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United States Army Corps of Engineers
Ravenna Army Ammunition Plant (RVAAP)
Position Paper for the Application and Use of Facility-Wide Human Health Cleanup Goals

Ravenna Army Ammunition Plant
Ravenna, Ohio

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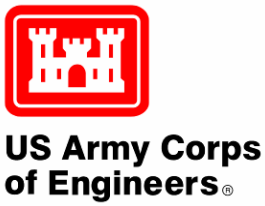

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14. ABSTRACT

This Position Paper will serve as guidance until the Updated Facility-wide Human Health Risk Assessment Manual is released. This revised Position Paper contains one major change that is related to the Sum of Ratios for chemicals with non-carcinogenic effects. The 2009 Position Paper stated that if a chemical was at least 10% of the total contribution then it could be dismissed. The revised Position Paper has been changed to state that a chemical can be dismissed if it is 5% or less of the Sum of Ratios. The revised Position Paper also states that if the chemical is 5% to 10% of the Sum of Ratios then additional review and consideration is required to adequately determine if the chemical should be retained or excluded. Another change incorporated into this revised Position Paper also deals with the Sum of Ratio determination for chemicals with non-carcinogenic effects. If a chemical does not have a specific critical effect identified, it should be summed into all the Sum of Ratios for each target organ/effect.

15. SUBJECT TERMS
Facility-wide human health cleanup goals, facility-wide cleanup goals (FWCUGs), risk assessment, contaminants of potential concern (COPCs), contaminants of concern (COCs), sum of ratios, carcinogenic, non-carcinogenic, weight of evidence.

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United States Army Corps of Engineers, Ravenna Army Ammunition Plant (RVAAP) Position Paper for the Application and Use of Facility-Wide Human Health Cleanup Goals

1.0 PURPOSE AND NEED

The purpose of this Position Paper is to provide *interim* guidance from the United States Army Corps of Engineers, Louisville District (USACE) to Contractors regarding the use and application of facility-wide cleanup goals as part of the path forward in the risk assessment process for:

- Determining presence/absence of contamination,
- Assessing data gaps,
- Evaluating nature and extent of contamination, and
- Identifying cleanup requirements.

Ravenna Army Ammunition Plant (RVAAP) has worked closely with the Ohio Environmental Protection Agency (Ohio EPA) and other stakeholders such as the Ohio Army National Guard (OHARNG) to develop an acceptable approach to the completion of human health risk assessments. Because of the initial successes of the human health risk assessment program, there was mutual agreement to streamline the process. Streamlining the Human Health Risk Assessment process resulted in the establishment of Facility-wide Cleanup Goals (FWCUGs). The FWCUGs were developed by Science Applications International Corporation (SAIC) and are presented in the document *Facility-wide Human Health Remediation Goals, Ravenna Army Ammunition Plant, Ravenna, Ohio, March 2010* (FWCUG Report). The original intent of developing the FWCUGs was to eliminate the need for baseline risk assessments. Since the development of the FWCUGs, they also have been recognized as appropriate tools to be used in screening-level assessments.

The FWCUGs were developed to reduce the level of effort and to limit the amount of time required to make informed risk management decisions regarding sampling locations, delineations of contamination, data gaps, and remediation of contaminants without needing to complete a baseline risk assessment. The selection of chemicals requiring a FWCUG is based upon the screening process outlined in the *Ravenna Army Ammunition Plant Facility-Wide Human Health Risk Assessor Manual, Amendment 1* (USACE 2005), herein referred to as the Risk Manual.

Besides the screening process, the Risk Manual requires that prior to commencing any risk assessment activities at the Ravenna Army Ammunition Plant (RVAAP), a White Paper should be developed to ensure regulatory agreement with the processes proposed. The White Paper for the development of the FWCUGs can be found as an attachment to the FWCUG Report. The White Paper provided clarification of technical issues related to developing the FWCUGs that were not defined in the Risk Manual. The White Paper also included the exposure pathways and

parameters pertinent to two newly identified receptors: the Engineering School use and the Small Arms Range use.

The intent of USACE is to develop a single document that includes pertinent information from the Risk Manual, FWCUG Report (including the White Paper), FWCUGs, risk assessment information found in previously published documents, and technical guidance and agreements that USACE has developed in conjunction with the Ohio EPA. It is planned that the FWCUG Report will be modified and updated to include all these items. The FWCUG Report will then replace the Risk Manual. The USACE believes that this approach will clarify requirements for the completion of screening level human health risk assessments, selection of appropriate FWCUGs, and the determination of remediation levels that are risk-based. Because this draft unified document will not be available for several months, USACE identified the need for this Interim Guidance.

2.0 DATA EVALUATION – DETERMINATION OF THE CHEMICALS OF POTENTIAL CONCERN

The first step in using the FWCUGs and determining which ones should be used depends upon what phase of investigation under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) process is being completed and what decisions will be made using the FWCUGs. If the data are being evaluated to determine the presence or absence of contamination, nature and extent of contamination, characterization of contamination, sampling locations, or for other reasons where data identifies potential contamination, then the initial evaluation step should be completed. The end result of the initial data screening process is a list of chemicals of potential concern (COPCs). The COPC screen follows the general guidance of the Risk Manual (Sections 3.4 and 3.5):

1.) The concentrations of inorganics shall be compared to the soil background concentrations in the report titled *Phase II Remedial Investigation Report for the Winklepeck Burning Ground at RVAAP, OH* (USACE April 2001). If exceedances above background occur, then the respective metals are retained as COPCs.

2.) Consistent with the Risk Manual (Section 3.5), chemicals identified as essential nutrients will be screened out. Chemicals that are considered essential nutrients (e.g., *calcium, chloride, iodine, iron, magnesium, potassium, phosphorous, and sodium*) are an integral part of the human food supply and are often added to foods as supplements. The USEPA recommends that these chemicals not be evaluated as COPCs as long as they are: (1) present at low concentrations (i.e., only slightly elevated above naturally occurring levels), and (2) toxic at very high doses (i.e., much higher than those that could be associated with contact at an Area of Concern (AOC).

3.) Chemicals, except explosives and propellants that meet the <5% detection rule may be screened out per Section 3.4.1 of the Risk Manual; however, this screening step is based upon having a statistically valid data set (sample size of at least 20).

4.) For the determination of the COPCs, all chemicals that have not been eliminated should be screened against their specific FWCUG at the 1.0 X 10-6 cancer risk level and non-carcinogenic risk Hazard Quotient (HQ) of 0.1 for the Residential Farmer Adult, Residential Farmer Child, and the National Guard Trainee. If there are no FWCUGs developed for the particular chemical, then the USEPA's Regional Screening Levels (RSLs) should be used using the same risk goal and hazard quotient of 1 x 10-6 and HQ of 0.1. The Risk Manual required that the maximum concentrations be compared to the USEPA Region 9 Preliminary Remediation Goals (PRGs); however, the RSLs have replaced the USEPA's Region 9 PRGs. The RSLs should only be used if a FWCUG is not available for the chemical. The RSL for the Residential Receptor should be used. This Guidance requires that the comparison be completed using the FWCUGs from the Final FWCUG Report.

The steps listed below should be followed for the comparison process to be acceptable and complete when establishing COPCs or characterizing the contamination in an area:

- Use the FWCUGs developed for the Residential Farmer Adult and Child Receptors and the National Guard Trainee for each chemical. See Table 4-2 of the FWCUG Report. If no FWCUG is available, use the USEPA's RSL for the chemical. If neither the FWCUG nor the RSL is available, then an AOC-specific CUG should be developed or another approach (i.e., use of an RSL from a surrogate chemical – a chemical with similar chemical characteristics) must be developed with concurrence from USACE and Ohio EPA.

- Select the FWCUGs at the 1.0 X 10-6 carcinogenic value and the non-carcinogenic hazard value termed Hazard Quotient (HQ) of 0.1.

- Report all carcinogenic risk and non-carcinogenic hazard values for each chemical for the Adult and Child Residential Farmer and the National Guard Trainee.

- Complete a comparison of the selected FWCUG to the Exposure Point Concentration (EPC). The EPC will be the maximum value detected concentration for each compound. Consider the chemical as a COPC if the EPC exceeds the most stringent risk value for the Adult Resident Farmer, the Child Resident Farmer, or the National Guard Trainee for either one of the 1.0 X 10-6 carcinogenic value and the non-carcinogenic risk value termed Hazard Quotient (HQ) using the 0.1 risk value.

3.0 DETERMINATION OF THE CHEMICALS OF CONCERN

The original application of the FWCUGs was that they would be used to determine remediation levels and to assist in the completion of remedial design and processes. Once the COPCs are established and all sampling has been completed so that the nature and extent of the contamination is known, the next step is to determine which of the COPCs are Chemicals of Concern (COCs). The determination of the COCs consists of a screening of the chemical concentration to specific FWCUGs. However, unlike the COPC comparison, the COCs are determined by comparing the chemical concentration to different risk levels and potentially, for different receptors.

The determination of the COCs uses a less stringent risk value but must address the potential for additive effects. To account for the potential additive effects from exposure to multiple chemicals or exposure to multiple chemicals that can cause the same effect (e.g., cancer) or affect the same target organ, then the "Sum of Ratios" (SOR) approach should be used. Chemicals which affect multiple organs should be included in the total estimates of all identified organs or organ systems. In addition, when there is no specific target organ effect available, this chemical should be included in calculations of all non-carcinogenic effects for determination of the COCs.

The SOR approach compares the chemical concentration (e.g., 95 % UCL of the mean concentration, ISM result or concentration in confirmation samples) of the COPC to the individual CUG to determine a ratio. The SOR method is based upon the principle that a ratio greater than 1.0 represents unacceptable hazard. If there are multiple chemicals in the samples that are being evaluated and they are carcinogens or if there are non-carcinogens that affect the same target organ (or do not have an identified target organ), then the Sum of Ratios of both the carcinogens and the non-carcinogens, respectively, must be less than or equal to 1.0. If the SOR is > 1 and there are chemicals sum is greater than 5% but less than 10% must be further evaluated before eliminated as a COC. This additional evaluation should be conducted using a risk-based weight-of-evidence approach to determine if they are true COCs or if they can be eliminated. Chemicals whose percent contribution to the sum is greater than 10% will automatically be included as a COC.

Several examples of the SOR approach are presented in the following. Example 1 of the Sum of Ratios is for three chemicals (i.e., A, B, and C) that may affect the same target organ.

Example 1. Sum of Ratios less than 1 and no chemical identified as a COC.

Chemical	EPC or Maximum Concentration	FW CUG	Ratio of EPC to FWCUG	% Contribution to the total sum	COC Yes or No
Chemical A	1	2.1	0.5	88	No
Chemical B	2	56	0.04	7	No
Chemical C	8	320	0.03	5	No
		Sum of Ratios	0.57		

In Example 1, Chemical B and Chemical C are eliminated because they do not contribute more than 10% of the total SOR value. Chemical A is not retained as a COC although it is contributing more than 10% of the total SOR, but the total is less than 1. Without doing the Sum of Ratios approach, no consideration would have given to the chemicals collectively to determine if there was potential for any of them being a COC since their EPCs was less than their FWCUGs.

Example 2 shows the Sum of Ratios follows for three chemicals (i.e., E, F, and G) that may affect the same target organ where the Sum of Ratios is greater than 1.0 and several COCs are identified.

Chemical	EPC or Maximum Concentration	FW CUG	Ratio of EPC to FWCUG	% Contribution to the total sum	COC Yes or No
Chemical E	1	2	0.5	32	Yes
Chemical F	57	56	1.02	66	Yes
Chemical G	8	320	0.03	2	No
		Sum of Ratios	1.55		

In this example, Chemical G is eliminated because its ratio does not contribute more than 5% of the total Sum of Ratios. Chemicals E and F are retained as COCs because their ratios are contributing more than 10% of the total Sum of Ratios. Without the Sum of Ratios approach, only chemical F would have been considered a COC since its EPC exceeds its CUG value.

The determination of the COCs should follow this Interim Guidance until the Final FWCUG Report is available. The screening process is as follows:

- Select the FWCUGs developed for the Resident Farmer Adult and Child Receptors and the receptor for the planned future land use by the Ohio Army National Guard.
- Select the FWCUGs at the 1 X 10-5 carcinogenic value and the non-carcinogenic risk value termed Hazard Quotient (HQ) using the 1 risk value.
- Report all carcinogenic and non-carcinogenic values for each chemical for all receptors.
- Report critical effect and target organ(s) for each of the non-carcinogenic hazard values.
- Complete a comparison of the selected FWCUG to the EPC. The EPC will be either the ISM result, 95% UCL of the mean for each chemical concentration or the maximum value detected, depending upon whichever value is the lowest. In comparisons where the 95% UCL can not be determined, the maximum concentration of the chemical should be compared to the appropriate FWCUGs.
- For non-carcinogens, compare the chemical-specific concentration to the target risk FWUG. Sum the ratios of chemicals that affect similar organs.
- For carcinogens, compare the chemical-specific concentration to the target risk CUG. Sum the ratios of all carcinogens.
- Consider the chemical as a COC if the EPC exceeds the most stringent risk value for either of the Adult Resident Farmer or the Child Resident Farmer, and/or the OHARNG planned future use receptor, for either one of the 1 X 10-5 carcinogenic value and the non-carcinogenic Hazard Quotient (HQ) of 1. The Sum of Ratios for all carcinogens and

all non-carcinogens that may affect the similar organs must be less than or equal to 1 as well. If the Sum of Ratios for all carcinogens and all non-carcinogens (that may affect the similar organs or do not have a specific target organ indentified) are greater than 1 then the chemicals contributing at least 5% to the sum are considered COCs.

4.0 USE OF FWCUGS DURING REMEDIATION AND CONFIRMATION

In general, the FWCUGs for each of the COCs identified are the actual remediation levels unless there are cumulative effects. In some circumstances there may be a risk management analysis such as a "Weight of Evidence" approach that may allow the COC to be re-assessed. As described in the previous section, the SOR approach is used to account for the potential additive effects from exposure to multiple chemicals that can cause the same effect (e.g., cancer) or affect the similar target organ(s). This approach compares the chemical concentration (e.g., mean concentration or concentration in confirmation samples, the EPC) of the COC to the individual CUG to determine a ratio. In some cases, the aggregated effects of exposure to multiple media should be considered.

This final application of FWCUGs would generally occur during the Feasibility Study (FS) or during remediation. During the determination of COCs, and accounting for potential additive effects, the numbers that were obtained are essentially the remediation levels and would be used for the confirmation samples. The target risk values are the same for remediation levels as they are for the determination of the COCs. The cancer risk is a cumulative 1 X 10-5 and the non-carcinogenic HQ or HI of 1.

Chemicals that are identified in confirmation samples that were not identified as COCs need to be considered in the overall estimation of the success of the remediation. For example, if a chemical is detected and is shown to affect the same target organ as one that has a remediation level established, then the chemical should be considered using a Sum of Ratio approach to determine if there are any risks remaining for the designated end user.

5.0 REFERENCES

Science Applications International Corporation (SAIC). 2001. Facility-Wide Sampling and Analysis Plan for Environmental Investigations at the Ravenna Army Ammunition Plant, Ravenna, Ohio.

United States Army Corps of Engineers (USACE). 2004. Focused Feasibility Study for the Winklepeck Burning Grounds at the Ravenna Army Ammunition Plant, Ravenna, Ohio, DACA62-00-D-0001, D.O. CY08, March.

USACE. 2005. Ravenna Army Ammunition Plant Facility-Wide Human Health Risk Assessor Manual, Amendment 1, Prepared by the U.S. Army Corps of Engineers, Louisville District, November.