

Chemical Producers & Distributors Association
1730 Rhode Island Avenue, N.W.
Suite 812
Washington, D.C. 20036
Telephone: (202) 386-7407
Fax: (202) 386-7409

Keeping an Eye on Washington

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EPA Announces Revised Schedule for Pesticide Registration Review

EPA has announced its updated schedule for the pesticide registration review program which provides the timetable for opening dockets for the next four years through Fiscal Year 2013. PRIA requires EPA to complete registration review decisions by October 1, 2022 for all pesticides registered as of October 1, 2007. To ensure this deadline is met, the Agency plans to open approximately 70 pesticide registration review dockets annually through 2017. EPA notes that some biopesticide dockets will be opened in 2018 through 2020. The Agency states that this scheduling will provide adequate lead times to complete registration review decisions by the PRIA mandated date of October 1, 2022. EPA anticipates a total of about 721 pesticide cases comprising 1,135 pesticide active ingredients to undergo registration review by 2022. According to EPA, the updated registration review schedule reflects the Agency's decision to review all pesticides in two groups – the fumigants and the triazines – within the same time frame.

A *Federal Register* notice announcing the updated schedule states, "In recent years, the Agency moved these pesticides ahead in the schedule so that dockets for all pesticides in these groups will open in FY 2013. While EPA is implementing risk mitigation decisions for the soil fumigants, new research is underway to address current data gaps and to refine understanding of factors that affect how fumigants move in the environment...By moving the soil fumigants forward in registration review from 2017 to 2013, the Agency will be able to consider new data and new technologies sooner, determine whether mitigation included in its decisions is effectively addressing risks as EPA believes it will, and include other fumigants that were not part of the reregistration review of these pesticides."

EPA initiated a reevaluation of the triazine pesticide atrazine in fall 2009. Drawing on the availability of new scientific information as well as the documented presence of atrazine in both drinking water sources and other bodies of water, EPA has deemed it appropriate to consider the new research and ensure that its regulatory decisions about atrazine protect health and the environment. EPA states that its reevaluation process is based on transparency and sound science, including independent scientific peer review. According to EPA, the current atrazine reevaluation will help address aspects of the atrazine registration review scheduled to begin in 2013 that involve human health risk assessment. As a result, EPA anticipates that the current

reevaluation should reduce the scope and resources needed to complete the atrazine registration review.

The updated registration review schedule is posted on EPA's web site and may be accessed at http://www.epa.gov/oppsrd1/registration_review/schedule.htm.

EPA Proposes One-Year Extension of Pesticide Container Labeling Requirements

In the June 15, 2010 *Federal Register*, EPA published a proposed rule to amend the pesticide container and containment regulations to provide a one-year extension of the labeling compliance date from August 16, 2010 to August 16, 2011. Under the proposal, pesticide products released for shipment by a registrant after August 16, 2011 would be required to bear a label that complies with the container requirements.

The pesticide container and containment regulations, promulgated on August 16, 2006, include requirements for container design; procedures, standards, and label language to facilitate removal of pesticide residue prior to container disposal or recycling, and criteria for containment of stationary pesticide containers and procedures for container refilling operations. A final rule published on October 29, 2008 amended the 2006 regulations to extend the original compliance date of August 16, 2009 to August 16, 2010. However, EPA has concluded there is insufficient time to change all labels by the revised August 16, 2010 compliance date due to several factors: 1) more antimicrobial product labels than expected require alternate rinsing instructions rather than the standard text as set forth in the regulations (such statements on the label must be made through the more time-consuming amendment process rather than through the more simplified notification mechanism); 2) EPA's position on the appropriate container-related statements, particularly rinsing and treatment of rinsate, for certain pesticides has changed over time as a result of experience with product-by-product label reviews and this, EPA notes, has created confusion within the registrant community; and, 3) the length of time for states to review and approve labels is increasing due to staffing reductions and furloughs brought about by budget shortfalls.

The Agency estimates that there are at least 1,000 labels and possibly as many as several thousand pesticide product labels that await submission and review. The Agency explains, "...Even if all of those applications were submitted immediately, there would not be enough time for the label changes to be approved by EPA and the states, printed, and applied to all products that will be released for shipment after August 16, 2010." EPA is confident that a one-year extension will provide enough time for the Agency and the states to review the label changes and for registrants to incorporate the changes into their labels provided that all applications are submitted soon.

Concurrent with the proposed one-year extension, EPA also issued a final rule to extend the current compliance date by four months. The Agency contends that there is not enough time for it to complete the full notice and comment procedures for the one-year extension by the impending compliance date of August 16, 2010. EPA states that the four-month extension will allow time for the public participation process to take place for the proposed extension.

EPA Posts Online Pesticide Label Training Tutorial on its Web Site

EPA has posted on its web site an online pesticide label tutorial aimed at training EPA employees whose job includes the review of labels as part of the registration process. In announcing the online tutorial, the Agency states that pesticide industry employees who develop labels for submission to EPA will also benefit from the training as the material will give these individuals a better understanding of what constitutes an acceptable label.

The online training course is divided into five modules as follows: Label Basics, Parts of the Label, Special Issues, Applying the Principles of Pesticide Label Review, and Emerging Issues and Course Completion. The five modules track the key concepts and requirements set forth in EPA's Label Review Manual. EPA states that the entire training can be completed in one or two sittings. Individuals may come back to the training tutorial where they left off. A quiz is provided at the end of the tutorial to help individuals assess their basic comprehension of the key labeling concepts covered in the training course. To take the labeling training course, visit EPA's web site at <http://www.epa.gov/pesticides/regulating/labels/pest-label-training/module1/index.html>.

EPA Invites Public Comment on Draft Biological Opinion that Addresses Effects of Twelve Pesticides on Pacific Salmonids

EPA is seeking comments from pesticide users, registrants, and other interested parties on draft Reasonable and Prudent Measures (RPMs) and Alternatives (RPAs) included in a draft Biological Opinion received by the Agency from the National Marine Fisheries Service (NMFS) on June 16, 2010. The draft Biological Opinion addresses the potential effects from 12 pesticides to Pacific salmon and steelhead listed as endangered or threatened under the Endangered Species Act. The 12 pesticides include: Azinphos Methyl, Bensulide, Dimethoate, Disulfoton, Ethoprop, Fenamiphos, Methidathion, Methamidophos, Methyl Parathion, Naled, Phorate, and Phosmet.

Under Section 7 of the Endangered Species Act (ESA), EPA is required to initiate formal consultation with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service (i.e., the "Services") if the Agency determines that a pesticide's registered uses are likely to adversely affect a federally listed threatened or endangered species or modify its critical habitat. The draft Biological Opinion concludes that EPA's proposed registration of pesticides containing bensulide, dimethoate, disulfoton, ethoprop, methidathion, methyl parathion, naled, phorate, and phosmet is likely to jeopardize the continued existence of 23 endangered and threatened Pacific salmonids and is likely to destroy or adversely modify designated critical habitats for 23 threatened and endangered salmonids. The registrations of disulfoton, methidathion, and methyl parathion are cancelled or in the process of being cancelled and the draft Biological Opinion notes that exposure to these three active ingredients will decline accordingly. However, the terms of the cancellation of these three chemicals allow for pesticide product sales and use to continue for several years. As such, the RPAs and RPMs outlined in the draft Biological Opinion also apply to these three chemicals.

The draft Opinion lists several elements that would be required to appear on the label of bensulide, dimethoate, disulfoton, ethoprop, methidathion, methyl parathion, naled, phorate, and phosmet including instructions directing the user not to apply product when wind speeds are greater than or equal to 10 mph immediately prior to application. The user would also be directed to refrain from applying the product when soil moisture is at field capacity or when a storm event that is likely to produce runoff from the treated area is forecasted by the National Weather Service to occur within 48 hours following application. The draft Biological Opinion calls upon EPA to implement NMFS approved risk reduction measures to ensure that the maximum concentrations of the affected pesticides will not exceed specified levels. Such measures could include but are not limited to the use of buffers (the draft Opinion does not recommend a specific buffer size), vegetated filter strips, reduction in the maximum single or seasonal application rates, reductions in the number of applications allowed, increases in the minimum application interval, restrictions on application methods, and restrictions on use sites. The draft Biological Opinion also includes a reporting requirement for any fish kills that occur within the vicinity of the treatment area within four days of application. In addition, the draft Biological Opinion would require EPA to develop and implement an “effectiveness monitoring plan” for flood plain habitats.

The draft Biological Opinion is included in the docket ([EPA-HQ-OPP-2008-0654](http://www.epa.gov/oppfead1/endanger/litstatus/effects/bio-op-nmfs.pdf)) and may also be accessed on EPA’s web site at <http://www.epa.gov/oppfead1/endanger/litstatus/effects/bio-op-nmfs.pdf>. Comments on the draft RPMs and RPAs must be submitted within 30 days of the date the Biological Opinion was included in the docket in order for EPA to consider these comments in its response to the NMFS recommendations (the draft Biological Opinion was posted to the docket on June 17, 2010). Comments received by EPA on other aspects of the draft Biological Opinion will be forwarded to the Services for their consideration. EPA states that no extensions to this comment period will be provided because NMFS has a legal deadline to issue the final Biological Opinion by August 31, 2010.

EPA Plans New Limitations on Three Carbamate Pesticides to Protect Endangered and Threatened Salmon and Steelhead

In related ESA developments, EPA recently announced its intentions to place additional restrictions on the use of carbaryl, carbofuran and methomyl in response to recommendations contained in a Biological Opinion issued by the National Marine Fisheries Service (NMFS) on April 20, 2009. The Opinion and EPA’s response focus on the potential effects of these three pesticides on 29 threatened or endangered Pacific salmon and steelhead species in the states of California, Idaho, Oregon, and Washington. Among the measures that EPA will adopt is the requirement for spray drift buffers. NMFS recommended that a buffer of 200 feet to 600 feet be established for the ground application of carbaryl and carbofuran and that a 1000 foot buffer be implemented for aerial application of these chemicals to order to protect salmon and steelhead habitats. NMFS also recommended that the use of methomyl be prohibited within 50 feet of salmon and steelhead habitats when applied by ground or within 600 feet when applied by air. EPA states that while it will require spray drift buffers adjacent to salmon and steelhead habitat, it will impose different width buffers depending on factors such as application rate, spray droplet size, and water body size. EPA states that in no case will buffers be less than 25 feet or more than 1000 feet.

In other actions, EPA is adopting the following NMFS recommendations included in the Biological Opinion: 1) application of the three pesticides will be prohibited when wind speeds exceed 10 mph immediately prior to application; 2) use of the pesticides will be prohibited when soil moisture is at field capacity or when a storm event likely to produce runoff within 48 hours after application is forecast by the National Weather Service; and, 3) incidents of fish mortality that occur within four days of application and within the vicinity of the treatment area must be reported to the Office of Pesticide Programs (EPA will require that such incidents be reported to the pesticide registrant within the existing statutory framework provided under the FIFRA Section 6(a)(2) adverse effects reporting provisions). EPA will also implement an effectiveness monitoring program that will allow the Agency to determine whether these risk reduction measures are effective at limiting the amount of pesticide residues in the most vulnerable types of salmon and steelhead habitat. The Agency will require the manufacturers of the three pesticides to fund and carry out the monitoring study.

EPA states that it will request the manufacturers to voluntarily adopt the new use limitations, which will be enforceable once pesticide labels are modified to refer to Endangered Species Protection Bulletins. If the manufacturers decline this request, EPA signals that it will pursue regulatory action to impose the limitations.

A description of the Agency's plans to implement the recommendations contained in the NMFS Biological Opinion are detailed in a May 14, 2010 letter from Rick Keigwin, Director of EPA's Pesticide Re-evaluation Division to James H. Lecky, Director of the NMFS Office of Protected Resources. The letter and accompanying technical appendix may be accessed at <http://www.epa.gov/espp/litstatus/wtc/biop-ltr-to-jhlecky-may-2010.pdf>.

EPA Releases Draft Pesticides General Permit for Public Comment

EPA has released its draft National Pollutant Discharge Elimination System (NPDES) permit for point source discharges from the application of pesticides to, over, or near waters of the United States. The Agency's development of the draft Pesticides General Permit (PGP) was prompted by a United States Sixth Circuit Court of Appeals decision, handed down in January 2009, that vacated an EPA rule which held that a pesticide applied in or near a receiving water of the U.S. in accordance with the FIFRA approved label is not subject to NPDES permitting requirements under the Clean Water Act. Public comment on EPA's draft permit will be accepted through July 19, 2010.

The draft Pesticides General Permit, once finalized, will regulate discharges to waters of the U.S. from the application of biological pesticides, and chemical pesticides that leave a residue. The following pesticide use patterns are covered under the PGP: mosquito and other flying insect pest control, aquatic weed and algae control, aquatic nuisance animal control, and forest canopy pest control. The PGP does not authorize coverage for discharges of pesticides or their degradates to waters already impaired by these specific pesticides or degradates nor does it authorize discharges to outstanding national resource waters (also known as Tier 3 waters). Such

discharges will require coverage under individual NPDES permits. Furthermore, the PGP does not include terrestrial applications to control pests on agricultural crops or forest floors.

The draft general permit imposes certain basic requirements on all entities subject to the permit, and additional requirements on entities that exceed specific application thresholds. As such, all operators with pesticide applications involving the four uses potentially affecting navigable waters must comply with the minimum requirements of the general permit. Operators responsible for applications that exceed treatment thresholds (i.e., specified acres or linear miles), must submit a Notice of Intent (NOI) to be covered by the general permit and must comply with additional requirements, such as a pesticide discharge management plan, integrated pest management practices, and annual reporting. All other operators would obtain permit coverage immediately upon engaging in any of the four activities, with an on-going obligation to comply with the basic requirements (e.g., conducting certain activities to minimize pesticide applications and reporting adverse incidents). EPA conducted multiple outreach events during the past year to solicit input before issuing the draft permit. However, the Agency concedes the weak basis for some permit provisions and the need for more reliable information in some areas of the permit to develop a final permit that is a fair and reasonable scheme for regulating these pesticide applications under the CWA.

CPDA is preparing comments on the draft permit and encourages its members to provide our office with any input or concerns they have regarding this issue. A copy of the draft Pesticides General Permit and supporting documents are available on EPA's web site at http://cfpub.epa.gov/npdes/home.cfm?program_id=410.

EPA Reissues Draft PR Notice on False or Misleading Pesticide Product Brand Names for Public Comment

On June 14, 2010, EPA announced a 60-day extension of the public comment period from June 18, 2010 to August 17, 2010 on its draft PR Notice entitled "False or Misleading Pesticide Product Brand Names." This announcement follows a formal request for extension submitted to EPA by CPDA on May 28, 2010. Comments on the draft PR Notice may be submitted electronically at www.regulations.gov and must be identified by docket number EPA-HQ-OPP-2010-0282. The draft PR Notice was previously published for public comment on March 28, 2002 but was never finalized. In reissuing the draft PR Notice for public comment, EPA has included revisions in response to comments it received in 2002.

The revised draft PR Notice explains the statutory and regulatory requirements that a pesticide product brand name, either by itself or in close proximity to a company name or trademark, must meet in order not to be deemed false or misleading under FIFRA. The draft PR Notice provides examples of potentially false or misleading product brand names. The document encourages applicants and registrants to review their product names and, if warranted, take corrective action within two years of the issuance of the final PR Notice. EPA states that after the final implementation date, the Agency may consider the guidance in the final PR Notice when determining whether a product is misbranded under FIFRA.

In late 2009, CPDA and its industry partners learned that EPA label reviewers were rejecting words such as "professional (Pro)," "maximum (Max)," "super," "plus," and "ultra," based on their potential to be false or misleading. Registrants would have to either remove the word or develop acceptable qualifying label language to minimize the potential for a brand name to be false or misleading under FIFRA. This unexpected and unannounced change in policy would have an immediate and costly impact on the pesticide industry and was not consistent with the Agency's express commitment to increased transparency in Agency decision making. Moreover, it was not clear how reasonable and flexible EPA would be in working with registrants in developing qualifying label language. In response, CPDA along with CLA, CSPA and RISE wrote a December 3, 2009 letter to then OPP Director Debbie Edwards asking her to suspend further implementation of the policy until it was subjected to public review. In addition, the letter asked EPA to reissue draft PR Notice (2002-X) for public comment.

On May 12, 2010, CPDA and other members of the industry coalition received a written response from Steven Bradbury, the newly appointed Director of OPP. In his letter, Bradbury stated, "...While I am not aware that our Office has requested any changes in product names based solely on the guidance in the draft PR Notice, I am aware that the registering divisions have begun reviewing brand names that are submitted for supplemental distributor products and in some cases basic product registrations. In several cases, suggested brand names have been found to be potentially false or misleading and have either been rejected or revised to no longer be false or misleading. Each of those situations has been resolved on a case-by-case basis." He agreed with CPDA and other members of the industry group that EPA should not broadly implement a draft PR Notice until a final PR Notice has been issued. In response to the industry coalition's request, Bradbury agreed to reissue a revised draft PR Notice for public comment.

Bradbury advised the industry group that EPA will continue to respond to potentially false or misleading terms in product brand names in a manner "that is consistent with what has been done historically." Bradbury explained, "That is, if there is precedent for considering a term to be false or misleading, EPA will generally continue to do that. However, if there is no precedent for questioning a particular claim that is listed in the PR Notice, EPA will generally not act on that claim until the PR Notice is issued in final form. Further brand names that constitute claims that are clearly false cannot, and will not, be approved regardless of the status of the PR Notice."

EPA Announces Settlement on Human Subjects Testing Rule

On June 18, 2010, EPA announced that it had reached an agreement with a coalition of environmental, public health, and farm worker advocacy groups in settlement of a lawsuit over the Agency's 2006 regulation that established protections for individuals who are the subject of intentional human dosing studies involving pesticides. Under the terms of the settlement, EPA will propose amendments to the rule that would strengthen standards for human testing and broaden existing testing prohibitions applicable to children and pregnant women.

The Agency states that the proposed changes will formalize many existing procedures that EPA has been following in implementing the 2006 rule. EPA believes that the proposed changes respond to the three principal areas of concern identified by the petitioners including the scope of the rule, its consistency with the 2004 National Academy of Science recommendations, and its

consistency with the Nuremberg Code. The settlement agreement requires EPA to publish the proposed amendments in a *Federal Register* notice before January 16, 2011, and to open a public comment period at the same time. The amendments will be finalized by December 16, 2011. The proposed settlement agreement has been submitted to the Second Circuit Court of Appeals for approval.

Legislation to Amend the Clean Water Act Introduced in House

On April 21, 2010, Representative Jim Oberstar (D-MN), Chairman of the House Transportation & Infrastructure (T&I) Committee, introduced his fifth version of the Clean Water Restoration Act (CWRA) rebranded as “America’s Commitment to Clean Water Act” (H.R. 5088) and hopes to have it on the House floor in September. While the name has changed, the essence of the bill remains the same – the term ‘navigable’ is struck from the law and replaced with ‘waters of the United States’ and is defined broadly. Oberstar also included exemptions for prior converted cropland and waste treatment facilities.

Last summer the Senate Environment & Public Works Committee passed S. 787, the Clean Water Restoration Act, introduced by Senator Russ Feingold (D-WI). After committee passage, Senator Mike Crapo (R-ID) declared he would place a ‘hold’ on the bill in an attempt to stop it from going any further. However, even Senate aides concede it would be hard to vote against clean water on the eve of an election.

While the Oberstar bill still faces obstacles, the fact that he is the chairman of the Transportation & Infrastructure Committee, the largest committee in the House of Representatives at 75 seats, is important considering Democrats have a 45 to 30 seat majority. Additionally, the fact that the committee will not be taking up the massive 6-year highway authorization bill means Oberstar can focus on this issue and can mobilize the committee’s formidable resources in support of the bill.

However, agricultural groups and energy groups remain opposed to the bill despite his attempt to placate them through exemptions. Additionally, multiple other industries remain unified in opposition to the legislation, including the National Association of Manufacturers. Finally, House Republicans on the Transportation and Infrastructure Committee remain united in opposition to the bill and plan to fight the bill if Oberstar tries to move it.

CPDA believes that the revised Oberstar definition of what is a ‘water of the United States’ is concerning. The new bill retains an expansive definition of what is federal jurisdiction and includes a new phrase regarding ‘affects on the property of the United States’ which introduces more uncertainty to the regulated community.

This broad expansion of the reach of the CWA and new phrase will, like previous iterations, give EPA regulatory authority over all, or nearly all, inter and intra-state waters and their tributaries. This expanded jurisdiction would likely result in a tidal wave of new permit requests, which will undoubtedly clog the system and cause further delays in an already slow permit process.

Senate Democrats Block Resolution Repealing EPA's Ability to Regulate Carbon Dioxide

On June 10, 2010, Senate Democrats scored a face-saving victory by convincing enough of their members not to support a Republican led measure (S.J. Res. 26) that would have overturned EPA's endangerment finding that greenhouse gases are a threat to humans. The resolution failed 47 to 53, four votes short of the 51 needed to pass. The finding is the legal crux for new regulations designed to reduce greenhouse gas emissions from cars and trucks, power plants, refineries, businesses, and more. Senator Lisa Murkowski (R-AK), who sponsored the resolution, contends the EPA rules will impose a costly emissions requirement on 100 percent of the economy.

The White House opposed the measure and threatened to veto the resolution if it passed. The Administration was joined by environmental groups in lobbying for no votes. Proponents of climate change have been using the endangerment finding as leverage to pass a bill capping emissions and did not want to lose that leverage.

While the resolution failed, Senate Democrats are still struggling to craft a comprehensive climate/energy bill that can pass the chamber before the August break. It is likely that the issue will rise again during debate of that bill, whenever it happens.

Chemical Site Security Legislation Not Likely to Move Any Time Soon

Despite a Senate hearing in March that focused attention on the issue, the Administration has yet to propose legislation to strengthen chemical site security. In addition, outside events – such as the Times Square attempted bombing, nomination proceedings for a new Director of National Intelligence, and the oil disaster in the gulf – are keeping the staff of the Senate Homeland Security and Governmental Affairs Committee busy on other priorities. As Congress moves into the summer months it appears less likely there will be enough time on the Senate floor to deal with a contentious chemical security bill, which it is likely to be if Democrats retain the Inherently Safer Technology requirement proposal.

At this juncture the Senate Homeland Security and Governmental Affairs Committee has not scheduled a hearing or mark-up on an Administration proposal. Nevertheless, when the Department of Homeland Security does put forth draft legislation, CPDA staff will make sure members understand what the bill does and how it could impact their business.

TSCA Reform Update

When Representative Henry Waxman (D-CA), Chairman of the House Energy & Commerce Committee, introduced his discussion draft of TSCA reform in April, he laid down a marker for the industry to consider. According to industry and committee sources, he is likely to introduce a second version soon, but that depends on two things – whether the Republicans work towards a compromise or simply oppose his efforts and whether industry is able to support the bill.

While it is unlikely that TSCA reform can pass the full House and Senate this year, if the House Energy & Commerce Committee marks up a bill – that bill will likely become the starting point for all future negotiations.

TSCA Reform Legislation Could Have Significant Impacts on Chemicals Containing Nanoscale Materials

TSCA reform legislation now under Congressional consideration could have a significant impact on substances containing nanoscale materials. The bill introduced in April by Senator Frank Lautenberg (D-NJ) includes a provision on “special substance characteristics” defined as any physical, chemical, or biological characteristics, other than molecular identity, that the EPA Administrator determines by order or rule, “may significantly affect the risks posed by substances exhibiting those characteristics.”

In determining the existence of special substance characteristics, the EPA Administrator would be directed to consider size or size distribution, shape and surface structure reactivity, and any other properties that may significantly affect the risks posed. In essence, under this legislation if a substance is found to contain nanoscale particles, it could be considered a new chemical or new use subject to pre-manufacture reporting requirements under TSCA. CPDA staff will continue to closely monitor Congressional action on TSCA reform and alert our members as further developments warrant.