



DoD INSTRUCTION 4715.18

EMERGING CHEMICALS (ECs) OF ENVIRONMENTAL CONCERN

Originating Component: Office of the Under Secretary of Defense for Acquisition and Sustainment

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Approved by: Ellen M. Lord, Under Secretary of Defense for Acquisition and Sustainment

Purpose: In accordance with the authority in DoD Directive 5134.01, the July 13, 2018 Deputy Secretary of Defense Memorandum, and the guidance in DoD Directives 4715.1E and 3020.40 and DoD Instruction (DoDI) 5000.02, this issuance establishes policy, assigns responsibilities, and provides procedures for an enterprise-wide approach to the identification, assessment, and management of "DoD ECs" (referred to in this issuance as "ECs") with new or changing toxicity values or environmental risk assessment regulations.

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SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY. This issuance:

a. Applies to:

(1) 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 DoD (referred to collectively in this issuance as the “DoD Components”).

(2) All DoD operations, activities, and installations worldwide, unless superseded by international agreement, including government-owned, contractor-operated facilities.

b. Does not apply to:

(1) Contractor-owned 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 actions.

(4) The civil works function of the U.S. Army Corps of Engineers.

1.2. POLICY. The DoD establishes the EC Program to:

a. Identify ECs; assess the likelihood and severity of impacts associated with ECs to people, the environment, and DoD mission, programs, and resources enterprise-wide; and take management actions to reduce these impacts.

b. Work cooperatively and collaboratively with representatives from regulatory agencies, industry, and academia on issues and initiatives related to ECs.

SECTION 2: RESPONSIBILITIES

2.1. UNDER SECRETARY OF DEFENSE FOR ACQUISITION AND SUSTAINMENT (USD(A&S)). The USD(A&S) establishes policies and procedures for the EC Program in accordance with DoDD 4715.1E.

2.2. ASSISTANT SECRETARY OF DEFENSE FOR SUSTAINMENT (ASD(S)). Under the authority, direction, and control of the USD(A&S), the ASD(S):

a. Oversees the implementation of this issuance in coordination with the Assistant Secretary of Defense for Acquisition (ASD(A)), the Assistant Secretary of Defense for Readiness (ASD(R)), and the Assistant Secretary of Defense for Health Affairs (ASD(HA)); the Director of Defense Research and Engineering for Research and Technology; and the DoD Component heads.

b. Establishes, chairs, and identifies a deputy chair for the Emerging Chemicals of Concern Governance Council (ECGC).

c. Oversees membership of the ECGC to ensure representation of the five DoD functional areas.

(1) Environment, safety, and health represented by the ASD(S), ASD(R), and ASD(HA).

(2) Training and readiness represented by the ASD(R).

(3) Production, operations, maintenance, and disposal of DoD assets represented by the ASD(S).

(4) Cleanup represented by the ASD(S).

(5) Acquisition and research, development, testing, and evaluation represented by the ASD(A) and the Director of Defense of Research and Engineering for Research and Technology.

d. Engages with the Service assistant secretaries responsible for ECs, or the Service acquisition executives, to invite the participation of program executive officers and program managers, as appropriate, in the assessment of ECs and implementation of risk management actions (RMAs) for ECs.

2.3. DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR ENVIRONMENT (DASD(ENV)). Under the authority, direction, and control of the ASD(S), the DASD(ENV):

a. Manages and oversees the EC Program.

b. Establishes and chairs an emerging chemicals of concern steering group (ECSG).

- c. Establishes and oversees the Tri-Service Toxicology Consortium (TSTC).
- d. Prepares budget requests and justifications to implement the EC Program.
- e. Provides updates to senior DoD leadership on newly identified enterprise-wide impacts that could be reduced through proactive RMAs.
- f. Serves as the focal point for EC issues with federal and State agencies, industry, and academia in accordance with DoDI 5105.18.
- g. Develops policies for consistent EC-related actions within the DoD and prepares congressional briefings and testimony, as required.
- h. Coordinates, reviews, and provides consolidated DoD Component comments to federal and State agencies on EC-related assessments, evaluations, draft legislation, and proposed regulations concerning hazards, exposures, and conditions of use.

2.4. ASD(A). Under the authority, direction, and control of the USD(A&S), the ASD(A):

- a. Provides representatives to the ECGC and ECSG as outlined in Paragraphs 2.2., 4.1., and 4.2.
- b. Appoints representatives to the TSTC as outlined in Paragraph 4.3.
- c. Provides comments on EC-related assessments, evaluations, legislation, and proposed toxicity/risk assessment regulations on hazards, exposures, and conditions of use to the ASD(S) and the DASD(ENV).
- d. Plans, programs, and budgets for the implementation of RMAs needed to reduce the likelihood or severity of impacts to people, the environment, and DoD missions, programs, and resources.

2.5. ASD(R). Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, the ASD(R):

- a. Provides representatives to the ECGC and ECSG as outlined in Paragraphs 2.2., 4.1., and 4.2.
- b. Appoints representatives to the TSTC as outlined in Paragraph 4.3.
- c. Provides comments on EC-related assessments, evaluations, legislation, and proposed toxicity/risk assessment regulations on hazards, exposures, and conditions of use to the ASD(S) and the DASD(ENV).
- d. Plans, programs, and budgets for the implementation of RMAs needed to reduce the likelihood or severity of impacts to people, the environment, and DoD missions, programs, and resources.

2.6. ASD(HA). Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, the ASD(HA):

- a. Provides representatives to the ECGC and ECSG as outlined in Paragraphs 2.2., 4.1., and 4.2.
- b. Appoints representatives to the TSTC as outlined in Paragraph 4.3.
- c. Provides comments on EC-related assessments, evaluations, legislation, and proposed toxicity/risk assessment regulations on hazards, exposures, and conditions of use to the ASD(S) and the DASD(ENV).
- d. Plans, programs, and budgets for the implementation of RMAs needed to reduce the likelihood or severity of impacts to people, the environment, and DoD missions, programs, and resources.

2.7. DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING FOR RESEARCH AND TECHNOLOGY. Under the authority, direction, and control of the Under Secretary of Defense for Research and Engineering, the Director of Defense Research and Engineering for Research and Technology:

- a. Provides representatives to the ECGC and ECSG as outlined in Paragraphs 2.2., 4.1., and 4.2.
- b. Appoints representatives to the TSTC as outlined in Paragraph 4.3.
- c. Provides comments on EC-related assessments, evaluations, legislation, and proposed toxicity/risk assessment regulations on hazards, exposures, and conditions of use to the ASD(S) and the DASD(ENV).
- d. Plans, programs, and budgets for the implementation of RMAs needed to reduce the likelihood or severity of impacts to people, the environment, and DoD missions, programs, and resources.

2.8. DOD COMPONENT HEADS. The DoD Component heads:

- a. Provide representatives to the ECGC and the ECSG as outlined in Paragraphs 2.2., 4.1., and 4.2.
- b. Appoint representatives to the TSTC as outlined in Paragraph 4.3.
- c. Provide comments on EC-related assessments, evaluations, legislation, and proposed toxicity/risk assessment regulations on hazards, exposures, and conditions of use to the ASD(S) and the DASD(ENV).

d. Plan, program, and budget for the implementation of RMAs needed to reduce the likelihood or severity of impacts to people, the environment, and DoD missions, programs, and resources.

SECTION 3: THE EC PROCESS: IDENTIFICATION, ASSESSMENT, AND MANAGEMENT

3.1. IDENTIFICATION. The EC Program staff:

a. Identifies chemicals that may qualify as ECs using various sources of information. To be considered an EC, a chemical must:

(1) Be relevant to the DoD (e.g., used by the DoD, incorporated into research and development).

(2) Have a perceived or real threat to human health or the environment.

(3) Have new or changing toxicity values or regulatory standards as a result of new science, detection capabilities, or exposure pathways. Appendix 3A provides a framework to recognize new or changing toxicity values.

b. Writes screening reports to document the identification of the chemical as an EC.

c. Provides the ECSG with the screening report for review. The ECSG then advises the EC Program staff on whether the chemical should be an EC.

d. Determines if the chemical they identified is an EC and places it on the EC Watch List. Chemicals that are not ECs are removed from consideration.

e. Documents their decision, in accordance with Paragraph 3.1.d., in writing and distributes this information to the ECSG.

3.2. ASSESSMENT.

a. The assessment portion of the EC process incorporates qualitative data, quantitative data, or a combination of both. EC Program staff and the ECSG, as well as subject matter experts (SMEs) identified by the EC Program staff and the ECSG, participate in this assessment process. The EC Program staff, in collaboration with the ECSG and SMEs, as needed:

(1) Assess the EC Watch List to determine the likelihood and severity of impact to the five DoD functional areas.

(2) Write reports to document the impact assessments, which include an initial assessment and verification and validation of findings.

(3) Provide the ECSG with impact assessment reports for review. The ECSG advises the EC Program staff on the next step in the EC process depending on whether the results of the initial assessment or subsequent verification and validation indicate low, moderate, or high risk of impact to any of the five DoD functional areas.

(4) Determine if the EC they assessed will remain on the EC Watch List or be moved to the EC Action List.

(a) If the initial assessment, or subsequent verification and validation, indicate **low or moderate risk** of impact to any of the five DoD functional areas, the EC remains on the EC Watch List.

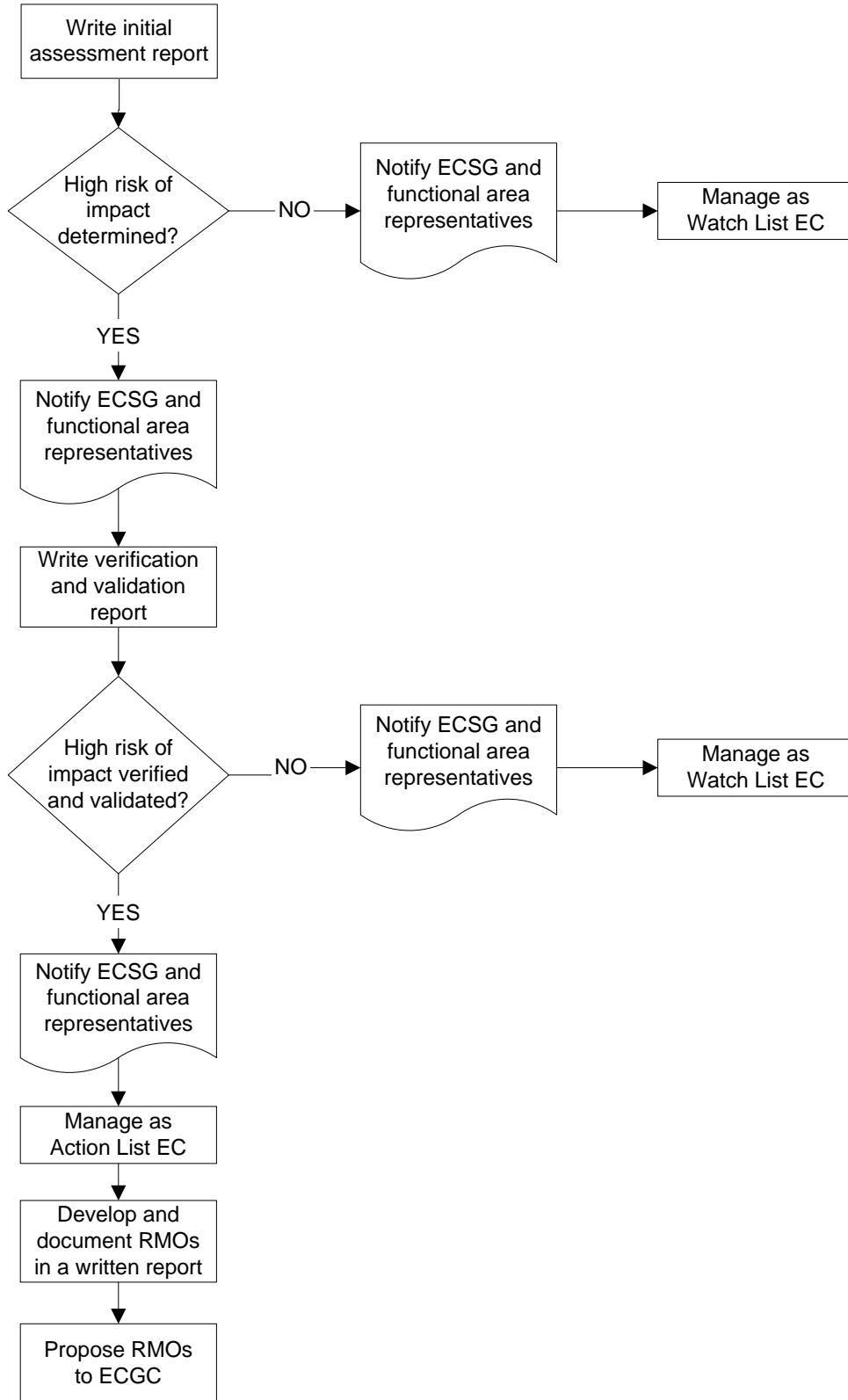
(b) If the initial assessment, and subsequent verification and validation, indicate **high risk** of impact to any of the five DoD functional areas, the EC is moved to the EC Action List.

(5) Document the determination made in accordance with Paragraph 3.2.a.(4) in writing, distribute the information to the ECSG, and notify the representatives for the functional areas about the potential consequences of the impact assessment report findings. The notification process ensures accurate and efficient information exchange between the EC Program and the functional area representatives when an EC has a potential impact on a specific functional area.

(6) Develop risk management options (RMOs) for action list ECs as advised by the ECSG and propose RMOs to the ECGC for endorsement.

b. Assessment generally follows the process shown in Figure 1.

Figure 1. EC Assessment, Notification, and Reporting Process



3.3. MANAGEMENT.

a. The chair and deputy chair of the ECGC document the endorsements made by the ECGC and send out the results to its members, the ECSG, and the appropriate DoD Components for action. Endorsed RMOs are designated as RMAs. If the ECGC does not endorse an RMO, the EC Program staff will repeat one of the following appropriate assessment actions to address the recommendations made by the ECGC:

- (1) Dismiss the RMO.
- (2) Develop a new RMO.
- (3) Refine an existing recommended RMO.

b. The EC Program staff monitors the implementation of the RMAs by the appropriate DoD Components and periodically reports on the status to the ECSG, the DASD(ENV), and the ECGC.

c. The EC Program staff manages the EC Watch List and the EC Action List through routine monitoring of new or changing toxicity values or new or changing human health or environmental regulatory standards.

(1) For the EC Watch List, the ECSG advises on the removal of ECs or their movement to the EC Action List, and the EC Program staff documents these decisions in writing.

(2) For the EC Action List, the ECGC endorses and documents in writing the removal of ECs, or their movement to the EC Watch List.

APPENDIX 3A: TIERED TOXICITY VALUES FOR ECS

3A.1. GENERAL. This appendix provides a framework to recognize new or changing toxicity values. The DoD advocates the types of assessments in Paragraphs 3A.2. and 3A.3. to determine these toxicity values. The DoD protects human health and the environment pursuant to federal and State mandates, using the best available toxicity data.

a. Paragraph 3A.2. outlines the hierarchy of tiered values. Unless compelling scientific reasons suggest otherwise (e.g., recently published peer-reviewed scientific research), the hierarchy of tiered values should be used.

b. Paragraph 3A.3. outlines the types of assessments for toxicity values. This information complements the hierarchy presented in Paragraph 3A.2.

3A.2. HIERARCHY OF TOXICITY VALUES. The tiers described in Paragraphs 3A.2.a. through 3A.2.c. are consistent with the Environmental Protection Agency (EPA) Office of Solid Waste and Emergency Response Directive 9285.7-53.

a. **Tier 1 – EPA’s Integrated Risk Information System (IRIS).** The toxicity values published by the EPA’s IRIS Program have undergone rigorous peer review and are considered 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.

b. **Tier 2 – EPA’s Provisional Peer-Reviewed Toxicity Values (PPRTVs).** The Superfund Health Risk Technical Support Center of the EPA’s National Center for Environmental Assessment develops PPRTVs on a chemical-specific basis when requested by the EPA’s Superfund Program for use in site-specific risk assessments. In the absence of IRIS values, PPRTVs should be used.

c. **Tier 3 – Other Toxicity Values.** Tier 3 includes additional EPA and non-EPA sources of toxicity information with priority given to those toxicity values that achieve the recommendations listed in Paragraph 3A.3.

3A.3. TYPES OF ASSESSMENTS.

a. The types of assessments that should be used to recognize new or changing toxicity values:

(1) Are transparent, clearly identifying the information used and how it was used to derive the toxicity values.

(2) Have been externally and independently peer reviewed, where reviewers and affiliations are identified. Assessments with extensive peer review are preferred. Panel peer reviews are preferable to letter peer reviews.

(3) Were completed with a previously published and publicly available methodology. Methodologies that are externally peer reviewed are preferred.

(4) Consider the quality of studies used, including the statistical power to detect effects, corroborate data among pertinent studies, and make best use of all available science.

(5) Are publicly available or accessible. Public comment may be invited and considered, but should not replace the process of external peer review.

(6) Are consistent with the duration of human exposure being assessed.

b. While assessments using established methodologies to derive toxicity values are preferred, these methodologies should also be informed by the current best scientific information and practices. New assessment methodologies should provide reproducible results and meet generally accepted quality assurance and quality control requirements.

c. All sources of toxicological and human health information should be searched to ascertain the best available science and identify uncertainties. In addition, if gaps in human health science exist, the DoD can make recommendations to appropriate State agencies, the EPA, or other agencies for additional studies to reduce uncertainty.

SECTION 4: EC SUPPORT FUNCTIONS

4.1. ECGC. The ECGC:

- a. Comprises Assistant Secretary of Defense-level executives, representing the five DoD functional areas, with authority, direction, and control over the ECSG.
- b. Is led by a chair and deputy chair.
- c. Provides executive-level, enterprise-wide strategic direction.
- d. Endorses proactive RMOs, movement of ECs from the action list, and documents and disseminates the endorsements.
- e. Complies with the requirements of DoDI 5105.18.

4.2. ECSG. The ECSG:

- a. Comprises senior staff-level action officers, under the authority, direction, or control of the ECGC, representing the five DoD functional areas.
- b. Reviews publications relevant to the EC process, including reports from the TSTC.
- c. Advises the EC Program staff on strategic decisions emerging from the EC process, including:
 - (1) Movement of ECs to and from the EC Watch List and to the EC Action List.
 - (2) Refining RMOs.
- d. Coordinates data collection for use in the EC process.
- e. Coordinates SMEs to participate in the EC process.

4.3. TSTC. The TSTC:

- a. Comprises scientific and technical experts in toxicology from the Departments of the Army, Navy, and Air Force.
- b. Participates in technical reviews, interagency organizations, and evaluation of various techniques and methodologies for toxicology assessments.
- c. Reports to and submits recommendations and findings to the ECSG and other DoD and non-DoD organizations regarding relevant topics.

GLOSSARY

G.1. ACRONYMS.

ASD(A)	Assistant Secretary of Defense for Acquisition
ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASD(R)	Assistant Secretary of Defense for Readiness
ASD(S)	Assistant Secretary of Defense for Sustainment
DASD(ENV)	Deputy Assistant Secretary of Defense for Environment
DoDI	DoD instruction
EC	emerging chemical
ECGC	Emerging Chemicals of Concern Governance Council
ECSG	emerging chemicals of concern steering group
EPA	Environmental Protection Agency
IRIS	Integrated Risk Information System
PPRTV	provisional peer-reviewed toxicity value
RMA	risk management action
RMO	risk management option
SME	subject matter expert
TSTC	Tri-Service Toxicology Consortium
USD(A&S)	Under Secretary of Defense for Acquisition and Sustainment

G.2. DEFINITIONS. These terms and their definitions are for the purpose of this issuance.

EC Action List. A list of ECs with a probable high risk of impact to at least one of the five functional areas and for which proactive RMOs are being developed or actions are ongoing.

EC Program staff. Action officers within the Office of the DASD(ENV) who are responsible for the EC process.

ECs. Chemicals relevant to the DoD that are characterized by a perceived or real threat to human health or the environment and that have new or changing toxicity values or new or changing human health or environmental regulatory standards. Changes may be due to new science discoveries, detection capabilities, or exposure pathways.

EC Watch List. A list of ECs with a potential risk of impact to at least one functional area.

functional areas. Enterprise-wide categories that represent DoD-relevant areas of concern.

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

PPRTV. A toxicity value developed by the EPA for use in the Superfund Program and derived after a review of the relevant scientific literature using established EPA guidance on human health toxicity value derivations.

RMA. An RMO that has been endorsed by the ECGC.

RMO. Actionable, measurable enterprise-wide initiatives focused on proactively mitigating or eliminating risks identified during the assessment portion of the EC process. Initiatives include new DoD policies or research, development, testing, or evaluation of alternative chemicals.

SMEs. Experts in an EC or one or more of the functional areas.

toxicity value. A numerical expression of a substance's dose-response relationship that is used in risk assessments. The most common toxicity values published by regulatory and health agencies are reference doses and reference concentrations, which are levels where no adverse effects are expected for non-carcinogens; and slope factors and inhalation unit risk factors, which are estimates of low-dose cancer potency for carcinogenic effects.

REFERENCES

- Deputy Secretary of Defense Memorandum, “Establishment of the Office of the Under Secretary of Defense for Research Engineering and the Office of the Under Secretary of Defense for Acquisition and Sustainment,” July 13, 2018
- DoD Directive 3020.40, “Mission Assurance (MA),” November 29, 2016, as amended
- DoD Directive 4715.1E, “Environment, Safety, and Occupational Health (ESOH),” March 19, 2005, as amended
- DoD Directive 5134.01, “Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)),” December 9, 2005, as amended
- DoD Instruction 5000.02, “Operation of the Defense Acquisition System,” January 7, 2015, as amended
- DoD Instruction 5105.18, “DoD Intergovernmental and Intragovernmental Committee Management Program,” July 10, 2009, as amended
- Environmental Protection Agency, “Integrated Risk Information System”¹
- Environmental Protection Agency, Office of Solid Waste and Emergency Response Directive 9285.7-53, “Human Health Toxicity Values in Superfund Risk Assessments,” December 5, 2003²

¹ Available at <https://www.epa.gov/iris>

² Available at <https://www.epa.gov/sites/production/files/2015-11/documents/hhmemo.pdf>