National Alliance of Independent Crop Consultants

EPA REGULATORY UPDATE

Memphis, Tennessee

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United States Environmental Protection Agency
THINK GLOBAL

ANY UNITED STATES GLP FIELD TRIAL MAY BE SUBMITTED TO OTHER COUNTRIES IN THE WORLD
FY2008 - INSPECTIONS BY DISCIPLINE

- Field Sites: 41.4% (36 inspections)
- Toxicology: 10.3% (9 inspections)
- Ecotox: 1.1% (1 inspection)
- Insecticide: 8.0% (7 inspections)
- Chemistry: 13.8% (19 inspections)
- Antimicrobial: 3.4% (3 inspections)
- Product Chemistry: 21.8% (12 inspections)

Total Inspections: 87
Total data audits: 225
Human studies: 5
Biotech Studies: 11

2/26/2009
NAICC REG UPDATE 01-09
COMPLIANCE PROFILE FY 2008
High Level Violations

FIELD SITES

Total GLP Inspections 87
Inspections 36
In Compliance 36 (100%)
GLP COMPLIANCE RATE - FY2008

<table>
<thead>
<tr>
<th>Field</th>
<th>Inspections</th>
<th>Compliance Rate (No findings)</th>
<th>Compliance Rate (High Level Violations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicology</td>
<td>100%</td>
<td>89%</td>
<td>92%</td>
</tr>
<tr>
<td>Antimicrobial</td>
<td>89%</td>
<td>92%</td>
<td>92%</td>
</tr>
<tr>
<td>Chemistry</td>
<td>67%</td>
<td>86%</td>
<td>86%</td>
</tr>
<tr>
<td>Insect Efficacy</td>
<td>100%</td>
<td>42%</td>
<td>58%</td>
</tr>
<tr>
<td>Prod Chemistry</td>
<td>89%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Ecotox</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

COMPLIANCE RATE: 71%
INSPECTOR'S FINDINGS: 93%
HIGH LEVEL VIOLATIONS: 93%
FIELD SITES
FY2004-FY2008 COMPLIANCE STATISTICS

Total Inspections | Field Sites | In Compliance (No findings) | In Compliance (High level violations)
--- | --- | --- | ---
76 | 16 | 15 | 15
96 | 30 | 23 | 29
102 | 38 | 35 | 34
96 | 36 | 36 | 34
87 | | | 36

GLP FIELD SITE VIOLATIONS
BY CITATION FY2008

• Subpart B
  – Master schedule was not kept up to date
  – QA inspection reports were not sent to SD and management in a timely manner
GLP FIELD SITE VIOLATIONS
BY CITATION FY2008

• Subpart E
  – Lack of expiration date on test substance container
  – SOP deviation
GLP FIELD SITE VIOLATIONS
BY CITATION FY2008

• Subpart F
  – Lack of test substance characterization data
GLP FIELD SITE VIOLATIONS
BY CITATION FY2008

• Subpart G
  – Lack of raw data for test substance application
GLP FIELD SITE VIOLATIONS
BY CITATION FY2008

• Subpart J
  – Lack of test substance characterization data
  – Archives material was not indexed for expedient retrieval
FY2008 STUDY REJECTIONS

- Product chemistry and antimicrobial efficacy
  - Twenty eight studies (28)
  - Eleven laboratories (11)
FY2008 STUDY REJECTION REASONS

• Lack of protocol
• Lack of raw data
• Chromatographic peaks improperly integrated
FY2008 GLP INTERNATIONAL ACTIVITIES

- OECD event with industry - NAICC participation
- Foreign GLP inspectors at EPA
  - Japan, Finland, The Netherlands, Korea, Malaysia and Thailand
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