Overview of Upcoming Requests
to
Homeland Security Advisory Committee
Science Advisory Board

November 13, 2006

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**

(J Toxicol. & Environ Health – Part A, 68:901-926)

<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>NIOSH</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 15-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>IHLH – Immediately Hazardous 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-STEEL – 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>NAC/AEGL</td>
<td>Emergency Response</td>
<td>Yes</td>
<td>10- and 30-minute; 1-, 4- and 8-hour</td>
</tr>
<tr>
<td>ERPG – Emergency Response Planning Guidelines</td>
<td>ACGIH</td>
<td>Emergency Response</td>
<td>Yes</td>
<td>4-hour</td>
</tr>
<tr>
<td>TEEL – Temporary Emergency Exposure Level</td>
<td>NIOSH</td>
<td>Emergency Response</td>
<td>Yes</td>
<td>4-hour</td>
</tr>
<tr>
<td>EAC – Emergency Action Concentration</td>
<td>NIOSH</td>
<td>Emergency Response</td>
<td>Yes</td>
<td>8-hour</td>
</tr>
</tbody>
</table>

**Public Health**

- MDL – Minimum Detectable Limit | AHR | Public Health |
- CMRL – Confirmation Minimum Reporting Limit | AHR | Public Health |
- EPA – Acute RLC | EPA | IRIS |
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

Health-Based Exposure Values for Air and Water

<table>
<thead>
<tr>
<th>Reference Value</th>
<th>Organization</th>
<th>Exposure Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEL - Permissible Exposure Limit</td>
<td>OSHA</td>
<td>8-hour</td>
</tr>
<tr>
<td>Ceiling</td>
<td>OSHA</td>
<td>Up to 10-minute</td>
</tr>
<tr>
<td>REL - Recommended Exposure Limit</td>
<td>NIOSH</td>
<td>8-hour</td>
</tr>
<tr>
<td>IDLH - Immediately Dangerous to Life and Health</td>
<td>NIOSH</td>
<td>Up to 30-minute</td>
</tr>
<tr>
<td>STEL - Short Term Exposure Limit</td>
<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 IA – Drinking Water Health Advisary (water only)</td>
<td>EPA/OW</td>
<td>1-day; 10-day; longer-term</td>
</tr>
<tr>
<td>PAL - Provisional Advisory 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 OEHHA</td>
<td>1-8 hours</td>
</tr>
<tr>
<td>EPA – Acute RIC</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><strong>PALs</strong> Acute RfC (limited)</td>
<td><strong>PALs</strong> DW HA</td>
</tr>
<tr>
<td>&gt;1 to 30 days</td>
<td><strong>PALs</strong> MRLs</td>
<td><strong>PALs</strong> MRLs, DW HA</td>
</tr>
<tr>
<td>Less-than-lifetime</td>
<td><strong>PALs</strong> MRLs</td>
<td><strong>PALs</strong> MRLs, DW HA</td>
</tr>
<tr>
<td>Lifetime</td>
<td>RfC, MRLs</td>
<td>RfD, MRLs</td>
</tr>
</tbody>
</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**

**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?
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 Paradigm

- Recognition
- Threat ID
- Evaluation
- Exposure Assessment
- Risk Characterization
- Risk Management
- Control
- Toxicty Assessment

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
- Timescales
- 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.

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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

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# 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.**