REREGISTRATION UPDATE for PPDC– October 7-8, 2008

REREGISTRATION STATUS

In September 2008, EPA completed the last non-food pesticide Reregistration Eligibility Decisions (REDs), meeting the PRIA deadline of October 3, 2008.

As mandated by the 1988 amendments to FIFRA, EPA has reevaluated 613 cases or groups of related pesticide active ingredients first registered before November 1, 1984, and determined whether these pesticides are eligible for reregistration – that is, if they can be used without causing unreasonable adverse effects on human health and the environment. The goal of the reregistration program has been to mitigate risks associated with older pesticides while preserving their vital social and economic benefits.

Outcomes for the 613 reregistration cases include:
- 384 completed REDs (63%)
- 229 voluntary cancellations (37%) during the early years of reregistration

Through the reregistration program, EPA has assessed the human health and the environment risks of older pesticides, as well as their benefits, as appropriate. The Agency has made decisions about these pesticides' future use through an open, transparent process that includes consultation with stakeholders and obtaining input from the public. To mitigate risks of concern, EPA has cancelled pesticides, terminated specific uses, or imposed new use restrictions, as needed.

As a result of this program, significant enhancements in human health and environmental protection have been achieved, and all pesticides registered for use in the U.S. meet current scientific and regulatory standards.

Tolerance Reassessment
- EPA generally conducted reregistration in conjunction with tolerance reassessment.
- FQPA of 1996 amended the FFDCA requiring EPA to reassess within 10 years the 9,721 existing tolerances and tolerance exemptions to ensure that they met the new, "reasonable certainty of no harm" safety standard.
- The Agency completed over 99% of this task by August 3, 2006. The remaining 84 tolerance reassessment decisions for five pesticides were completed in September 2007 when the Agency concluded the cumulative risk assessment for the N-methyl carbamate pesticides.
- Completing tolerance reassessment was an enormous milestone in US food safety and human health protection.
- As part of the process of implementing the tolerance revocations and other changes resulting from REDs and tolerance reassessment decisions, EPA is completing final tolerance rules to revoke, modify or establish tolerances. The Agency estimates that:
  - 755 final tolerance rules were completed during FY 2008;
  - 2,910 final tolerance rules have been completed, in total;
  - 850 final tolerances rules remain to be completed.

Cumulative Risk Assessment

- EPA also must assess the cumulative risks of pesticides that share common mechanisms of toxicity.
- During 2006 and 2007, the Agency completed cumulative risk assessments for the organophosphate (OP), triazine, chloroacetanilide, and N-methyl carbamate pesticides, and concluded that these groups meet the FFDCA safety standard.

Risk Mitigation through Reregistration and Tolerance Reassessment

- Cancellations – Many OPs and other pesticides posing risk concerns have been voluntarily cancelled; some have uses that are phasing out over several years. (For example, the last uses of AZM are phasing out between November 2006 and September 30, 2012.)
  - Examples include AZM, benomyl, cyanazine, ethion, ethyl parathion, fenamiphos, fenthion, lindane, mevinphos, molinate, zineb.
  - Carbofuran – EPA has concluded that dietary, worker, and ecological risks are of concern for all uses. The Agency's July 2008 action to remove all carbofuran tolerances is part of a broader decision to cancel all uses of carbofuran in the U.S. (See Post-RED Activities.)

- Dietary Risks Addressed – EPA has eliminated pesticides and pesticide uses that drove dietary (food and/or drinking water) risks, especially risks to children.
  - Examples include AZM, methyl parathion.
  - Examples of drinking water risks addressed include atrazine, aldicarb.

- Residential Risks Addressed – EPA has eliminated pesticide uses or imposed new use restrictions to address residential risks, especially to children.
  - Examples – All indoor and outdoor residential uses were cancelled for the OPs chlorpyrifos, diazinon, dimethoate, fenthion, naled, phosmet, propetamphos. Cancellation of most residential uses and mitigation of other uses was required for the OPs acephate, bensulide, disulfoton, DDVP, ODM, tetrachlorvinphos, trichlorfon.
  - Rodenticides – EPA is requiring new safety measures to protect children, pets and wildlife from accidental exposure to rodent-control products. (See Post-RED Activities.)

- Worker Risks Addressed – EPA has cancelled pesticide uses or imposed new use restrictions to address worker safety concerns.
  - Examples include AZM, diazinon, ethyl parathion, methamidophos, methyl parathion, mevinphos, terbufos.
  - Soil Fumigant REDs – EPA is requiring a suite of important new safety measures to increase protections for agricultural workers and bystanders. (See Post-RED Activities.)

- Ecological Risks Addressed – EPA has cancelled pesticide uses and imposed new use restrictions to address ecological risk concerns.
  - Examples include aldicarb, atrazine, AZM, diazinon, ethyl parathion, fenthion, methamidophos, methyl parathion, phorate, terbufos.

Results

- Correlated with tolerance reassessment/reregistration decisions, the use of OP pesticides on kids' foods between the years 1994 – 2004 has been reduced from approximately 28 million lbs AI to approximately 12 million lbs AI – a **57%** reduction.
- Correlated with tolerance reassessment/reregistration decisions, the number of unintentional OP poisonings has been reduced **70%** between 1994 and 2004.
- Correlated with the mitigation required in the chlorpyrifos RED (cancellation of home termiticide use in existing structures and other residential uses) and the introduction of a reduced-risk alternative (Sentricon), a **66%** reduction in reported poisoning incidents for chlorpyrifos has occurred since 1995.
- A comparison of estimated concentrations of a chlorpyrifos metabolite (TCPY) in urine using the NHANES III (1988-1994) and the NHANES (1998-2002) data bases indicates roughly a **50%** reduction.
- Correlated with the phase out of all diazinon residential uses (2000 to 2004) and roughly a 33% reduction in diazinon agricultural uses that were required in the RED, 5 urban and mixed use streams analyzed by USGS as a part of the NAWQA program have recorded statistically significant decreases in seasonal diazinon concentrations in surface water ranging from **20% - 41%.**

Additional Information

- Reregistration Web Page: http://www.epa.gov/pesticides/reregistration/index.htm
- Reregistration Status (REDs): http://www.epa.gov/pesticides/reregistration/status.htm
- Tolerance Reassessment: http://www.epa.gov/pesticides/tolerance/reassessment.htm
- Cumulative Risk Assessment: http://www.epa.gov/pesticides/cumulative/

POST-RED ACTIVITIES

ATRAZINE UPDATE

Ecological Effects

Stream Monitoring –

- As required under the Agency's reregistration decision, atrazine registrants conducted monitoring of 40 watersheds that are statistically representative of 1,200 other watersheds identified as most potentially vulnerable to atrazine contamination.
- The results of three years (2004-2006) of intensive monitoring in corn and sorghum growing areas in the midwest indicated that two Missouri monitoring sites had atrazine exposure patterns that exceeded the Agency's level of concern.
- To further implement EPA's decision, atrazine registrants have been conducting watershed stewardship activities, consistent with Total Maximum Daily Load (TMDL) implementation program requirements. The registrants have been working with the growers and other stakeholders in the Missouri watersheds of concern. Intensive monitoring in these watersheds is ongoing to evaluate the effectiveness of the stewardship program.
- In December 2007, EPA consulted with the FIFRA SAP on the approaches and methodologies of the atrazine monitoring program, and the Agency's preliminary interpretations of monitoring results.
- In May 2009, the Agency will return to the SAP with its revised methodology, based on feedback from the December 2007 SAP, for assessing the impact of atrazine exposure patterns to aquatic environments. The Agency will also present its work on identifying the watershed attributes (e.g., soil type, depth to restrictive layer) associated with increased vulnerability to atrazine run-off, and its preliminary assessment of where additional watersheds are located that may be exceeding the level of concern.

Amphibian Studies –

- In 2003 and 2007, the Agency presented its White Papers and assessments on the potential effects of atrazine on amphibian gonadal development to the FIFRA SAP.
- Based on the results of two studies conducted by Syngenta in 2005 and 2006, in addition to other studies published in the scientific literature, the FIFRA SAP concurred with the Agency's assessment that atrazine does not consistently affect amphibian gonadal development.
- The Agency will continue to review data as they become available and if necessary will take appropriate regulatory action under FIFRA to prevent unreasonable adverse effects on amphibians and other species.

Human Health

Drinking Water (CWS) –

- As required under the atrazine reregistration decision, an intensive monitoring program to look for atrazine residues in 128 'most vulnerable' Community Water Systems (CWS) has been conducted during the past five years.

- CWS drinking water monitoring results from 2003, 2004, 2005, 2006, and 2007 show no exceedences of the level of concern for atrazine plus its chlorinated metabolites.

Cancer –

- EPA concluded in its reregistration decision that atrazine is not likely to cause cancer in humans.
- EPA expects to receive two additional epidemiological studies in 2009 from NCI's Agricultural Health Study.
- The Agency will convene a final SAP meeting no sooner than in 2010 after review of these studies.

Additional Information

- Atrazine Reregistration Web Page: http://www.epa.gov/pesticides/reregistration/atrazine/
- Atrazine Updates: http://www.epa.gov/pesticides/reregistration/atrazine/atrazine_update.htm

CARBOFURAN UPDATE

Carbofuran Reregistration Eligibility Decision (RED), August 2006

- Indicated that carbofuran is not eligible for reregistration due to ecological, worker, and dietary (food alone or water alone) risks.
- EPA sent Draft Notice of Intent to Cancel (Draft NOIC) to SAP and USDA, January 2008.
- SAP meeting held February 2008.
- SAP Report received March 2008.

Proposed Tolerance Revocation, July 2008

- Given the dietary risks to children, EPA published a proposal to revoke all carbofuran tolerances under FFDCA (July 31, 2008, Federal Register).
  - Starting with the proposed tolerance revocation under FFDCA resolves the dietary risk (risk-only standard), thereby
  - Providing the most direct and timely means to realize protection of children from dietary risks, and
  - Provides greater clarity for stakeholders by first resolving the "risk only" standard of FFDCA and then addressing any remaining uses in terms of the occupational and ecological risk-benefit standard of FIFRA through the NOIC process.
- Farmers can still use purchased carbofuran products on food crops this season. EPA's proposed tolerance revocations will not likely be final until sometime in 2009. The Agency intends to provide growers with sufficient advance notice regarding the effective date of these actions to prevent the potential for market disruption.

Voluntary Cancellation Request, September 29, 2008

- EPA received request from registrant, FMC, for voluntary cancellation of all carbofuran uses, except:
  - 4 food uses (corn, potatoes, pumpkins, sunflowers) and
  - 2 non-food uses (pine seedlings and spinach grown for seed).
- EPA is immediately beginning process for acting on this request.
- The requested cancellation actions should be completed prior to tolerance revocations; this will help address concerns about adequate notification of growers.

Next Steps

- Proposed Tolerance Revocation
  - Comment period closed September 29, 2008; comments are being reviewed.
  - Any final tolerance revocation and response to comments to be published.
  - After a final revocation is published, any person may file objections, provided the issues raised therein were previously raised in public comments, and may also request that EPA hold a hearing.
- Voluntary Cancellation Request
  - 6(f) notice announcing receipt of request for voluntary cancellation will be published in Federal Register with 30-day comment period.
- NOIC
  - Following resolution of tolerance revocation, proceed with NOIC for any remaining uses due to ecological and worker risks that do not meet FIFRA risk-benefit standard.

Additional Information

- Carbofuran Reregistration Web Page: http://www.epa.gov/pesticides/reregistration/carbofuran/
- Carbofuran Cancellation Process: http://www.epa.gov/pesticides/reregistration/carbofuran/carbofuran_noic.htm#proposal

FUMIGANTS UPDATE

Soil Fumigant Reregistration Eligibility Decisions (REDs), July 2008

- EPA completed risk management decisions including a suite of new safety measures for the soil fumigants:
  - chloropicrin
  - dazomet
  - metam sodium/potassium (including MITC)
  - methyl bromide
- The risk mitigation measures are designed to work together to protect workers and bystanders from inadvertent exposure and adverse health effects.
- Public comment period on implementation of risk mitigation measures in the REDs opened July 16, 2008; has been extended through October 30, 2008.
- EPA encourages stakeholders to carefully review the mitigation measures and provide constructive input.
- After considering new information received during public comment period, EPA will refine plans for implementation of risk mitigation measures, as needed.

Public Participation

- EPA developed the fumigant REDs over the past four years using an extensive public participation process that included many opportunities for public comment and consultation.
- The Agency has provided three to four comment periods for each pesticide, inviting public input on human health and ecological risk assessments, proposed risk mitigation measures, and now implementation of those measures.
- Comment periods have been opened a total of 375 days to 435 days for each soil fumigant.
- To obtain fuller input, EPA has hosted public meetings around the country and consulted with stakeholders representing a broad range of interests.
- Diverse input from stakeholders helped inform the fumigant risk mitigation measures.
- Agency staff is continuing to meet with stakeholders in key areas of the U.S. during the comment period to obtain feedback and constructive input on implementation issues.

Review Processes

- During reregistration, EPA reviewed the soil fumigants as a group to ensure that similar risk assessment tools and methods were used for all and risk management approaches were consistent.
- EPA plans to review the soil fumigants together again during registration review, beginning in 2013.

Additional Information

- Soil Fumigant Risk Mitigation Measures Web Page: http://www.epa.gov/pesticides/reregistration/soil_fumigants/
- Soil Fumigant REDs: http://www.epa.gov/pesticides/reregistration/status.htm

ORGANIC ARSENICALS UPDATE (MSMA, DSMA, CAMA, and Cacodylic Acid)

Reregistration Eligibility Decision (RED), July 31, 2006

- EPA concluded that all uses of MSMA, DSMA, CAMA, and cacodylic acid are ineligible for reregistration and that the associated tolerances do not meet the reasonable certainty of no harm standard due to concerns for dietary and drinking water exposure to inorganic arsenic, a more toxic break down product of organic arsenicals.

Status

- The RED public comment period began August 9, 2006, was extended in late December 2006 at the registrants' request, and closed on January 19, 2007. Numerous comments were received and have been evaluated.
- The technical registrants comprising the MAA (Monomethyl Arsonic Acid) Research Task Force (MAATF) have provided some preliminary information and analyses suggesting that little if any inorganic arsenic residue (derived from MSMA use on cotton) would be found in food items. The MAATF is pursuing data to confirm this result.
- Even if the dietary exposure to inorganic arsenicals can be resolved, the potential for inorganic arsenicals to reach drinking water sources still needs to be mitigated.
- Cotton growers and USDA have expressed concern about an apparent increase in glyphosate resistance among cotton weeds and the current lack of alternatives for cotton weed management if these products are eliminated.
- Sod farmers, golf course superintendents, and turf management companies have expressed concerns that due to the lack of chemical control alternatives for certain weed species, elimination of these products will result in challenges for the turf industry.
- Both groups have provided additional benefits information since the RED was issued.
- EPA is actively engaged with stakeholders and the registrants in developing a plan to implement the findings contained in the RED. Expected timing for a plan is in 2009.
- EPA also has met with stakeholders to gather feedback and any new information/data. The arsenicals team visited Georgia in July 2007 to meet with growers, university/extension experts, state officials, and environmental organizations to learn more about the risks and benefits of organic arsenicals. In addition, members of the RED team have met with the National Cotton Council of America, MAATF, USDA, growers, and university experts to discuss benefits and alternatives as well as the conclusions in the RED.

Additional Information

- Methanearsonic Acid Salts Web Page: http://www.epa.gov/pesticides/reregistration/methanearsonic_acid/
- Cacodylic Acid Web Page: http://www.epa.gov/pesticides/reregistration/cacodylic_acid/

RODENTICIDE UPDATE

Final Risk Mitigation Decision for Ten Rodenticides, May 2008

- EPA is requiring new safety measures to protect children, pets and wildlife from accidental exposure to rodent-control products. The practical and low cost measures will provide protection while ensuring that rodent control products continue to be effective and affordable for all consumers.
- Rodenticides are important for controlling mice, rats, and other rodents that pose threats to public health, critical habitats, native plants and animals, crops, and food supplies. However, these products also present human and environmental safety concerns.
- Children's risk mitigation – To minimize children's exposure, all rodenticide bait products available for sale to consumers must be sold only with bait stations. Loose bait such as pellets will be prohibited. A range of different types of bait stations will meet the new requirements, providing cost flexibility.
- Ecological risk mitigation – To reduce wildlife exposures and ecological risks, EPA is requiring sales and distribution and packaging restrictions for products containing four of the 10 rodenticides that pose the greatest risk to wildlife (the second-generation anticoagulants – brodifacoum, bromadiolone, difenacoum, and difethialone), to prevent purchase on the consumer market.

Mitigation Decision Follow-up

- EPA mailed letter to registrants, June 2008 – Requires statement of intent to comply with risk mitigation requirements for each rodenticide product within 90 days of receipt of letter.

Next Steps

- Registrant responses will be posted in docket, October 2008.
- By December 4, 2009, registrants must submit applications that comply with the mitigation decision.
- June 4, 2011 – last day for "release for shipment" of non-compliant products.
- Define Federal Action for ESA Assessment and proceed with Endangered Species assessment and effects determination – TBD

Past Milestones

- Rodenticide Cluster and Zinc Phosphide REDs issued (1998)
- Proposed risk mitigation decision issued (January 2007); comments accepted for 120 days (until May 2007). Over 750 comments received from stakeholders representing diverse interests.

Additional Information

- Rodenticides Web Page: http://www.epa.gov/pesticides/reregistration/rodenticides/index.htm
- Fact Sheet on Risk Mitigation Decision: http://www.epa.gov/pesticides/reregistration/rodenticides/finalriskdecision.htm
- Risk Mitigation Decision for Ten Rodenticides (May 28, 2008): Document #EPA-HQ-OPP-2006-0955-0764 at http://www.regulations.gov

PRODUCT REREGISTRATION STATUS

At the end of the reregistration process, after EPA has completed a Reregistration Eligibility Decision (RED) for a pesticide active ingredient and declared it eligible for reregistration, individual end-use products that contain the pesticide still must be reregistered. Product reregistration is the Agency's program for implementing the REDs by ensuring that risk reduction measures identified in those decisions are reflected on pesticide product labels.

Although the last REDs were completed in FY 2008, EPA does not expect to complete product reregistration before 2014.

Progress and Goals

As RED production winds down, EPA is placing increased emphasis on post-RED work and product reregistration.

- As detailed below, after completing just over 500 product reregistration actions in FY 2005 and FY 2006, the Agency completed almost twice as many (979) actions in FY 2007.
- In FY 2008, the Agency exceeded its goal (1,075 actions) and completed 1,197 actions.
- EPA's goal is to complete 1,250 actions in FY 2009.

Historical Product Reregistration Decisions

	FY 02	FY 03	FY 04	FY 05	FY 06	FY 07	FY 08
Products reregistered	77	53	78	104	169	529	680
Products amended	51	40	35	63	40	80	205
Products cancelled	186	213	14	342	297	370	309
Products suspended	0	5	0	0	0	0	3
TOTAL	314	311	127	509	506	979	1,197

Product Reregistration Universe

The product reregistration universe consists of a total of 22,531 products. EPA has completed decisions for almost 9,500 of these products, and still must complete decisions for over 13,000 products.

• Products reregistered	3,274
• Products amended	857
• Products cancelled	5,355
• Products suspended	9
• Total completed	9,495
• Products pending	13,036
• Total product universe	22,531

REDs with Product Reregistration Decisions Completed

- Product reregistration has been completed for 184 REDs (out of a total of 384).
- These 184 REDs include 23 OPs (out of a total of 31) that have completed product reregistration.
- Five of the eight OPs that have not yet completed product reregistration are only awaiting their final cancellation orders.

EXTERNAL REVIEW

- OPP had an external review of the product reregistration process conducted during FY 2006 and FY 2007 to identify potential opportunities for innovation and streamlining in order to ensure timelier implementation of the mitigation measures required in the RED.
- External review document, "Evaluation of the U.S. EPA Pesticide Product Reregistration Process: Opportunities for Efficiency and Innovation" (March 2007) can be found at http://www.epa.gov/evaluate/reports.htm under the subheading, Office of Prevention, Pesticides, and Toxic Substances.

Major Findings of External Review

The average time from RED signature to product reregistration decision was 54 months:

- 40 months from RED signature, through batching, DCI approval, DCI issuance, data generation, data submission, data and label reviews package sent from SRRD to RD;
- 14 months from receipt of package by PM in RD, through label revisions with registrant to label approval and product reregistered.

Of the 13,178 products still pending reregistration decisions at that time:

- 83% of the pending products were associated with REDs signed from FY 2005 through FY 2008;
- 12% of the pending products were associated with REDs signed from FY 2001 through FY 2004;
- 4% of the pending products were associated with REDs signed from FY 1997 through FY 2000;
- 1% of the pending products were associated with REDs signed before FY 1997.

Sources of Delay in Product Reregistration Identified by External Review

- Unresolved issues in signed REDs;
- New data submitted to rebut RED conclusions;
- OPP's historical focus on RED completion to meet statutory deadlines;
- Lengthy post-RED DCI justification process;
- Lack of an integrated tracking system for product reregistration;
- Breakdowns in internal communication;
- Duplication of label reviews in SRRD and RD;
- Failure of OPP to use suspension authority to ensure timely responses;
- Inadequate resources allocated to product reregistration.

Streamlining Efforts Initiated by SRRD and RD

- SRRD streamlined its batching process for 2,4-D's 603 products resulting in more than a 50% reduction in the number of product-specific acute toxicity studies required;
- The handoff of the final, reviewed, product package from SRRD to RD was streamlined resulting in significant time savings for RD PMs;
- Instead of trickling packages to RD on a product-by-product basis, packages are transmitted from SRRD to RD only when 95% - 100% of the products are ready;
- An expedited mitigation on labels effort was piloted with propanil resulting in 40 out of 43 labels being amended with the RED-specified mitigation within 5 – 8 months after the RED was signed.

Recommendations of the External Review

- Improve transition from RED completion into product reregistration process by convening handoff meetings to summarize RED content, mitigation, and issues and to coordinate/delineate roles and responsibilities regarding any post-RED issues [*adopted by OPP management*];
- Increase participation of RD PMs in label table development to enhance quality and consistency of label language [*adopted by OPP management*];
- Implement mitigation in an expedited manner (i.e., require amended labels immediately after RED is signed that incorporate the mitigation required in the RED) when it is cost-effective based on the level of mitigation required by the RED [*adopted by OPP management*];
- Pursue electronic labels to streamline the label review process [*already under development in RD for registration*];
- Pursue additional regulatory action when registrant is in non-compliance [*adopted by OPP management*];
- Modify REDs to include explicit justification for each data requirement to be called in [*adopted by OPP management*];
- Expand streamlined batching efforts to other REDs with industry taskforces [*adopted by OPP management and being implemented for permethrin (1,185 products), MGK-264 (706 products) and PBO (1,704 products)*];
- Label review function should reside in RD [*still under consideration by OPP management*];
- Create incentives for registrants to provide expedited responses such as reduced maintenance fees [*rejected by OPP management*];
- Establish hand-off meetings when final product package sent from SRRD to RD [*adopted by OPP management*];
- Increase resource allocation to product reregistration since the external review concluded that 2018 is a more likely completion date than the 2012 date provided by OPP [*still under consideration by OPP management; would depend on future budget allocations*];
- Use SWAT teams and other strategies to reduce backlogs [*adopted by OPP management*];
- Obtain more science support for DCI justification process [*still under consideration by OPP management*];

- Incorporate quantitative performance goals for product reregistration into PARS for all managers and staff in participating divisions [*adopted by OPP management*];
- Ensure that PRISM has the functionality for integrated tracking and reporting for all critical components of the product reregistration process [*still under consideration by OPP management; would depend on future budget allocations*];
- Improve internal and external communication about the status of product reregistration [*adopted by OPP management*];
- Maintain the web site as a repository of reregistration decisions including amendments to the REDs [*adopted by OPP management*].