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## Pesticidal Devices: Legal Perspective

Michael Boucher  
McKenna Long & Aldridge LLP

December 9, 2014  
Ft. Lauderdale, Florida



# Products Regulated by FIFRA

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- Pesticides
  - Basic requirement is registration (FIFRA § 3)
- Devices
  - Exempt from FIFRA registration
  - Other FIFRA requirements apply
  - Some U.S. states require registration
- Application equipment
  - A “pesticide product” when sold or distributed with one (40 C.F.R. § 152.3)
  - But not a device when sold separately from a pesticide (FIFRA § 2(h))



# Devices – Basic Concepts

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- Defined in FIFRA § 2(h)
  - Any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest
  - Excludes application equipment when sold separately from the pesticide
- 1976 policy, 41 Fed. Reg. 51,065 (Nov. 19, 1976)
  - Article that uses physical or mechanical means against any pest is a device
  - Article that incorporates a substance or mixture intended to control any pest is a pesticide



# Devices – EPA Policies

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- 1976 policy declares many products to be devices
  - Ultraviolet light systems, ozone generators, water and air filters (except those containing pesticides), and ultrasonic devices that claim to control fungi, bacteria, or viruses
  - High frequency sound generators, carbide cannons, foils, and rotating devices that claim to repel birds
  - Black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper that claim to kill or entrap insects
  - Mole thumpers, sound repellents, foils, and rotating devices that claim to repel mammals
- 1976 policy also exempts devices that
  - depend primarily on user performance (fly swatter)
  - operate to entrap vertebrate animals (mouse or fish trap)



## Devices – EPA Policies

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- 2007 policy on ion-generating equipment, 72 Fed. Reg. 54,039 (Sept. 21, 2007)
  - “Key distinction between pesticides and devices is whether the pesticidal activity is due to physical or mechanical actions or due to a substance or mixture of substances”
  - Declared as pesticides “ion generators that that incorporate a substance (e.g., silver or copper) in the form of an electrode, and pass a current through the electrode to release ions of that substance for the purpose of preventing, destroying, repelling, or mitigating a pest (e.g., bacteria or algae)”



## Devices – EPA Decisions

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- Since 1976, EPA has determined that the following products also are devices
  - Claim to control pests by electromagnetic or electrical emissions
  - Claim to control burrowing animals by product-caused subterranean explosions
  - Work by principles indicated in the 1976 policy but claim to control pests of different types
    - Sticky traps for rodents
    - Light or laser repellents for birds



# FIFRA Requirements for Devices

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- 40 C.F.R. § 152.500 lists the applicable FIFRA provisions and cites to EPA's 1976 policy
  - No false or misleading label statements (no “misbranding”)
  - Label must include EPA Establishment Number
    - **EPA enforcement has focused on wrong or missing Est. Nos.**
  - Producer must register its establishment, report production annually, keep books and records, and subject itself to EPA inspection
  - Importer must file Notice of Arrival with EPA Regional Office
  - Exporter must use prescribed export labeling (new § 168.71 created by Jan. 18, 2013 final rule)
  - U.S. states that register: CA\*, CO, DC, HI, IN, NM, OK, WY



## Case Study: Small Differences Matter

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- Bed bug trap with an electrical heat source – different configurations
  - Requires user-supplied CO<sub>2</sub>, sold with pest control claims: **DEVICE**
  - Requires user-supplied CO<sub>2</sub>, sold with pest control claims and biochemical lure: **PESTICIDE**
  - Requires user-supplied CO<sub>2</sub>, sold with detection claims and biochemical lure: **EXEMPT PESTICIDE**
  - Requires user-supplied CO<sub>2</sub>, sold with detection claims: **DEVICE?**





# Case Study: Appearances are Deceiving

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- Dental waterline “filter”
    - A “large quantity” of “redox media” in the product contains an “alloy” that “force[s] a radical change” in “the oxidation/reduction potential of the water”
    - Uses chemical substances to generate ions and cause chemical reactions that kill microbes in water



## Case Study: User-Supplied Pesticides

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- Vaporized hydrogen peroxide generator for “biodecontamination” of hospital premises
  - System #1 requires use of EPA-registered  $H_2O_2$ :  
**PESTICIDE**
  - System #2 requires user-supplied, unregistered  $H_2O_2$ :  
**DEVICE**
  - Could system #2 also be application equipment?
  - For system #2, how does EPA determine which efficacy claims constitute misbranding?
  - Spoiler: **System #2 now uses registered  $H_2O_2$**



## Case Study: User-Produced Pesticides

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- Salt sold with a claim that it can or should be used with a salt water chlorine generator to produce hypochlorous acid ( $\text{HClO}$ ) and sodium hypochlorite ( $\text{NaClO}$ ) to disinfect pool water

**PESTICIDE**

- A salt water chlorine generator that uses electrolysis in the presence of dissolved salt to produce  $\text{HClO}$  and  $\text{NaClO}$  in a salt water pool

**DEVICE**



## Case Study: User-Produced Pesticides

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- Is the pesticidal activity of a salt water chlorine generator due to physical or mechanical actions? What about an ozone generator?
- If users do not buy registered pool salt, how does EPA determine which efficacy claims for salt water chlorine generators constitute misbranding?



# Final Thoughts

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- Congress likely did not envision devices that use or produce substances or mixtures for pest control
- Industry could benefit from further EPA guidance and policy development to address novel devices
- FIFRA § 3(a) rules also could address special cases
  - “To the extent necessary to prevent unreasonable adverse effects on the environment, [EPA] may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under [FIFRA] and that is not the subject of an experimental use permit under [FIFRA § 5] or an emergency exemption under [FIFRA § 18].”