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Keeping an Eye on Washington

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Register for the CPDA Annual AIC Conference

The 2009 AIC Conference will be held May 18th through the 21st at the Marriott Plaza San Antonio in San Antonio, TX. The meeting kicks off May 18th with the Drift Reduction Technology (DRT) Work Group, Adjuvants in Residue Trials (AR) Work Group and AIC Executive Committee meetings. On May 19th the AIC Committee and Inerts Steering Committee (ISC) will meet, both of which are open to anyone who wishes to attend. A welcome reception sponsored by CPDA members Huntsman Corporation and WinField Solutions, LLC will be held that evening in the Marriott's historic courtyard.

May 20th is a full day of programming with presentations on topics such as Smart Stacks, Formulation Patent Review, and NIS and Arrested Ear Syndrome. CPDA members Wilbur Ellis and Rhodia, Inc. are sponsoring a networking reception that evening at Paesanos Riverwalk, located along San Antonio's famed Riverwalk. The final day of the conference offers the choice of a morning of skeet shooting or the famous CPDA Golf Tournament, with cash and other prizes for players. An additional registration fee is required for both, and payment for golf must be in the form of a personal check as this is a CPDA PAC event.

To register for the AIC Conference please visit www.cpdo.com/2009-AIC-Conference. A room block is available at the Marriott Plaza San Antonio, reservations can be on our website or by calling 1-800-266-9432. Request to be placed in the CPDA room block and you'll receive the discounted room rate of \$189.00 a night. The room block closes April 21st, so book your room now!

President Obama Seeks Recommendations to Ensure Integrity of Scientific Processes Used in Executive Branch

President Barack Obama has issued a memorandum dated March 9, 2009 instructing the Director of the White House Office of Science and Technology Policy to develop a set of recommendations intended to guarantee the integrity of scientific and technological processes used throughout the Executive Branch. The recommendations must be presented to the President within 120 days from the date of the memorandum.

The President has directed that the recommendations be based on the following principles as set forth in the March 9th memorandum: 1) the selection and retention of candidates for science and technological positions in the Executive Branch should be based on the candidate's knowledge, credentials, experience, and integrity; 2) each agency should have appropriate rules and procedures to ensure the integrity of the scientific process used within the agency; 3) when scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards; 4) except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions; 5) each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised; and 6) each agency should adopt such additional procedures, including any appropriate whistleblower protections, as are necessary to ensure the integrity of scientific and technological information and processes on which the agency relies in its decision-making activities.

EPA Revises 21-day PRIA 2 Content Review Worksheet to Include Guidance on Inert Ingredients

EPA has posted a revised PRIA 21-day content screen review worksheet on the Agency's web site. The document may be accessed at http://www.epa.gov/pesticides/regulating/fees/questions/pria21day_wrksht.pdf.

The revised worksheet includes a question 2(a) which specifically asks whether all inerts, including fragrances, listed in the Confidential Statement of Formula (CSF) are approved for the proposed use. The worksheet also includes a substantially expanded footnote that sets forth guidance on the options that an applicant has if the Agency identifies an unapproved inert on the CSF. During the 21-day initial content screening, all CSFs will be reviewed to determine whether listed inerts, including fragrances, are approved for the proposed uses. If EPA identifies an apparent unapproved inert, the applicant must either: 1) remove the inert and use an approved inert or correct erroneously identifying information in the submitted CSF; 2) provide data to support approval of the inert; or 3) withdraw the application. Removal or substitution of an inert ingredient will require a new CSF and may require submission of data. EPA emphasizes that all information resolving the inert issue must be received by the Agency (or the application must be withdrawn) within the 21-day period. Otherwise, EPA will reject the application.

EPA encourages applicants to verify that all inert ingredients have been approved for the proposed uses before submitting an application, even if a product is currently registered by consulting the Agency's inert web site at <http://www.epa.gov/opprd001/inerts/lists.html>. Applicants should obtain approval for unapproved inerts prior to submitting applications to avoid delays in obtaining registrations for products containing that inert. If an inert is not listed on the inert

ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch at inertsbranch@epa.gov. Finally, when a brand, trade, or proprietary name of an inert ingredient is listed on the CSF, an applicant must also include information such as an alternate name of the inert, CAS number or other information the Agency would need to determine if it has been approved. Each component of an inert mixture, including a fragrance, must be identified, which in some cases may require the supplier of the mixture or fragrance to provide such information to the Agency. EPA warns that if the identification of the inert ingredients in a proprietary blend, including fragrances, is not provided within the 21-day content review period, the application will be rejected.

EPA Announces Updated Registration Review Schedule

EPA has announced the availability of an updated schedule for pesticide registration review which provides the timetable for opening dockets for the next four years from fiscal year 2009 through fiscal year 2012. PRIA 2 directs EPA to complete registration review decisions by October 1, 2022 for all pesticides registered as of October 1, 2007. EPA states that to ensure it meets this statutory deadline, the Agency will open approximately 70 pesticide registration review dockets annually beginning in FY 2009 and continuing through 2017. The Agency expects a total of about 710 pesticide cases comprising 1,136 pesticide active ingredients to undergo registration review by 2022.

The Agency also states that it intends to review the neonicotinoid pesticides as a group and has moved several of these pesticides ahead in the updated schedule so that dockets for all will open no later than fiscal year 2012. EPA explains that the neonicotinoids are a class of insecticides with a common mode of action that affects the central nervous system of insects, causing paralysis and death. The Agency references European studies suggesting that neonicotinic residues can accumulate in pollen and nectar of treated plants and represent a potential risk to pollinators.

The EPA states that beginning in 2009, all new dockets for conventional pesticide cases entering registration review will have a 60-day public comment period. The Agency explains, “Based on over 2 years of experience in implementing the registration review program, EPA believes that 60 days will both allow the public to review these dockets and identify any additional information that the Agency should consider, and enable the Agency to open 70 new dockets annually and comply with the PRIA II requirement that each pesticide case be reevaluated within a 15-year timeframe.” The new registration review schedule is available on EPA’s web site at http://www.epa.gov/oppsrrd1/registration_review/schedule.htm.

Three Companies File Suit against NMFS over Proposed Restrictions on Agricultural Products

Three companies including Cheminova, Inc.; Dow AgroSciences LLC; and Makhteshim Agan of North America, Inc., have jointly filed suit against the U.S. National Marine Fisheries Service (NMFS) over a Biological Opinion issued by the

Agency last November. The Biological Opinion would require further restrictions on authorized uses of the insecticides chlorpyrifos, diazinon and malathion near habitats of certain endangered west coast salmon and steelhead populations. To read the announcement regarding the suit, please click [here](#).

EPA Announces Availability of National Marine Fisheries Service Draft Endangered Species Act Biological Opinion for Three Pesticides

EPA has announced that it has received and posted to its web site a Draft Biological Opinion from the National Marine Fisheries Service (NMFS) that responds to requests for consultation under the Endangered Species Act for the potential effects on Pacific salmon and steelhead from three pesticides. EPA initiated consultation for carbaryl and methomyl on April 1, 2003, and for carbofuran on December 1, 2004. The Draft Biological Opinions for these chemicals may be accessed at <http://www.epa.gov/oppfead1/endanger/litstatus/effects/index.htm>.

The Agency states that in addition to posting the Draft Biological Opinion to its web site, it has established a public docket (EPA-HQ-OPP-2008-0654) for this and other Draft Biological Opinions related to pesticides and Pacific salmon and steelhead. EPA notes that it will consider public comment on the Reasonable and Prudent Alternatives (RPAs) and Measures (RPMs) within the Draft Biological Opinion in its comments to the National Marine Fisheries Service. Input on RPAs and RPMs received after EPA has provided comments to NMFS will be considered by EPA as it determines how to implement the final Biological Opinion. NMFS is scheduled to issue the final Biological Opinion on April 20, 2009.

USDA and Several House Members Urge EPA to Request Rehearing of Court Ruling on NPDES Permitting of Pesticides

As reported previously, on January 7, 2009 a three-judge panel of the Sixth Circuit Court of Appeals vacated an EPA final rule that exempted pesticides applied in accordance with FIFRA from Clean Water Act (CWA) National Pollutant Discharge Elimination System (NPDES) permitting requirements. The rule exempted both applied pesticides and any “residual materials” and “excess pesticide” that remain in water after the treatment period. The Court’s decision will require American farmers to obtain redundant permits for the application of all FIFRA compliant biological pesticides, including terrestrial applications, when they are reasonably likely to result in discharges to navigable waters. CPDA is concerned about the potentially disruptive effects this ruling will have on agriculture production. Not only will the ruling require farmers and commercial applicators that serve them to be regulated through specific or general NPDES permits, but it will also subject farmers to possible lawsuits, due to citizen-action provisions in the CWA, as EPA currently has no permitting system in place.

In conjunction with allied industry groups, CPDA has been working to enlist the support of USDA and members of the House and Senate Agriculture Committees in pressing EPA to petition the Court for a rehearing of the recent decision. The deadline for a petition for rehearing is April 9, 2009. CPDA is pleased that USDA Secretary Tom

Vilsack, and House Agriculture Committee Ranking Member Frank Lucas (R-OK) along with Subcommittee on Horticulture and Organic Agriculture Ranking Member Jean Schmidt (R-OH) recently sent letters to EPA Administrator Lisa Jackson urging her to petition the U.S. 6th Circuit Court of Appeals for a rehearing prior to the April 9th deadline.

In his March 6, 2009 letter to Administrator Jackson, USDA Secretary Vilsack states, "...The court's adverse decision will have profound implications for American farmers. The panel's ruling effectively broadens the potential application of the CWA to reach agricultural activities that the EPA has never regulated under the provisions of the CWA. By broadening the Act's reach, the court burdens American agriculture with a newly minted NPDES permit requirement for the application of all FIFRA-compliant biological pesticides whenever these pesticides might find their way into waters of the United States, and for all FIFRA-compliant chemical pesticides whenever the residues of those pesticides find their way into waters of the United States. The permit requirement could reach almost any pesticide application, requiring farmers to navigate a permitting system that is ill-suited to the demands of agricultural production. Failure to obtain a timely permit for pesticide application could cripple American farmers' emergency pest management efforts and hamper their ability to respond quickly to new pest infestations or threats of infestations, thus increasing the risk of crop loss."

Secretary Vilsack further emphasized that subjecting FIFRA-compliant pesticides to the additional regulatory regime of the CWA is duplicative and will not help protect the environment. "FIFRA mandates that the EPA approve and issue a registration for a pesticide product only after the EPA has determined that the product will not cause 'unreasonable adverse effects on the environment.' The pesticide registration and reregistration process under FIFRA considers the effects of pesticides on both human health and aquatic resources," the Secretary wrote. "If the EPA has concluded that a pesticide satisfies FIFRA and will not have an 'unreasonable adverse effect on the environment,' then it is reasonable to exclude the application of that pesticide from the permitting requirements of the CWA."

The March 19, 2009 letter from Representatives Lucas and Schmidt echoed sentiments similar to those expressed by Secretary Vilsack and warned that the extension of the Court's decision to terrestrial application of pesticides could place farmers in legal jeopardy under the citizen-action provisions of the Clean Water Act. In addition, they pointed out that the Court's decision "can be construed to apply to non-agricultural/non-pesticide applications and emissions, including spraying for mosquito control, vegetation management, and chemical deicing of roads and highways." Representatives Lucas and Schmidt concluded that the Court's ruling is "inconsistent with the intent of Congress and would drastically change decades of EPA regulatory practices."

In related developments, the Weed Science Society of America has written a March 30th letter to EPA Administrator Jackson urging her to request a rehearing of the Court decision. In a press release announcing the request, the Society states that the new permitting system mandated by the Sixth Circuit Court of Appeals "overrides FIFRA without offering any additional protection." The Society emphasizes that the Court ruling places "an unnecessary, unfunded burden on states, growers, homeowners, and

applications and will discourage the timely and effective management of invasive plants and weeds.”

CPDA will continue to monitor this issue closely and will report on further developments as they occur.

CPDA Submits Comments to OMB on Regulatory Review

On March 16, 2009, CPDA submitted comments to the White House Office of Management and Budget (OMB) in response to the Obama Administration’s request for recommendations on the development of a new executive order on regulatory review. As reported previously, President Obama issued a January 30, 2009 memorandum in which he calls for a review of the formal regulatory rulemaking process as set forth in Executive Order 12866 released on September 30, 1993 during the Clinton Administration. President Obama states, “...A great deal has been learned since that time. Far more is now known about regulation – not only about when it is justified, but also about what works and what does not. Far more is also known about the uses of a variety of regulatory tools such as warnings, disclosure requirements, public education, and economic incentives. Years of experience have also provided lessons about how to improve the process of regulatory review.”

In its comments, CPDA emphasized that many of the principles and processes set forth under Executive Order 12866 have proven to result in the promulgation of regulations that are effective, consistent, sensible, and understandable. In addition, CPDA pointed out that the review process implemented by OMB’s Office of Information and Regulatory Affairs (OMB/OIRA) provides a transparent mechanism for ensuring the promulgation of appropriate public health and environmental safety regulation that is cost-effective and supported by the best available science. This mechanism is governed by the requirements and principles established under several statutes including the Unfunded Mandates Reform Act, the Regulatory Flexibility Act, and the Paperwork Reduction Act of 1995.

CPDA stated that an amended Executive Order 12866 should provide guidance on the appropriate use of analytical tools that are available to inform regulatory decision-making including those in the behavioral and biological sciences. For example, a revised Executive Order 12866 could provide greater specificity with regard to where and when a cost-effectiveness analysis of alternative regulatory approaches might be appropriate. In addition, a revised Executive Order could call for the use of such tools as risk-risk analysis as well as regulatory economic impact analysis in evaluating the impact of proposed regulatory actions. Furthermore, CPDA pointed out that cost-benefit analysis could be improved upon by using distributional costs and benefits rather than point estimates.

In other issues, CPDA expressed its support for continued OMB/OIRA review of “significant” regulations defined as those actions having an annual economic impact of \$100 million or more, or adversely affecting, in a material way, a sector of the economy. CPDA also called for the reinstatement of the review of “significant guidance” if such guidance contains enforceable provisions.

Finally, CPDA called for a revised Executive Order 12866 that strengthens the role of the Small Business Administration (SBA) and its Office of Advocacy in providing input on proposed rules affecting small businesses to ensure full compliance with the Regulatory Flexibility Act. CPDA cited an SBA study which concluded that on a per employee basis, it costs 45 percent more on average for small firms to comply with regulations than large firms. The study also found that the differential in the costs of environmental regulations shouldered by small businesses compared with large companies exceeds 300 percent. CPDA offered the following recommendation in its comments: “The executive order could direct the agencies to address SBA [Office of] Advocacy comments in the *Federal Register* on the proposed rule, the certification of no significant impacts on a substantial number of small businesses, and on promulgation of the final rule. To meet this commitment, agencies should provide to the SBA [Office of] Advocacy a copy of the proposed rule, certification of no significant impacts on a substantial number of small businesses, and the final rule no less than 30 days prior to submission of the proposed or final rule to OIRA.”

OPP Director Debbie Edwards Addresses CPDA Mid-Year Meeting

On March 11, 2009 EPA Office of Pesticide Programs (OPP) Director Debbie Edwards appeared before CPDA Mid-Year Meeting attendees and outlined a lengthy list of Agency priorities for the coming year. Among these, Edwards told the audience that a major EPA objective is to meet the statutory goals under PRIA 2. She noted that registration review is now a statutory mandate requiring the review of pesticide registrations every fifteen years. Edwards then offered a quick update on the Agency’s Endocrine Disruptor Screening Program (EDSP) noting that staff from OPP recently briefed EPA Administrator Lisa Jackson on this initiative and that test orders will likely go out sometime during the first half of 2009. Edwards also indicated that most Tier 1 screening batteries for the EDSP are in place with 11 assays “ready to go.” In addition, she signaled that the list of 9 inerts and 64 active ingredients proposed as initial screening candidates for the EDSP will likely be subject to slight changes in response to the public comment EPA received after publishing the draft list.

In her other remarks, Edwards reported that the Agency’s draft PR Notice on spray drift is on hold until EPA gets more “clarity” on the Sixth Circuit Court decision handed down earlier this year vacating the Agency’s final rule which exempted pesticides from NPDES permitting requirements when applied in, on, or around water in accordance with FIFRA labeling requirements. Edwards added that at the moment the Sixth Circuit Court decision ranks as the number one issue in pesticides.

In other areas, Edwards stated that EPA’s Office of Pesticide Programs is looking to harmonize ecological risk assessments with the Agency’s Office of Water. The goal of this activity is to have one set of harmonized standards so as to eliminate duplicative efforts coming from both EPA offices. She told the CPDA audience that the Agency is hoping to unveil a proposal on harmonization perhaps this spring.

Turning to EPA’s implementation of its Endangered Species Act (ESA) obligations with regard to pesticides, Edwards told meeting attendees that the Agency

recently obtained three biological opinions from the National Marine Fisheries Service (NMFS) and is expecting to receive three more (see related story in this issue of *Keeping an Eye on Washington*). Edwards noted that in terms of consultations with the Services, EPA has forwarded as many as fifteen packages to NMFS. However, these packages were returned to the Agency as being “incomplete” for failing to address tank mixes and various other issues (a contention that EPA seemingly does not agree with). In her other comments regarding ESA, Edwards stated that EPA has done several nationwide endangered species assessments (as part of registration review) which will soon be released for public comment.

In her other remarks, Edwards reported that the Agency may make a decision late this year, but certainly no later than next year, on a petition filed by the Natural Resources Defense Council (NRDC) that requests EPA to revoke all tolerances and cancel all registrations for the pesticide 2,4-dichlorophenoxyacetic acid (2,4-D). She indicated that the Agency is attempting to craft a careful response to the NRDC petition since procedurally the filing of a petition is generally required before moving forward with the filing of a lawsuit against EPA. As such, EPA is taking its time in responding to the NRDC petition.

CPDA Mid-Year Meeting Attendees Hold Meeting with EPA Personnel at OPP

Attendees of the CPDA Mid-Year Meeting had the opportunity to meet with Office of Pesticide Programs (OPP) personnel at the Agency’s Arlington, Virginia office on the afternoon of March 11, 2009. Registration Division Director (RD) Lois Rossi was on hand to brief attendees on organizational changes being contemplated within RD. She suggested that an internal reorganization within RD would hopefully increase efficiencies and ease the significant work load that product teams are now experiencing. Rossi added that EPA is “not that far ahead” of its statutorily mandated PRIA deadlines and that an internal restructuring might help in this regard. In her other comments, Rossi stated that the Registration Division no longer issues “not grant” decisions as they are an “administrative nightmare” that essentially take the applicant “out of PRIA.” With regard to the initial 21-day PRIA application content screening, Rossi reported that the Agency is using a contractor to perform this activity to reduce staff “burn-out” and to provide some relief to resource limitations. Rossi noted that the performance of initial screening by contractors allows for better consistency particularly given the fact that the Agency trains the contractor.

In other discussion, EPA staff at the March 11th meeting addressed the Agency’s process for transferring pesticide registrations from one entity to another. FIFRA allows the transfer of pesticide registrations without a new application for registration by the transferee upon submission of and EPA approval of a transfer agreement. OPP personnel reported that the EPA has been working to reduce a backlog of transfer applications with the goal of eliminating nearly all remaining pending actions within the next 90 days. According to EPA staff, approximately 20 transfer applications currently await Agency action. Of these, all but one or two transfer applications are expected to be completed within the 90-day timeframe. EPA intends to publish in its revised Blue Book a sample of a transfer agreement along with examples of affirmation agreements.

In response to a question regarding the status of the electronic Confidential Statement of Formula (CSF), Debbie McCall reported that this tool is still in the process of being programmed. In her other remarks, McCall stated that the 21-day PRIA 2 content screen has helped to reduce problems and deficiencies in the area of product chemistry and that the Agency is seeing a reduction in the number of applications containing unapproved inerts.

Chemical Facility Security Update

CPDA and other members of the Chemical Sector Coordinating Council (CSCC) met on March 31, 2009 to discuss the ongoing efforts of the U.S. Department of Homeland Security (DHS) to implement the Chemical Facility Anti-Terrorism Standards (CFATS). The meeting included personnel from DHS who provided an update on Congressional activities surrounding chemical site security. Recently, DHS personnel met with the House and Senate authorizing committees that have jurisdiction over chemical facility security to answer questions regarding the current mandates contained in the CFATS and the impact of possible statutory changes now under Congressional consideration. As reported previously, DHS promulgated the CFATS as an interim final rule under the authority of Section 550 of the DHS Appropriations Act of 2007. In the absence of further Congressional action, CFATS will sunset on October 1, 2009. DHS personnel told Congressional staff that a legislative directive requiring the implementation of inherently safer technology (IST) was not necessary and could subject industry to “overly onerous” mandates unrelated to chemical site security. In addition, DHS personnel relayed to Congressional staff concern that major legislative changes to current chemical site security mandates could disrupt the ongoing efforts of the Department to administer CFATS. DHS personnel signaled their preference for codifying the current CFATS by removing the October 1, 2009 sunset date so as to give permanent status to the regulations. *(Editor’s Note: As of this writing, reports continue to circulate that House Homeland Security Committee Chairman Bennie Thompson is nearing completion of a legislative draft and intends to introduce chemical facility security legislation prior to the Memorial Day Congressional recess. Meanwhile, there are no reports to suggest that the Senate Homeland Security and Governmental Affairs Committee is developing a companion bill on chemical site security at this time).*

President Obama Announces Nominee for OPPTS Assistant Administrator

President Obama has nominated Stephen A. Owens to serve as Assistant Administrator for the EPA Office of Prevention, Pesticides and Toxic Substances. Owens served as Director of the Arizona Department of Environmental Quality from January 2003 until January 2009. While at the Arizona Department of Environmental Quality, Owens established an office of Children’s Environmental Health. From 1982 to 1984, Owens served as counsel to the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology. During 1985-1986, Owens was chief counsel and later state director for then U.S. Senator Al Gore.

In related news, on March 27, 2009, EPA Administrator Lisa Jackson announced the interim appointment of Marcia Mulkey as the Acting Associate Administrator for the

Office of Policy, Economics and Innovations and Peter C. Grevatt as Senior Advisor for Children's Environmental Health. Mulkey is currently Director of the EPA Office of Site Remediation Enforcement within the Agency's Office of Enforcement and Compliance Assurance. From 1998 to 2003, Mulkey directed the EPA's Office of Pesticide Programs.

Grevatt served as Director of the Economics, Methods and Risk Analysis Division within the EPA Office of Solid Waste where he worked on RCRA implementation and provided health risk assessments and economic cost-benefit analyses on major rulemakings. He also served as Senior Science Advisor in the EPA Office of Solid Waste and Emergency Response (OSWER) where he worked on a range of issues related to asbestos, PCBs, lead and arsenic.

Meanwhile, on April 1, 2009 the Senate Committee on Environment and Public Works approved the nomination of Thomas L. Strickland as Assistant Secretary for Fish and Wildlife within the U.S. Department of the Interior. Strickland is presently the Chief of Staff to Interior Secretary Ken Salazar.

Upcoming Meetings

April 5-8, 2009: AAPCO Spring Conference, Sheraton Inner Harbor Hotel, Baltimore, MD

April 14-15, 2009: National Bed Bug Summit, Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA

April 20, 2009: PPDC PRIA Process Improvement Workgroup Meeting, One Potomac Yard South, Conference Center – Lobby Level, 2777 S. Crystal Drive, Arlington, VA

April 21, 2009: PPDC Web-Distributed Labeling Workgroup Meeting, One Potomac Yard South, 2777 S. Crystal Drive, Arlington, VA

April 20-22, 2009: Pesticide Program Dialogue Committee Meeting, One Potomac Yard South, Conference Center – Lobby Level, 2777 S. Crystal Drive, Arlington, VA

April 27-28, 2009: SFIREG Pesticide Operations and Environmental Quality Issues Working Committees joint meeting, One Potomac Yard (South Building), 4th Floor Conference Center, 2777 S. Crystal Drive, Arlington, VA