

US EPA ARCHIVE DOCUMENT

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).