WEEK ENDING AUGUST 30, 2013

OPP Weekly Activity Report

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PESTICIDE RE-EVALUATION DIVISION

EPA Reaches Agreement with Methyl Bromide Registrants on Label Changes. On August 27, 2013, EPA received a letter from the Methyl Bromide Industry Panel (MBIP) agreeing to changes to the methyl bromide commodity and structural fumigant labels. EPA and MBIP have been negotiating these label revisions over the past year; they are needed to conform to changes in the Agency's approach to fumigant risk mitigation. EPA plans to seek input from our state partners on the new labeling before changes will be made to the methyl bromide labels. Approval of the labels, anticipated for later this year, will implement the 2006 Methyl Bromide Tolerance Reassessment and Risk Management Decision. (PRD: Susan Bartow, 703-603-0065; Cathryn Britton, John Leahy, Kevin Costello; RD: Erin Malone; FEAD: Jeanne Kasai; and FEAD/PRD: Carolyn Schroeder)

OPP Discusses Paraquat Dichloride Accidental Ingestion Incidents with Syngenta. On August 27, 2013, staff from PRD, RD, BEAD, and HED held a teleconference with Syngenta, a technical registrant for paraquat dichloride, to discuss incidents involving paraquat dichloride. In July 2013, Dr. Richard Geller, Director of California Poison Control System, sent an email to OPP describing a series of deaths in the San Joaquin Valley of California that occurred due to accidental ingestion of the pesticide paraquat dichloride. OPP described Dr. Geller's email and EPA's response to Syngenta, both of which will be posted in the paraquat dichloride docket (EPA-HQ-OPP-2011-0855) in the near future. EPA informed Syngenta that it is currently conducting a review of paraquat dichloride incidents resulting from accidental exposure. While Syngenta implemented a number of changes to paraquat products in the late 1980's (i.e., emetic and stenching agents) to mitigate potential accidental ingestion risk, accidental deaths are still occurring. EPA asked Syngenta to consider Dr. Geller's suggestion to reformulate paraquat products with a lower percent of active ingredient, as well as propose additional potential mitigation options. (Molly Clayton, 703-603-0522)

Chlorpyrifos Team Meets with Dow AgroSciences to Discuss PBPK Model. On August 27, 2013, PRD, HED, ORD, EFED, and CaDPR met with Dow AgroSciences (DAS) to discuss their PBPK model. DAS had previously presented model enhancements related to dermal and oral exposure. This meeting focused on the complete model, which now includes an inhalation component as well as the already completed dermal and oral model components. DAS is currently having the model validated. The inhalation component of the PBPK model will be submitted to EPA in the coming weeks. EPA has already received the oral and dermal components, and will be conducting its own validation of the model. (Joel Wolf, 703-347-0228)

Aminopyralid Registration Review First Team Meeting Held. On August 28, 2013, team members from BEAD, EFED, HED, RD, and PRD met to discuss and coordinate the registration review of aminopyralid. Aminopyralid is pyridine carboxylic acid herbicide use to control broadleaf weeds in pastures, rangeland, wheat, and non-crop areas, including rights-of-way. While aminopyralid has a favorable human health and ecological risk profile, many incidents have been reported in the last 10 years concerning damage caused by aminopyralid residues in compost. The team discussed how to best address compost issues in registration review. The Preliminary Work Plan is scheduled for completion in March 2014. (Katie Weyrauch, 703-308-0166)

PRD Holds First Team Meeting for Clopyralid Registration Review. On August 28, 2013, members of the clopyralid registration review chemical team (PRD, HED, EFED, RD, BEAD) held a kick-off meeting for the registration review of clopyralid. Clopyralid is a carboxylic acid herbicide of the pyridine class registered for use to control established broadleaf weeds. It is used primarily on corn, sugar beets, wheat, barley, and pasture/rangelands but includes non-agricultural uses such as cemeteries, farm buildings, fencerows, ornamental lawns and turf, athletic fields, and parks. The pyridine class of pesticides is associated with incidents involving persistent toxic residues in compost. This issue will be considered and addressed in a comprehensive and consistent manner, where appropriate, across this class of compounds in registration review. The registration review docket for clopyralid is scheduled to open in March 2014 for public comment on the Preliminary Work Plan. (Steven Snyderman, 703-347-0249)

BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

Revision to the AOAC Use-dilution Method (UDM) Performance Standard Approved. Final approval was granted by the Journal of AOAC International to the Microbiology Laboratory Branch's manuscript entitled "Use of Statistical Modeling to Reassess the Performance Standard for the AOAC Use-dilution Method". The manuscript provides the justification and process used to adjust the UDM's performance standard (i.e., the number of positive carriers allowed for a passing outcome), and proposes a new performance standard based on recently published information on the method's variability. The new performance standard allow up to 3 positive carriers out of 60 for *Staphylococcus* and up to 6 positive carriers out of 60 for *Pseudomonas*. The new standard also requires replicate testing (three total tests per microbe); both microbes must pass (six total tests) to meet a hospital disinfectant claim. MLB will work with AOAC to revise the standard methods on-line, and will assist the Antimicrobials Division with communication and outreach initiatives. (Stephen Tomasino, 410-305-2976)

Expert on Biofilm Provides Results of Collaborative Study. Dr. Darla Goeres, Assistant Research Professor at Montana State University's (MSU) Center for Biofilm

Engineering, provided the results of a collaborative study of the ASTM Single Tube Method – E2871-12 via webinar. The Single Tube Method is used to measure the efficacy of antimicrobial products against *Pseudomonas* biofilm. Biofilm form when bacteria adhere to surfaces in moist environments by excreting slime. Biofilm are considered more tolerant to disinfectants than typical surface contaminants. Assessing the method's performance across multiple labs was the main goal of the collaborative study. The data suggest that the untreated control counts (amount of bacteria in biofilm) are very predictable; however, more variability was noted from the treated carriers (viable bacteria remaining after treatment). MSU plans on conducting additional analysis of the data to ascertain the number of replicates and labs necessary to have a high degree of confidence in the outcome of the test method. The Antimicrobials Division is considering the requirements for new label claims for control of biofilm, the appropriate test methods and associated performance standards. Use of the Single Tube Method as a regulatory procedure is under consideration. (Stephen Tomasino, 410-305-2976)

CSPA Concurs with Workshop Co-sponsorship Agreement. The OPP Microbiology Laboratory Branch hosts an annual multi-day laboratory workshop in November with the regulated community and private contract laboratories to discuss and demonstrate antimicrobial efficacy test methods. In the past, the laboratory has managed all aspects of the workshop which has proven to be resource intensive. In an effort to minimize EPA's resource investment, the laboratory approached the Consumer Specialty Products Association (CSPA) with a request to co-sponsor the workshop. CSPA agreed to the request. The co-sponsorship agreement was drafted by the lab, reviewed by OGC, and then shared with CSPA. The agreement lays out the purpose of the workshop, the roles and responsibilities of CSPA and EPA, whether fees can be collected etc. CSPA has reviewed the agreement and agrees with the conditions. CSPA has agreed to be responsible for the administrative aspects of the workshop including registration, registration fees, development of a participant list and name tags, providing industry speakers, as well as managing lunch and refreshments. EPA will manage the technical aspects of the workshop. (Susan Lawrence, 410-305-2954)

PDP Meeting in Manassas, VA. The Federal/State Pesticide Data Program (PDP) director invited Thuy Nguyen and Terry Cole of the Analytical Chemistry Branch (ACB) to give a presentation about the National Pesticide Standard Repository (NPSR). The meeting was attended by PDP Administrative Managers, Technical Program Managers, and Quality Assurance Officers. The presentation that Terry gave was well received and prompted good conversation and questions. The PDP laboratories rely on the NPSR to supply analytical standards. Many request come in marked *urgent* and the Repository must give priority to those requests.

Potential projects for FY2014 that may include collaboration with ACB were also discussed. (Thuy Nguyen 410-305-2905; Terry Cole 410-305-2907)

ANTIMICROBIALS DIVISION

EPA Proposes Registration of Nanosilver Pesticide Product. Nanosilva Proposed Decision On August 27, 2013, the EPA announced a proposed decision to register a nanosilver-containing antimicrobial pesticide product named "Nanosilva." This silver-based product is used as a non-food-contact preservative to protect plastics and textiles from odor and stain causing bacteria, fungi, mold and mildew. The EPA evaluated the exposure to nanosilver from Nanosilva using data showing that plastics and textiles treated with the product released, at most, exceedingly small amounts of silver. The EPA used information on the product submitted by the applicant along with data from the scientific literature to evaluate the hazard of nanosilver. Based on this evaluation, the agency determined that Nanosilva will not cause unreasonable adverse effects on people, including children, or the environment. As a condition of registration, the EPA is requiring the company to generate additional data. During the 30-day comment period, anyone may submit comments, relevant data or information for the agency's consideration. The Proposed Decision Memo is available at http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2012-0594 (Jed Costanza, 703-347-0204).

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

Ongoing efforts with EPA initiative OneEPA continues. – The Web Team continues to work with the Program to stand up the following Microsites and Resource Directories: Worker Protection, Endangered Species (Coloring Book), Pesticides Registration and Pesticides Re-evaluation. These web pages are in the development area of Drupal/WebCMS. If you would like to view the progress of these pages, please call (Les Hoot, 703-305-0876 or Miriam Organic, 703-605-0583)

Soil Fumigant Tarps name changes – The Web Team worked with PRD to change the names of TARPS currently listed on the webpage. This comes at the request of the manufacturers who did not make it clear that Canslit Inc. only manufactures the Shine N' Ripe product line, while Imaflex USA in Thomasville, NC is the manufacturer of the Can-Block product line. Both Imaflex USA and Canslit Inc. are wholly own subsidiaries of Imaflex Inc. (Miriam Organic, 703-605-0583)

Updated FIFRA Section 18 Database: Pesticide Emergency Exemptions Database is now available online at http://cfpub.epa.gov/oppref/section18/search.cfm (Mark Heflin, 703-605-0703, Marcel Howard, 703-305-6784)

Update on Electronic Reporting of Pesticide Production Data In the Section Seven Tracking System (SSTS). Mark Heflin, SDDB, is currently working with Kate Bouve, Chuck Ruple, Region 6, Glenda Dugan, Region 9, Julie Simpson, OECA, Michelle Yaras, OECA. The effort to transition electronically reporting of pesticide production data using EPA's Central Data Exchange (CDX) has been pushed to Production. We will invite a few companies to serve as "beta testers" and submit their mock reports electronically to the Agency via CDX. We are targeting mid-October 2013 as the launch date. (Mark Heflin, 703-605-0703, Kate Bouve 703-305-5032)

OPP FOIA Request Status Report – Aug 19 – 23, 2013							
Requests Received		***Requests Closed***			***Requests Open***		
FY13	***This Week***	***FY13***	***FYTD***	***This Week***	***FY13***	***Prior Years***	***Total***
472	10	277	369	7	195	122	317

(Ana Espinoza, 703-347-0102)

HEALTH EFFECTS DIVISION

OPP Epidemiologist attends ORD public meeting on using Systematic Reviews in Chemical Risk Assessment: On Monday, August 26th, 2013 the EPA/IRIS program held a public forum entitled "Applying Systematic Review to Assessments of Health Effects of Chemical Exposures." The workshop included a discussion of the importance of utilizing systematic review methods for both the analysis of experimental toxicology data as well as observational epidemiology data. Systematic review is a formalized process of literature review in which the research question (e.g., is chemical X related to specific disease outcome Y in specific population Z?) is formally stated, study inclusion and exclusion criteria are delineated, study review criteria are stipulated and all studies initially identified, reviewed and included as well as excluded are retained for public review. This is more resource-intensive than a traditional, generic literature review, but the added resources are expected to result in increased transparency of the overall assessment process. The workshop included formal presentations as well as informal panel discussions regarding different 'tools' or scales proposed for evaluating epidemiology studies, a recent effort by National Toxicology Program(NTP) to propose a systematic review process within a chemical evaluation scheme reflecting both animal and human data, and the often under-appreciated role of mechanistic information in the systematic review process.

Panelists and participants agreed the use of formalized systematic review procedures has the potential to shift the focus of public conversation around EPA risk assessments away from a critique of the process and methods of analysis, and more toward a discussion of the resulting decision and quality of the supporting evidence. (Carol Christensen, 305-6230)

REGISTRATION DIVISION

Tolerances Established for Pyraclostrobin On August 28, 2013, the *Federal Register* published a final rule, which established tolerances for residues of the fungicide pyraclostrobin in or on globe artichoke, Belgium endive, persimmon, bulb vegetable group 3-07, fruiting vegetable group 8-10, citrus fruit group 10-10, pome fruit group 11-10, oilseed group 20, caneberry subgroup 13-07A, bushberry subgroup 13-07B, small vine climbing fruit (except fuzzy kiwifruit) subgroup 13-07F, and low growing berry subgroup 13-07G (except cranberry), associated with pesticide petition (PP) 2E8069. This regulation additionally established a permanent tolerance on sugarcane associated with PP# 2F8083. The permanent tolerance will replace the time-limited tolerance established to support this use under Section 18 of FIFRA. EPA has granted emergency exemptions for sugarcane since 2008. Finally, this regulation removes several additional established tolerances that are superseded by tolerances established by this action. Pyraclostrobin belongs to the strobilurin class of fungicides, which are synthetic analogs of a natural antifungal substance that inhibits spore germination, mycelial growth, and sporulation of the fungus on the leaf surface. BASF Corporation owns the pesticide product labeling associated with the new uses approved by this action. The Interregional Research Project No. 4 (IR-4) and BASF Corporation requested the tolerances associated with PP#s 2E8069 and 2F8083, respectively. (Laura Nollen, 703/305-7390)

Tolerances Established for Halosulfuron-methyl On August 28, 2013, the *Federal Register* published a final rule establishing permanent tolerances for residues of halosulfuron-methyl in or on artichoke and caneberry subgroup 13-07A. The Interregional Research Project Number 4 (IR-4), in collaboration with Canyon Group, LLC and Gowan Company, requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). Halosulfuron-methyl, a selective herbicide, is a member of the sulfonylurea chemical family which acts to inhibit acetolactate synthase (an enzyme in the biosynthetic pathway). It is registered for pre- and post-emergence control of annual broadleaf weeds and nutsedges in certain crops as well as residential turf grass and ornamentals. (Sidney Jackson, 703/305-7610)

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	**Company**	**Registration Number**	**Action Code***	**Due Date**	**Response Date**
The Herbicide Branch granted:					
2,4-D, 2-ethylhexyl ester	PBI/Gordon Corporation	2217-979 2217-980 2217-982	R314 R314 R310	9/10/2013 9/10/2013 9/18/2013	8/26/2013
Pinoxaden	Syngenta Crop Protection, LLC	100-1256 100-1314	R350	9/10/2013	
Fluroxypyr 1-methylheptyl ester		100-1389			
Bethany Benbow, 703/347-8072					
Glyphosate-isopropylammonium	Monsanto Company	71995-59	R310	8/30/2013	8/27/2013
Mindy Ondish, 703/605-0723					
Picoxystrobin	E. I. Dupont de Nemours and Company	352-883	R314	8/26/2013	8/26/2013
Emily Hartman, 703/347-0189					
The Insecticide Branch granted:					
MGK 264, Ethofenprox	Wellmark International	2724-809	R340	8/26/2013	8/22/2013
Kevin Sweeney, 703/305-5063					
Permethrin	Univar Environmental Sciences	73748-11	R301	9/20/2013	8/29/2013
Linda DeLuise, 703/305-5428					
Methoxyfenozide	Dow AgroSciences LLC	62719-667	R314	8/29/2013	8/29/2013
Melody Banks, 703/305-5413					
The Insecticide-Rodenticide Branch granted:					
Diflubenzuron	Central Garden & Pet Company	89459-1	R301	9/16/2013	8/27/2013
Dani Daniel, 703/305-5409					

R301 – New product identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner; **R310** – New end-use or manufacturing use product; requires review of data package within RD; includes reviews and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy; R**314** – New end use product containing two or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry, acute toxicity, public health pest efficacy, and/or child resistant packaging (2), (3); **R340** – Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient) (2); and **R350** – Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement)(2)

BIOPESTICIDES & POLLUTION PREVENTION DIVISION

BPPD Registration Actions Completed Under PRIA: May – July 2013

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Active Ingredient	**Company**	**EPA Registration #**	**PRIA Code + Action**	**PRIA Date**	**Registration Date**
The Biochemical Branch granted:					

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Active Ingredient	**Company**	**EPA Registration #**	**PRIA Code + Action**	**PRIA Date**	**Registration Date**
Homobrassinolide	Repar Corp.	69361-38	B670	6/3/13	5/21/13
					Leonard Cole, 305-5412
Sodium lauryl sulfate	Beeaware, Inc.	84072-R (withdrawn)	B672	6/15/13	5/29/13
					Leonard Cole, 305-5412
Indole-3-butyric acid	Advanced Nutrients	88452-1	B670	7/8/13	6/24/13
					Colin Walsh, 308-0298
(Z,Z)-11,13-Hexadecadienal	Suterra, LLC	73479-3	B730	8/14/13	7/3/13
					Colin Walsh, 308-0298
Indole-3-butyric acid	SJ Enterprises LTD.	89385-1	B660	8/22/13	7/23/13
					Leonard Cole, 305-5412
Hydrogen Peroxide	Solvay Chem. Inc.	68660-14	B672	7/23/13	7/23/13
					Menyon Adams, 347-8496
The Microbial Branch granted:					
Bacillus thuringiensis galleriae strain SDS-502	Phyllom, Inc.	88347-EUP; 88347-1	B620; B600	5/8/2013; 6/7/13	5/8/2013; 6/6/13
					Jeannine Kausch, 347-8920
Chromobacterium subtsugae PRAA4-1T	Marrone Bio Innovations	84059-17	B680	5/13/2013	5/13/2013
					Jeannine Kausch, 347-8920
Bacillus thuringiensis israelensis strain SUM-6218	Summit Chemical Co.	6218-83	B600	5/16/2013	5/13/2013
					Denise Greenway, 308-8263
Bacillus pumilus, strain Bu F-33	Becker Underwood, Inc.	71840-12	B590	6/2/13	5/31/13
					Jeannine Kausch, 347-8920
Bacillus amyloliquefaciens D747	Certis USA, LLC	70051-115	B673	10/24/13	7/4/2013
					Shannon Borges, 305-7175
Pasteuria nishizawae Pn1	Syngenta Crop Protection, LLC	100-1524	B680	10/17/13	7/10/13
					Jeannine Kausch, 347-8920
Bacillus thuringiensis galleriae SDS-502	Phyllom, LLC	88347-3	B600	1/17/14	7/11/13
					Jeannine Kausch, 347-8920
Wolbachia pipientis	Mosquitomate, Inc.	89668-EUP-1	B620	7/29/13	7/26/13
					Shanaz Bacchus, 308-8097

PRIA Codes: B590 - New active ingredient; food use; establish tolerance exemption; **B600** - New active ingredient; non-food use; **B620 -** New active ingredient; Experimental Use Permit application; non-food use including crop destruct; **B650** - New use; non-food; **B660** - New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Active Ingredient	**Company**	**EPA Registration #**	**PRIA Code + Action**	**PRIA Date**	**Registration Date**
submission or data matrix; **B670** - New product; registered source of active ingredient; all Tier I data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data waivers supported by scientific rationales; **B672** - New product; non-food use or food use having established tolerance or tolerance exemption; unregistered source of active ingredient; no data compensation issues; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with request for data waivers supported by scientific rationales; **B673:** New product MUP/EP; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency. Requires an Agency determination that the cited data supports the new product. **B680** - Label amendment requiring data submission; **B730** - Label amendment requiring data submission.					