



Department of Defense INSTRUCTION

NUMBER 4715.18

June 11, 2009

USD(AT&L)

SUBJECT: Emerging Contaminants (ECs)

References: See Enclosure 1

1. PURPOSE. This Instruction establishes policy and assigns responsibilities for the identification, assessment, and risk management of ECs that have the potential to impact the Department of Defense in accordance with the authority in DoD Directive (DoDD) 5134.01 (Reference (a)) and the guidance in DoDD 4715.1E, DoD Instruction 5000.02, and Defense Acquisition University Risk Management Guide (References (b), (c), and (d)).

2. APPLICABILITY. This Instruction:

a. Applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereafter referred to collectively as the "DoD Components").

b. Applies to the DoD activities and programs involving the development, production, use, storage, or release of chemicals and materials that can be considered ECs at DoD operations, activities, and installations in the United States.

c. Applies to the DoD-managed response actions at formerly used defense sites.

d. Does not apply to:

(1) Contractor-owned or contractor-operated facilities.

(2) Radiological data collected under the Naval Nuclear Propulsion Program or other DoD radiological programs.

(3) Chemical, biological, radiological, nuclear, and explosive incident training or response programs.

3. DEFINITIONS. See Glossary.

4. POLICY. It is DoD policy that:

a. Chemicals and materials used, or planned to be used, by the Department of Defense that meet the definition of an ECs shall be identified as early as possible.

b. Risks to people, the environment, and DoD missions, programs, and resources shall be assessed and, when appropriate, actions shall be taken to reduce risks related to ECs development, use, or release.

c. The Department of Defense, where necessary, perform sampling, conduct site-specific risk assessments, and take response actions for ECs released from DoD facilities in accordance with chapter 160 of title 10, United States Code (U.S.C.) (Reference (e), known as the “Defense Environmental Restoration Program”), and consistent with chapter 103 of title 42, U.S.C., (Reference (f), known as the “Comprehensive Environmental Response, Compensation, and Liability Act of 1980”) and the procedures in this Instruction.

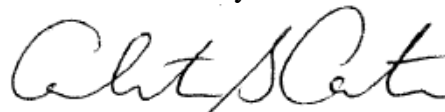
d. Subject to appendix 2 to title 5, U.S.C. (Reference (g), known as the “Federal Advisory Committee Act”), the Department of Defense shall work cooperatively and collaboratively with appropriate representatives from regulatory agencies, industry, and academia on ECs issues and initiatives.

5. RESPONSIBILITIES. See Enclosure 2.

6. PROCEDURES. See Enclosures 3 and 4.

7. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the DoD Issuances Web Site at <http://www.dtic.mil/whs/directives>.

8. EFFECTIVE DATE. This Instruction is effective immediately.



Ashton B. Carter
Under Secretary of Defense
for Acquisition, Technology and Logistics

Enclosures

1. References
2. Responsibilities
3. Use of Provisional Toxicity Values
4. Initiation of Actions Related to EC Releases

Glossary

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5134.01, "Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L))," December 9, 2005
- (b) DoD Directive 4715.1E, "Environment, Safety, and Occupational Health (ESOH)," March 19, 2005
- (c) DoD Instruction 5000.02, "Operation of the Defense Acquisition System," December 8, 2008
- (d) Defense Acquisition University, "Risk Management Guide for DoD Acquisition (Sixth Edition, Version 1.0)," August 2006
- (e) Chapter 160 of title 10, United States Code
- (f) Chapter 103 of title 42, United States Code
- (g) Appendix 2 to title 5, United States Code
- (h) DoD Directive 5105.18, "DoD Committee Management Program," February 8, 1999
- (i) U.S. Environmental Protection Agency Web Site, "IRIS Substance Assessment Tracking System"¹
- (j) California Environmental Protection Agency, Office of Environmental Health Hazard Assessment Web Site, "Toxicity Criteria Database"²
- (k) U.S. Department of Human and Health Services, Agency for Toxic Substances and Disease Registry Web Site, "Minimal Risk Levels"³
- (l) U.S. Environmental Protection Agency Web Site, "Health Effects Assessment Summary Table"⁴
- (m) U.S. Environmental Protection Agency EPA-505-B-04-900A/DTIC ADA 427785, "Uniform Federal Policy for Quality Assurance Project Plans: Evaluating, Assessing, and Documenting Environmental Data Collection and Use Program," March 2005
- (n) U.S. Environmental Protection Agency EPA-505-F-03-00/DTIC ADA 39530, "Uniform Federal Policy for Implementing Environmental Quality Systems: Evaluating, Assessing, and Documenting Environmental Data Collection/Use and Technology Programs," March 2005

¹ Available at <http://cfpub.epa.gov/iristrac/index.cfm>

² Available at <http://www.oehha.ca.gov/risk/chemicalDB/index.asp>

³ Available at <http://www.atsdr.cdc.gov/mrls/index.html>

⁴ Available at <http://www.epa.gov/radiation/heast>

ENCLOSURE 2

RESPONSIBILITIES

1. DEPUTY UNDER SECRETARY OF DEFENSE FOR INSTALLATIONS AND ENVIRONMENT (DUSD(I&E)). The DUSD(I&E), under the authority, direction, and control of the Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)), shall:

- a. Provide oversight and guidance to ensure the early identification, assessment, and mitigation of risks related to ECs.
- b. Invite the participation of Program Executive Offices and program managers (PMs), as appropriate, in the assessment of risks and implementation of risk management actions.
- c. Maintain a dynamic list of ECs with potential impacts on DoD personnel and functions.

2. ASSISTANT DEPUTY UNDER SECRETARY OF DEFENSE FOR ENVIRONMENT, SAFETY, AND OCCUPATIONAL HEALTH (ADUSD(ESOH)). The ADUSD(ESOH), under the authority, direction, and control of the DUSD(I&E), shall:

- a. Develop and manage an EC program to:
 - (1) Provide early identification of EC issues.
 - (2) Conduct cross-Service, cross-system assessments of the impacts of ECs on DoD personnel, missions, and business functions. The impact assessments shall use information from other programs to the extent practical (e.g., safety and occupational health assessments).
 - (3) Develop, in coordination with the DoD Components, risk management options for potential investments by PMs for those ECs with high risk to the Department of Defense.
 - (4) Maintain a “watch list” of ECs with potential high risks to the Department of Defense and an “action list” of ECs with probable high risk to the Department.
- b. Ensure consultation with the DoD Components and appropriate OSD offices through a staff-level ECs Steering Group and an executive-level ECs Governance Council. The Governance Council shall comply with the requirements of DoDD 5105.18 (Reference (h)).
- c. Prepare budget requests and justifications to implement the ECs program.
- d. Provide updates to senior DoD leadership concerning newly identified risks and risks that could be reduced through proactive risk management actions.

e. Serve as the focal point for ECs issues with Federal and State agencies, industry, and academia.

f. Develop policies and prepare Congressional briefings and testimony as required.

3. DIRECTOR, DEFENSE LOGISTICS AGENCY (DLA). The Director, DLA, under the authority, direction, and control of the USD(AT&L), through the Deputy Under Secretary of Defense for Logistics and Materiel Readiness, shall provide data to the ADUSD(ESOH) related to National Stock Numbers and requisition history for chemicals and materials being assessed by the ADUSD(ESOH).

4. HEADS OF THE DoD COMPONENTS. The Heads of the DoD Components shall:

a. Comply with this Instruction.

b. Provide subject matter experts for specific ECs impact assessments when requested by the ADUSD(ESOH).

c. Provide representatives, as appropriate, for the ECs Steering Group and ECs Governance Council.

d. Plan, program, and budget, as appropriate, for the implementation of risk management actions needed to mitigate risks to human health, the environment, and DoD functions. These actions can include toxicological studies, materials substitution, research and development, testing and qualification of alternative materials and processes, source and scope of use studies, new analytical techniques, implementation of treatment and cleanup technologies, and deployment of new or improved personal protective equipment.

ENCLOSURE 3

USE OF PROVISIONAL TOXICITY VALUES

1. GENERAL. The identification of toxicity values is a crucial step in conducting site-specific risk assessments for contaminated sites. The identification of toxicity values for ECs presents special challenges.

2. HIERARCHY OF TOXICITY VALUES. The Department of Defense shall use the hierarchy in paragraphs 2.a. through 2.c. of this enclosure for selecting toxicity values for ECs.

a. Tier 1 – U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS). The toxicity values listed on the EPA IRIS Web Site (Reference (i), known as the “IRIS Substance Assessment Tracking System” or “IRIS Track”) have undergone rigorous peer review and are considered to be validated. The completion of IRIS assessments is a multi-step process including internal peer review, EPA program and regional office review, Federal interagency review, and external peer review with a public notice and comment period. The various steps are described in Reference (i).

b. Tier 2 – EPA Provisional Peer-Reviewed Toxicity Values (PPRTVs). The Office of Research and Development/National Center for Environmental Assessment/Superfund Health Risk Technical Support Center develops PPRTVs on a chemical-specific basis when requested by the EPA’s Superfund Program for use in site-specific risk assessments. However, the PPRTVs are developed in a shorter period of time than the IRIS assessments and, although these assessments undergo external peer review, this review may be more limited and does not include EPA and interagency review as is done with the IRIS assessments. Furthermore, their development typically includes a limited evaluation of information on mode of action, other toxicological end points, and other information that provides a better understanding of the toxicology of these chemicals. Often, the amount of relevant information on the toxicity of these chemicals is less because fewer studies have been conducted and reported. However, the PPRTVs are generally the best quantification of the dose-response scientific data that are available at the time they are developed because the PPRTVs utilize current information and methodologies.

c. Tier 3 – Other Toxicity Values. Tier 3 includes additional EPA and non-EPA sources of toxicity information. Priority should be given to sources of information that use sound science and are the most current, peer-reviewed, transparent, and publicly available. Example sources for Tier 3 include the California State EPA Toxicity Criteria Database, the U.S. Department of Human and Health Services Minimal Risk Levels, and the EPA’s Health Effects Assessment Summary Table (References (j), (k), and (l)). Values may also be found by using an Internet search engine to search for “toxicity values” for a specific chemical.

3. TYPES OF ASSESSMENTS. The types of assessments that should be used to guide the selection of toxicity values in all cases are:

a. Transparent assessments (in which toxicity values are derived) that clearly identify the information used and how it was used.

b. Assessments that have been externally and independently peer reviewed, where reviewers and affiliations are identified. Other things being equal, assessments with more extensive peer review are preferred. Panel peer reviews are considered preferable to letter peer reviews.

c. Assessments that were completed with a previously promulgated and publicly available methodology. Methodologies that were externally peer reviewed are preferred over those that were not externally peer reviewed.

d. Assessments that consider the quality of studies used, including the statistical power or lack thereof to detect effects, corroborate data among pertinent studies, and make best use of all available science.

e. Assessments and values that is publicly available or accessible. There may be a further preference for toxicity assessments that invited and considered public comment (as well as, but not in lieu of, external peer review).

f. Other things being equal, toxicity values that are consistent with the duration of human exposure being assessed. For example, an externally peer-reviewed subchronic reference dose (RfD) should be preferred to an externally peer-reviewed chronic RfD when assessing an exposure of 2 years for non-cancer toxicity.

4. ADDITIONAL CONSIDERATIONS

a. While there should be a preference for assessments using established methodologies to derive toxicity values, these methodologies should also be informed by the current best scientific information and practices. New assessment methodologies should provide reproducible results and meet quality assurance and quality control requirements.

b. Parties involved in the risk assessment should seek to identify the best, or most scientifically defensible, toxicity value. When the DoD Component with lead agency responsibility for response actions is unable to identify a scientifically defensible toxicity value, for example, due to the lack of relevant toxicological studies or lack of an appropriate surrogate for a given chemical, the site-specific risk assessment should identify this as an uncertainty in the risk characterization.

ENCLOSURE 4

INITIATION OF ACTIONS RELATED TO ENVIRONMENTAL EC RELEASES

1. GENERAL. The Department of Defense and regulators should strive to reach agreement on how and when to sample for ECs, the means to determine the nature and scope of the risk to human health and the environment, and the response actions needed in accordance with References (e) and (f).

2. PRINCIPLES FOR DETERMINING ACTIONS. These principles should be applied in determining appropriate site-specific actions related to ECs consistent with References (e) and (f).

a. Based on the site history and site inspection, determine whether there is a known or suspected release of an ECs that would trigger a need for sampling at a site and whether there is an appropriate analytical method.

b. If information exists to support sampling, develop a field sampling and analysis plan with agreed-upon data quality objectives. The quality assurance project plan for such efforts should comply with the EPA's Uniform Federal Policies for Quality Assurance Project Plans and for Implementing Environmental Quality Systems (References (m) and (n)). Among other things, the plan should identify an approved analytical method that meets the required detection limits for the ECs. In the event the sample quantification limit (SQL) is insufficient to analyze at the levels necessary to determine whether an unacceptable risk exists, other options such as analytic surrogates may be explored. If an analytical method with a sufficiently sensitive SQL is not available, the issue generally should be brought to the attention of the DoD Environmental Data Quality Work Group for consultation with counterparts in regulatory agencies.

c. All sources of toxicological and human health information should be searched to ascertain the best available science and identify uncertainties. (This process is more fully described in Enclosure 3.) In addition, if gaps in the human health science exist, recommendations should be made to appropriate State agencies, the EPA, or other agencies for additional studies to reduce uncertainty.

d. Baseline risk assessments shall integrate the toxicological data with site-specific exposure factors and provide the basis for determining the extent of the risk and for taking any necessary response action.

e. If agreement cannot be reached at the site level, the DoD Components should consult with their chain of command in accordance with established policies to determine an appropriate course of action. In such cases, the parties reserve all rights and authorities under existing laws and regulations.

f. Where agreement is not reached on cleanup levels, interim response actions to reduce risk (for example, plume migration control, provision of drinking water, land use controls, or monitoring) may be appropriate until risk-based values are identified.

GLOSSARY

PART I: ABBREVIATIONS AND ACRONYMS

ADUSD(ESOH)	Assistant Deputy Under Secretary of Defense for Environment, Safety, and Occupational Health
DLA	Defense Logistics Agency
DoDD	Department of Defense Directive
DUSD(I&E)	Deputy Under Secretary of Defense for Installations and Environment
ECs	emerging contaminants
EPA	Environmental Protection Agency
IRIS	Integrated Risk Information System
PM	Program Manager
PPRTV	provisional peer-reviewed toxicity values
RfD	reference dose
SQL	sample quantification limit
U.S.C.	United States Code
USD(AT&L)	Under Secretary of Defense for Acquisition, Technology, and Logistics

PART II: DEFINITIONS

These terms and their definitions are for the purpose of this Instruction.

EC

As identified by the DUSD(I&E), a contaminant that:

Has a reasonably possible pathway to enter the environment;

Presents a potential unacceptable human health or environmental risk; and

Does not have regulatory standards based on peer-reviewed science, or the regulatory standards are evolving due to new science, detection capabilities, or pathways.

ECs are identified and assessed exclusively through a three-tiered process called “scan-watch-action.”

installation. A base, camp, post, station, yard, center, homeport facility for any ship, Government-owned and/or contractor-operated facility, or other activity under the jurisdiction of the Department of Defense, including any leased facility. Such term does not include any facility used primarily for civil works, rivers and harbors projects, or flood control projects.

IRIS. A database administered by the EPA that contains toxicity data related to the risks to human health from chemicals and materials.

State. Includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, the United States Virgin Islands, and American Samoa.

United States. Includes the States as defined in this Glossary, as well as Midway and Wake Islands and any other territory or possession of the United States and the associated navigable waters, contiguous zones, and ocean waters of which the natural resources are under the exclusive management authority of the United States.