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

April 2, 2009

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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, 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.
- Some (OPPTS "biodegradable" guidance/USDA "bio-based" cleaning product rulemaking) are existing Federal policy.
- Underlying test methods (OECD series 301 Methods/ASTM carbon dating method D6866) also currently in use.

Options for Process Implementation

1. Documentation for each claim must be submitted to EPA and reviewed within the time frame for EPA to disapprove notifications set forth in Section 136a (c) (9).
2. Documentation for each claim is submitted to EPA but not reviewed. In the event of a complaint or concern, EPA can review the materials and determine whether documentation is adequate.
3. Documentation is not submitted but is maintained by the registrant, much as documentation of some efficacy data is today. In the event of an issue or complaint, EPA can request the documentation and review it.

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.