exemption” from registration. Such products must be registered under FIFRA and submit efficacy data using EPA-approved protocols to support the claim.



