Statutory Jurisdiction Over Products

- Adjuvants and Inerts (Before Pesticide)
- Regulated Under TSCA and OSHA *not* FIFRA
- Adjuvants Require State Registration
- Inerts in Pesticide Products Regulated under FIFRA
- FIFRA Requires Inert Approvals
Pesticide Ingredients

- **Active Ingredient** – Functions as a Pesticide (i.e., Controls the Pest)
- **Inert (“Other”) Ingredient** – Any purpose other than controlling a pest (i.e., surfactants, solvents, carriers, stabilizers, foaming agents, buffers, dyes, and preservatives)

**ACTIVE INGREDIENT:**
Bifenthrin. . . . . . . . . . . . . . . . . . . . . . . . . . . . 2.0%

**OTHER INGREDIENTS:** . . . . . . . . . . . . . . . 98.0%

**TOTAL:** . . . . . . . . . . . . . . . . . . . . . . . . . . . 100.0%
Definition of “Inert Ingredient”

- Inert ingredient
  “Any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product”
  - 40 C.F.R. § 152.3

- Not “unreactive” or “non-toxic”

- Not impurities
General Characteristics of Inerts

- Part of the delivery system
- No direct pesticidal affect
- Can affect efficacy
- Wide degree of biological activity, including toxicity, ecotoxicity

- *If an “Active” in one product, can it be an “Inert” in another product?*
EPA’s Regulation of Inerts

- **Listed on Pesticide “CSF”**
  - Chemical Identity/CAS # or Trade Name
  - Supplier Information and Function in Pesticide
  - Supplier Discloses Ingredients Only to EPA for Trade Name

- **Food use inerts require a tolerance or exemption from a tolerance**

- **EPA Inert Lists**
  - Published database of inerts ("Inert Ingredient Finder")
  - Categorized Lists of Inert Ingredients (old “lists A, B…”)
    - [https://www.epa.gov/pesticide-registration/categorized-lists-inert-ingredients-old-lists](https://www.epa.gov/pesticide-registration/categorized-lists-inert-ingredients-old-lists)
  - Previously reviewed trade name ingredients

40 C.F.R. Part 180
Categories of Inerts

- General Approval Categories
  - Food and Non-food Use
  - Non-food Use Only
  - Fragrance Ingredient List (FIL)
    - Pilot program:
      http://www.epa.gov/opprd001/inerts/fragrancenote.pdf
    - The list:
      http://www.epa.gov/opprd001/inerts/fmaingredient.pdf
Fragrance Ingredient List

- **Fragrance Ingredient List (FIL)**
  - Ingredients for use as fragrances
  - Non-food use only
  - 1,531 ingredients
  - Quick link to Fragrance Ingredient List:
    
    https://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:1:::NO:1::
Other Inert Ingredient Lists

- **Minimum Risk**
  - FIFRA Section 25(b)
  - List of minimum risk inert ingredients
    - Old list 4A

- **USDA’s National Organic Program (NOP) Ingredients List**

- **Trade Name Inert Ingredients**
  - Adding trade names
Tolerance Exemptions

- Inert Ingredient Categories
  - Subject to Limits and Uses
    - § 180.910 Pre- and post-harvest
    - § 180.920 Pre-harvest
    - § 180.930 Applied to animals
    - § 180.940 Antimicrobial formulations (Food-contact surface sanitizing solutions)
    - § 180.950 Minimal risk
    - § 180.960 “Polymers”

- Inerts approved for food use also approved for non-food use unless stated
Limits and Uses

- 40 CFR section 180.910
- Cetyl alcohol (CAS # 36653-82-4)
  - Limit: Not more than 5.0% of pesticide formulation
  - Use: Evaporation retardant
- Sodium alkyl naphthalenesulfonates (CAS Nos. 68909-83-1, 68909-84-2, 68909-82-0, 27213-90-7, 26264-58-4, 27178-87-6, 111163-74-7, 908356-16-1, 25417-20-3, ....etc.)
  - Limited to no more than 30% by weight in pesticide end-use products
  - Use: Surfactants, related adjuvants of surfactants
Limits and Uses: Low Risk Polymers

- 40 CFR section 180.960
- Meet definition of a polymer and the criteria specified for defining a low-risk polymer in 40 CFR section 723.50

- Butadiene-styrene copolymer, “None”

- Polyvinyl acetate - polyvinyl alcohol copolymer, minimum number average molecular weight (in amu), 50,000. CAS # 25213-24-5
Submit Application If Inert Not Approved

- Pesticide Registration Improvement Extension Act (PRIA 3)
- Ten Inert PRIA 3 Categories (2016-17)

<table>
<thead>
<tr>
<th>EPA No.</th>
<th>Action</th>
<th>Decision Review Time (Months)</th>
<th>FY’17 &amp; FY’18 Registration Service Fee ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I001</td>
<td>Approval of new food use inert ingredient</td>
<td>12</td>
<td>19,845</td>
</tr>
<tr>
<td>I002</td>
<td>Amend currently approved inert ingredient tolerance or exemption from tolerance; new data</td>
<td>10</td>
<td>5,513</td>
</tr>
<tr>
<td>I003</td>
<td>Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data</td>
<td>8</td>
<td>3,308</td>
</tr>
<tr>
<td>I004</td>
<td>Approval of new non-food use inert ingredient</td>
<td>8</td>
<td>11,025</td>
</tr>
<tr>
<td>I005</td>
<td>Amend currently approved non-food use inert ingredient with new use pattern; new data</td>
<td>8</td>
<td>5,513</td>
</tr>
<tr>
<td>I006</td>
<td>Amend currently approved non-food use inert ingredient with new use pattern; no new data</td>
<td>6</td>
<td>3,308</td>
</tr>
<tr>
<td>I007</td>
<td>Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern</td>
<td>4</td>
<td>1,654</td>
</tr>
<tr>
<td>I008</td>
<td>Approval of new polymer inert ingredient, food use</td>
<td>5</td>
<td>3,749</td>
</tr>
<tr>
<td>I009</td>
<td>Approval of new polymer inert ingredient, non-food use</td>
<td>4</td>
<td>3,087</td>
</tr>
<tr>
<td>I010</td>
<td>Petition to amend a tolerance exemption descriptor to add one or more CASRNs; no new data</td>
<td>6</td>
<td>1,654</td>
</tr>
</tbody>
</table>
Inert Data Requirements

- **Same but Different than Actives**
  - Assumed less hazardous than active ingredients
  - Not necessarily intended to have biological activity

- **Flexible – “risk assessment objectives approach”**
  - Use existing data from the open literature
  - Approvals by other agencies (FDA, EPA, TSCA PMN program, etc.)
  - Modeling, etc.
Inert Ingredient Data Compensation

- **Support tolerances or tolerance exemptions (i.e., food use data)**
  - Data compensation (15 years)
  - Exclusive use data rights (10 years)

- **Non-food use**
  - Limited
  - Submitted in response to test orders as part of the Endocrine Disruptor Screening Program (EDSP)
EPA Inert Group (in Registration Division)

- **Guidance documents**
  - Establishment of a New/Amended Food Use Inert Ingredient Tolerance or Tolerance Exemption
  - Low Risk Polymer Submissions
  - Requesting New Non-food Use Inert Ingredients

- **Available tools to determine status of inert**
  - “Inert Finder” searches by chemical name or CASRN
  - Trade Name – unfortunately limited
    - EPA reluctant to confirm if components of a trade name/mixture are approved (Confidential Business Information)
Trade Name Submissions

- Letters to EPA’s Inert Branch
- Not Subject to PRIA
- Submit Trade Name, Approval Status of Ingredient(s) and CAS #s, Name of Manufacturer
- Takes 1-2 Months
- Listed Internally for CSF Reference and Publicly in Inert Finder?
- Can Amend Trade Name
- Can Amend Ingredient in Trade Name Mixture
- Defined Mixture – Add Alternative CAS #?
THANK YOU

Michael T. Novak, Partner
Keller and Heckman LLP
Washington, DC Office
+1 202.434.4485
votaw@khlaw.com