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ISSUES DISCUSSED RELATED TO EXPOSURE SCENARIOS AND PRELIMINARY REMEDIATION GOALS

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LETTER

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MAR 11 1994

Mr. James A. Saric, Remedial Project Director
U. S. Environmental Protection Agency
Region V-5HRE-8J
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

Mr. Graham E. Mitchell, Project Manager
Ohio Environmental Protection Agency
40 South Main Street
Dayton, Ohio 45402-2086

Dear Mr. Saric and Mr. Mitchell:

ISSUES DISCUSSED RELATED TO EXPOSURE SCENARIOS AND PRELIMINARY REMEDIATION GOALS

The intent of this letter is to document the principal conclusions reached during the February 24, 1994 meeting between the United States Environmental Protection Agency (USEPA), United States Department of Energy (DOE) and Fernald Environmental Management Company (FERMCO). The Ohio Environmental Protection Agency (OEPA) participated in the meeting by telephone. This letter serves only as documentation of DOE's understanding and to provide the USEPA and OEPA with the current path forward concerning the development of recreational exposure scenarios and the associated Preliminary Remediation Goals (PRGs).

The following conclusions were reached as a result of the February 24, 1994, meeting:

1. The expanded trespasser exposure scenario, as it exists in the Operable Unit 4 (OU4) Feasibility Study (FS), will remain in the OU1, 2, and 3 RI/FS without modification of the input parameters. However, language will be added to these documents, in the form of change pages for existing documents in the review process, to reaffirm that the description of this scenario includes continued Federal ownership of the area and that fences and signs will be maintained. Language will also be added, to OU1 and OU2 RI/FS documents, to reaffirm that DOE will evaluate an array of trespassing and recreational exposure scenarios from no trespassing to full recreational use of the site and these will be submitted separately from the OU RI/FS documents.

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2. The approach to presenting trespassing and recreational exposure factors will be presented to the USEPA and OEPA for review and approval prior to submittal of the OU5 RI (the end of March 1994 was designated as the expected time frame for submittal of the first draft of these scenarios and PRGs). The documentation of the scenarios and PRGs will include:

   - Description of exposure scenarios that range from trespassing to full recreational use.
   - A table which shows preliminary remediation goals for all key COCs for each exposure scenarios.
   - A table showing the percentage of total risk for each pathway for each key COC.
   - The pathways evaluated will cover only surface soil for direct radiation exposure, inhalation, dermal contact, and ingestion. These PRGs will not consider Fate and Transport other than resuspension of dust.

3. DOE will submit a letter documenting the commitments in item number 1 for OU1 and 2 (this letter serves to fulfill this commitment and it is understood that the conclusions reached are not binding and the USEPA and the OEPA have no obligation to respond). There will be a single submittal for the changes pages for the OU1 and OU2 documents. The changes pages are to be transmitted to USEPA and OEPA no later than March 18, 1994. The purpose of the change pages is to assist in the review of documents already submitted to USEPA and OEPA and to ensure that the changes are consistent among the other OUs.

4. The OU5 Feasibility Study will develop and evaluate a range of proposed remediation levels (PRLs) for sitewide soil, sediment, and groundwater in concert with the evaluation of viable land use objectives for the FEMP property. The support the development of these PRLs, the detailed analysis portion of the OU5 FS must consider the potential sitewide cumulative residual risks across all OUs. To accommodate this process, the type of information presently conveyed in the source operable unit CRAREs will be incorporated into the individual alternatives evaluation in the OU5 FS. More specifically, exposure point concentrations derived from F&T modeling for the selected or leading remedial alternatives for OUs 1, 2, 3, and 4 will be brought in to the OU5 detailed analysis of alternatives as an overlay on the F&T results for each OU5 alternative. This approach to evaluating sitewide risk is consistent with the intent perspective on sitewide residual risks while developing PRLs for site environmental media. Since the CRARE is, in effect, being incorporated into the body of the OU5 FS, the information contained in the appendix

presently reserved for the CRARE will be limited to F&T results for non OU5 sources, and a semi-quantitative analysis of the cumulative short-term impacts of the coincidental implementation of remedial actions for the five OUs.

5. In place of submitting a revised Risk Assessment Work Plan Addendum (RAWPA) DOE proposed to submit distinct policy documents reflecting the key areas where there have been revisions (either as a result of USEPA and OEPA comments, such as the statistical evaluation to determine COCs, or as a result of new models, guidance, etc.). The policy documents prepared by FERMCO and reviewed by DOE will be submitted, for review and approval, to the USEPA and OEPA along with an explanation of which section (or portion of a section) of the RAWPA that is to be superseded. The possibility that at some time in the future it may be necessary to submit the revise the RAWPA to document these changes was discussed.

6. An inhalation rate of .5 cubic meters per hour will be used for a child in the resident exposure scenarios. An inhalation rate of .83 cubic meters per hour will be used for a child in the trespassing and recreational scenarios. Supporting explanations will be included in the OU1 and OU2 as change pages. No change will be made in the OU4 documents.

7. DOE will not calculate risks for the dermal absorption of PAHs but will discuss this pathway qualitatively in the RI. The risk from the oral pathway will be doubled to account for the contribution and uncertainties from the dermal pathway when calculating PRGs.

8. USEPA will confer with the authors of the skin surface area parameters for mixing RME surface areas and CT body weights and will initiate contact with Fernald to resolve this issue. The current value of 2.3 square meters will be used until a change occurs.

If you have any comments or questions concerning these conclusions please contact Randy C. Janke at (513) 648-3123.

Sincerely,

Johnny Reising

for Jack R. Craig
Fernald Remediation Action
Project Manager

FN:RC Janke

Enclosures: As Stated

cc w/enc:

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Attachment:

Issues discussed at February 24, 1994 Meeting

PAHs,
Skin Surface Area, and
Ventilation Rates

The following discussions are provided as attachments to the letter and to formally document the nature of the issues discussed at the meeting on February 24, 1994. These positions (policies) are considered draft and are provided for discussion and further consideration (as in the case of the surface area for dermal exposures).

CHILDREN VENTILATION RATES

EPA guidance provides that exposure factors should be used **unless alternate or site specific values** can be justified by supporting data. Accordingly, the value of $0.5M^3$/hour is recommended as the reasonable maximum inhalation rate for children, 0-6 years of age. This value was developed, in consultation with pediatric physicians from Childrens Hospital at the University of Cincinnati Medical Center and is based upon known physiological activity.

The rate at which hemoglobin is re-saturated with oxygen determines human ventilatory rates and volumes. For a moderately active person, the saturation of hemoglobin with oxygen occurs within a few minutes, with a ventilation rate appropriate to the body size. The rate is controlled by the autonomic nervous system and continued hyperventilation beyond the point where hemoglobin is re-saturated with oxygen does not continue. Since ventilatory rate decreases as oxygen saturation of hemoglobin occurs, continued hyperventilation at an hourly rate beyond a few minutes duration is unlikely and can cause narcosis.

Based upon recommendations of pediatric medical practitioners at The Childrens' Hospital at the University of Cincinnati Medical Center, the ventilation volume for children between birth and six years of age is 15-20 cc's per breath per kg body weight.

The low and high range of ventilation rates are;
20 to 30 breaths/minute for infants, birth-2 y.o.;
15 to 20 breaths/minute for a 3-4 y.o. small child; and
12 to 15 breaths/minute for a 5-6 y.o. older child.

Using conservative weight values of 10 Kg for an infant (0-2yrs.), 15 Kg for a small child (3-4 yrs.) and 20 Kg for an older child (5-6yrs.), we can calculate reasonable ventilation rates.

The low and high minute ventilatory volume ranges are;
2.0-3.0L/min. (low) and 3.0-4.5L/min (high) for a 10Kg infant,
2.3-3.4L/min. (low) and 3.0-4.5L/min (high) for a 15Kg child and
2.4-3.6L/min. (low) and 3.0-4.5L/min (high) for a 20 Kg child.

The calculated higher minute ventilatory volumes for children 0-6 years of age are identical. Assuming the maximum values are for the active child, these are applicable to children from 0-6 years. To assure a conservative assessment, an activity factor of 2.1, for a

moderately active child, is introduced into the calculated rate. In spite of the moderate activity, realistically, children could not continue to breath at a maximum value (hyperventilation) for more than several minutes. However, they are assumed to be moderately active so we will use the higher ventilation rate.

The lower rate is; 3.0L/min x 60min/hr x 2.1 = 378 L/hr., or 0.3 M^3/hr. At a high rate of 4.5L/min x 60min/hr x 2.1 = 570 L/hr. or 0.5 M^3/hr.

Therefore, using the higher ventilation rate and the moderate activity factor, for an active child, who will ventilate at a higher rate, but not continuously, the ventilatory rate of 0.5 M^3/hr. is appropriate for children between 0-6 years of age. It is a realistic, yet conservative value based upon physiological parameters established within the greater Cincinnati Medical community. It will provide valuable and reasonably accurate decision making information for use in conducting risk assessments.

DERMAL SLOPE FACTORS FOR PAH'S (OR OTHER COCs).

An EPA comment regarding dermal toxicity assessment was the inappropriate use of PAH dermal cancer slope factors extrapolated from oral slope factor values. Also, dermal information was not properly considered nor presented in the RI, as described below.

> "Dermal absorption of PAH's in this manner (using oral slope factors) will not be protective, **<u>and dermal toxicity values should not be derived for these compounds."</u>** PVL, 8/10/93.

Dermal slope factors were unavailable from EPA's recommended documents; IRIS, HEAST or from ECAO. Extrapolation of cancer slope factors from other routes of exposure is inappropriate due to varied absorption, metabolic transformations and target organ end point responses. In the OU4RI, the assessors extrapolated dermal risk slope factors from oral values in an attempt to provide a quantitative estimate of the possible contribution to OU site risk from the dermal path of PAH exposure. The assessors misread the EPA comment to mean those values should be completely removed from the RI. They removed the values however, they failed to provide alternative qualitative information of the possible impact on risk from that path due to PAHs. Therefore, the following policy guidance is provided.

POLICY; When slope factors are unavailable in IRIS, HEAST or from ECAO, for dermal PAHs, or for any chemical, the alternative action requires the manager/assessor to conduct a separate search for such information. The first step is, seek out any information published by ATSDR (Agency for Toxic Substances Disease Registry). If that is unavailable, the assessor must conduct an independent review of the

toxicology, epidemiology and pathology literature.

Start the search by identifying suitable citations in refereed journals that provides information on the toxicity of the chemical in question. Conduct a critical examination of the citation. Identify the quality of the study. Determine the suitability of the experimental animal, tissue, cells or biochemical process toward answering the questions. Determine the appropriateness of the experimental protocol or methodology used to answer the question the author is asking. Describe how this methodology and evidence supports the conclusion(s).

Determine and describe, in the text, any health effects and the extent that COC can impact the risk. In the text describe, and reference the information found and explain qualitatively, the effects of exposure to the COC and how that pathway impacts risk. Describe the route of exposure, the dose, target organ, response time, and any sensitivities of the animal. Describe the target organ tissue and end point associated with this exposure path. Correlate potency of this chemical and how that may contribute to the risk from this pathway. In the text, provide a qualitative discussion of the possible impact of this exposure path to the total risk, correlating the possible affects on human response.

Provide a discussion on the amount and type of uncertainty of this relationship is required in the uncertainty section.

FOR PAHs:

When presenting risk information on the B2 PAH's, the report requires risk evaluation using oral and inhalation slope factors. For dermal exposure, provide a discussion as above. The proper input into text should be "the contribution to cancer risk from dermal exposure to PAHs indicates that path to be at least as toxic as the oral route. Therefore, you should double the final oral risk value (i.e., 2X's 1.0 x 10E-6 = 2.0 x 10E-6) to account for the impact or contribution from the dermal route of exposure. Also, when calculating the PRG's, this value should be halved.

Concurrently, it is important to prepare an evaluation of the risks using the following relative potency values.

COMPOUND	RELATIVE POTENCY
Benzo(a)pyrene	1.0
Benz(a)anthracene	0.1
Benzo(b)fluoranthene	0.1
Benzo(k)fluoranthene	0.01
Chrysene	0.001
Dibenz(a,h)anthracene	1.0
Indeno[1,2,3-c,d]pyrene	0.1

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The data indicate Benzo(a)pyrene (BaP) is the index toxin among the group of PAHs; Dibenz(a,h)anthracene is equally as potent. However, all PAHs are referenced with BaP. Since carcinogenic capabilities among PAHs varies across routes of exposure, describe the relationship of exposure concentrations and the potency. The uncertainty accompanying these descriptions must be addressed in the uncertainty section of text.

There is a decision matrix (Dermal Exposure Assessment: Page 9-2) available when identifying whether dermal exposure is a matter to be assessed. It is described below to help determine the importance of dermal exposures when conducting risk analysis.

1. Will dermal contact occur in the scenario?
   a.No-Do not consider further.
   b.Yes-Review dermal toxicology and determine if chemical causes skin effects.
2. Is same contaminant in water/soil being consumed as is dermally contacted?
   a.No-Conduct detailed assessment of water/soil exposure and consider possible contribution from dermal exposure.
   b.Yes-Examine water/soil exposure.
3. Is water Kp>10E-1cm/hr? or is absorption from skin greater than 10%?
   No-Dermal analysis may not be necessary.
   Yes-Conduct a detailed risk analysis and evaluate any possible contribution from dermal exposure.

POLICY: HUMAN SURFACE AREA (SA); DERMAL CONTACT WITH SOILS

Another issue from the EPA comments was the use of the upper bound ($2.3M^2$) surface area parameter. The comment is quoted below.

> **"Regarding surface area (SA) parameter values for the dermal contact with soil/sediments pathways. Please reread the OSWER Directive, 9285.6-03. The directive specifies that the upper-bound values should be used for IR (intake/contact rate). It goes on to say.."the body surface area is a measure of contact rate (<u>contact area</u>) in the dermal equations. Therefore, it is appropriate to use upper bound values (95th percentile values) as indicated in the dermal guidance." PVL, from 10/27/93.**

CURRENT APPROACH;
The value of $2.3M^2$ for the human body surface area was used for all dermal calculations for risk assessment purposes, as per Region V EPA guidance. However, USDOE has cited a dissenting opinion to the

EPA that this guidance is inappropriate. It will be examined by EPA headquarters.

DISAGREEMENT:

The evaluation of EPA guidance and established human surface area parameters indicates the guidance to be inappropriate. It is inappropriate to use a physiological relationship that suggests the average 70 Kg reference man has the body surface area of a 100+Kg person. This value extends outside physiological reality.

It is further suggested that the values are inappropriate when examined in light of EPA guidance (Exposure Factors Handbook, EPA600/8-89/043, Chapter 4 and Appendix 4A). The guidance cites several references and equations ($SA=K*B.Wt.^{2/3}$; and $SA=Ao*Ht^{a1}*Wt^{a2}$) identifying the high degree of correlation between body weight, body height and body surface area, and uses that relation extensively. Since these physiological parameters are highly correlated, the relationship indicates that an average weight reference man is tied in closely to an average body surface area. Any other use would be incorrect.

The above quote that contact rate and contact area are equivalent is incorrect. RAGs guidance, Section 6, page 6.2. definitions support the fact that contact rate and contact area are not the same. The EPA cited definition for "contact rate" is a measure of the amount of medium (L/day water ingested, or, mg/cm^2-day soil contacted) per unit time. Contact area is the body surface area of available for contact with contaminated medium, in M^2.

RAGs guidance, Section 6.4, page 6-19. On the subject of exposure quantification. "The reasonable maximum **exposure** (RME) is the maximum exposure that is reasonably expected to occur at the site. Under this approach, some intake variables may not be individual maximum values but in combination with other variables will result in estimates of RME (**reasonable maximum exposure**). Determination of "reasonable" cannot be based solely on quantitative information but requires the use of professional judgement." The maximum body surface area used with an average body weight and average lifetime exposure is inconsistent with professional toxicological judgement.

March 25, 1991, OSWER directive 9285.6-03, Supplemental Guidance, Standard Default Exposure Factors, Interim Final. Page 1. The introduction to the guidance states that "**exposure factors**" (not physiological parameters) in the document should be used unless alternate or site specific values can be justified by supporting data."

A review of the OSWER directive concludes that guidance does not clearly establish using the upper bound surface area with the average body weight and average lifetime. Text on page 2 states;

"The goal of the RME estimates for each scenario at each site is to combine the upper bound and mid-range **exposure factors** as in the following equation."

Intake = (CxIRxEfxED)/(B.wt.x Ave time).

where:

C = Concentration of chemical in medium of concern.
IR = Intake/contact rate (upper bound value)
EF = Exposure frequency (upper bound value)
ED = Exposure duration (upper bound value)
BW = Body weight (average value)
AT = Averaging time (exposure duration in days for non-carcinogens and a 70 year lifetime for carcinogens).

Contact rate is the concentration of chemical contaminant in contact with the body surface area per unit time or event. This is an exposure rate and is denoted by mg/M^2/unit time period. Based upon EPA's definitions above, the contact rate is an **exposure parameter** and should be the upper bound (RME). However, the body surface area exposed is a physiological parameter that should be an average, and is consistent with the average body weight and the average lifetime value (for cancer calculations). There are several reasons for this relationship.

In the above equation, the exposure parameters are upper bound while the physiological parameters, b.wt. and averaging time, are clearly average (central tendency) values. It is appropriate that the body surface area of a human physiological parameter should also be the average (central tendency) value.

Federal Register, Vol 57, No 104/Friday May 29, 1992. Page 22895, recommends using dose estimates that can be compared with the available dose-response data; it also describes use of an average dose rate (average dose [mg] of chemical per unit time) for a time period as a useful number for risk assessment. It also states the **average surface area** should be used in calculating the uptake dose via dermal exposure (p. 22896, Section 2.1.4.2).

Dermal Exposures Handbook,(DEH) Jan. 1992, page 8-9, describes the equations used to develop surface area. Section 8.4, includes discussions by several authors, (most notably Gehan) to support EPAs position, that skin surface area is a highly correlated function of body weight and height. Since the average person surface area is a closely correlated function of body weight and height, any relationship of the dermal exposure to the surface area must be correlated with average body weight (70kg). To use 70 Kg in the dermal equation with a RME surface area is scientifically and medically inappropriate. Risk calculations, using an average person body weight with an RME surface area, present a significant bias

and is scientifically indefensible (Phillips L.J., Fares R.J. and L.G. Schweer, 1993, Distributions of Total Skin Surface Area to Body Weight Ratios for use in Dermal Exposure Assessments, Journal of Exposure Analysis and Environmental Epidemiology, Vol. 3: 331-338).

DEH, Part 2. Application of The Dermal Exposure Assessment document identifies the human body surface areas to range from 17,000 to 23000 cm^2. The mean value is 20000 cm^2 (2.0M^2). Thus the appropriate mean surface area that should be used for reference man is 2.0M^2.

DEH, Chapter 9.1, page 9-1, the example used for EPA's decision matrix regarding the importance of dermal uptake uses an exposed surface area of 20,000cm^2 or 2.0M^2.

DEH, Table 8-6 is an example where the table headings for central tendency (mean) surface areas is 20000cm^2 and the RME value for surface area is 23000cm^2. In both examples, the situations reflect the use of central tendency values of surface area with the central tendency event time, frequency and duration (see table 8-6, page 8-20.

DEH, Page 9-18, in comparing the amount of dose received by the average adult via dermal uptake and ingestion, the equation example uses the average skin surface area of 20,000cm^2.

An additional consideration is the use of data from ECAO for dermal uptake from soil. The use of an upper limit value for ABS with two central tendency values AF and SA results in an overall DA_{event} = that is above the average. If the upper bound for AF and SA are also used, then the DA_{event} would result in a 99.78th percentile value. This is clearly outside a reasonable approach as directed by RAGs. (Burmaster, D.E. and Harris R.E., 1993 The Magnitude of Compounding Risks in Superfund Assessments, Risk Analysis, Vol 13: 131-34.

Section 4 of the Exposure Factors handbook, Skin surface area, EPA used regression equations to correlate height and weight to establish surface areas. Section 4 of the Exposure Factors Handbook also describes the use of surface area in relation to the height and body weight. Nowhere do any of the references or examples explicitly state that the upper bound SA should be used with normal body weight and average lifetime. (EPA citation, Gehan, George. 1970 Estimation of human body surface area from height and weight, Cancer Chemotherapy Reports, Vol. 54 No.4: 225-235).

However, guidance on using average body surface area in the exposure assessment equation is found in the Federal Register, Vol 57, No 104, in section 2.1.4.2. this section deals with the dermal route of uptake. Each of the equations, 2.8, 2.9 and 2.10 describe the average daily dose calculations using the average body surface area (bar above the SA parameter).

The guidance from RAGs (p 6-41 et seq., Exhibit 6-15 et seq.) bottom of pages and exhibits state "for dermal contact with chemicals in soil, use 95th or 90th percentiles for **contact rate and exposure frequency variables** and the **50th percentile total body surface area** **(1.94/2.0 M^2) for (SA).**

Based upon the above, EPA philosophy and published documents are consistent in their philosophy that mean surface area should be used with mean body weight when used in risk assessments. Thus 1.94/2.0M^2 (19400-20000cm^2) central tendency physiological parameter value should be used with mean physiological parameters, but that exposure parameters should be at the reasonable maximum value (RME).

Based upon the review of philosophy espoused in EPA documents, a realistic approach to evaluating the dermal risk would be to prepare two sets of calculations. One using 50th percentile exposure doses with the 50th percentile physiological parameters and a second set of calculations using 90th/95th percentile RME exposure parameters. These risk values will provide a realistic, yet conservative range of risks and indicate probable mean risk and the reasonable maximum risk accompanying the average and maximum worst case exposure scenarios. The combination allows for realistic decision making.

The foundation of toxicology indicates that dose and duration are the most important factors when discerning toxicity. The risk values identifies the possible adverse effects associated with some dose rate (mg chemical/per kg body wt) and duration of exposure. This dose rate reasonably can be an average (CT) rate or for greater conservatism, be the reasonable maximum exposure (RME). However, physiological parameters must be chosen appropriately: either they should all be mean values (50th percentile values) or they should be 90-95th percentile values). However, they should not be mixed for a realistic and practical estimate of risk.