U.S. Army Public Health Center (APHC) Mission

Enhance Army readiness by identifying and assessing current and emerging health threats, developing and communicating public health solutions, and assuring the quality and effectiveness of the Army's Public Health Enterprise.

APHC Vision

World-class provider of public health services across the Department of the Army and the Department of Defense.

Toxicology Directorate (TOX) Mission

Promote health and prevent disease, injury, and disability of Soldiers and civilians by identifying the toxicity of military-unique and military-relevant compounds and the risks they pose to humans and the environment.

Maintain Soldier and civilian readiness through the evaluation and clearance of products, materials, and compounds proposed for military use.

TOX Guiding Principles

Provide toxicology expertise and services of exceptional quality to meet customer needs.

Perform all experiments in compliance with the U.S. Food and Drug Administration (FDA) and U.S. Environmental Protection Agency (EPA) Good Laboratory Practice (GLP) regulations.

Toxicity Testing, Assessments, and Clearances

Toxicology Directorate Contact Information:

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APHC

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APHC Toxicology Directorate

Office of Toxicologic Pathology (OTP)

Health Effects Research Division (HEF)

Toxicity Evaluation Division (TEV)

APHC

U.S. Army Public Health Center **Toxicology Directorate**

Office of Toxicologic Pathology (OTP)

The Office of Toxicologic Pathology (OTP) provides expert veterinary medical and pathology services in direct support of the Toxicity Evaluation and Health Effects Research division within the Toxicology Directorate (TOX), as well as Department of Defense (DOD) customers external to the U.S. Army Public Health Center (APHC). The OTP's board-certified veterinary pathologist and staff provide expert necropsy, clinical chemistry, and pathology support to all studies involving animals.

Expertise areas:

- Toxicologic histopathology
- Diagnostic histopathology
- Immunohistochemical and specialty stains
- Photomicrography
- Tissue dissection and gross evaluation

As ethical research animal users, TOX works closely with the Quality, Safety, and Regulatory Compliance Office (QSARC) and the Institutional Animal Care and Use Committee to ensure animal facilities and the APHC Animal Care and Use Program maintain AAALAC accreditation and strict compliance with Federal and DOD laws, directives, regulations, policies, and guidelines. All studies are conducted in accordance with Good Laboratory Practice (GLP).

Health Effects Research Division (HEF)

The Health Effects Research Division (HEF) within TOX focuses on environmental toxicology and support to Army Research, Development, Test, and Evaluation (RDT&E) in developing sustainable, safe products. HEF performs computer predictions (*in silico*) of toxicity and conducts specific *in vitro* tests for new chemicals or those with sparse toxicity data. Toxicity information is researched and translated within Toxicity Assessments that provide recommendations on new compounds and materiel for military use. HEF performs direct support in the conduct of human and environmental health assessments, providing data and reports regarding toxicity of military-unique and military-relevant compounds and the risks they pose to Soldiers, civilians, and the environment.

Key capabilities:

- *In silico* assessment such as quantitative structure-activity relationship (QSAR) modeling
- *In vitro* toxicology assays using bacteria, invertebrates, or cell culture methods
- *Ex vivo* assessments such as precision-cut tissue slices tissue slices
- *In vivo* animal models for oral toxicity studies using various lab and wild species
- All studies performed in accordance with GLP

Major Deliverable: Toxicity Assessments

Toxicity Assessments (TAs) provide the technical foundation for Toxicity Clearances of chemicals and materiel for military use, are required by Army Regulation (AR) 40-5 and and AR 70-1, and are described in APHC Technical Guide 389. TAs interpret toxicity, bioaccumulation, persistence, and fate and transport data to foster understanding of potential health and environmental hazards. These data not only inform product life cycle decisions but also inform Army decision makers and other customers of potential toxicity issues related to use of a proposed chemical product.

Toxicity Evaluation Division (TEV)

The Toxicity Evaluation Division (TEV) directly supports the APHC and DOD's public health mission by providing toxicological expertise for the identification and elimination of potential health hazards resulting from occupational and military-unique exposure scenarios. TEV supports the Army's Preventive Medicine Program, acquisition programs, and Soldier readiness through consultations, data evaluations, modeling, and laboratory animal testing. Scientists within TEV conduct toxicity studies to determine occupational exposure levels (OELs) and military-unique health effects criteria. TEV scientists produce Toxicity Clearances (TCs) that are decision documents required for all substances and systems entering the Army supply chain. TEV services provide critical information needed to protect the Soldier, the worker, and the environment; and to sustain operations required for military readiness.

Key capabilities:

- *In vivo* small and large animal studies ranging from acute to chronic durations
- Multiple modes of exposure (i.e., inhalation, oral, dermal)
- Expertise with challenging materials
  - Energetics, smokes, pyrotechnics
  - Toxic industrial chemicals, aerosols, powders
  - Fire-suppression agents, combustion by-products

Major Deliverable: Toxicity Clearances

APHC TOX is the Office of The Surgeon General's lead agent for TCs. TCs are toxicological evaluations of materials prior to their introduction into the Army supply system to ensure the safety of Army personnel, and are required by AR 40-5, AR 70-1, DA Pam 70-3, and AR 40-10. The results of these toxicological evaluations are used as a basis for granting the required authorization for use and deployment of various chemicals, compounds, materials, and equipment.