Other Ingredients and Their Roles in Crop Protection: Commodity Inert Ingredients

Kerry Leifer, Team Leader
Chemistry Inerts and Toxicology Assessment Branch
Registration Division
Office of Pesticide Programs

2018 CLA/RISE Regulatory Conference
April 27, 2018
Commodity Inert Ingredients Proposal

• Initial proposal submitted to Agency by Crop Life America (CLA)/Council of Producers & Distributors of Agrotechnology (CPDA) in 2012

• The proposal sought to allow specific inert ingredients designated as commodity inert ingredients to be listed on the Confidential Statement of Formula for a pesticide product, without the need to include their specific commercial sources
Commodity Inert Ingredients Proposal (cont.)

- The proposal provided some definitional criteria for commodity inert ingredients and noted that a proposed list of commodity inert ingredients was also under development.
- Based on some initial feedback from CITAB, a revised proposal was submitted by CLA/CPDA.
- The revised proposal made some modifications to the definitional criteria and included a proposed list of commodity inert ingredients.
Confidential Statement of Formula Form

- EPA’s Confidential Statement of Formula (CSF) Form (EPA Form 8570-4) includes Box 11—Supplier Name & Address
- The 8570-4 instructions for Box 11: “Provide the name and address of the supplier of each component in the formulation. If one or more components will be obtained from more than one source, specify the names addresses of the alternate sources also.”
Office of Pesticide Programs (7505C) - Confidential Statement of Formula

<p>| | | | | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Name and Address of Applicant/Registron (Include ZIP Code)</td>
<td>2.</td>
<td>Name and Address of Producer (Include ZIP Code)</td>
<td>3.</td>
<td>Product Name</td>
<td>4.</td>
<td>Registration No./File Symbol</td>
<td>5.</td>
<td>EPA Product Mgr/Team No.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Pounds/Gal or Bulk Density</td>
<td>8.</td>
<td>pH</td>
<td>9.</td>
<td>Flash Point/Flame Extension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
% by Weight | 15. Purpose 
in Formulation |
|   |   |   |   |   | a. Amount | b. % by Weight | a. Upper Limit | b. Lower Limit |
|   |   |   |   |   |   |   |   |   |
| 16. | Typed Name of Approving Official | 17. | Total Weight | 100% |

EPA Form 8570-4 (Rev. 6-94)
EPA Consideration of Proposal

- EPA is evaluating the proposal to determine its ability to reduce burden to both OPP and the regulated community.
- Options for adoption of the concept of commodity inert ingredients are being evaluated.
EPA Consideration of Proposal (cont)

- Based upon a preliminary examination of the proposed list of commodity inert ingredients by OPP, the vast majority of the substances listed appear to meet criteria for designation as commodity inert ingredients.
- Final determination as to which ingredients are on the list and could be considered commodity inert ingredients is within EPA's discretion under 40 CFR 158.325(a)(2)(iii)
Next Steps

- Further evaluation of the list of commodity inert ingredients and criteria for listing by EPA
- Development of potential implementation plan
- Further guidance is being developed will be provided to staff and regulated community/public