US EPA ARCHIVE DOCUMENT
Presentation topics

- Introduction and Roles of Environmental Fate and Effects Division and Pesticide Review Division – Donald Brady & Richard Keigwin

- November 2008 biological opinion from NMFS and schedule for future biological opinions – Donald Brady

- EPA’s implementation of reasonable and prudent alternatives for November 2008 biological opinion – Arty Williams

- Applicant role in consultation – Arty Williams

- National assessments under registration review – clomazone and fomesafen – Dana Spatz

- Questions and comments
Biological opinions received

- November 2008
  - Chlorpyrifos
  - Diazinon
  - Malathion

- April 2009
  - Carbofuran
  - Carbaryl
  - Methomyl
## Schedule for future BiOps

<table>
<thead>
<tr>
<th>Date</th>
<th>Azinphos methyl Dimethoate Phorate Methidathion</th>
<th>Naled Methyl parathion Disulfoton Fenamiphos</th>
<th>Methamidophos Phosmet Ethoprop Bensulide</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 30, 2010</td>
<td>Azinphos methyl Dimethoate Phorate Methidathion</td>
<td>Naled Methyl parathion Disulfoton Fenamiphos</td>
<td>Methamidophos Phosmet Ethoprop Bensulide</td>
</tr>
<tr>
<td>Nov. 30, 2010</td>
<td>2,4-D Chlorothalonil</td>
<td>Captan Diuron</td>
<td>Linuron Triclopyr BEE</td>
</tr>
<tr>
<td>Feb. 29, 2012</td>
<td>1,3-D Bromoxynil Diflubenzuron Fenbutatin-oxide Lindane</td>
<td>Molinate Oryzalin Pendimethalin Prometryn</td>
<td>Propargite Racemic metolachlor Thiobencarb Trifluralin</td>
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EPA’s implementation of Nov. 2008 BiOp

| Buffers of 500 feet for ground and 1000 feet for aerial application + a 20 foot vegetative buffer adjacent to salmon waters | Buffers generally modeled to result in < 1.12 ppb in water  
- Varying spray drift buffers based on application rate, method, spray droplet size and water body size  
- Not less than 100 feet to account for potential runoff  
- Maximum 1000 feet |
| --- | --- |
| Wind and weather limitations | No use when winds >10mph  
- Applications adjacent to salmon waters commence nearest water and proceed away  
- No use when soil moisture is at field capacity or storm event likely to produce runoff, forecasted to occur within 48 hrs. of application. |
| Report to EPA, incidents of fish mortality occurring within 4 days of application and in the vicinity of the application | User to report to pesticide manufacturer, fish mortality incidents occurring within 4 days of application, in waters within or adjacent to the application site. |
| Effectiveness monitoring | EPA will work with NMFS and engage USGS to develop monitoring study protocol to determine effectiveness of mitigation measures.  
- EPA intends to require the registrants of the pesticides to fund and carry out such a monitoring study. |
### Applicant role in consultation

**Applicant** - Any “person” who requires formal approval or authorization from a Federal Agency as a prerequisite to conducting the action

- After initiation of consultation and once the Service begins work on a biop, EPA will identify potential “applicants” and schedule meeting with Service
  - *Federal agency (EPA) provides applicant opportunity to submit information for consideration during the consultation.*  
  - *Service must discuss with the Federal agency (EPA) and applicant the Service’s review and evaluation, the basis for any finding in the biop, and the availability of reasonable and prudent alternatives.*
Applicant role in consultation

- EPA has and will request a draft of any biop related to pesticides and will make public for purpose of obtaining input on any RPAs or RPMs
  
  - *If requested, Service makes available to the Federal agency (EPA) the draft biop for the purpose of analyzing the RPAs. The applicant may request a copy of the draft biop from EPA.*
  
  - *All comments on the draft biop must be submitted to the Service through EPA, although the applicant may send a copy of its comments directly to the Service*
Clomazone and fomesafen - overview

- Overall risk conclusions for each of the two chemicals

- What is similar/different about these "National Listed Species Assessments" vs risk assessments typically completed in the past (e.g., REDs)?

- How do the clomazone and fomesafen assessments differ from one another in approaches/methodologies and how did we reconcile those differences?

- What did we learn from the two pilots for future national Listed Species assessments?
# Assessment conclusions

<table>
<thead>
<tr>
<th>CLOMAZONE</th>
<th>FOMESAFEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>The compound is mobile and volatile</td>
<td>The compound is persistent, mobile, but not volatile</td>
</tr>
<tr>
<td>The primary risk concern is direct effects on terrestrial plants and associated indirect effects on listed species dependent on plants</td>
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</tr>
<tr>
<td>Risks off field are a function of spray drift AND there is evidence to support a concern for off site risks to extend long distances</td>
<td>Risks off field are a function of spray drift with limited distances off the treatment site</td>
</tr>
</tbody>
</table>
Similarities with past assessments supporting REDs

- Active ingredient analysis
- LOC process retained
- Basic exposure models retained
- Fate property endpoint selection process retained
Differences from past assessments supporting REDs

- Moved beyond active ingredient alone to address degradates, formulations, and multiple active ingredient products
- Sublethal effects considered
- Literature searches implemented
- Dose response analyses presented to evaluate LOCs and RQs
- Moved beyond screening methods in key areas:
  - Consideration of species and use site geography at resolutions beyond typical county level analyses
  - Consideration of individual species biology
Differences between assessments for clomazone and fomesafen

• Major differences reflect different refinement approaches
  • Fomesafen’s listed species assessment uses standard geographical tools and taxa screening tools, but refines with expanded biological characteristics
  • Clomazone’s assessment uses more refined geographical analyses from FESTF-based products
• BOTH analyses are consistent with overview methods
FESTF information management system (IMS)

- Land use cover information – NLCD
- USDA 2002 Census of Agriculture
- Species occurrence – NatureServe Multi-jurisdictional Database (MJD)
- Critical habitat location – USFWS Critical Habitat Portal
Clomazone

Screening ID Taxa of Concern

Establish distances of effect concern from Incidents

FESTF Product provides species within counties for the crop sites and adjacent areas

Overlay species location and Ag area

Eliminate Species as a concern if they are outside impact areas
Fomesafen

1. Screening ID Taxa of Concern
2. List of Species in counties with use sites
3. Screen out species not in taxa of concern
4. Screen out species by weight and diet
5. Establish distances with AgDrift or areas of concern

Collect available data to describe biology of species

Final species list with expected distance of concern
Lessons learned

- ES analyses from industry based on FESTF products are very complex and extremely voluminous

- Parts of these analyses are not necessarily compatible with our risk assessment process (exclusions not placed in the context of action area, areas of expected effects, etc.)

- Post processing of available location information from IMS increased its utility

- Broad discussions conducted early with registrants
  - Clarified uses and formulations supported
  - Clarified uses and products not supported

- Future assessments should begin engaging in discussion of potential mitigations early and incorporate mitigation in the Registration Review document to the extent we can
Questions and Comments?

- Thank you for your attention to this issue
- We are happy to try to address questions
- We are happy to hear your input