

National Homeland Security Research Center
**Threat and Consequence
Assessment Division**

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?"



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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



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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

- **Homeland Security Presidential Directive (HSPD) #8 for National Emergency Preparedness**
 - **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**



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Example Acute Inhalation Reference Values

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

	Reference Value	Organization	Type Value	TWA (Yes/No)	Exposure Duration
Occupational	PEL - Permissible Exposure Limit	OSHA	Occupational	Yes	8-hour
	Ceiling	OSHA	Occupational	No	Up to 10-minute
	REL - Recommended Exposure Limit	NIOSH	Occupational	Yes	8-hour
	IDLH - Immediately Dangerous to Life and Health	NIOSH	Occupational	No	Up to 30-minute
	STEL - Short Term Exposure Limit	NIOSH	Occupational	Yes	15-minute
	TLV - Threshold Limit Value	ACGIH	Occupational	Yes	8-hour
	TLV-STEL - TLV Short Term Exposure Limit	ACGIH	Occupational	Yes	15-minute
Emergency Response	AEGL - Acute Exposure Guideline Level	NAC/AEGL; NRC/AEGL	Emergency Response		10- and 30-minute; 1-, 4- and 8-hour
	ERPG - Emergency Response Planning Guideline	AIHA	Emergency Response		1-hour
	TEEL - Temporary Emergency Exposure Level	DOE	Emergency Response		1-hour
	ERG - Emergency Response Guidebook	DOT	Emergency Response		Specialized application
Public Health	MRL - Minimal Risk Level	ATSDR	Public Health		1-14 days (acute); 15-364 days (intermediate); >365 days (chronic)
	CA-REL - Reference Exposure Level	Cal-EPA/DEHHA	Public Health		1-8 hours
	EPA - Acute RIC	US EPA - IRIS	Public Health		1-, 4-, 8-, and 24-hours



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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



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Health-Based Exposure Values for Air and Water

	Reference Value	Organization	Exposure Duration
Occupational	PEL - Permissible Exposure Limit	OSHA	8-hour
	Ceiling	OSHA	Up to 10-minute
	REL - Recommended Exposure Limit	NIOSH	8-hour
	IDLH - Immediately Dangerous to Life and Health	NIOSH	Up to 30-minute
	STEL - Short Term Exposure Limit	NIOSH	15-minute
	TLV - Threshold Limit Value	ACGIH	8-hour
	TLV-STEL - TLV Short Term Exposure Limit	ACGIH	15-minute
Emergency Response	AEGL - Acute Exposure Guideline Level (air only)	NAC/AEGL; NRC/AEGL	10- and 30-minute; 1-, 4- and 8-hour
	DW HA - Drinking Water Health Advisory (water only)	EPA/OW	1-day; 10-day; longer-term
	PAL - Provisional Advisory Level (air and water)	EPA/ORD	24 hours; up to 30 days; up to 2 years
	ERPG - Emergency Response Planning Guideline	AIHA	1-hour
	TEEL - Temporary Emergency Exposure Level	DOE	1-hour
	ERG - Emergency Response Guidebook	DOT	Specialized application
Public Health	MRL - Minimal Risk Level (air and water)	ATSDR	1-14 days (acute); 15-364 days (intermed.); >365 days (chronic)
	CA-REL - Reference Exposure Level	Cal-EPA OEHHA	1-8 hours
	EPA - Acute RFC	US EPA / IRIS	1-, 4-, 8-, and 24-hours

PALs Fill Exposure Gaps

<u>Duration</u>	<u>Inhalation</u>	<u>Oral</u>
10 min to 8 hours	AEGL, ERPG, TEEL	None
24 hours	PALs Acute RfC (limited)	PALs DW HA
>1 to 30 days	PALs MRLs	PALs MRLs, DW HA
Less-than-lifetime	PALs MRLs	PALs MRLs, DW HA
Lifetime	RfC, MRLs	RfD, MRLs



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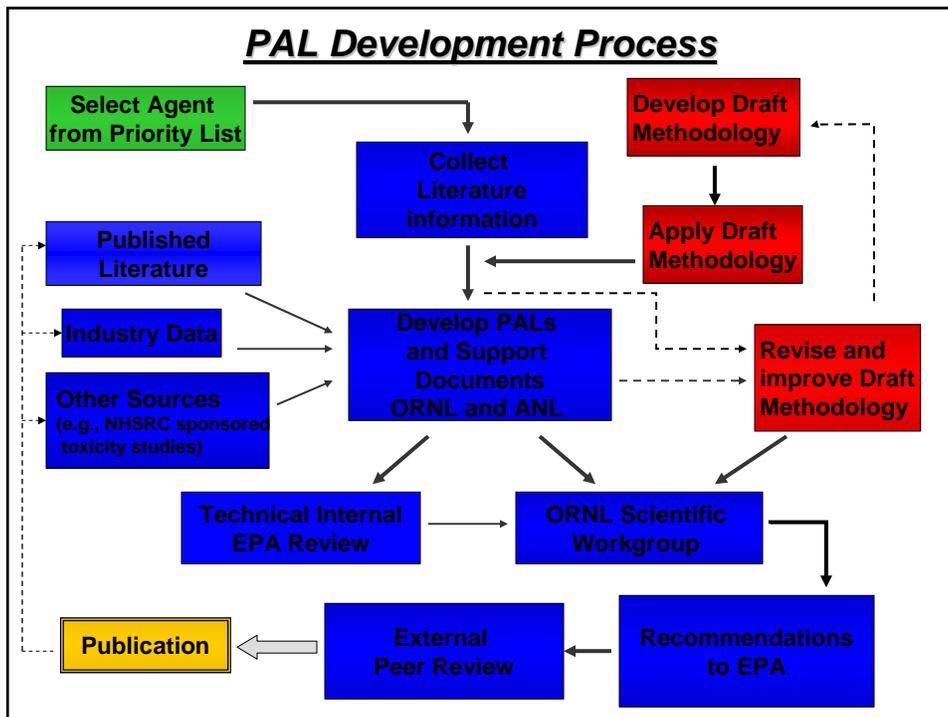
What are PALs?

- **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**



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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



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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.



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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?



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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

ECAT IS A PROTOTYPE SYSTEM. DO NOT CITE OR QUOTE.

U.S. Environmental Protection Agency
Emergency Consequence Assessment Tool

Search Go Advanced

- Agent Information
 - Quick Reference
 - Guides
 - RTRR Factsheets
 - Information Sources
 - Agent FAQ
- Subject Matter Experts
 - NHRSC Red Team
- Tools/Links
 - Risk Communication (Message Maps)
 - HAZUS Database
 - CAMEO
 - EPANET
 - WCIT
 - CBHelpline
 - BDRTool
 - Unit Conversion
 - Local Weather
 - Blue Book
 - American Red Cross
 - U.S. Coast Guard
 - EPA Emergency Response Team (ERT)
 - NIOCH Pocket Guide to Chemical Hazards
 - Emergency Response Guidebook
 - Acute Exposure Guideline Levels (AELs)
 - Integrated Risk Information System (IRIS)
- Notification Centers
 - Report Terrorist Activity
 - NRC
 - ODC

Outline

- Background
 - Purpose, vision, users, history
 - Challenges
- Overview of ECAT
 - Guiding principles
 - Features
 - Status and plans
- Issues

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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

Aspect	Typical Assessments (low-level exposure)	Homeland Security Assessments
Contaminants of concern	Industrial pollutants	Chemical, biological, & radiological agents
Exposure duration	70-year lifetime	Less than lifetime
Time to complete assessment	Years	Hour or days

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Notification Centers
 Report Terrorist Activity
 NRC
 CDC

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

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Subject Matter Experts
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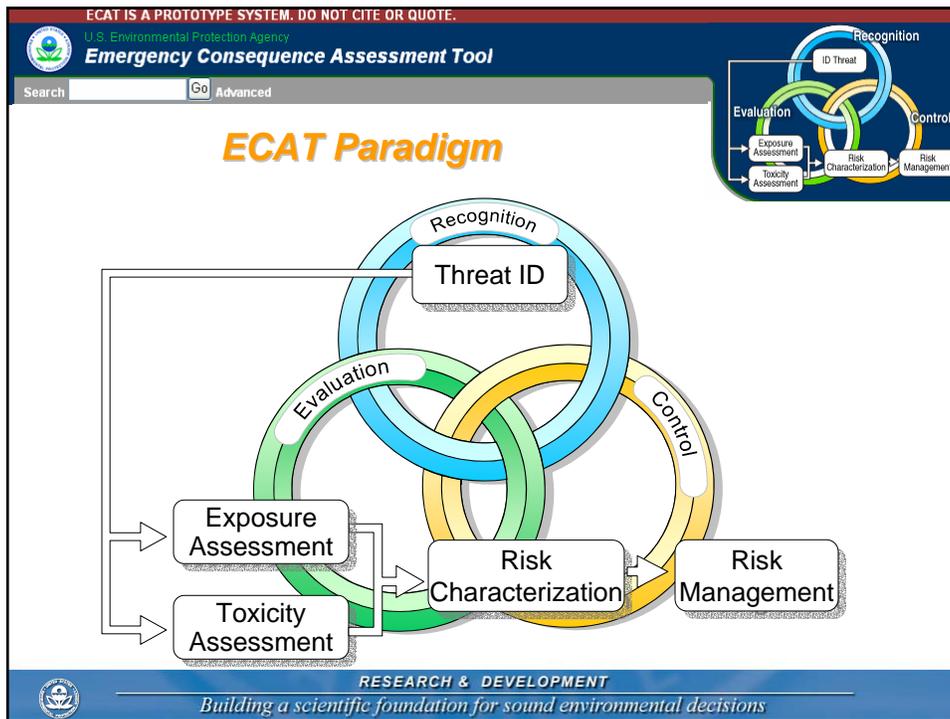
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Notification Centers
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Guiding Principles

- 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

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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

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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

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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

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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?

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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?

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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

Incident-Based Microbial Risk Assessment and Decision Framework

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.



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Incident-Based Microbial Risk Assessment and Decision Framework

Applications:

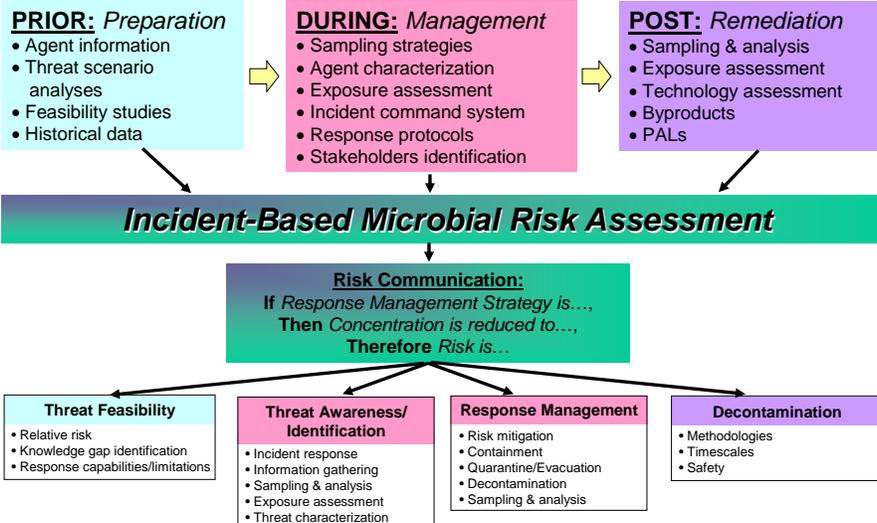
- Scenario-based risk assessment guidance to support on-site decisions and associated activities to control and mitigate risk of exposure to select bioagents as a consequence of deliberate contamination events.
- Methodology-based communication to first-responders to collect relevant information to support 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.



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



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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.



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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.



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