Committee: Science Advisory Board’s Homeland Security Advisory Committee (HSAC) (See Roster - Attachment A.)

Date and Time: Monday, November 13, 2006; 12:00 pm – 3:00 pm (see Federal Register Notice – Attachment B)

Location: Participation By Telephone Conference Only

Purpose: To hear the Agency’s updates on the WaterSentinel Program and Standard Analytical Methods and be briefed on three upcoming advisory activities: Provisional Advisory Levels (PALs), ECAT and Preliminary Microbials Risk Framework (See Meeting Agenda - Attachment C.)

Attendees: HSAC Members: See Attachment A

EPA Presenters: David Travers and Dan Schmelling (WS Program - OW); Oba Vincent (SAM – NHSRC); Femi Adeshina (Provisional Advisory Levels - NHSRC); Kevin Garrahan (Emergency Consequence Assessment Tool - NHSRC) and Tonya Nicols (Preliminary Microbial Risk Assessment Methodologies - NHSRC)

SAB Staff Office: Vanessa Vu (Director); Anthony Maciorowski (Associate for Science); Vivian Turner (HSAC DFO); Tom Miller

Public: (See Attachment D)

Meeting Summary:

The meeting followed the issues and general timing as presented in the meeting Agenda.

a) Opening Statement of the Designated Federal Officer (DFO)

Vivian Turner, the DFO, opened the meeting, noting that the HSAC is chartered as a Federal Advisory Committee under the Federal Advisory Committee Act. She acknowledged the teleconference as being open to the public and stated that no sensitive information would be discussed. The FR notice announcing the teleconference was published on October 24, 2006. She noted there were no requests from the public for time to present oral statements and no
written statements were submitted by the public.

For the development of accurate notes, she requested that all individuals from the EPA and the general public who were not presenting information to the Committee, verify via email their attendance to all or portions of the discussion, as that would allow for names and affiliations to be reflected in the official minutes of the teleconference.

b.) Welcome by the SAB Chair, Dr. Baruch Fischhoff

The meeting was turned over to the Chair, Dr. Baruch Fischhoff, who thanked everyone for calling in for the teleconference. Dr. Fischhoff asked for an update of the WS Program. Dr. David Travers (OW) gave a brief introduction of the WS topic and Dr. Dan Schmelling (OW) presented updated information to the Committee on WS.

c.) Update on WS
The following is a condensed list of recent accomplishments and activities that will soon be performed by the Agency:

- Developed a cooperative agreement with Cincinnati on WS (specific details not provided)
- Completed the Water quality Monitoring Assessment
- Is working to enhance contamination detection
- Is working to enhance physical security awareness
- Is working to enhance public health surveillance system (i.e., reports to poison control call centers; monitoring hospital visits)
- Is preparing for study on baseline analysis
- Purchasing of certain vital equipment has occurred
- Developed Standard Operating Procedures (SOPs) on information flow for consequence management
- Held a training session for 1st responders in Cincinnati on consequence management
- Installed wireless transmitters
- Installed priority dispatch software
- Developed site characterization protocol
- Implemented the currently used technology to detect contamination and will continue to look for better technology

The Chair and Committee members noted that the WS Program made significant progress since the Jan ’06 meeting but voiced concern that more efforts should be directed towards implementing better communication efforts and increased involvement of the public. Comments and questions posed by the Committee Members for consideration by the Agency included:

- Can the System respond to false positives?
- Have simulation studies been performed?
- When presented to 1st responders, what were their recommendations?
• What are the procedures for handling power outages &/or monitoring failures?
• Has the general public been involved in any of the simulations, as this is a valuable segment to consider?

d) Update on SAM
Jonathan Herrmann, Director of the Agency’s National Homeland Security Research Center, thanked the HSAC for its previous consultations and introduced Oba Vincent as the presenter of the SAM update. The advances for SAM are listed below:

• A third version of SAM is due in Feb ‘07
• A companion document describing the collection is due for release in March ‘07
• A cross-reference guide is being developed
• An advisory group of 1st responders is being formed for the purpose of identifying what best fits their needs
• The scope of SAM is being clarified
• A user-friendly roadmap explaining SAM’s utility will be developed
• A web-site will be developed that will house documents that serve as an accessory capacity to SAM
• A detailed response to comments and concerns raised by HSAC members at the Jan’06 consultation is being prepared for release to the Committee

The Committee Members and the Chair thanked the Agency for the SAM update and urged that investment in public communication and social science not lag. Additionally, the Committee posed the following questions for consideration by the Agency:

• What is the long-term plan for SAM; what is the future role of SAM?
• How will one know the cut-off or starting point for levels of concern?
• Given the lag-time of occurrence and notification of the public (approx 72 hours), what is being done to shorten that time-frame?

e) Upcoming HSAC activities
Cynthia Sonich-Mullin, (Director of the Threat and Consequence Assessment Division in the Agency’s National Homeland Security Research Center), introduced the upcoming activities and the presenters. They are: Provisional Advisory Levels – Femi Adeshina; Emergency Consequence Assessment Tool – Kevin Garrahan and Preliminary Microbial Risk Assessment Methodologies – Tonya Nicols. Brief descriptions of these activities are listed below and the full presentation for each is in Attachment E.

Provisional Advisory Levels (PALS) - These are threshold exposure limits for the general public, and are derived for acute (24 hours), short-term (1–30 days), and longer-term (30 days to 2 years) oral and inhalation exposures to industrial chemicals, biologicals, radionuclides, and warfare agents. Scientific judgment and credible data are used to identify appropriate toxicity endpoints for establishing the point of departure (POD) for developing PAL values. The three levels (PAL1, PAL2, and
PAL3) for each exposure period are distinguished by the degree of severity of toxic effects.

Emergency Consequence Assessment Tool (ECAT) is an interactive, web-based tool designed to assist first responders, health advisors, and decision-makers in analyzing and understanding complex information on risk assessment, risk management, and communication during an environmental emergency.

Preliminary Microbial Risk Assessment Methodologies - The preliminary framework considers the three exposure pathways: inhalation, ingestion, and dermal. It is designed as a two-tier process to support risk management decisions for evacuation and site re-entry. A Tier I Site Assessment supports rapid decisions, such as the decision to evacuate potentially exposed populations that are required within hours of knowledge of the incident. Tier II provides a more extensive approach for incident-based site assessment and requires site-specific data to support science-based risk management decisions, such as site re-entry.

As explained to the Committee, the Agency is seeking a consultation with the HSAC on ECAT and the microbial risk assessment framework and a peer review on PALs. After hearing the presentations on these 3 topics, the HSAC Members and SAB management agreed on the need to supplement the Committee’s expertise to accommodate these projects. The DFO will take care of fulfilling this action item. The DFO will also work with the Agency and the HSAC members to determine the exact meeting dates for these activities.

The DFO adjourned the meeting at 3:00 p.m.

Respectfully Submitted:  
Certified as True:  

______________________________  ______________________________
/S/ Vivian Turner  /S/ Baruch Fischhoff, Chair
Designated Federal Official  Homeland Security Advisory Committee

Dated 3/7/07

List of Attachments

Attachment A – HSAC Roster and Member Attendance
Attachment B – Federal Register Notice
Attachment C – Teleconference Agenda
Attachment D – Public Attendance (via teleconference)
Attachment E – Slide Discussion for ECAT, PALs and Microbial Risk Assessment
Attachment A

US EPA SAB Homeland Security Advisory Committee (HSAC) Roster

CHAIR

Dr. Baruch Fischhoff, Howard Heinz University Professor, Department of Social and Decision Sciences and Department of Engineering and Public Policy, Carnegie Mellon University, Pittsburgh, PA

SAB HSAC MEMBERS

Dr. William Bellamy, Fellow and Vice President of CH2MILL, a Water Supply and Treatment Engineering Company (Did not participate in the SAM & WS Consultation in Jan ’06)

Dr. Vicki Bier, Professor, Departments of Industrial Engineering and Engineering Physics; Director, Center for Human Performance and Risk Analysis, University of Wisconsin, Madison, WI

Dr. Mary Durfee, Associate Professor, Social Sciences Department; Assistant Provost for Academic Improvement, Michigan Technological University, Houghton, MI

Dr. David S. Ensor, Director for the Center of Aerosol Technology and Senior Fellow, Research Triangle Institute, Research Triangle Park, NC

Dr. Lynda Knobeloch, Research Scientist Manager in the Wisconsin Department of Health and Family Services’ Bureau of Environmental and Occupational Health and Adjunct Professor of Molecular and Environmental Toxicology at the University of Wisconsin-Madison, Madison, WI

Dr. Paul Lioy, Deputy Director and Professor, Environmental and Occupational Health Sciences Institute, UMDNJ – Robert Wood Johnson Medical School, Piscataway, NJ; Vice Chair, Department of Environmental and Occupational Medicine, Professor, Graduate Faculty of Rutgers University: Department of Environmental Science, Public Health Program and Toxicology Program, New Brunswick, NJ

Dr. Lee D. McMullen, Chief Executive Officer and General Manager, Des Moines Water Works, Des Moines, IA

Dr. Royal J. Nadeau, President, The Eco-Strategies Group, Allamuchy, NJ (Did not participate in the SAM & WS Consultation in Jan ’06)
Dr. Robert E. Pitt, Cudworth Professor of Urban Water Systems and Director of Environmental Engineering Programs, Department of Civil and Environmental Engineering, University of Alabama, Tuscaloosa, AL (Unable to Participate on the Nov’06 Teleconference Call)

Dr. Robert Snyder, Associate Dean for Research and Professor of Pharmacology and Toxicology, Ernest Mario School of Pharmacy, Rutgers University, New Brunswick, NJ

Dr. Linda Stetzenbach, Director, Microbiology Division, Harry Reid Center for Environmental Studies, University of Nevada, Las Vegas, NV

Dr. W. Kip Viscusi, University Distinguished Professor, Owen Graduate School of Management; Department of Economics; the Law School, Vanderbilt University, Nashville, TN (Unable to Participate on the Nov ‘06 Teleconference Call; not available for the Jan’06 meeting)

Dr. Daniel C. Walsh, Adjunct Associate Professor & Senior Research Scientist, Institute for Economic and Social Research and Policy, Columbia University, New York, N.Y.

Dr. James E. Watson, Professor Emeritus, University of North Carolina, Chapel Hill, NC (Unable to Participate on the Nov ‘06 Teleconference Call)

Dr. Rae Zimmerman, Professor of Planning and Public Administration and Director of the Institute for Civil Infrastructure Systems, Robert F. Wagner Graduate School of Public Service, New York University, New York, NY

OTHER MEMBERS Who Participated on the WS and SAM

Dr. Mark Borchardt, Research Scientist and Director of the Public Health Microbiology Laboratory, the Marshfield Clinic Research Foundation, Marshfield, WI; (also a member of the SAB Drinking Water Committee)

Dr. Christine Owen, Water Quality Assurance Officer, Tampa Bay Water, Clearwater, FL; (also a member of the SAB Drinking Water Committee)

Mr. Richard Sustich, Managing Director of The Center of Advanced Materials for Purification of Water with Systems, University of Illinois at Urbana-Champaign, Urbana, IL; (also a member of the EPA National Advisory Council for Environmental Policy and Technology (NACEPT))

Dr. Michael Trehy, Analytical Chemist, Food and Drug Administration, Center for Drug Evaluation and Research, St. Louis, MO.
EPA Science Advisory Board; Notification of a Public Telephone Conference of the Homeland Security Advisory Committee

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public telephone conference of the Homeland Security Advisory Committee (HSAC) to be briefed on the status of the Agency’s Standard Analytical Methods (SAM) and WaterSentinel (WS) projects and upcoming projects by the National Homeland Security Research Center in the Office of Research and Development.

DATES: November 13, 2006, the meeting will begin at 12 p.m. and end by 3 p.m. (Eastern Time).

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain general information concerning this teleconference should contact Ms. Vivian Turner, Designated Federal Officer (DFO), EPA Science Advisory Board (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via telephone/voice mail (202) 343-9697; fax (202) 233-0643; or e-mail at: turner.vivian@epa.gov. General information concerning the EPA Science Advisory Board and the Homeland Security Advisory Committee can be found on the EPA Web site at: http://www.epa.gov/sab.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that the EPA SAB HSAC will hold a public teleconference to be briefed on the status of the Agency’s Standard Analytical Methods (SAM) and WaterSentinel (WS) projects and upcoming projects by the National Homeland Security Research Center in the Office of Research and Development. The SAB was established by 42 U.S.C. 4365 to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee
chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. As a subcommittee of the SAB, the HSAC will comply with the provisions of FACA and all appropriate EPA and SAB Staff Office procedural policies.

Background

The purpose of the public teleconference is: (1) To obtain Agency feedback on the HSAC's comments presented to the Agency on its SAM and WS Programs discussed at the consultation held on January 30-31, 2006; and (2) to be briefed on three upcoming HSAC projects, including Provisional Advisory Levels (PALS), the Emergency Consequence Assessment Tool (ECAT), and Preliminary Microbial Risk Assessment Methodologies.

Standard Analytical Methods (SAM) and WaterSentinel (WS)

On January 30-31, 2006 the HSAC provided a consultation with the Agency on its SAM and WS projects (Federal Register Notice dated December 19, 2005, Volume 70, Number 242, pages 75173-75174). The SAM project standardizes the analytical methods for use by all laboratories when responding to incidents that require rapid analysis. The WS program is being developed by the EPA in partnership with drinking water utilities and other key stakeholders. This initiative involves designing, deploying, and evaluating a model contamination warning system for drinking water security. The Agency will provide updates to the HSAC on WS and SAM.

Provisional Advisory Levels (PALS)

Health-based exposure guidelines to identify acceptable re-entry levels following a terrorist attack or natural disaster are not available for most chemical and biological agents. The National Homeland Security Research Center (NHSRC) is developing health-based exposure levels for the general public, including the susceptible and sensitive subpopulations of all age groups. In particular, the developed PALS will address the limitations of other derived exposure values. For example, PALS can fill the critical exposure gap between acute exposure guideline levels (AEGLs) and short-term RfC/RfD exposure values.

The PALS can be applied for national emergency programs, community planning, and public health protection. Specifically, PALS are appropriate for establishing health-based criteria for re-entry into buildings, reuse of drinking water, and cleanup of contaminated facilities.

Emergency Consequence Assessment Tool (ECAT)

The NHSRC is developing an interactive online risk assessment software tool designed to provide health advisors and other emergency response officials with rapid access to critical information during an environmental emergency or training exercise. ECAT is designed to (1) Assess and provide site-specific numeric estimates of health risks (where feasible) for selected chemical, biological, and radiological threat agents, (2) identify what response actions might be appropriate to mitigate health risks, and (3) provide guidance on how to effectively communicate key risk messages to the public.

Preliminary Microbial Risk Assessment Methodologies

The NHSRC conducts research in support of safe buildings, secure water systems and the rapid assessment of risk. The question ``How clean is safe?'' has confronted several EPA program offices. Recent
national homeland security interests have increased demand for answers to this question. Because consensus methodologies for evaluating biological contaminants and establishing cleanup levels are not available, NHSRC is developing a biological risk assessment methodology. NHSRC has compiled a Compendium of Prior and Current Microbial Risk Assessment Methods. This Compendium has been used to develop a Microbial Risk Assessment Framework for Incident Response to Bioagents. The preliminary framework considers inhalation, ingestion, and dermal exposure pathways and is designed as a two-tier process to support risk management decisions for evacuation and site re-entry. A Tier I Site Assessment supports rapid decisions, such as when evacuating populations within hours of an incident is required. Tier II provides an incident-based site assessment approach and requires site-specific data to support re-entry decisions. The Tier II consists of Hazard Identification, Dose-Response Assessment and Exposure Assessment, which are combined to characterize risk to exposed population(s) at a site.

Availability of Meeting Materials

The draft agenda and other materials will be posted on the SAB Web site at: http://www.epa.gov/sab/ prior to the meeting.

Procedures for Providing Public Input

Interested members of the public may submit relevant written or oral information for these SAB committees to consider during the advisory process. Oral Statements: In general, individuals or groups requesting an oral presentation at a public SAB teleconference will be limited to three minutes per speaker, with no more than a total of one-half hour for all speakers. Interested parties should contact Ms. Vivian Turner, DFO, in writing (preferably via e-mail), by November 6, 2006, at the contact information noted above, to be placed on the public speaker list for this meeting. Written Statements: Written statements should be received in the SAB Staff Office by November 2, 2006, so that the information may be made available to the HSAC for its consideration prior to this meeting. Written statements should be supplied to the DFO in the following formats: One hard copy with original signature, and one electronic copy via e-mail (acceptable file format: Adobe Acrobat PDF, WordPerfect, MS Word, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format).

Accessibility

For information on access or services for individuals with disabilities, please contact Ms. Vivian Turner at (202) 343-9697 or turner.vivian@epa.gov. To request accommodation of a disability, please contact Ms. Turner preferably at least ten days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: October 17, 2006.
Anthony F. Maciorowski,
Associate Director for Science, EPA Science Advisory Board Staff Office.
[FR Doc. E6-17804 Filed 10-23-06; 8:45 am]
BILLING CODE 6560-50-P
Purpose: The purpose of this teleconference is: 1) for the Agency to update the HSAC on WaterSentinel (WS) and Standard Analytical Methods (SAM) as it relates to the January 30-31, 2006 consultation; 2) to brief HSAC on upcoming advisory activities; and 3) for HSAC to discuss other planning activities.

12:00 pm Convene the Teleconference and Opening Remarks
Ms. Vivian Turner
Designated Federal Officer, SAB Staff Office

12:05 pm Purpose of the Teleconference and Introduction of Advisory Members
Dr. Baruch Fischhoff, Chair
and Committee Members

Review of the Agenda
Dr. Fischhoff, Chair

12:15 pm Update on WS
Dr. David Travers,
Division Director &
Dr. Dan Schmelling,
Project Coordinator
GWDW/OW

12:45 pm Update on SAM
Mr. Jonathan Herrmann,
Director &
Mr. Oba Vincent, Technical Expert, NHSRC/ORD

1:15 pm Overview of EPA’s Upcoming Requests:
- Provisional Advisory Levels (PALS)
- Emergency Consequence Assessment Tools (ECAT)
- Preliminary Microbial Assessment Methodologies
Ms. Cynthia Sonich-Mullin,
Technical Expert,
NHSRC/ORD

2:15 pm Other Committee Planning Activities
Dr. Fischhoff, Chair
& Committee Members

2:45 pm Public Comments

3:00 pm Adjourn
Ms. Turner, DFO
Contact Vivian Turner, (202 343-9697), for access to the teleconference number.
Attachment D

Public Attendance (via teleconference)

Jonathan Herrmann – Director, National Homeland Security Research Center/USEPA

Peter Jutro – Deputy Director, Homeland Security Research Center/USEPA

Cynthia Sonich-Mullin – Division Director, National Homeland Security Research Center/USEPA

Eletha Brady-Roberts – National Homeland Security Research Center/USEPA

Brendlyn Faison - US EPA

John Ravenscroft - US EPA (OW/OST/HECD)

Shalini Jayasundera - sjayasundera@csc.com; Computer Sciences Corporation (CSC) staff

Yves Mikol - YMikol@dep.nyc.gov

Dave Lipsky, Ph.D., - First Deputy Director, Drinking Water Quality Control, Bureau of Water Supply, NYCDEP

Jack Bennett - Jack.Bennett@po.state.ct.us>

Herman Gibb - hgibb@sciences.com

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National Discipline Lead for Risk Assessment
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Ronald.Marnicio@tteci.com

Alan R. Spallato - spallato@mail.slh.wisc.edu

Patty_Quinlivan@URSCorp.com

Clifford Bowen - (DHS-DDWEM)" <CBowen1@dhs.ca.gov>

Henry Leibovitz - Henry.Leibovitz@health.ri.gov

Steve Fann, (NFESC) - <steve.fann@navy.mil>

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www.aphl.org  

Mary Shaffran - www.aphl.org  
Laura Dice - www.aphl.org  
Karen Noggle - knoggle@uhl.uiowa.edu  
Ramon Rosal - rrosal@health.nyc.gov  

Joan E Cuddeback - jcuddeback@csc.com  
Sr. Project Manager - Chemistry Studies  
Computer Sciences Corporation  
6101 Stevenson Avenue  
Alexandria, VA 22304-3540  
Phone: (703) 461-2025  
Fax: (703) 461-8056  

Danielle Carter  
Computer Sciences Corporation (CSC) staff
Attachment E
NHSRC
Threat and Consequence Assessment Division

Focus:
- rapid evaluation of chemical, biological and radiological effects and risks to human health associated with a terrorist attack
- assistance to emergency personnel and the general public

Research:
- provide information to facilitate hazard identification associated with potential terrorist attacks;
- enable rapid evaluation and estimation of risks from biological, chemical, and radiological agents
- accelerate the development of risk assessment methodologies by adopting and/or modifying available approaches

Products:
- tools and methods, to inform decision-making and enable the determination of “how clean is clean?”
Projects

- Provisional Advisory Levels
  - Femi Adeshina, Ph.D
  - Peer Review
- Emergency Consequence Assessment Tool
  - Kevin Garrahan, Ph.D
  - Consultation
- Preliminary Microbial Risk Assessment Methodology
  - Tonya Nichols, Ph.D
  - Consultation

Provisional Advisory Levels (PALs)

Femi Adeshina, Ph.D., ACT
Program Manager
ORD/National Homeland Security Research Center
Washington, DC

SAB’s Homeland Security Advisory Committee (HSAC)
Briefing
November 13, 2006
Background

  - Requires the development of national emergency preparedness exposure guidelines for terrorist incidents and natural disasters
  - Currently, available exposure guidelines do not
    - Address identified chemical/biological/radiological agents of concern related to terrorist incidents
    - Characterize breakdown products in environmental media
    - Identify potential health hazards of breakdown products
    - Assess health effects at different exposure durations

Example Acute Inhalation Reference Values

<table>
<thead>
<tr>
<th>Reference Value</th>
<th>Organization</th>
<th>Type Value</th>
<th>TWA (Yes/No)</th>
<th>Exposure Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEL - Permissible Exposure Limit</td>
<td>OSHA</td>
<td>Occupational</td>
<td>Yes</td>
<td>8-hour</td>
</tr>
<tr>
<td>Ceiling</td>
<td>OSHA</td>
<td>Occupational</td>
<td>No</td>
<td>Up to 10-minute</td>
</tr>
<tr>
<td>REL - Recommended Exposure Limit</td>
<td>NIOSH</td>
<td>Occupational</td>
<td>Yes</td>
<td>8-hour</td>
</tr>
<tr>
<td>IDLH - Immediately Dangerous to Life and Health</td>
<td>NIOSH</td>
<td>Occupational</td>
<td>No</td>
<td>Up to 30-minute</td>
</tr>
<tr>
<td>STEL - Short Term Exposure Limit</td>
<td>NIOSH</td>
<td>Occupational</td>
<td>Yes</td>
<td>15-minute</td>
</tr>
<tr>
<td>TLV - Threshold Limit Value</td>
<td>ACGIH</td>
<td>Occupational</td>
<td>Yes</td>
<td>8-hour</td>
</tr>
<tr>
<td>TLV-STEL - TLV Short Term Exposure Limit</td>
<td>ACGIH</td>
<td>Occupational</td>
<td>Yes</td>
<td>15-minute</td>
</tr>
<tr>
<td>AEGL - Acute Exposure Guideline Level</td>
<td>NRC/AEGL, NAC/AEGL</td>
<td>Emergency Response</td>
<td></td>
<td>10- and 30-minute; 1-, 4-, and 8-hour</td>
</tr>
<tr>
<td>ERPG - Emergency Response Planning Guideline</td>
<td>ASHA</td>
<td>Emergency Response</td>
<td></td>
<td>1-hour</td>
</tr>
<tr>
<td>STEL - Temporary Emergency Exposure Level</td>
<td>DOE</td>
<td>Emergency Response</td>
<td></td>
<td>1-hour</td>
</tr>
<tr>
<td>ERG - Emergency Response Guidebook</td>
<td>DOT</td>
<td>Emergency Response</td>
<td></td>
<td>Specialized application</td>
</tr>
<tr>
<td>MRL - Minimal Risk Level</td>
<td>ATSDR</td>
<td>Public Health</td>
<td></td>
<td>14-days (acute); 15-364 days (intermed.); &gt;365 days (chronic)</td>
</tr>
<tr>
<td>CA-REL - California Reference Levels</td>
<td>CalEPA, OEHHA</td>
<td>Public Health</td>
<td></td>
<td>1-8 hours</td>
</tr>
<tr>
<td>EPA - Acute RfC</td>
<td>US EPA, IRIS</td>
<td>Public Health</td>
<td></td>
<td>1-4, 8, and 24-hours</td>
</tr>
</tbody>
</table>
Purpose

- Develop innovative health-based Provisional Advisory Levels (PALs) to:
  - Fill the gaps in existing emergency exposure guidelines
    - Exposure routes
    - Exposure durations
  - Support national emergency programs, community planning, and protect public health

<table>
<thead>
<tr>
<th>Reference Value</th>
<th>Organization</th>
<th>Exposure Duration</th>
</tr>
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<tbody>
<tr>
<td>PEL - Permissible Exposure Limit</td>
<td>OSHA</td>
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<td>REL - Recommended Exposure Limit</td>
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<td>NIOSH</td>
<td>15-minute</td>
</tr>
<tr>
<td>TLV - Threshold Limit Value</td>
<td>ACGIH</td>
<td>8-hour</td>
</tr>
<tr>
<td>TLV-STEL - TLV Short Term Exposure Limit</td>
<td>ACGIH</td>
<td>15-minute</td>
</tr>
<tr>
<td>AEGL - Acute Exposure Guideline Level (air only)</td>
<td>NAC/AEGL, NRC/AEGL</td>
<td>10- and 30-minute; 1-, 4- and 8-hour</td>
</tr>
<tr>
<td>DW HA – Drinking Water Health Advisory (water only)</td>
<td>EPA/OW</td>
<td>1-day; 10-day; longer-term</td>
</tr>
<tr>
<td>PAL – Provisional Advisary Level (air and water)</td>
<td>EPA/ORD</td>
<td>24-hours; up to 30 days; up to 2 years</td>
</tr>
<tr>
<td>ERPG – Emergency Response Planning Guideline</td>
<td>AIHA</td>
<td>1-hour</td>
</tr>
<tr>
<td>TEEL – Temporary Emergency Exposure Level</td>
<td>DOE</td>
<td>1-hour</td>
</tr>
<tr>
<td>ERG – Emergency Response Guidebook</td>
<td>DOT</td>
<td>Specialized application</td>
</tr>
<tr>
<td>MRL - Minimal Risk Level (air and water)</td>
<td>ATSDR</td>
<td>1-14 days (acute); 15-364 days (intermed.); &gt;365 days (chronic)</td>
</tr>
<tr>
<td>CA-REL - Reference Exposure Level</td>
<td>Cal-EPA OEHHHA</td>
<td>1-8 hours</td>
</tr>
<tr>
<td>EPA – Acute RfC</td>
<td>US EPA / IRIS</td>
<td>1-, 4-, 8-, and 24-hours</td>
</tr>
</tbody>
</table>
**PALs Fill Exposure Gaps**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Inhalation</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 min to 8 hours</td>
<td>AEGL, ERPG, TEEL</td>
<td>None</td>
</tr>
<tr>
<td>24 hours</td>
<td>PALs</td>
<td>PALs</td>
</tr>
<tr>
<td></td>
<td>Acute RfC (limited)</td>
<td>DW HA</td>
</tr>
<tr>
<td>&gt;1 to 30 days</td>
<td>PALs</td>
<td>PALs</td>
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<td>MRLs</td>
<td>MRLs, DW HA</td>
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<td>Less-than-lifetime</td>
<td>PALs</td>
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<td>MRLs, DW HA</td>
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<td>Lifetime</td>
<td>RfC, MRLs</td>
<td>RfD, MRLs</td>
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</table>

**What are PALs?**

- Threshold exposure limits for general public, applicable to national emergency programs, community planning, and response
- Provide exposure levels for industrial chemicals, biologicals, radionuclides, and warfare agents
- PALs are for acute (24 hours), short-term (30 days), and long-term (2 years) exposures to air and water
- Three levels (PAL 1, PAL 2, and PAL 3), distinguished by the degree of severity of toxic effects
**PAL Development Process**

- **Select Agent from Priority List**
- **Collect Literature information**
- **Develop Draft Methodology**
- **Develop PALs and Support Documents ORNL and ANL**
- **Revise and improve Draft Methodology**
- **Technical Internal EPA Review**
- **ORNL Scientific Workgroup**
- **External Peer Review**
- **Recommendations to EPA**
- **Publication**

**Major Application of PALs**

- Use in homeland security efforts by health and law enforcement agencies, as well as emergency response officials
- Decision-making for re-entry into buildings or areas and water use, following a terrorist event or incident of national significance
- Health-based decisions for controlling acute, short-term, and long-term exposures of the general public to chemical, biological and radiological agents
- To establish health-based advisory levels for decision officials during the course of an event and to inform clean-up decision-making
- To develop emergency exposure guidelines, applicable at Federal, State, and local levels
Status of PAL Program

Completed or in progress
- Draft methodology for the development of PALs for chemical agents
  - Evaluation by the ORNL Scientific Workgroup
- Identification about 100 priority chemicals and radionuclides for PAL development
- Developed about 12 draft chemical and warfare agents for oral and inhalation exposures
- Completed internal EPA review and ORNL Scientific Workgroup Evaluation

Future efforts
- Update the preliminary list of priority threat agents (Fall 2007 – projected)
  - Work with stakeholders and other federal agencies
- Develop PALs for priority agents
- Initial methodology for the development of PALs for radionuclides (Spring 2007 – projected)
- Pilot PALs for radionuclides
- Initial methodology for the development of PALs for biological agents.

Issues for HSAC Peer Review

1. Is the presented information and overall technical approach in the methodology scientifically sound?

2. Are both primary and secondary sources of data adequately presented in the draft PALs?

3. Are the choices of critical toxicity data, points of departure, and extrapolation models appropriate and well justified?

4. Is the rationale for the applied uncertainty factors well presented?

5. Are developed PALs scientifically defensible and communicated in a transparent and sufficient manner to allow decision-makers to make sound decisions and inform the general public?
Emergency Consequence Assessment Tool (ECAT)

Science Advisory Board
Homeland Security Advisory Committee
Public Teleconference
November 13, 2006

Kevin G. Garrahan, PhD, PE
Task Order Manager
US Environmental Protection Agency
Threat and Consequence Assessment Division
National Homeland Security Research Center
Washington, DC

Outline

• Background
  ▪ Purpose, vision, users, history
  ▪ Challenges

• Overview of ECAT
  ▪ Guiding principles
  ▪ Features
  ▪ Status and plans

• Issues
**Background**

**Purpose:** Develop a prototype software tool that can rapidly assess health risks during an environmental emergency and help determine appropriate actions

**Vision:** An interactive platform that provides instant access to current information about potential health impacts and how best to mitigate them

**Users:** Health advisors, emergency responders, risk managers

**History:** Project initiated July 2004; about $1M effort to complete 21 pilot scenarios and 17 threat agents

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**Challenges for Homeland Security Risk Assessment**

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Typical Assessments (low-level exposure)</th>
<th>Homeland Security Assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contaminants of concern</td>
<td>Industrial pollutants</td>
<td>Chemical, biological, &amp; radiological agents</td>
</tr>
<tr>
<td>Exposure duration</td>
<td>70-year lifetime</td>
<td>Less than lifetime</td>
</tr>
<tr>
<td>Time to complete assessment</td>
<td>Years</td>
<td>Hour or days</td>
</tr>
</tbody>
</table>
**Design Challenges**

- How to best organize complex, technical information so that users can rapidly access during the stress and confusion of an emergency
- Finding the appropriate level of detail and complexity for different user types
- How to integrate knowledge from many diverse domains
- How best to provide advice where much of the science is incomplete

**Guiding Principles**

- Organize info by the risk paradigm
- Scenario-driven (21 pilot scenarios)
- Utilize available information
- Be transparent
- Avoid complexities (where feasible)
- Holistic applications
  - Risk assessment, management, communication
  - Chemical, biological, radiological
  - Indoors and outdoors
  - Terrorist attacks and natural disasters
- Build prototype, evaluate, then proceed
ECAT Features

- Rapidly identify threat agents based on scene descriptions and/or health symptoms
- Immediately access fact sheets from multiple agencies
- Rapidly derive quantitative estimates of exposure for multiple receptors (adults or children) and multiple routes of exposure (inhalation, dermal, ingestion) using either environmental measurements or models
- Immediately identify adverse health effects and health benchmarks for chemical, biological, and radiological threat agents
**ECAT Features (cont’d)**

- Rapidly develop numeric estimates of health risk by comparing exposure estimates to health benchmarks and/or health advisories
- Provide recommendations to protect public health, such as whether to evacuate or shelter in place, utilize personal protective equipment, decontamination and cleanup options, and methods for communicating with the public during crises
- Extensive hyperlinks to subject matter experts, other sources of critical information and key organizations such as CDC, ATSDR, DHS, and the FBI

**ECAT Status and Plans**

- Beta tests and workshops:
  - Early versions of ECAT were beta tested by 48 EPA staffers during June and September 2005
  - ECAT workshops were held in Cincinnati and Washington during March and April 2006
- ECAT Version 3.0 has been completed and transferred to the EPA secure server
- Future: Evaluate pilot, revise, peer review, and regularly update
Issues

1. Is the broad scope of ECAT (covering risk assessment, management, and risk communication) appropriate?
2. Does ECAT target the right types of users? Too many? How widely should ECAT be released? General public? Should there be public and classified versions? Should ECAT contain rapid risk assessment capability for both terrorist scenarios and non-terror emergency management scenarios?
3. Do the seven guiding principles make sense? Does the prototype stay true to them?

Issues (cont’d)

4. Is the system adequately organized? Is it intuitive? Is information in ECAT understandable for the different users?
5. Is there adequate transparency describing sources of information and assumptions?
6. Given that some of the supporting science is incomplete, does ECAT handle limitations and uncertainties appropriately?
7. Are the simple models utilized by ECAT appropriate?
8. What does HSAC recommend as the next steps? Does it make sense to evaluate scope and concept before peer-reviewing the details?
Incident-Based Microbial Risk Assessment and Decision Framework

Tonya Nichols and Irwin Baumel

Presentation to
EPA Science Advisory Board
Homeland Security Advisory Committee (HSAC)

13 November 2006

**Background:**

- Currently, no consensus-based methodology exists for evaluating risks of exposure to biological contaminants and establishing safe clean-up levels.
- Biological contamination presents a unique consequence management and cleanup challenge, particularly with respect to the ability of pathogenic microorganisms to infect and replicate in a host as well as be transmitted from host to host and/or transported in the environment.

**Purpose:**

- To support incident management, cleanup, and mitigation of hazards in response to any future terrorist events, a critical need exists for the development and application of a rapid risk assessment methodology to support incident-based decision making.
Incident-Based Microbial Risk Assessment and Decision Framework

Applications:
- Scenario-based risk assessment guidance to support on-site decisions and associated activities to control and mitigate risk of exposure to select bioagents as a consequence of deliberate contamination events.
- Methodology-based communication to first-responders to collect relevant information to support decisions on evacuation and quarantine.
- Maintain currency by modifying Decision Framework to reflect results of on-going methods development efforts utilizing innovative approaches to derive achievable clean-up goals.

Response to a Biological Contamination Incident is based on ... RISK

PRIOR: Preparation
- Agent information
- Threat scenario analyses
- Feasibility studies
- Historical data

DURING: Management
- Sampling strategies
- Agent characterization
- Exposure assessment
- Incident command system
- Response protocols
- Stakeholders identification

POST: Remediation
- Sampling & analysis
- Exposure assessment
- Technology assessment
- Byproducts
- PALs

Incident-Based Microbial Risk Assessment

Risk Communication:
If Response Management Strategy is..., Then Concentration is reduced to..., Therefore Risk is...

Threat Feasibility
- Relative risk
- Knowledge gap identification
- Response capabilities/limitations

Threat Awareness/ Identification
- Incident response
- Information gathering
- Sampling & analysis
- Exposure assessment
- Threat characterization

Response Management
- Risk mitigation
- Containment
- Quarantine/Evacuation
- Decontamination
- Sampling & analysis

Decontamination
- Methodologies
- Timelines
- Safety
Incident-Based MRA Decision Framework
Use of Rapid Risk Determinations for Onsite Guidance

Issue:
Does provision of scenario-based threat-related risk determinations to first responders covering early-on to later stages of incident management serve to provide critical input and guidance to minimize consequences of inadvertent exposure?

Example:
Inform responders of potential risk augmentation from incident management actions that may result in significant re-aerosolization and subsequent inhalation of additional anthrax spores. Include recommended precautions and corrective actions to minimize and/or avoid consequences.

Issues Regarding Status of Information on Biological Threat Organisms

- The near-term urgency of the Homeland Security agenda dictates the need to optimize use of current data on biological organisms to achieve necessary goals.
- Significant data gaps in key areas, lack of animal models and generally poor quality data regarding characteristics of biological agents, necessitate the design and application of innovative approaches and defaults to bridge the large data gaps.
- Bridging the data gaps introduces large uncertainties in extrapolating to humans such as modeling of low dose portions of infectivity dose response curves.
- The uncertainties underlying subsequent rapid risk outcomes communicated to first responders need to be adequately represented.
Project Status

Microbial Risk Assessment Framework is an on-going project that will continue to be updated as new research and data becomes available.

TCAD biological threat research agenda:

- Review of microbial risk assessment literature
- Compilation of bioagent data - transmission, dose-response, fate/transport
- Exposure assessment - bioaerosols
- PBPK modeling dose-response data
- Intra/Interagency coordination to harmonize MRA approach
- Communication with first responders/experts to identify needs/data gaps
- Derivation of bioagent exposure limits - short-term (responders) & long-term (clean-up goals)

Resources:

- 2 FTE (divided)
- $100K for framework development
- > $2M in research projects to address data gaps

Microbial Risk Assessment

Request for SAB Consultation:

- Assessment of the scientific credibility and usability of the Incident-Based Microbial Risk Assessment and Decision Framework to address rapid risk assessment needs and applications during a crisis situation.

- Seeking guidance on how to address significant uncertainties due to data gaps while striving to derive realistic cleanup goals.

- Seeking advice on overall approach and strategy regarding application of the Incident-Based Microbial Risk Assessment and Decision Framework to incident support.