N00102.AR.000255
NSY PORTSMOUTH
5090.3a

DEPARTMENT OF THE NAVY
NORTHERN DIVISION
NAVAL FACILITIES ENGINEERING COMMAND
10 INDUSTRIAL HIGHWAY
MAIL STOP, #82
LESTER, PA 19113-2090

IN REPLY REFER TO

5090
Ser 2284/1823/JMC

OCT 24 1994

Mr. Ernest Waterman
U.S. Environmental Protection Agency
Region I
JFK Federal Building
Boston, MA 02203-2211

Re: REMEDIAL ACTION PROGRAM AT PORTSMOUTH NAVAL SHIPYARD

Dear Mr. Waterman:

Enclosed are minutes from the meeting with the State of Maine Bureau of Health and Department of Environmental Protection, held on 13 October 1994 at Portsmouth Naval Shipyard. The purpose of the meeting was to discuss the evaluation of the off-shore human health risk assessment.

If you have questions or comments regarding this matter, please contact me at (610) 595-0567 extension 117.

Sincerely,

Jim Conroy

J. M. CONROY, PE
LT, CEC, USN
Remedial Project Manager
By direction of the Commanding Officer

Encl: Meeting Minutes

Copy to:
MEDEP (N. Beardsley)
MEBH (L. Hicks)
PNS (Code 121, 870, 105.5)
NEHC (C. Grosse)
ATSDR Region I (L. House)
COMSUBGRU TWO (B. Jones)
NH DPHS (J. Dreisig)

Internal copies to:
1823/jmc
1823
1822/ml
1831/sh
1831/dm

MEETING MINUTES

TIME AND LOCATION: 13 OCT 94
11:00 a.m.
Portsmouth Naval Shipyard
Environmental Affairs Division

ATTACHMENTS:
(1) Roster
(2) Maine Department of Agriculture (F&RR) ltr dated October 13, 1994
(3) USEPA Risk Update #2, August 1994.

PURPOSE: To discuss efforts of Maine Bureau of Health to review the off-shore human health risk assessment and determine best approach to present information to the public.

ATTENDEES: See attachment.

The meeting opened with Lebelle Hicks, State of Maine Bureau of Health, providing the group a letter outlining her concerns with the off-shore human health risk assessment to-date, see attachment 2. Discussion on what the appropriate seafood consumption rate should be resulted in agreement that it should be based on a range of meals per year which would be safe to consume. The meal size definition would be provided by Maine Bureau of Health.

It was agreed to rerun the risk calculations using:

(1) the Maine defined meal sizes and annual reference consumption rate.
(2) appropriate portions of the new USEPA Region I risk assessment guidance (Enclosure 3)
(3) with and without arsenic, to allow for ATSDR Arsenic guidance to be considered.
(4) RfD for methyl mercury ~~vice~~ inorganic mercury.
(5) the Lower Piscataqua data set would be used.
(6) if necessary determine acceptable range of consumption (meals per year) 10^{-5} and 10^{-6}

The Navy agreed to provide technical support in revising the risk assessment tables for this purpose (Bureau of Health evaluation) based on input provided by the State of Maine. Input to be provided during conference call to be arranged by MEDEP, probably Monday October 17, 1994.

The results of the review by the Bureau of Health would be presented by the State at the upcoming PNS public workshop. This public workshop is being held for the Navy to present the results of the human health risk assessment and ecological media protection standards.

All parties agreed that what is at issue is providing risk calculations based on input assumptions provided by the Maine Bureau of Health for the purposes of evaluating the necessity for a health advisory on consumption of seafood from portions of the Piscataqua River. What is not at issue is the revision of the human health risk assessment submitted to satisfy RCRA/CERCLA regulatory requirements. However the possibility of revising the Human Health Risk Assessment, based on the new USEPA Region I guidance, is being considered.

OFFSHORE HUMAN HEALTH RISK ASSESSMENT ~ DISCUSSION MTG 10/13/94

NAME	COMPANY	NUMBER
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MAINE DEPARTMENT OF AGRICULTURE
FOOD & RURAL RESOURCES

Governor
John R. McKernan, Jr.

Commissioner
Bernard W. Shaw

To: Interested Parties

From: Lebelle Hicks MS DABT LRH

Re: Preliminary comments on the Portsmouth Naval Shipyard Risk Assessment.

October 13, 1994

****

At the request of Maine DHS and Maine DEP, I have started a review of the document titled: Final Human Health Risk Assessment Report for Off Shore Media Portsmouth Naval Shipyard, Kittery Maine, prepared by McLaren Hart Environmental Engineering Corp Albany, NY (1). This Risk Assessment has been generated under EPA permitting requirements of Hazardous and Solid Waste amendments of 1984 and follows a Resource Conservation and Recovery, RCRA, Facility Assessment where Solid Waste Management Units were identified. This report was created using EPA Office of Solid Waste Emergency Response, OSWER's, guidance documents which include standard default values (1).

My initial concerns are:

1.) The high rate of lobster and possibly mussel consumption which were used by default;

2.) The risks assessed for exposure to the essentially non-toxic fish arsenic;

3.) The use of the inorganic mercury Reference dose (RfD), where the methyl mercury RfD is more applicable;

In addition to the concerns several questions have arisen:

1.) Are the shellfish beds are open the clamming?

2.) Which other Navy bases are under going similar studies?

1.) THE HIGH RATE OF LOBSTER AND MUSSEL CONSUMPTION

Board of Pesticides Control
Deering Bldg., Room 333, AMHI

Station #28
Augusta, Me 04333

Tel: (207)287-2731
Fax: (207)287-7548

The daily intake for recreational and subsistence sea food consumers, is too high for lobster and possibly mussels; For example: at the recreational rate of intake of 0.054 kg/day a person would be consuming 43 pounds of lobster meat per year or approximately 170 pounders per year. Likewise the daily intake of 0.054 kgs/day of mussels (assuming that 25% of the mussel is edible tissue (5) results in a daily consumption of approximately 0.5 lbs and an annual consumption of 182 lbs of mussels per year. The methodology used in the dioxin risk assessments for fish and lobster could be used here to calculate the number of acceptable meals per year. This would get around the problem of using the default value. Another option is to make a more realistic assumption regarding lobster consumption such as New Hampshire, based on the Quincy bay, Metcalf and Eddy report has done. They assumed typical consumption of lobster is 6 lobster meals per year and a subsistence existence would include one lobster meal per week (4,5).

2.) THE RISKS ASSESSED FOR EXPOSURE TO FISH ARSENIC

The risk assessments for cancer and noncancer risk for arsenic does not consider the fact that arsenic found in fish and shellfish the so called "fish arsenic" is the chemical forms of arsenobetaine and arsenocholine and is essentially non toxic (2). For this reason ATSDR in their 1993 Toxicological Profile for Arsenic (2) made the following statement "Thus these compounds are not considered further here" (2). As such the risk assessments done for ingestion of arsenic from fish should not be included in their human health assessment of risks from this site.

3.) THE USE OF THE INORGANIC MERCURY REFERENCE DOSE

The risks assessed for mercury should however be based on the toxicological profile of methyl mercury rather than inorganic mercury. Methyl mercury makes up 99% of that found in fish muscle tissue. The inorganic and dimethyl forms of mercury are nondetectable from fish tissue (3).

QUESTIONS:

1.) ARE THE SHELLFISH BEDS ~~ARE~~ OPEN ~~THE~~ FOR CLAMMING?

(Scallops open Nov-Dec ?) you don't eat liver, heart + other organs muscle tissue only.

The amount and types of shellfish harvested, from this area need to be determined. Also consumption patterns will be useful in addressing the actual risks to people in Maine consuming shellfish. If the beds are closed, we need to find out why they are closed, is this a temporary situation or a long term situation. If the risks from shellfish in these areas is high enough then the state may consider making the ban more permanent.

2.) Are there other Navy bases undergoing similar analysis?

If there are other bases undergoing similar studies, then it would be possible to rank Portsmouth as one of many rather than as a single hot spot. Where in the process are the other bases? Are Maine and New Hampshire going to be the first states to deal with this type of risk communication effort.

REFERENCES

1.) Final Human Health Risk Assessment Report for Off Shore Media Portsmouth Naval Shipyard, Kittery Maine, prepared by McLaren Hart Environmental Engineering Corp Albany, NY.

2.) ATSDR (1993) Toxicological Profile of Arsenic.

3.) ATSDR (1992) *Draft* Toxicological Profile of Mercury

4.) New Hampshire Department of Health (1994) Personal communication with John Dreisig

5.) Schwalbe, C. and Juchatz (1991) Health Risk Assessment of Pesticides and PCB's in Lobsters from the Great Bay Estuarine System New Hampshire NH DHHS

6.) Maine (1994) Risk Assessment for Dioxin in Lobster

7.) Massachusetts Department of Public Health (1988) Health Advisory for Contaminants in Fish and Shellfish from Quincy Bay

8.) US Navy (1994) prepared by: McLaren/Hart Environmental Engineering Corp. Human Health Risk Assessment Report for Off-shore Naval Shipyard: Kittery, ME

Table 1. Concentration (ppm) of Aldrin in Lobster Meat or Tomalley from the Areas Surrounding Portsmouth Naval Shipyard (8)

AREA	TABLE	AVERAGE	MAXIMUM
MEAT			
Lower Piscataqua	2-3	0.00017	0.00047
Lower Piscataqua excluding Seavey Island and Clark Island Embayment	2-4	0.00028	0.00047
Seavey Island	2-5	0.00015	0.00015
Clark's Island Embayment	2-6	0.00012	0.00015
TOMALLEY			
Lower Piscataqua	2-8	0.00110	0.00346
Lower Piscataqua excluding Seavey Island and Clark Island Embayment	2-9	0.00043	0.00058
Seavey Island	2-10	0.00058	0.00060
Clark's Island Embayment	2-11	0.00110	0.00346

Table 2. SUMMARY OF DATA AND RISK CALCULATIONS IN TERMS OF THE NUMBER OF MEALS PER YEAR FOR ALDRIN RESIDUES FROM PORTSMOUTH NAVAL SHIPYARD LOBSTER DATA (8)

	Aldrin ppm	# MEALS/YR 10^{-5} CANCER RISK	# MEALS/YR NONCANCER RISK
LOBSTER MEAT (only)			
LOW (single sample)	0.00015	1,055	5.4×10^4
HIGH (single sample)	0.00047	337	1.7×10^4
Average (LOW)	0.00012	1,318	6.7×10^4
Average (HIGH)	0.00028	565	2.9×10^4
TOMALLEY (only)			
LOW (single sample)	0.00058	1,364	6.9×10^4
HIGH (single sample)	0.00346	229	1.2×10^4
Average (LOW)	0.00043	1,839	9.4×10^4
Average (HIGH)	0.00110	719	3.7×10^4

ASSUMPTIONS: Lobster edible tissue; 17% tomalley; 83% is meat @ 4 oz (114 gms); 19 gms tomalley; 95 gm meat (6); Reference dose for aldrin is 3.0×10^{-5} and the cancer slope factor is 1.7×10^{1} (8).

ME-DMR values

95 g = 1 lb lobst

CALCULATIONS:

$$\textit{Lobster meat (Noncancer)} = \frac{\textit{RfD mg/kg/day X 70 kg X 365 days/year}}{\textit{Aldrin ppm X X 0.095 Kg/meal/day}}$$

$$\textit{Lobster tomalley (Noncancer)} = \frac{\textit{RfD mg/kg/day X 70 kg X 365 days/year}}{\textit{Aldrin ppm X 0.019 Kg/meal/day}}$$

$$\textit{Lobster meat (Cancer)} = \frac{10^{-5} \textit{ X 70 kg X 365 days/yr}}{\textit{Aldrin ppm X 17 (mg/kg/day) X 0.095 Kg/meal/day}}$$

$$\textit{Lobster tomalley (Cancer)} = \frac{10^{-5} \textit{ X 70 kg X 365 days/yr}}{\textit{Aldrin ppm X 17 (mg/kg/d) X 0.019 Kg/meal/d}}$$

Cancer potency factor

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Risk Updates

number 2 August 1994

US EPA Region One Waste Management Division

RISK UPDATES

Risk Updates is a periodic newsletter from the Region 1 risk assessors. This publication provides an update to Region 1's Supplemental Guidance for Risk Assessment for the Superfund Program (EPA 901/5-89-001), and new information concerning risk guidance, for contractors supporting Superfund and RCRA. Risk assessment questions can be addressed to the following EPA staff members at area code (617):

Superfund Human Health Assessment

Ann-Marie Burke 223-5528
Margaret McDonough 573-5714
Mary Ballew 573-5718
Maureen McClelland 565-3470
Jui-Yu Hsieh 565-3607
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Superfund Ecological Assessment

Susan Svirsky 573-9649
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RCRA Ecological Assessment

Dave Guest 223-5541
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A CHANGE IN THE APPROACH FOR ESTIMATING THE AVERAGE AND REASONABLE MAXIMUM EXPOSURE SCENARIOS FOR HUMAN HEALTH RISK ASSESSMENTS

INTRODUCTION

The Region 1 Waste Management Division will implement the Deputy Administrator's memo entitled "Guidance on Risk Characterization for Risk Managers and Risk Assessors" dated February, 1992, (1992 Risk Guidance) for all new Remedial Investigations/Feasibility Study (RI/FS) or Remedial Facility Investigation (RFI) starts in which the risk assessment is not substantially underway. The Superfund Program has interpreted this memo to require changes in how the average and reasonable maximum exposure (RME) scenarios are evaluated in the human health risk assessment.

Region 1 will adopt the use of the 95% upper confidence limit (the 95% UCL) of the arithmetic mean for the concentration term where appropriate and the use of central tendency and high end exposure parameters in human health risk assessments.

DISCUSSION

Region 1's approach to date for characterizing the range of potential human health risks at hazardous waste sites has been to combine the average and maximum contaminant concentration with reasonable maximum exposure parameters. The risks associated with the average and maximum concentration terms were considered to represent a central tendency and a high end (or reasonable maximum) exposure, respectively. Region 1's new approach is to adopt the 95% UCL as the concentration term in exposure calculations. The Supplemental Guidance to RAGS: Calculating the Concentration Term (OSWER Publication No. 9285.7-08I, May 1992, Attachment 1) discusses reasons for using the 95% UCL and presents the equations to be used for this calculation when data is normally or lognormally distributed. The 95% UCL replaces Region 1's use of the average and maximum values for the concentration term.

The use of one concentration term, the 95% UCL, requires a change in the way central tendency and reasonable maximum risks are calculated. Central tendency exposure estimates will now be calculated by combining the 95% UCL with the draft central tendency exposure parameters (see Attachment 2). For the RME estimate, the 95%UCL should be combined with the draft high end exposure parameters presented in Attachment 3. These draft exposure parameters were developed by a national EPA workgroup and are derived from the best available scientific information at this time. These values are currently undergoing review by EPA's Exposure Assessment Group and may change in the future. If exposure parameters are not listed for a particular pathway, consult a Region 1 risk assessor.

their use is well suited to tl ırticu-lar site" (NCP 53FR51394). As described below, if ARARs exist they may be the first choice for cleanup levels in surface water.

AWQC

Ambient water quality criteria (AWQC), developed by EPA in response to the Clean Water Act of 1977, are potential ARARs for surface water at Superfund sites. AWQC are protective criteria developed by EPA for ambient water contaminants that may adversely affect human or ecological health. AWQC for human health were derived to be protective of human exposure via consumption of water (as a drinking water source) and ingestion of chemically contaminated fish and shellfish. Federal AWQC have recently been adopted and promulgated by all six New England states. A list of AWQC specific for each state can be obtained from the state Department of Environmental Protection.

When are AWQC ARARs?

Two situations exist in which AWQC could be considered ARARs at Superfund sites. The first is when a remedial action (RA) at a site involves discharge to a surface water body. In this case AWQC are action-specific ARARs and will be the basis for discharge limits for the remedial action.

The second situation is when a site is in the remedial investigation/feasibility study stage (RI/FS) and it is discovered that a surface water body is actively contaminated by a site-related source, but no remedial action involving a discharge is contemplated. If the human health baseline risk assessment determines that an unacceptable human health risk exists from exposure to the contaminated surface water and an action is targeted for the surface water rather than the sediment or some other source, then cleanup levels for surface water will be developed in the Feasibility Study (FS).

As a basis for cleanup levels, AWQC are not "legally applicable" requirements under CERCLA but may be found to be chemical-specific ARARs by EPA if deemed "relevant and appropriate." AWQC are deemed relevant and appropriate, and should be used in setting the clean-up levels, if particular circumstances exist at the site that AWQC were specifically designed to protect. If humans are ingesting fish from a site-contaminated source and/or if contaminated surface water is being ingested as a drinking water source, then the corresponding state AWQC are relevant and appropriate. The appropriate state program should be contacted to determine where AWQC are to be measured to achieve compliance.

The state AWQC must, however, be based on the most recent scientific toxicity information (i.e. RfDs, CPFs). If the AWQC utilizes outdated toxicity information, then the AWQC is relevant but not appropriate and should not be used. The EPA project risk assessor should review the proposed clean-up levels to confirm that they are based on the most recent scientific information. If they are not, then AWQC should be updated by the risk assessor using the same formula applied by EPA in deriving the AWQC and by utilizing the most recent toxicity information from IRIS or HEAST. This "updated" AWQC falls into the category of a "to be considered" (TBC) requirement which includes nonpromulgated criteria, advisories, guidance, and proposed standards issued by the Federal and State governments. Compliance with TBCs is not mandatory in the same way that it is for ARARs. TBCs are the next choice for surface water cleanup levels if ARARs do not exist.

Deriving surface water cleanup levels when no ARARs or TBCs exist

Other surface water exposures which could occur include swimming or wading. AWQC are not relevant in these cases and should not be the basis for cleanup levels. The cleanup levels for a wading/swimming scenario should be derived by risk-based equations consistent with EPA's guidance for risk assessment. For a swimming scenario one concentration in surface water equivalent to a 1×10^{-6} cancer risk level for carcinogens or a hazard quotient of 1 for noncarcinogens should be estimated considering both the dermal route (utilizing the Dermal Exposure Assessment: Principles and Applications, January, 1992, EPA/600/8-91/011B and the oral route per the Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual (Part A), December, 1989, EPA/540/1-89/002. The resultant cleanup level should be based on a combined exposure to both incidental ingestion and dermal contact with surface water. When calculating cleanup levels for a wading scenario, the approach described above should be applied for the dermal route only. Final cleanup values for surface water will be the lower of the ecological or human health cleanup values.

When surface water cleanup values or surface water discharge levels are below detection limits

If proposed surface water cleanup or discharge levels are below EPA detection limits, they may not be appropriate and thus may not be ARARs. In addition, the application of these values as cleanup levels may be technically impracticable. The decision process in these situations involves complex legal and technical issues. The EPA remedial project manager (RPM) should be contacted as soon as possible to resolve these issues. Decisions will be made by the RPM in consult with EPA attorneys on a site-specific basis. In addition, state water quality criteria should be reviewed as soon as possible to determine if variances are allowed. To determine if variances will be allowed the RPM should consult the state, EPA Water Division, ORC and the project risk assessor as soon as possible.

A summary of the approach for developing surface water cleanup levels or effluent discharge limits is presented in Figure 1. It is important to note that this approach only considers human health endpoints. Ecologically based cleanup levels and discharge limits must also be developed. The final cleanup value should be the lower of the ecological or human health based cleanup value.

United States Environmental Protection Agency
Office of Solid Waste and Emergency Response Washington, D.C. 20460
Publication 9285.7-08I May 1992

EPA

Supplemental Guidance to RAGS: Calculating the Concentration Term

Office of Emergency and Remedial Response
Hazardous Site Evaluation Division, OS-230

Intermittent Bulletin
Volume 1 Number 1

The overarching mandate of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) is to protect human health and the environment from current and potential threats posed by uncontrolled releases of hazardous substances. To help meet this mandate, the U.S. Environmental Protection Agency's (EPA's) Office of Emergency and Remedial Response has developed a human health risk assessment process as part of its remedial response program. This process is described in *Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual* (RAGS/HHEM). Part A of RAGS/HHEM addresses the baseline risk assessment, and describes a general approach for estimating exposure to individuals from hazardous substance releases at Superfund sites.

This bulletin explains the concentration term in the exposure/intake equation to remedial project managers (RPMs), risk assessors, statisticians, and other personnel. This bulletin presents the general intake equation as presented in RAGS/HHEM Part A, discusses basic concepts concerning the concentration term, describes generally how to calculate the concentration term, presents examples to illustrate several important points, and, lastly, identifies where to get additional help.

THE CONCENTRATION TERM

How is the concentration term used?

RAGS/HHEM Part A presents the Superfund risk assessment process in four "steps": (1) data collection and evaluation; (2) exposure assessment; (3) toxicity assessment; and (4) risk characterization. The concentration term is calculated for use in the exposure assessment step. Highlight 1 presents the general equation Superfund uses for calculating exposure, and illustrates that the concentration term (C) is one of several parameters needed to estimate contaminant intake for an individual.

For Superfund assessments, the concentration term (C) in the intake equation is an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling results. Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent upper confidence limit (UCL) of the arithmetic mean should be used for this variable. The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated.

Why use an average value for the concentration term?

An estimate of average concentration is used because:

Supplemental Guidance to RAGS is a bulletin series on risk assessment of Superfund sites. These bulletins serve as supplements to *Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual*. The information presented is intended as guidance to EPA and other government employees. It does not constitute rulemaking by the Agency, and may not be relied on to create a substantive or procedural right enforceable by any other person. The Government may take action that is at variance with these bulletins.

arithmetic mean is appropriate regardless of the pattern of daily exposures over time or the type of statistical distribution that might best describe the sampling data. The geometric mean of a set of sampling results, however, bears no logical connection to the cumulative intake that would result from long-term contact with site contaminants, and it may differ appreciably from — and be much lower than — the arithmetic mean. Although the geometric mean is a convenient parameter for describing central tendencies of lognormal distributions, it is not an appropriate basis for estimating the concentration term used in Superfund exposure assessments. The following simple example may help clarify the difference between the arithmetic and geometric mean when used for an exposure assessment:

> Assume the daily exposure for a trespasser subject to random exposure at a site is 1.0, 0.01, 1.0, 0.01, 1.0, 0.01, 1.0, and 0.01 units/day over an 8-day period. Given these values, the cumulative exposure is simply their summation, or 4.04 units. Dividing this by 8 days of exposure results in an arithmetic mean of 0.505 units/day. This is the value we would want to use in a risk assessment for this individual, not the geometric mean of 0.1 units/day. Viewed another way, multiplication of the geometric mean by the number of days equals 0.8 units, considerably lower than the known cumulative exposure of 4.04 units.

UCL AS AN ESTIMATE OF THE AVERAGE CONCENTRATION

What is a 95 percent UCL?

The 95 percent UCL of a mean is defined as a value that, when calculated repeatedly for randomly drawn subsets of site data, equals or exceeds the true mean 95 percent of the time. Although the 95 percent UCL of the mean provides a conservative estimate of the average (or mean) concentration, it should not be confused with a 95th percentile of site concentration data (as shown in Highlight 2).

Why use the UCL as the average concentration?

Statistical confidence limits are the classical tool for addressing uncertainties of a distribution average. The 95 percent UCL of the arithmetic mean concentration is used as the average concentration because it is not possible to know the true mean. The 95 percent UCL therefore accounts for uncertainties due to limited sampling data at Superfund sites. As sampling data become less limited at a site, uncertainties decrease, the UCL moves closer to the true mean, and exposure evaluations using either the mean or the UCL produce similar results. This concept is illustrated in Highlight 2.

Should a value other than the 95 percent UCL be used for the concentration?

A value other than the 95 percent UCL can be used provided the risk assessor can document that high coverage of the true population mean occurs (i.e., the value equals or exceeds the true population mean with high probability). For exposure areas with limited amounts of data or extreme variability in measured or modeled data, the UCL can be greater than the highest measured or modeled concentration. In these cases, if additional data cannot practicably be obtained, the highest measured or modeled value could be used as the concentration term. Note, however, that the true mean still may be higher than this maximum value (i.e., the 95 percent UCL indicates a higher mean is possible), especially if the most contaminated portion of the site has not been sampled.

CALCULATING THE UCL

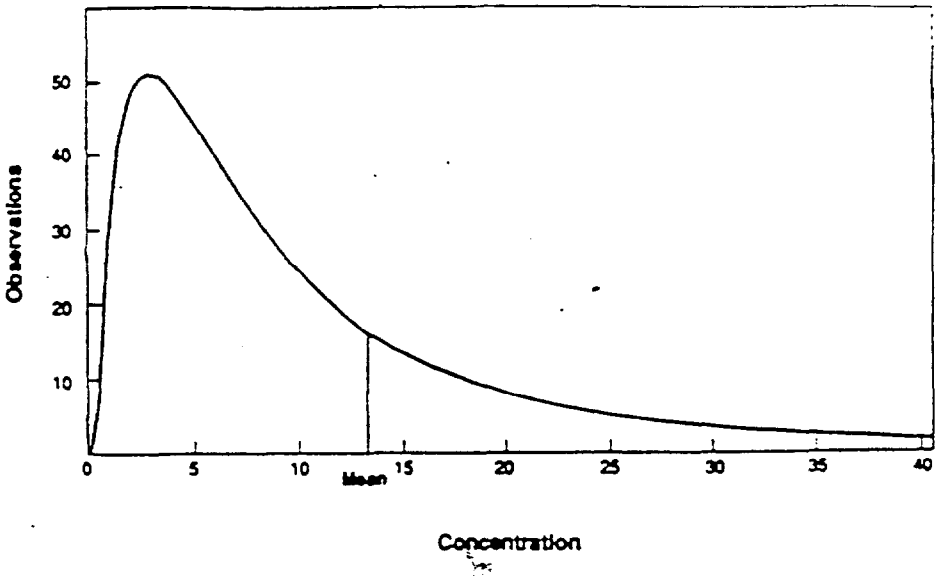
How many samples are necessary to calculate the 95 percent UCL?

Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration (i.e., there is a large difference between the sample mean and the 95 percent UCL), while data sets with 10 to 20 samples per exposure area provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean (i.e., the 95 percent UCL is close to the sample mean). Remember that, in general, the UCL approaches the true mean as more samples are included in the calculation.

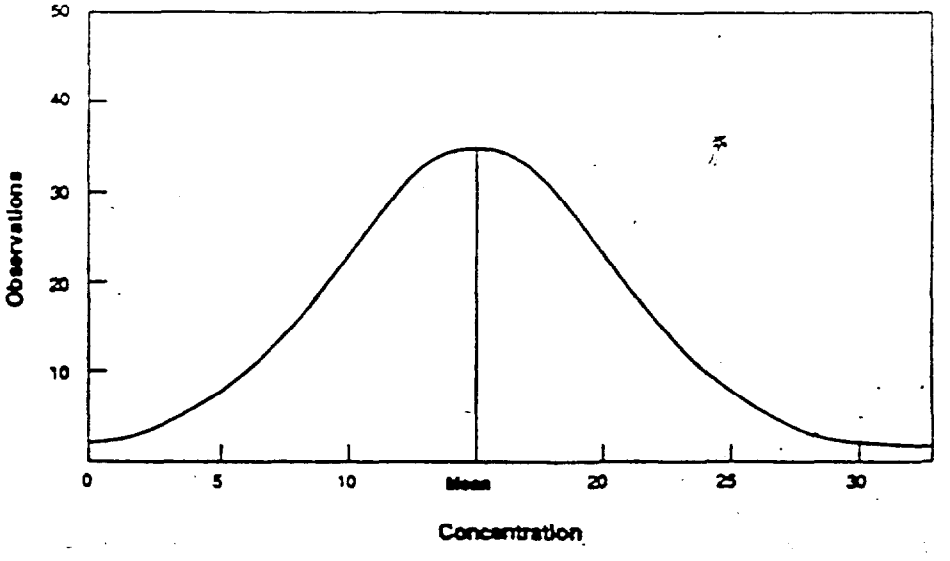
Should the data be transformed?

EPA's experience shows that most large or "complete" environmental contaminant data sets

Highlight 3
EXAMPLE OF A LOGNORMAL DISTRIBUTION



Highlight 4
EXAMPLE OF A NORMAL DISTRIBUTION



Highlight 7
EXAMPLE OF DATA TRANSFORMATION AND CALCULATION OF UCL

This example shows the calculation of a 95 percent UCL of the arithmetic mean concentration for chromium in soil at a Superfund site. This example is applicable only to a scenario in which a spatially random exposure pattern is assumed. The concentrations of chromium obtained from random sampling in soil at this site (in mg/kg) are 10, 13, 20, 36, 41, 59, 67, 110, 110, 136, 140, 160, 200, 230, and 1300. Using these data, the following steps are taken to calculate a concentration term for the intake equation:

(1) Plot the data and inspect the graph. (You may need the help of a statistician for this part [as well as other parts] of the calculation of the UCL.) The plot (not shown, but similar to Highlight 3) shows a skew to the right, consistent with a lognormal distribution.

(2) Transform the data by taking the natural log of the values (i.e., determine ln(x)). For this data set, the transformed values are: 2.30, 2.56, 3.00, 3.58, 3.71, 4.08, 4.20, 4.70, 4.70, 4.91, 4.94, 5.08, 5.30, 5.44, and 7.17.

(3) Apply the UCL equation in Highlight 5, where:

$\bar{x} = 4.38$
$s = 1.25$
$H = 3.163$ (based on 95 percent)
$n = 15$

The resulting 95 percent UCL of the arithmetic mean is thus found to equal $e^{(6.218)}$, or 502 mg/kg.

Highlight 8
COMPARING UCLS OF THE ARITHMETIC MEAN ASSUMING DIFFERENT DISTRIBUTIONS

In this example, the data presented in Highlight 7 are used to demonstrate the difference in the UCL that is seen if the normal distribution approach were inappropriately applied to this data set (i.e., if, in this example, a normal distribution is assumed).

ASSUMED DISTRIBUTION:	Normal	Lognormal
TEST STATISTIC:	Student-t	H-statistic
95 PERCENT UCL (mg/kg):	325	502

INTERIM DEFAULT EXPOSURE PARAMETERS FOR THE CENTRAL TENDENCY*
REGION 1

posure Pathway	Contact Rate	Frequency of Exposure (dy/yr)	Duration of Exposure (years)	Body Weight (kg)
ıestion of Drinking Water				
ıidential	1.4L/day	350	9	70
ıestion – Soil & Dust				
ıld – residential	100mg/day	150 or site–specific	2	15
ult – noncontact residential	50mg/day	150 or site–specific	7	70
u! ıoncontact worker	50mg/day	150 or site–specific	site–specific	70
ıalation				
ıidential	20m3/day	234dy/yr	9	70
ıh Ingestion	145g/meal**	site–specific	9	70
ıestion of Produce	142g/day(fruits) 201g/day(veg) or produce specific value for amt per meal	350dy/yr for values indicated or site–specific ave. if use amt/meal.	9	70

- E ɔsure parameters were developed by a national EPA workgroup. The technical document supporting ıse values is currently under review.
– or 6.7g/day for freshwater finfish in New England, 9.5g/day for saltwater fish in New England and 3.0g/day shellfish ingestion in New England (Rupp et. al. 1980. Some Results of Recent Surveys of Fish and Shellfish ınsumption by Age and Region of Some US Residents, Health Physics, Volume 39, pages 165 to 174.)
ıite–specific value for the fraction of fish ingested from the contaminated surface water should be included in the ɔosure equation with the use of the above values.

ATTACHMENT 4

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Office of
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Emergency Re nse

Publication 9234.2-09/FS
June 1990

EPA

ARARs Q's & A's:
Compliance With Federal Water Quality Criteria

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Quick Reference Fact Sheet

Section 121(d) of CERCLA, as amended by the 1986 Superfund Amendments and Reauthorization Act (SARA), requires that on-site remedial actions must at least attain Federal and more stringent State applicable or relevant and appropriate requirements (ARARs) upon completion of the remedial action. The 1990 National Contingency Plan (NCP) requires compliance with ARARs during remedial actions as well as at completion, and compels attainment of ARARs during removal actions whenever practicable. See NCP, 55 FR 8666, 8843 (March 8, 1990) (to be codified at 40 CFR section 300.414(i)), and 55 FR 8666, 8852 (March 8, 1990) (to be codified at 40 CFR 300.435(b)(2)).

To implement the ARARs provision, EPA has developed guidance, CERCLA Compliance With Other Laws Manual: Parts I and II (Publications 9234.1-01 and 9234.1-02), and has provided training to Regions and States on the identification of and compliance with ARARs. These "ARARs Q's and A's" are part of a series of Fact Sheets that provide answers to a number of questions that arose in developing ARAR policies, in ARAR training sessions, and in identifying and complying with ARARs at specific sites. This particular Q's and A's Fact Sheet addresses compliance with Federal Water Quality Criteria (FWQC) as ARARs.

Q1. What are the Federal Water Quality Criteria?

A. Federal Water Quality Criteria (FWQC) are nonenforceable guidance established by EPA for evaluating toxic effects on human health and aquatic organisms. FWQC are used or considered by the States in setting their water quality standards (WQSs) for surface water. State WQSs consist of designated uses (i.e., fishing, swimming, drinking water) and criteria for pollutants set at levels that are protective of those uses. State WQSs are regulatory requirements, and permit limits are established to ensure that the State use designations and criteria are met.

There are two categories of FWQC that relate to human exposure:

- Ingestion of contaminated drinking water and contaminated fish; and,
- Ingestion of contaminated fish alone.

FWQC have been published for many different contaminants (both noncarcinogens and carcinogens). FWQC for noncarcinogens are generally set above zero, and address chronic and toxic effects. FWQC for carcinogens are recommended at zero, although a range of concentrations corresponding to incremental cancer risks of 10^{-5}, 10^{-6}, and 10^{-7} are provided for informational purposes and do not represent an Agency judgement on an "acceptable" risk level.

In addition to the FWQC published for two human exposure scenarios, FWQC are published for four other categories. They consist of acute and chronic toxicity for fresh and saltwater aquatic life.

Q2. Do FWQC constitute potential ARARs for Superfund sites?

A. Yes. Although compliance with FWQC is not legally required at non-Superfund sites, and they are not "legally applicable" requirements under CERCLA, FWQC may be ARARs when found by the Agency to be relevant and appropriate (see final NCP preamble, 55 FR at 8742 (March 8, 1990). Specifically, CERCLA section 121(d)(2)(A) states that every remedial action "shall require a level or standard of control which at least attains ... water quality criteria established under section 304 or 303 of the Clean Water Act, where such ... criteria are relevant and appropriate under the circumstances of the release or threatened release."

Q3. When are FWQC best suited to serve as cleanup standards?

A. FWQC for specific pollutants should generally be identified as ARARs for surface-water cleanup if

particular circumstances exist at the site that FWQC were specifically designed to protect, unless the State has promulgated WQSs for the specific pollutants and water body at the site. Standards that are specifically suited to site circumstances should generally be used to establish cleanup levels at sites where those circumstances are present.[1] A State WQS may be a site-specific adaptation of a FWQC. In such cases, they are generally the appropriate standards for the specific pollutant and water body, rather than the FWQC. In the absence of any State WQSs specific to the pollutant and water body of concern, FWQC may be ARARs for surface-water bodies when:

- Protection of aquatic life is a concern. Examples include sites where:
  - adverse impacts to aquatic life are foreseen at the site; or
  - the surface-water bodies are designated for the protection of aquatic life.
- Human exposure from consumption of contaminated fish is a concern.

For sites where protection of aquatic life is a concern, the FWQC for fresh or saltwater aquatic life (whichever is pertinent) may be ARARs. When human exposure from consumption of contaminated fish is a concern (e.g., sites that require remediation of recreational water bodies, saltwater bodies, or estuaries used for fishing), the FWQC published for human exposure from consumption of fish may be ARARs for the sites. Examples include sites where the surface-water bodies are used for fishing and an exposure route consists of consumption of contaminated fish from the site.

Note, however, that if any of the above-mentioned water bodies are also used for drinking, standards for acceptable levels of contaminants in drinking water may also be potential ARARs for the site (e.g., non-zero maximum contaminant level goals (MCLGs), maximum contaminant levels (MCLs), State WQSs designated for drinking-water use, and FWQC adjusted to reflect cleanup standards for drinking water). (Question #5 of this fact sheet addresses how to determine the ARAR in these situations, when there are both drinking-water and environmental concerns at the site.)

[1] See proposed NCP preamble, 53 FR at 51442 (Dec. 21, 1988), and the final NCP preamble, 55 FR at 8755 (March 8, 1990). NOTE: the guidance set out in the proposed NCP is still effective where not superseded by guidance or regulations in the final NCP. See 55 FR at 8666, col. 3.

Q4. Should FWQC be used to set drinking-water cleanup levels for surface water at sites that do not present environmental concerns?

A. Rarely. FWQC should be used to set drinking-water cleanup levels only when surface water serves as an actual or potential drinking-water source and other cleanup standards for drinking water (e.g., non-zero MCLGs, MCLs, or State WQSs designated for drinking-water use) are not available. (see Question 5 if impacts to aquatic organisms have also been identified at the site). Where surface water serves as an actual or potential drinking-water source and there are no impacts to aquatic organisms, the following requirements, where relevant and appropriate, should be attained in the following order:

- State WQSs that are designated for drinking-water use, and are more stringent than MCLs or non-zero MCLGs, or specific to the uses of that water body; or, if none,
- Non-zero MCLGs; or, if none,
- MCLs; or, if none,
- FWQC adjusted for drinking-water use.

Q5. Should FWQC be used to set drinking water cleanup levels for surface water at sites that do present environmental concerns?

A. It depends. Generally, non-zero MCLGs or MCLs should be identified as the ARARs for cleanup of water that is or may be a potential source of drinking water. However, at sites that also present environmental concerns, RPMs should compare the stringency of the non-zero MCLGs or MCLs to the pertinent FWQC for aquatic life at the site. If the FWQC for the aquatic life are more stringent, they may be the relevant and appropriate requirements to meet at the site. For example, the levels needed to protect aquatic organisms from volatile organics are generally much less stringent than the levels needed to protect human exposure from drinking water. Therefore, non-zero MCLGs or MCLs would adequately protect both humans and most aquatic life from volatile organics. However, the levels needed to protect aquatic life from metals are more stringent than those levels required to protect human exposure from drinking water. As a result, the FWQC for aquatic organisms would protect both humans and aquatic life from metals, whereas non-zero MCLGs or MCLs may not.

because FWQC recommended at zero are not ARARs, the three alternative values are TBCs.

Q9. **What other factors should be considered in determining whether FWQC are relevant and appropriate requirements?**

A. CERCLA requires that in determining whether a FWQC constitutes a relevant and appropriate requirement, EPA must consider the designated or potential use of the surface or ground water, the environmental media affected, the purposes for which such criteria were developed, and the latest available scientific information available (see CERCLA section 121(d)(2)(B)(i)). With regard to this last factor, OWRS periodically publishes FWQC for additional constituents and occasionally updates existing ones. Prior to using an FWQC for a particular constituent, RPMs should consult the IRIS data base maintained by the EPA Office of Research and Development and contact their Regional Water Office for the most recent listing, to ensure consideration of the latest available scientific information. See Attachment 1 for a list of the FWQC, current as of June 15, 1990. [Note: the FWQC chart issued by the EPA Office of Water Regulations and Standards, dated January 2, 1987, is no longer current and should not be used as a reference.]

NOTICE: The policies set out in this ARARs Q's and A's are intended solely for guidance. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this Q's and A's, or to act at variance with the guidance, based on an analysis of specific site circumstances. The Agency also reserves the right to change this guidance at any time without public notice.

(#)	A: COMPOUND	CAS Number	B: FRESHWATER Criterion Maximum Conc. (ug/L) B1	B: FRESHWATER Criterion Continuous Conc. (ug/L) B2	C: SALTWATER Criterion Maximum Conc. (ug/L) C1	C: SALTWATER Criterion Continuous Conc. (ug/L) C2	D: HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Water & Organisms (ug/L) D1	D: HUMAN HEALTH (10^{-6} risk for carcinogens) For Consumption of: Organism Only (ug/L) D2
45	2-Chlorophenol	95578					120 *	
46	2,4-Dichlorophenol	120832					93 *	790 *
47	2,4-Dimethylphenol	105679						
48	2-Methyl-4,6-Dinitrophenol	534521					13.4	765
49	2,4-Dinitrophenol	51285					70 *	14000 *
50	2-Nitrophenol	88755						
51	4-Nitrophenol	100027						
52	3-Methyl-4-Chlorophenol	59507						
53	Pentachlorophenol	87865	20 ***	13 ***	13	7.9	1000 *	29000 *
54	Phenol	108952					21 *	4600 *
55	2,4,6-Trichlorophenol	88062					1.2 †	3.6
56	Acenaphthene	83329					1200 *	2700 *
57	Acenaphthylene	208968					0.0028 †	0.0311
58	Anthracene	120127					0.0028 †	0.0311
59	Benzidine	92875					0.00012 *†	0.00054 *
60	Benzo(a)Anthracene	56553					0.0028 †	0.0311
61	Benzo(a)Pyrene	50328					0.0028 †	0.0311
62	3,4-Benzofluoranthene	205992					0.0028 †	0.0311
63	Benzo(ghi)Perylene	191242					0.0028 †	0.0311
64	Benzo(k)Fluoranthene	207089					0.0028 †	0.0311
65	Bis(2-Chloroethoxy)Methane	111911						
66	Bis(2-Chloroethyl)Ether	111444					0.031 *†	1.4 *
67	Bis(2-Chloroisopropyl)Ether	108601					1400 *	170000 *
68	Bis(2-Ethylhexyl)Phthalate	117817					1.8 *†	5.9 *
69	4-Bromophenyl Phenyl Ether	101553						
70	Butylbenzyl Phthalate	85687					3000 *	5200 *
71	2-Chloronaphthalene	91587						
72	4-Chlorophenyl Phenyl Ether	7005723						
73	Chrysene	218019					0.0028 †	0.0311
74	Dibenz(a,h)Anthracene	53703					0.0028 †	0.0311
75	1,2-Dichlorobenzene	95501					2700 *	17000 *
76	1,3-Dichlorobenzene	541731					400	2600
77	1,4-Dichlorobenzene	106467					400	2600
78	3,3'-Dichlorobenzidine	91941					0.04 *†	0.077 *
79	Diethyl Phthalate	84662					23000 *	120000 *
80	Dimethyl Phthalate	131113					313000	2900000
81	Di-n-Butyl Phthalate	84742					2700 *	12000 *
82	2,4-Dinitrotoluene	121142					0.11 †	9.1
83	2,6-Dinitrotoluene	606202						
84	Di-n-Octyl Phthalate	117840						
85	1,2-Diphenylhydrazine	122667					0.041 *†	0.54 *
86	Fluoranthene	206440					42	54
87	Fluorene	86737					0.0028 †	0.031
88	Hexachlorobenzene	118741					0.00072 †	0.00074
89	Hexachlorobutadiene	87683					0.44 *†	50 *

* Criteria revised to reflec... current agency q_1^* or RfD, as contained in ... Integrated Risk Information System (IRIS).

** Freshwater aquatic life criteria for these metals are expressed as a function of total hardness (mg/L), as follows (where exp represents the base e exponential function). (Values displayed above correspond to a total hardness of 100 mg/L.)

$$CMC = \exp(m_a[\ln(hardness)] + b_a) \qquad CCC = \exp(m_c[\ln(hardness)] + b_c)$$

	m_a	b_a	m_c	b_c
Cadmium	1.128	-3.828	0.7852	-3.490
Copper	0.9422	-1.464	0.8545	-1.465
Chromium (III)	0.8190	3.688	0.8190	1.561
Lead	1.273	-1.460	1.273	-4.705
Nickel	0.8460	3.3612	0.8460	1.1645
Silver	1.72	-6.52		
Zinc	0.8473	0.8604	0.8473	0.7614

*** Freshwater aquatic life criteria for pentachlorophenol are expressed as a function of pH, and are calculated as follows. (Values displayed above correspond to a pH of 7.8.)

$$CMC = \exp(1.005(pH) - 4.830) \qquad CCC = \exp(1.005(pH) - 5.290)$$

† Criteria based on carcinogenicity (10^{-6} risk).

‡ Aquatic life criteria for these compounds were issued in 1980 utilizing the 1980 Guidelines for criteria development. The acute values shown are final acute values (fav) and according to the 1980 Guidelines the Acute values were intended to be interpreted as instantaneous maximum values, and the chronic values shown were interpreted as 24 - hou average values. EPA has not updated these criteria pursuant to the 1985 Guidelines. However, as an approximation, dividing the final acute values in columns B1 and C1 by 2 yields a Criterion Maximum Concentration. No numeric changes are required for columns B2 and C2, and EPA suggests using these values directly as Criterion Continuous Concentration.

GENERAL NOTES:

1) This chart lists all of EPA's priority toxic pollutants whether or not criteria recommendations are available. Blan spaces indicate the absence of criteria recommendations.

2) The following chemicals have organoleptic based criteria recommendations that are not included on this chart (for reasons which are discussed in the [illegible]

Copper	2,4-[illegible]phenol
Zinc	3-Methyl-4-Chlorophenol

3) For purposes of this rulemaking, freshwater criteria apply at salinity levels equal to or less than 5 parts per thousand (ppt); saltwater criteria apply at salinity levels greater than 5 ppt (0/00).

5/15/90