Draft "Factors to Consider" for DfE Logo Pilot for Hard Surface Disinfectants

For Discussion at June 30, 2009

PPDC Comparative Safety Statements Workgroup Meeting

Revised 6/29/09

Background

- Currently, cleaning products – similar to disinfectants – can apply for the Design for the Environment logo
- Many hard surface disinfectant (HSD) labels contain uses as pesticides and as cleaners

Background (cont'd)

- OPP and OPPT DfE are working together to determine the feasibility of allowing products that have passed the OPPT DfE review to submit a label amendment to OPP in order to place the logo on pesticide products
- OPP and OPPT envision that this would have to be a two-part review process
  - Products would have to make it through both the OPPT DfE review and the OPP review
- Following are the DfE criteria and some "OPP factors to consider" before a DfE logo would be allowed on a disinfectant pesticide product

OPPT DfE Evaluation

- DfE Criteria

  www.epa.gov/dfe/pubs/projects/formulat/label.htm

- DfE Evaluation of Pesticides
  - Whole-Product Criteria
  - Active Ingredients
  - Inert Ingredients
- DfE Screens – a little insight

  www.epa.gov/dfe/pubs/projects/gfcp/index.htm

DfE Evaluation – Criteria Document

- Whole Product Criteria
  - pH
  - synergistic effects
  - performance
- General Screen
- Component-Class Screens
- Partnership Agreement
  - formulation content
  - conditions of use of the DfE logo

www.epa.gov/dfe/pubs/projects/formulat/about.htm

DfE for Actives and Inerts

- Active Ingredients would be screened against the DfE General Screen for Safer Ingredients.
- Inert Ingredients would be screened based on existing DfE methodology
  - Criteria Document
  - Component-Class Screens for Safer Ingredients
- Possible future development for Active Ingredients in high-efficacy anti-microbials -- multi-stakeholder development of customized DfE screen.

DfE General Screen

- Acute Mammalian Toxicity
- Carcinogenicity
- Environmental Fate & Toxicity
- Genetic Toxicity
- Repeated Dose and Neurotoxicity
- Reproductive and Developmental Toxicity
- Respiratory Sensitization
- Skin Sensitization

DfE General Screen: C*arcinogenicity Example*

- No chemicals listed by IARC, NTP, or EPA as known, probable, or possible carcinogens
- Chemicals not listed:
  - Consider data and apply GHS criteria
  - Chemicals considered known or presumed human carcinogens (Category 1) or suspected human carcinogens (Category 2) do not pass

DfE General Screen:

Environmental Fate & Toxicity Example

	Acute Aquatic Toxicity Value (L/E/IC50)	**Persistence (Measured in terms of level of biodegradation)**	**Bioaccumulation Potential**
1	If ≤1 ppm…	…then may be acceptable if the chemical meets the 10-day window as measured in a ready biodegradation test without degradation products of concern…	…and BCF <1000.
2	If >1 ppm and ≤10 ppm…	…then the chemical must meet the 10-day window as measured in a ready biodegradation test without degradation products of concern …	
3	If >10 ppm and <100 ppm…	…then the chemical must meet the 28-day pass level as measured in a ready biodegradation test without degradation products of concern…	
4	If ≥100 ppm…	…then the chemical need not meet the 28-day pass level as measured in a ready biodegradation test, if there are no degradation products of concern and half-life < 180 days…	

Draft – OPP Factors to Consider

- Classified as an acute toxicity I or II product -- Danger or Warning signal word [DfE and OPP Factor]
  - Dermal sensitization
- Known, probable or possible carcinogen [DfE and OPP Factor]
- Known developmental, reproductive or neuro tox issues
  - Toxicity seen in sub chronic studies (any route)
  - Mutagenic concern
  - Data gaps
- Unapproved inerts or inert mixtures

Draft – OPP Factors to Consider (continued)

- Outstanding "conditional registration" data issues
- Submission of final label
- PPE required to use the product
- Unresolved 6(a)(2) issues
- Unresolved efficacy failures
- Current enforcement action
- Alternate formulations – each formulation would require review
- Approved OPP statement is made regarding the logo (see next slide)

DfE Label Statement

- The following DfE label statements (or tag lines) have been discussed
  - Low Hazard Pesticide
    - Must ensure this does not contradict the signal word
  - Low Toxicity Pesticide
    - Could not say Reduced Risk Pesticide because in most cases, no risk assessment will have been done)
  - Low Concern Pesticide
- OPP's Field and External Affairs Division (FEAD) will work on an appropriate DfE label statement and sentence that explains what the pesticide DfE means (e.g., "Passed EPA criteria for low hazard pesticides…)

Draft – OPP Factors to Consider

- Favorable complete product formulation and individual components review
  - Data submitted for DfE determination should also be submitted to OPP
- One electronic copy of label submitted
- PRIA Fee submitted – 120 Days (A570 PRIA category)
- Cover letter and Certification Statement required

Cover Letter

- State that you are participating in the voluntary OPP DfE Pilot and have enclosed your DfE clearance/certification and data
- State that you have included a DfE self-certification statement
- State that you have included 5 copies of label and 1 electronic copy with the approved DfE logo and tag line

Certification Statement

- Applicant agrees to a 1 year pilot use of approved label
  - If pilot is extended or adopted into program, DfE certification will expire after 3 years in line with present DfE requirements
- Applicant agrees to be responsible for appropriate use of logo and marketing statement which is in compliance with all EPA labeling statutes, regulations and guidance (for self and distributors)
  - Distributor label submitted as well for pilot
- Applicant agrees to submit any alternate formulation request through same review process and not by notification

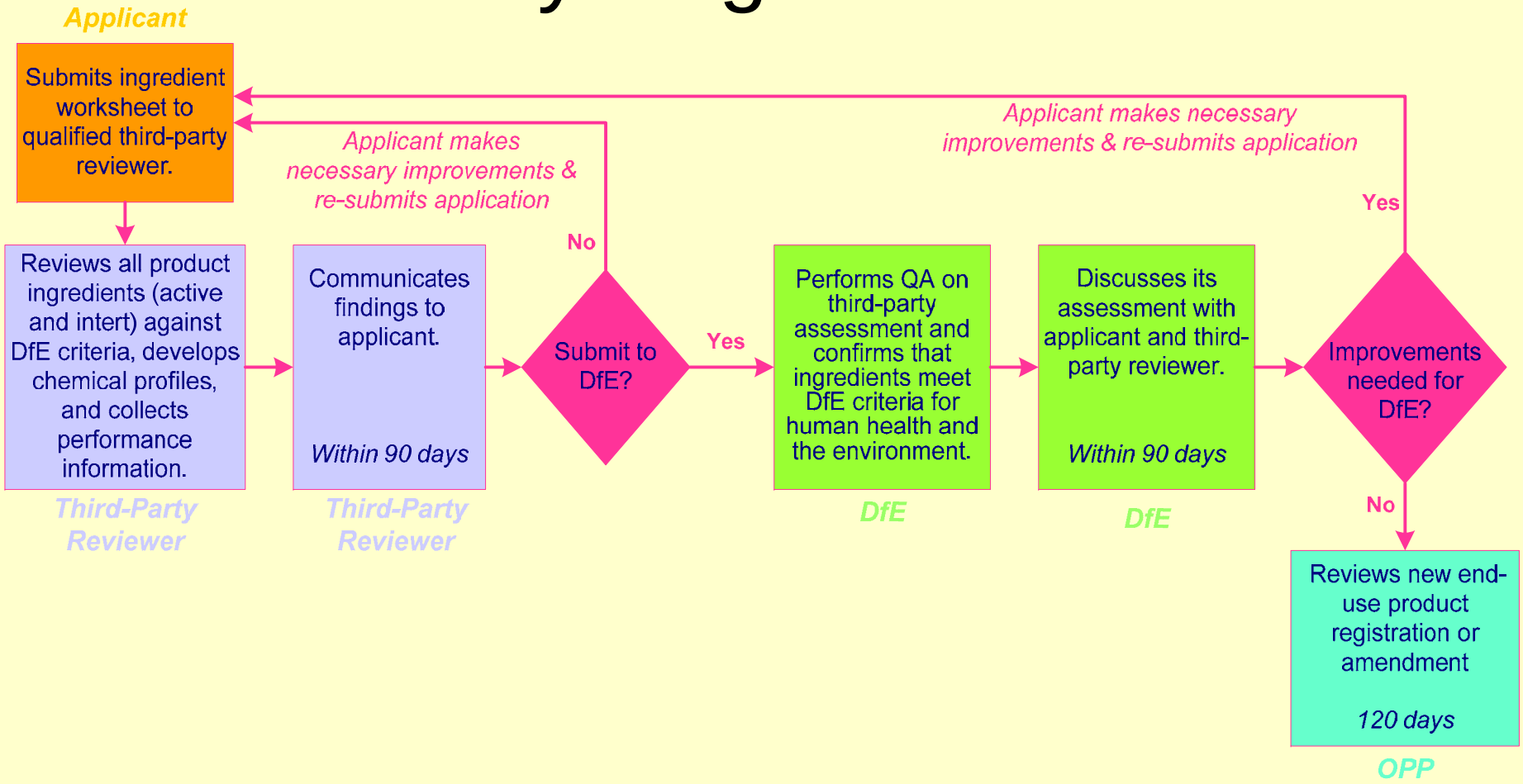
Certification Statement

- At any time a DfE marketing violation occurs under this pilot, the registrant agrees to immediately issue a voluntary recall of violative products or be found in violation of FIFRA Section 12(a)(1)(B) and Section 12(a)(1)(E)
- Applicant agrees to remove logo and amend registration if after 1 year pilot, OPP does not pursue a full DfE program
- If at any time, the Agency finds that one of its "OPP DfE factors to consider" has become a concern, the registrant agrees to immediately remedy the issue or issue a voluntary recall of violative products or be found in violation of FIFRA Section 12(a)(1)(B) and Section 12(a)(1)(E)
- Office of General Counsel will work on appropriate language for certification statement

The Process

- The Pilot would be open to all indoor, hard, non-porous surface products that have met or passed the aforementioned criteria and areas of concern
- The Pilot would run for 1 year. If, at that time, the Agency determines not to continue the Pilot, no new production of labeling would be permitted that bore the DfE logo for pesticides (logo must be removed).
- The Agency would permit the limited sale and distribution of products already in the channels of trade
- OPP still working through internal process issues (e.g., where and how screen will occur, flow chart for internal review, etc.)

Steps to Obtaining DfE Logo for a Currently Registered Product



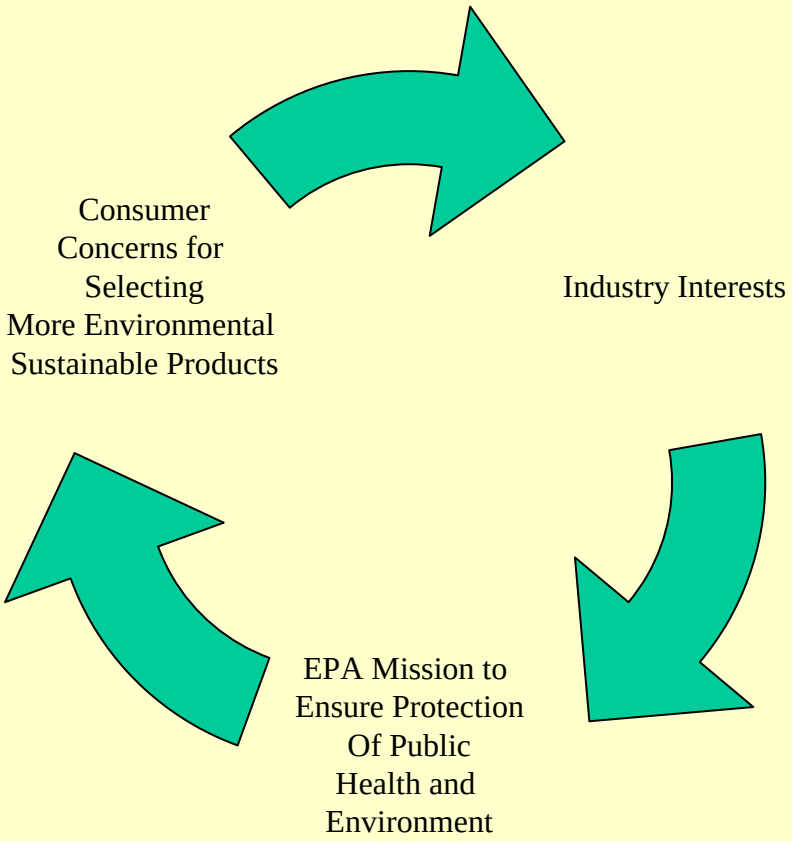
Conditions of Labeling

- No reference made in the marketing of the product involving terms that violate 40 CFR Part 156.10(a)(5).
- No comparisons with other registered products.
- Citation only of the DfE website for pesticides (to be created by FEAD)

Other DfE Issues of Concern and Questions

- Should OPP limit the pilot to only label amendments which are adding the DfE logo – no new uses, no new products, no additional organisms, etc.?
- Need to further discuss resource implications – where is screen done?
  - Contractor?
  - Endpoint committee?
- Working through which product changes would not require a new DfE review after the DfE logo has been granted
- Ensuring appropriate DfE label tracking in computer system
  - May have to create a new category in OPPIN and ID all DfE approved products with DfE/OPP tag in registration number

Questions?


Consumer Concerns for Selecting More Environmental Sustainable Products
Industry Interests
EPA Mission to Ensure Protection Of Public Health and Environment