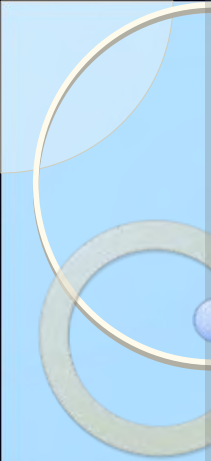


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Report of the Subgroup on Limited Factual Statements and Standards to the PPDC Workgroup on Comparative Safety Statements

April 23, 2009

Presented by Pat Quinn
Subgroup Chair



Background / Subgroup Charge

- Examine the potential basis for an OPP policy allowing expanded use of “factual statements” regarding antimicrobial products.
- Utilize existing standards, test methods and Federal policy to the extent possible.
- Avoid consumer misunderstanding; minimize EPA resource commitments while preserving review integrity.



Subgroup Composition / Process

- Diverse 20 member stakeholder group with EPA, industry, NGO, and state representation.
- EPA representatives from OGC, OECA, AD, DfE and elsewhere.
- Virtually all 20 Subgroup members participated in some or all of three (3) Subgroup conference calls on 3/3, 3/18 and 3/26.



Subgroup Work Products

- “Factual Statements: EPA’s Authority and Statutory Considerations.”
- “Potential Principles and Process for Including Factual Statements on Pesticide Labeling.”
- Compilation of Related Standards, Test Methods, Federal Policy.



EPA Authority / Statutory Considerations

- FIFRA parameters for pesticide labeling including 7 USC § 136 (q) prohibiting “...any statement, design, or graphic representation... which is false or misleading...”
- FQPA Amendments [7 USC § 136 (q)] specifically allow for **antimicrobial pesticides** “...relevant information on product efficacy, product composition, container composition... or other characteristics that do not relate to any pesticidal claim...”
- Regulations and Guidance including PRN 98-10, EPA Label Review Manual and FTC claims regulation.



Potential Principles / Examples

- Non-pesticidal factual statements regarding product characteristics other than the pesticide are presumptively acceptable. Examples include:
 - Recycled content of packaging
 - Content of ink used in printing
 - Container uses xx% less plastic than our previous bottle
- Corporate commitment statements are presumptively acceptable but must:
 - Be non-pesticidal; and
 - Cannot involve “cause marketing” statements except as otherwise allowed by existing EPA guidance.



Potential Principles / Examples (cont.)

- **Example:** “X Company is working to reduce its carbon footprint. Go to: www.xcolesscarbon.com to see how.”
- Factual statements concerning non-pesticidal properties of antimicrobial pesticides are presumptively acceptable and should be based upon existing standards, methods and policy. Examples include:
 - Fragrance or dye free
 - Readily biodegradable in water
 - Contains xx% of plant derived ingredients
 - Concentrated to minimize GHG emissions in shipping



Subgroup Issue Focus

- **Corporate Commitments:** Specific limitations.
- **Biodegradable:** Identification of OECD test methods/OPPTS guidelines.
- **Plant Derived:** USDA “bio-based” cleaning products rule/ASTM method/non-petroleum focus.
- **FTC Lead for Compliance:** Dropped from consideration.



Reliance Upon Existing Standards

- Widespread use of these statements (i.e. “biodegradable”) on non-FIFRA products has produced established standards and test methods.
- Existing Federal Standards:
 - 1) OPPTS “Guideline 835.3 I 10 Ready Biodegradability.”
 - 2) USDA “Designation of Biobased (Cleaning) Products for Federal Procurement” (7CFR Part 2902) 10/08.
- Underlying test methods (OECD series 301 Methods/ASTM carbon dating method D6866) also currently in use.



Subgroup Recommendations

- OPP should begin to allow limited factual statements for antimicrobial products based upon Subgroup principles and existing standards, methods and Federal policy.
- Implementation process options should be further considered and refined by a separate stakeholder workgroup with representation from the Subgroup.
- Limited factual statements should remain consistent with the principles and goals of any DfE “logo” program adopted by OPP.



Potential Pilot Parameters

- **Scope:** Registered antimicrobial products.
- **Duration:** Twelve months.
- **Review Mechanism:** Product amendment or new product registration.
- **Data/Documentation:** OPP to receive/review all relevant data/documentation during Pilot.
- **Projected Timing:** June, 2009 Federal Register announcement.
- **Public Comment/Evaluation:** During and at conclusion of Pilot.