Antimicrobial Product Claims
EPA Labeling & Registration Issues

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EPA requires registration of “pesticides” under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. §§ 136-136y)

“Pesticide”—any substance intended for preventing, destroying, repelling, or mitigating any “pest” [40 CFR § 152.3]

“Pest”—any fungus, bacterium, virus, or other microorganism, 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, and cosmetics. [40 CFR § 152.5]
Pesticide Registration

Intent test: Is the product intended for a pesticidal purpose?

- Types of advertising
- Product labeling claims
- Manner of sale
- Targeting of advertising
- “Totality of the circumstances”
Treated Articles Exemption

- Exemption from registration
  - Manufactured goods containing preservatives
    [FIFRA § 25(b); 40 CFR § 152.25]

- Elements:
  - Use a registered pesticide
    - use specific
    - broad, general use patterns insufficient
  - To protect the article
    - No broader claims implied or explicit
Treated Articles Exemption History

- Adopted in 1975, preservatives in paints and treated wood products
- 1997 EPA enforcement actions
  - Paints, toys, sponges, cutting boards, etc.
  - Stop Sale, Use and Removal Orders
  - Civil penalties
  - Recalls, relabeling and placarding
- Antimicrobial Treated Articles Coalition (ATAC)
PR Notice 2000-1

- EPA interpretive guidance on the treated article exemption:
  - Pesticide specifically registered for such use
  - Public health vs. Non-public health claims
  - Use of disclaimers
  - Use of trademarked names
- “Safe Harbor” Guidance—not binding!
Treated Article Claims

- Claims must be limited to protection of the article itself
  - *e.g.*, Mold and mildew control:
    - Mold or mildew resistant
    - Controls odors
    - Inhibits growth of microorganisms that cause spoilage of the *<article>*

- Use limiting language to reduce implied claims

- No-no’s: Implicit claims of beneficial impact on human health
  - No “allergen” claims
Public Health Claims

- Implicit or explicit “public health” claims that are impermissible, e.g.:
  - Claims to control specific microorganisms infectious to man (e.g., *E. Coli, Streptococcus*).
  - Sterilant, disinfectant, virucide, or sanitizer claims.
  - General claims of beneficial impact on public health by pesticidal means.
  - Unqualified claims of “antimicrobial” activity:
    - “antibacterial”
    - “germs”
“Antimicrobial” Claims

- Claims of “antimicrobial” activity
  - Only permissible when clearly qualified so no public health benefit is implied
  - e.g., “Antimicrobial properties built-in to protect the product.”
- Locate claims and qualifying statements together
- Give equal prominence
- Not the main product feature
Special precaution

- Claims may create the impression that the article provides protection against food-borne or disease-causing bacteria.
- Explicit disclaimer, e.g., “This product does not protect users or others from bacteria, viruses, germs or other disease-causing organisms.”
Trademarked Product Names

- Watch out for implied claims, or claims beyond protection of article itself
- Always assessed in context
  - On label or advertising?
  - Presence of disclaimers
  - Other relevant factors?
Permissible Treated Article Claim?

Example: Treated Hospital Gowns

“Resists stain and odor causing bacteria.”

“Antimicrobial protection built-in for a cleaner and fresher gown.”

“Provides an additional level of protection to combat microorganisms.”

“Provides a bacteria-resistant surface.”
Key Test: Customer Perception

- Will intended customers interpret the claims to extend beyond the article itself?
- How sophisticated is the intended customer?
- Carefully-designed customer perception surveys?
- Data BEFORE making claim
Commercial Speech Constitutional Issues

- FTC regulates false or deceptive claims
- Supreme Court Cases: least restrictive regulatory scheme;
  - See FDA cases on dietary supplement claims
    (Pearson v. Shalala D.C.Cir. 1999)
Regulating Potentially Misleading Speech

- Limits on Agency Power
  - Demonstrate “substantial interest” in limiting specific claims
  - Restrictions directly advance the asserted interest and
  - Must be reasonable
- Watch scope of actual pesticidal protection provided by the article
Dual FDA and EPA jurisdiction over antimicrobial treated surgical drapes, uniforms, hospital gowns, etc.

- EPA jurisdiction over antimicrobial intended to control microorganisms on the inanimate surface
- FDA jurisdiction over antimicrobial intended to prevent transfer of pathogens
Sharing Data with Customers

- Based on tests with finished materials
  - Necessary to register pesticide
- Generated with public health pathogens
  - EPA Guidance on efficacy testing
- NOT IN
  - Advertising
  - Label text
  - No identification of pathogens by customers
  - Confidentially!
  - Include disclaimers
Registering Treated Articles

Register if:

- Implied or explicit public health claims
- Claims for protection that extends beyond the article itself
  - *e.g.*, treated produce container inhibits growth of food spoilage bacteria
- Pesticide not registered for that specific use
Registering Treated Articles

- Active ingredient must be registered for the public health use
- Efficacy must support claims
- Claims significantly different from conventional sanitizers and disinfectants
Registering Treated Articles

- Difficult at best
  - No established performance standards or efficacy protocols for treated articles
  - Industry standard methods may need revision and validation before EPA accepts them
Registering Treated Articles

Issues

- Are claims for simply “reducing” microbial populations acceptable?
- Is a 3-Log reduction necessary?
- Are claims for supporting a more hygienic environment acceptable?
- Particularly in hospitals and schools?
Other Issues

- **Intermediates**
  - bulk products containing preservatives for further downstream processing
  - No recent enforcement action
  - Essentially unregistered pesticides.
  - Draft PR Notice being discussed
    - producers would register establishments
    - submit annual production reports
Other Issues

- Claiming the article contains an "EPA Registered" Pesticide
  - Implies government recommendation or endorsement
    - Is false and misleading if unlimited
- Refer to antimicrobial (and NOT article)
- Make clear protection of article
  - Always use disclaimer with "EPA Registered"
A Look Ahead…

- Need for amendment of the treated article exemption?

  ◆ Possible frameworks:

    ♦ Articles are not pesticides or are exempt pesticides if meet set efficacy standards
    ♦ Active ingredients are approved for use on certain articles if meet set efficacy standards