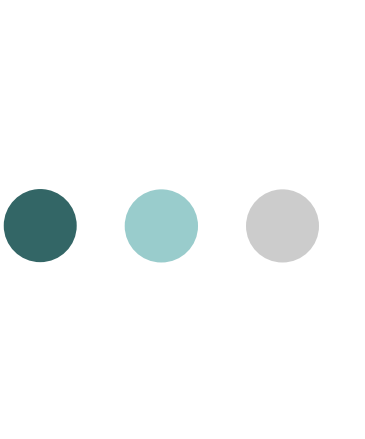


US EPA ARCHIVE DOCUMENT



Reregistration and Registration Review Overview

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Pesticide Program Dialogue Committee
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Progress in Pesticide Reevaluation Programs

- Reregistration
 - REDs and RED implementation
 - Product reregistration
- Tolerance Reassessment
- Cumulative Risk Assessment
- Special Review
- Registration Review



Reregistration

- FIFRA, as amended in 1988, authorized EPA to conduct a comprehensive pesticide reregistration program – a complete review of the human health and environmental effects of older pesticides first registered before November 1, 1984
- No “unreasonable adverse effects” standard



Reregistration

- EPA is reevaluating 613 pesticide cases to ensure they meet current health and safety standards
- Reviews complete sets of supporting data on human health and ecological effects
- With input from stakeholders and the public, assesses and mitigates risks
- Decisions captured in Reregistration Eligibility Decisions (REDs)



Risk Reduction Options in REDs

- Cancel or delete uses
- Limit amount, timing, frequency of use
- Restrict use to certified applicators
- Add personal protective equipment, restricted entry intervals, other user safety requirements
- Special packaging, engineering controls
- Ecological safeguards
- Ground and surface water safeguards



Reregistration Status

- Decisions are completed for 97% of all reregistration cases:
 - 366 REDs completed (60%)
 - 229 cases cancelled (37%)
 - 18 REDs to complete (3%)
 - Total: 613 cases (100%)
- EPA will complete the last REDs by October 3, 2008, the Pesticide Registration Improvement Renewal Act (PRIA 2) deadline



FY 2008 REDs (27)

- Acrolein
- Busan 77 **[completed]**
- Chloropicrin
- Chromated arsenicals (CCA)
- Creosote/coal tar
- Dazomet
- Diiodomethyl p-tolyl sulfone (Amical 48) **[completed]**
- Ethylene oxide **[completed]**
- Formaldehyde
- HHT/Grotan
- Inorganic thiosulfates **[completed]**
- Methyl bromide
- Methylthiocarbamate salts (metam sodium/metam potassium)
- MITC
- Naphthalene
- Nicotine **[completed]**
- Organic esters of phosphoric acid **[completed]**
- Pentachlorophenol
- Prometon **[completed]**
- Siduron
- Sodium fluoride **[completed]**
- Sulfometuron methyl
- Sumithrin
- TBT-containing compounds
- Tetramethrin
- Triclosan (irgasan)
- Triforine **[completed]**



RED Implementation Activities, FY 2008

- Carbofuran, arsenicals, PCNB, rodenticides
- Petition responses – atrazine, carbaryl, chlorpyrifos, DDVP, EBDCs, mancozeb, sodium cyanide and sodium fluoroacetate (1080)
- Responses to comments on decisions
- Any necessary addenda to REDs
- DCIs
- Data reviews (acute toxicity, product chemistry)
- Label reviews and product reregistration
- Tolerance rules



Product Reregistration

- Risk reduction is achieved post-RED through product reregistration
- Individual products are evaluated and may be reregistered
- Risk mitigation measures in REDs become label use directions, precautions
- Product reregistration is ongoing; will be completed several years after the last REDs



Tolerance Reassessment

- Pesticides with food uses must meet the safety standard of section 408 of FFDCA, as amended by FQPA – EPA must make a determination that pesticide residues in food are “safe”



FQPA Expanded Scope of Protection

- EPA was to reassess 9,721 tolerances in 10 years to make sure they met the new FFDCSA safety standard
- EPA was to consider:
 - Greater susceptibility of infants and children
 - Aggregate exposure
 - Cumulative effects
 - Possible estrogenic or endocrine effects



Tolerance Reassessment

- As directed by FQPA, EPA reassessed 9,721 tolerances to ensure that all meet the new FFDCA safety standard
- Completed tolerance reassessment in September 2007; an enormous milestone in food safety and human health protection
- Related risk management decisions are being implemented



Cumulative Risk Assessment

- Also per FQPA amendments to FFDCA, EPA assesses risks of pesticides that have common mechanisms of toxicity, or act the same way in the human body
- Completed cumulative risk assessments in 2006 and 2007 for four groups:
 - Organophosphates (OPs)
 - N-methyl carbamates
 - Triazines
 - Chloroacetanilides



Special Review

- EPA's intensive process for reviewing pesticides that may pose unreasonable adverse effects on human health or the environment
- 100+ Special Reviews completed since 1970s
- Remaining Special Reviews:
 - Aldicarb and ETO – close out after RED comment periods have closed
 - Atrazine, simazine, propazine – close out after SAP for cancer



Outcomes of Older Pesticide Reviews

- EPA's decisions on older pesticides have achieved significant enhancements in human health and environmental protection
- Many OPs and other pesticides posing risk concerns have been voluntarily canceled and/or uses are phasing out



Outcomes of Older Pesticide Reviews

- Eliminated many pesticide uses that drove dietary and residential risks, especially risks to children
- Improved worker safety
- Addressed important ecological risk concerns



Registration Review

- New FIFRA provision requires periodic review of each pesticide's registration
- Covers all pesticides
- 15-year review cycle
- Flexible, transparent, open process
- Includes public participation
- Ensures continuity in protecting human health and the environment



Ramping Up Registration Review

- RED follow-up will require significant resource investment through 2008
- Product reregistration should be completed by 2014
- Meanwhile, registration review is ramping up



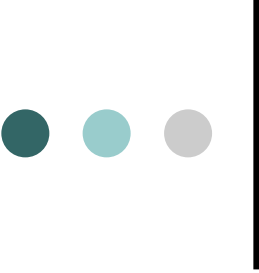
Registration Review Program Implementation

- Final rule became effective October 2006; EPA began implementing program in 2007
- **Complete first cycle by October 1, 2022**
- Huge job: currently includes 722 cases and 1135 pesticide active ingredients
- Reviews include national Endangered Species Act assessments
- Also include merging endocrine disruption into registration review, when ready



New Decision Paradigm

- What has changed since the pesticide's last assessment?
- How significant is this change?
- Do we need new information?
- Is the regulatory position likely to change as a result of the new information?



Reregistration vs. Registration Review

- Old pesticides
- One-time review
- ca. 20 pesticides/year
- Process set by law
- Comprehensive reviews
- Start from scratch
- Major data gaps
- Complete all REDs by 10-3-2008
- All pesticides
- 15-year cycle
- 45-70 pesticides/year
- Process set by rule
- Updated reviews as needed
- Add to what we know
- Fewer data needs
- Complete first review cycle by 10-1-2022



Beginning the Registration Review Process

- EPA assembles background information, prepares preliminary work plan for case, places in docket for comment period
- Reviews public comments and additional information received
- Develops final work plan stating whether new risk assessments are required and if data call-in is needed



Completing Registration Review Process

- EPA issues DCI, gets data when needed
- EPA completes
 - any new risk assessments, including national endangered species assessments when needed
 - any new risk management decisions
- Publishes decision for comment
- Consults with Fish and Wildlife Service and National Marine Fisheries Service if necessary for endangered species concerns
- Implements decision through label amendments



Public Participation in Registration Review

- Opportunities for participation and consultation throughout
- Public comment invited from all interested parties:
 - initial docket openings
 - significant risk assessments
 - all proposed decisions



Status of Dockets Opening

- Registration Review Dockets
 - first opened February 2007
 - to date, 42 dockets opened with Preliminary Work Plans (PWWPs)
- Final Work Plans (FWPs)
 - 26 FWPs completed and issued
 - Includes 4 FWPs for cases with no federal registrations



Pesticide Groups

- Certain groups of pesticides moved up in schedule; beginning registration review in 2008 - 2011
- EPA plans to review within same time frame for efficiency, consistency
 - OP pesticides begin registration review in FY 2008 and 2009
 - N-methyl carbamates in 2009
 - Pyrethrins, pyrethroids, synergists in 2010
 - Sulfonylurea herbicides in 2011-2013



FY 2008 Dockets Opening; Conventional Pesticides

- Coumaphos
- Temephos
- Phosalone
- Tetrachlorvinphos & Gardona
- Terbufos
- Dicrotophos
- Diazinon
- Oxydemeton-methyl
- Bensulide
- Profenofos
- Propetamphos
- Benzenemethanaminium
- Quizalofop
- Cyanamide
- Isoxaben
- Sulfluramid
- Aliette
- Quinclorac
- Sodium tetrathiocarbonate
- Sulfur
- Glufosinate
- Acetic acid and salts
- Carbon and carbon dioxide
- Inorganic nitrate/nitrite
- Propionic acid and salts
- Silica and silicates
- Flutolanil
- Clethodim
- Trinexapac-ethyl
- Flumetsulam
- Citric acid and salts



FY 2008 Dockets Opening; Antimicrobials, Biochemicals, Microbials

Antimicrobials

- Alkyl amine hydrochloride
- Capric acid
- Sodium hydroxide
- Biobor
- Oxazolidine-E
- Barium metaborate
- Cosan 145
- Caprylic acid

Biochemicals

- Thyme herbs & ground sesame plant
- L-lactic acid
- Azadirachtin
- Dried blood

Microbials

- Bacillus subtilis
- Nosema locustae



Registration Review Schedule

- Complete 4-year schedule for beginning reviews
 - Updated in November 2007
 - EPA will continue to update annually
 - http://www.epa.gov/oppsrrd1/registration_review/schedule.htm



EPA Information on Web

- Office of Pesticide Programs

<http://www.epa.gov/pesticides/>

- Pesticide Reregistration

<http://www.epa.gov/pesticides/reregistration/>

- REDs

<http://www.epa.gov/pesticides/reregistration/status.htm>

- Special Review

http://www.epa.gov/oppsrrd1/special_review/



EPA Information on Web

- Registration Review

- www.epa.gov/oppsrrd1/registration_review/

- Schedule for Beginning Reviews

- http://www.epa.gov/oppsrrd1/registration_review/schedule.htm

- Pesticide Registration Review Status

- http://www.epa.gov/oppsrrd1/registration_review/reg_review_status.htm