

# Activities of the Inert Ingredient Assessment Branch (IIAB)

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# FY '08 Activities

1. Petitions: Great progress in managing workload
  - Granted 10 food-use petitions so far in FY '08
  - Approved 11 non-food use inerts so far in FY '08
  - Voluntary withdrawal of 14 old food-use petitions to be published in FR
  - 35 petitions are in various stages of review

# FY '08 Activities

## 2. Three “PRIA 2” food-use petitions received

- Conducted 21-Day Completeness reviews to ensure petitions were not deficient (required materials are present, complete, and accurate)
- One petition contained several serious deficiencies
- Submission of complete and accurate petitions is critical under PRIA

# FY '08 Activities

## 3. CSF Review.

- Registration actions cannot be completed with unapproved or unknown inert ingredients – only viable submissions are placed on the workplan.
- Helpful guidance is being developed to assist submitters with understanding the basic information and data needed for inert ingredient requests.

# FY '08 Activities

4. Updated website listings of approved inert ingredients in December '07
  - Updated non-food listing
  - Link to e-CFR for locating food-use tolerance exemptions
  - Consolidated 25(b) inert ingredient listing
  - Link to USDA's National Organic Program listing

# Revocation Update

## 1. Background:

- 123 tolerance exemptions revoked August 2006 due to insufficient data; exemptions to expire August 9, 2008
  - EPA allowed time for industry to make decisions on which of these exemptions they would support by committing to data development.
- Published in FR (11/02/07) listing of support status of revoked exemptions:
  - 64 Supported
  - 59 Unsupported

# Revocation Update (continued)

2. Working with Joint Inert Ingredient Task Force
  - The Task Force is supporting certain tolerance exemptions revoked due to insufficient data on August 9, 2006
  - The Task Force has provided EPA with their data development schedules
  - EPA is actively reviewing studies already submitted by the Task Force

# Revocation Update (continued)

## 3. EPA extending revocation date for supported exemptions

- EPA will extend the expiration dates for exemptions that industry has shown clear evidence of support (submission of data and study development plans)
- Federal Register will be published soon extending the expiration dates for supported exemptions to August 9, 2009
- By August 9, 2009, EPA will establish new tolerance exemptions for chemicals that meet the FQPA safety standard

# Revocation Update (continued)

4. Unsupported revoked tolerance exemptions
  - Advance notice in 2006; believe most products have already been reformulated
  - EPA is confirming by checking our records
  - Based on results of this check, we will be communicating with affected registrants about options, including reformulation and cancellation
  - Tolerance exemptions will expire August 9, 2008
  - Registration actions that contain inerts with revoked exemptions will not be granted after August 9, 2008.

# Data Compensation

## 1. Data Compensation.

- FQPA provides for data compensation for food use inert ingredients.
- The Advance Notice of Proposed Rulemaking (ANPRM) for food use inerts:
  - Expected by the end of the year.
  - Developing Inert Ingredient Data Submitters List - Agency will develop initial inert ingredient list and will make it available for stakeholder review and comment.
  - OPP has coordinated with Agency's Endocrine Disruption program to ensure data compensation provisions are compatible.
- In the meantime, internal procedures for implementation of data compensation have been established.

# Inert Disclosure Petitions

- In August 2006, 14 States and 22 environmental and health groups filed petitions to EPA for disclosure on the label of certain inerts listed as hazardous under various authorities.
- OPP has been working with OGC and other program offices to investigate the cited environmental statutes and standards used for listing
- Next steps
  - Reconcile these standards with FIFRA authorities
  - Make determinations under FIFRA authority

# Coming Attractions

## 1. CFR cleanup and addition of CAS Reg. No. to tolerance exemptions.

- EPA will be correcting obvious errors in the CFR. Errors include misspellings, wrong purpose in formulations, incomplete names, etc.
- Have received large number of requests to add CAS # to tolerance exemptions in CFR.
- Will make it easier to identify currently approved food-use inert ingredients. Will be able to search on-line by CAS #.
- CAS # that clearly fall within an existing tolerance exemption expression can be added (no expansion of the exemption).
- EPA envisions an easy and quick process for adding CAS # to existing tolerance exemptions.
- Federal Register will propose the CAS# addition process and invite comments. Publication timeframe -- tentatively early summer.

## 2. EPA expanding OPPIN functionality for inerts. Will assist in tracking and processing of all inert ingredient requests, including mixtures, PRIA, and non-PRIA requests (food and non-food).