

## ISSUE PAPER

# Initiation of Emerging Contaminants Characterization and Response Actions for Protection of Human Health

### **Introduction:**

The ECOS-DoD Sustainability Work Group was formed in 2004 in an effort to forge partnerships to “exchange information and ideas across state and jurisdictional boundaries and to further solutions to create sustainable bases and ranges in harmony with local communities.”<sup>1</sup> This effort is being applied across two issue areas, each represented by a Task Group: Compatible Use and Sustainability, and Emerging Contaminants. This issue paper is one in a series of papers being developed by the ECOS-DoD Sustainability Work Group’s Emerging Contaminants (EC) Task Group.

The EC Task Group seeks to develop a common understanding of the underlying facts and issues, and develop mutually acceptable processes to address emerging contaminants. Clarity and understanding of the issues will increase public confidence in federal and state governments’ abilities to protect public health and the environment and help sustain DoD’s primary mission of national defense. Each paper frames an issue identified at the 2005 ECOS Emerging Contaminants Forum as a priority for discussion among the parties.

The following working definition for emerging contaminants was agreed to by participants of the ECOS-DoD work group:

*Emerging Contaminants are chemicals or materials of interest that are characterized by:*

- *a perceived or real threat to human health or environment, and*
- *there is no currently published health standard or there is an existing health standard, but the standard is evolving or being re-evaluated.*

*Emerging contaminants may have insufficient or limited human health or environmental information available. They may also become of interest because a new source, pathway or detection limit has been discovered.*

### **Issue:**

Many ECs don’t have health-based risk levels (e.g., reference doses [RfDs]) or established standards (e.g., Maximum Contaminant Levels [MCLs]). Thus, it is often not clear to some field personnel if action should be taken requiring the use of funds, especially for actions not previously identified in budgets, or what concentration may trigger site characterization or cleanup. This paper examines some key conditions, considerations, statutory authorities, or criteria that could be used to evaluate potential characterization and response actions with a related expenditure of funds<sup>2</sup>. The goal is for

<sup>1</sup> ECOS Resolution 04-8, [http://www.ecos.org/files/1192\\_file\\_Copy\\_of\\_Resolution\\_04\\_8.pdf](http://www.ecos.org/files/1192_file_Copy_of_Resolution_04_8.pdf)

<sup>2</sup> Respond or Response as defined by section 101(25) of CERCLA, means remove, removal, remedy, and remedial action, and all such terms (including removal and remedial action) including enforcement activities related thereto.

DoD and regulators to provide recommendations for a common-sense, protective, policy/practice framework that is supported by, and consistent with, existing statutes, regulations and guidance.

### **Scope:**

This initial paper is focused only on the human health aspects of ECs as defined above. It does not cover natural resources, ecological risk, beneficial use, anti-degradation issues that may also trigger response action on emerging contaminants. The paper covers characterization and cleanup activities conducted under the Defense Environmental Restoration Program (DERP); the Comprehensive Environmental Response Compensation and Liability Act (CERCLA); the Resource Conservation and Recovery Act (RCRA); related state cleanup laws; and parts of other federal/state laws that may involve characterization and cleanup of sites. It does not cover non-cleanup related activities, such as drinking water monitoring carried out solely for regulatory purposes under the Safe Drinking Water Act. The paper is intended to be used by DoD, EPA, and state regulatory personnel to help inform decisions related to characterization and response actions for ECs. It is also anticipated that the paper may support future EC policies by these parties.

### **Background:**

The following provides a summary of some of the key considerations regarding triggers for action, response selection, and funding. However, for a more complete and detailed understanding, please refer to existing language in the statute, regulatory preamble and regulatory text, and guidance.

#### Environmental Statutes and Regulations

- Several statutes provide requirements for site characterization and cleanup of ECs.
- Under CERCLA, the federal government has broad authority to undertake a response action consistent with the National Oil and Hazardous Substances Spill Contingency Plan (NCP) where there is a release or threat of release of a hazardous substance, or a release or substantial threat of a release of any “pollutant or contaminant” which may present an imminent and substantial danger to public health or welfare. Many state cleanup laws have similar provisions.
- The NCP states in 40 CFR 300.430 (d)(4) that “Using the data developed under paragraphs (d)(1) (Remedial Investigation) and (d)(2) (Site Characterization) of this section the lead agency shall conduct a site-specific baseline risk assessment to characterize the current and potential threats to human health and the environment that may be posed by contaminants migrating to ground water or surface water, releasing to air, leaching through soil, remaining in the soil, and bioaccumulating in the food chain. The results of the baseline risk assessment will help establish acceptable exposure levels for use in developing remedial alternatives in the FS.” Chemical specific standards that define acceptable risk levels (e.g., MCLs) also may be considered in determining the risk to human health or the environment posed by actual or potential exposure to contamination at a site.

- On-site response actions under CERCLA generally comply with Applicable or Relevant and Appropriate Requirements (ARARs) unless those ARARs are waived. However, many ECs are not addressed by ARARs.
- Under CERCLA and the NCP, nine criteria are considered when evaluating alternatives in the remedy selection process. The selected remedies must meet the threshold criteria of protecting human health and the environment, and complying with ARARs.
- Cleanup levels also may be based on “to be considered” (TBCs) information, which may include non-promulgated criteria, advisories, guidance and proposed standards issued by Federal or State governments. While TBCs are not considered ARARs because, among other things, they are not promulgated regulations, nor are they legally enforceable, they still can be helpful in developing protective remedies.
- As a policy matter, “it is similarly appropriate to treat Indian tribes as states for purposes of identifying ARARs under section 121(d)(2).” (55 FR 8741)
- States have also adopted cleanup statutes and regulations, most of which are also risk-based and have requirements similar to CERCLA. Many states have toxicology, standard setting, and risk assessment programs, which focus on state or local environmental problems involving contaminants that have not been addressed by EPA.
- DoD generally is subject to the requirements of RCRA, and routinely samples and analyzes material in order to determine if it constitutes hazardous waste. Where emerging contaminants are not RCRA “listed” hazardous wastes, they may still be a RCRA-regulated characteristic waste (characteristics include toxicity, corrosiveness, reactivity, and ignitability).
- In addition to CERCLA and RCRA, there are a number of other state and federal laws that authorize regulatory agencies to undertake characterization or response action, or require others to take action, when there is a threat or potential threat to human health or the environment.

### DoD Characterization and Cleanup Programs

- The DERP statute provides the program structure and goals (including the funding accounts) for carrying out environmental restoration activities subject to, and consistent with, CERCLA. 10 U.S.C 2701 provides the statutory authority for DoD to identify, investigate, research and develop and clean up hazardous substances, pollutants or contaminants, where emerging contaminants may qualify as hazardous substances, pollutants or contaminants as defined by CERCLA.
- In DoD’s environmental program, funding is justified by statutory and regulatory requirements. Budget reviewers want to know which laws or regulations require a project or action to be funded.
- DoD has a complicated and robust Planning, Programming and Budgeting System (PPBS). Resource planning is done for a six-year window called the Future Year Defense Plan (FYDP).

- The timing of the Federal budget cycle means that key resource decisions are made well in advance of the current budget year. For example, key DoD decisions for FY 2008 were made in the Jan-Feb 2006 time frame. Based on the decisions for funding levels for specific programs, the detailed DoD FY-08 budget was prepared during the summer of 2006 and became a part of the President's Budget for FY2008, presented to Congress in February 2007. This timing creates challenges for DoD installations when unplanned needs arise after the budget has been approved by Congress.
- Cleanup and compliance projects are usually known well in advance and are reflected in federal planning and budget decisions. New requirements that arise after budget preparation must be accommodated within a given fiscal year's budget controls and thus other work must be deferred. In other words, it is a "zero-sum" game for federal agencies.

### **Discussion:**

- State and Federal regulators expect that Federal agencies and potentially responsible parties will respond in a timely manner to their requests to assess current or potential sites or provide information on known or suspected releases or take response actions. However, most regulators are understanding of the federal budget cycle challenges, and generally will take this into consideration in developing reasonable timeframes for addressing contamination, depending on site-specific circumstances.
- Existing laws and regulations provide flexibility and authorities for DoD to take appropriate action requiring the expenditure of funds to protect public health and the environment and/or for regulators to take or require actions to protect public health.
- For many ECs, professional judgment may be an important component and may weigh heavily in establishing protective levels based on the state-of-the science for an EC and the site-specific threat to human health or the environment. Under CERCLA, the NCP, and Executive Order 12580, EPA and DoD both have roles and responsibilities for ensuring the protection of human health and the environment when carrying out characterization and response actions. State statutes may provide similar authority to the State regulator. DoD has the ability and authority to conduct response actions related to releases from its facilities. CERCLA section 120 and 10 USC 2705 (b) address the roles and responsibilities of DoD and EPA. In addition, DoD and EPA, have promulgated extensive policy and guidance documents elaborating on how to implement or interpret the statutes and regulations. It is important to note these policy and guidance documents do not impose requirements as do the statutes and regulations.
- Regulatory or health agencies have the ability and authority to determine whether the science for an EC is sufficient to determine risk to human health and whether a specific site presents a threat to public health, and normally do so in coordination with DoD. However, DoD may have subject matter experts for a particular EC, especially if it is a military-unique compound (e.g., explosives). Federal and state public health agencies also possess unique expertise and may provide focused public health consultations. DoD will present the available toxicological data to the appropriate regulators so that the agencies can collaborate on determining the sufficiency of the data. While DoD is mindful of budgeting requirements, it is committed to protecting human health and the environment. National and state administrative procedures exist to ensure transparency, public involvement and the use of sound science.

- Requests to fund characterization and/or response actions related to ECs can raise two problems for DoD:
  - These actions for ECs are often “emergent” and may not be identified in the budget that is prepared about 2 years in advance of the execution year. DoD does have flexibility to re-prioritize, but as a policy matter, for ECs this would normally only be done for reasons of an imminent and substantial endangerment to public health. However, DoD will take appropriate budget programming actions in subsequent years.
  - The human health science for an EC may be incomplete and related regulatory requirements (i.e., ARARs) may be lacking.
- Examples of actions that might be taken (depending on the circumstances) for ECs follow. These actions would normally be taken in conjunction with other actions to address releases or potential releases of hazardous substances, pollutants or contaminants (or hazardous or solid waste) at a site as part of the CERCLA (or RCRA) response process.
  - Toxicological studies
  - Preliminary Assessments/Site Inspections (PA/SI), including sampling
  - Remedial Investigations/Feasibility Studies (RI/FS), including risk assessments
  - Removal actions or interim measures to mitigate or eliminate exposure
  - Remedial (CERCLA) and Corrective (RCRA) actions, which may include land use controls
- At least four typical scenarios relating to response actions may exist for ECs<sup>3</sup>.

Table 1

	EC present at levels requiring action	EC present but necessity for action uncertain
Other contaminants present at levels requiring action	Scenario 1	Scenario 2
Other contaminants not present or at levels that do not require action	Scenario 3	Scenario 4

For the purposes of this table, an EC at levels requiring action means that the parties agree action is needed.

The scenarios below include potential use of interim remedies or possibly involve the delay of remedies. Furthermore, it is anticipated that using the best available current science typically should facilitate reaching agreement as to whether response action is warranted and determining appropriate, protective cleanup levels. Consistent with CERCLA section 121(c) and the NCP, remedial actions will be reviewed to ensure continued protectiveness.

*Scenario 1*

- In scenario 1, other contaminants trigger a response action.

<sup>3</sup> Note that under CERCLA remedies must be evaluated using nine criteria in the NCP. While the modifying criteria of cost is an important consideration from a budgeting standpoint, remedies first and foremost must meet the primary criterion of being protective of human health and the environment. Thus protectiveness is a threshold criterion under the NCP.

- The concentrations of ECs are sufficiently elevated such that all parties agree that action is necessary for the ECs.
- Remedial alternatives for other contaminants may address ECs.
- Remedial alternatives for other contaminants may not address ECs, in which case an alternate remedy needs to be evaluated.
- If there is agreement on the EC cleanup level by the parties, a remedy is implemented.
- If the parties disagree on the ultimate cleanup level for the EC, one or more interim response actions may be appropriate until risk-based values are identified for the EC (e.g., plume migration control, provision of drinking water, land use controls, monitoring).
- If the parties agree that there is no actual or potential future exposure (for example, there is no current pathway and human receptor for ECs), it may be possible to delay further action until there is a greater certainty over the risk (e.g., more complete toxicity information). For example, if there is soil contamination or a stable plume this might be appropriate. Alternately, DoD may wish to make a risk management decision in consultation with regulatory agencies.
- At a minimum, the parties should seek to delineate or determine the extent of contamination until there is greater certainty regarding the risk. If the parties agree to delay further action until risk-based values are identified, the DoD may want note the area of contamination on their Base Master Plan or other appropriate documents

#### *Scenario 2*

- In this scenario, other contaminants trigger a response action.
- ECs are detected but regulators and DoD cannot agree that they pose an unacceptable risk (e.g. there may be incomplete science and/or a lack of peer reviewed toxicity information).
- Remedial alternatives for other contaminants may address ECs. If so, and agreement can be reached on the EC cleanup level by the parties, a remedy is implemented.
- If the parties disagree on the ultimate cleanup level for the EC one or more interim response actions may be appropriate until risk-based values are identified for the EC (e.g., monitoring, land use controls, plume migration control, provision of drinking water).
- If the remedial alternatives for other contaminants do not address ECs and the parties agree that there is no actual or potential future exposure (for example, there is no current pathway and human receptor), it may be possible to delay further action until there is a greater certainty over the risk (e.g., more complete toxicity information). Alternately, DoD may wish to make a risk management decision in consultation with regulatory agencies.
- At a minimum, the parties should seek to delineate or determine the extent of contamination until there is greater certainty regarding the risk. If the parties agree to delay further action until risk-based values are identified, the DoD may want note the area of contamination on their Base Master Plan or other appropriate documents

#### *Scenario 3*

- In scenario 3, other contaminants do not trigger a response action.
- The concentrations of ECs are sufficiently elevated such that all parties agree that action is necessary for ECs.
- Remedial alternatives need to be evaluated for ECs.
- If there is agreement on the cleanup level by the parties, a remedy is implemented.
- If the parties disagree on the ultimate cleanup level for the EC one or more interim response actions may be appropriate until risk-based values are identified for the EC (e.g., plume migration control, provision of drinking water, monitoring, land use controls).
- If the parties agree that there is no actual or potential future exposure (for example, there is no current pathway and human receptor for ECs), it may be possible to delay further action until there

is a greater certainty over the risk (e.g., more complete toxicity information). For example, if there is soil contamination or a stable plume, this might be appropriate. Alternately, DoD may wish to make a risk management decision in consultation with regulatory agencies.

- At a minimum, the parties should seek to delineate or determine the extent of contamination until there is greater certainty regarding the risk. If the parties agree to delay further action until risk-based values are identified, the DoD may want note the area of contamination on their Base Master Plan or other appropriate documents

#### *Scenario 4*

- In this scenario, other contaminants do not trigger a response action.
- ECs are detected but regulators and DoD cannot agree that they pose an unacceptable risk (e.g. there may be incomplete science and/or a lack of peer reviewed toxicity information).
- The parties should seek to agree on whether one or more interim response actions may be appropriate until risk-based values are identified for the EC (e.g., monitoring, land use controls, plume migration control, provision of drinking water).
- If the parties agree that there is no actual or potential future exposure (for example, there is no current pathway and human receptor), it may be possible to delay further action until there is a greater certainty over the risk (e.g., more complete toxicity information). Alternately, DoD may wish to make a risk management decision in consultation with regulatory agencies.
- At a minimum, the parties should seek to delineate or determine the extent of contamination until there is greater certainty regarding the risk. If the parties agree to delay further action until risk-based values are identified, the DoD may want note the area of contamination on their Base Master Plan or other appropriate documents

#### **Summary/Recommendations:**

- The parties 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 response actions needed. Therefore, the following recommended approach is offered for addressing site-specific situations.
  - 1) Based on the site history and site inspection, determine whether there is a real or suspected release of an EC that would trigger a need for sampling at a site and whether there is an appropriate analytical method.
  - 2) If information exists to support sampling, develop a field sampling and analysis plan with agreed-upon data quality objectives (DQOs). The quality assurance project plan for such efforts should comply with the Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP) and be consistent with DoD 4715.RR-M-1, DoD 4715.RR-M-2 and DoD 4715.RR-M-3<sup>4</sup>. Among other things, the plan should identify an appropriate analytical method that meets the required detection limits for the EC. In the event that the sample quantification limit (SQL) is insufficient to analyze at the anticipated levels of concern, 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.

<sup>4</sup> DoD 4715.RR-M-1 "Department of Defense Quality Systems Manual for Environmental Laboratories," DoD 4715.RR-M-2, "Uniform Federal Policy for Implementing Environmental Quality Systems," DoD 4715.RR-M-3 "Uniform Federal Policy for Quality Assurance Project Plans.

- 3) 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 the companion ECOS-DoD issue paper *Identification and Selection of Toxicity Values/Criteria for CERCLA and Hazardous Waste Site Risk Assessments in the Absence of IRIS Values*. In addition, if gaps in the human health science exist, recommendations should be made to states, EPA or other agencies for additional studies to reduce uncertainty.
- 4) Baseline risk assessments 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. As discussed in the scenarios above, a range of response options typically can be considered to protect human health and the environment, as appropriate.
- 5) If agreement cannot be reached at the site level, the parties should consult with their respective organizations to determine an appropriate course of action. In such cases, the parties reserve all rights and authorities under existing law and regulations.
- 6) Even where agreement is not reached, the DoD component may want to consider risk management actions that would prevent, for example, further plume expansion, groundwater discharge to surface water and access to contaminated areas.
- 7) A working group of States, EPA and the DoD Environmental Data Quality Work Group should develop procedures and criteria for sampling ECs.
- 8) While the EC Task Group reached consensus on the above recommendations, the Task Group noted that implementation issues remain. Thus, all parties need to strive for consistent application within their organizations.