(OSWER Directive 9285.6-03, dated February 6, 2014)

1. Why is EPA updating the default exposure factors for use in CERCLA risk assessment equations?

The prior EPA default exposure values were issued in 1991 as OSWER Directive 9285.6-03 (EPA, 1991) and a few were updated or supplemented by subsequent *Risk Assessment Guidance for Superfund (RAGS)*. OSWER Directive 9285.6-03 stated, "As new data become available, either for the factors themselves or for calculating RME [reasonable maximum exposure], this guidance will be modified accordingly."

New data became available in September 2011, when EPA's National Center for Environmental Assessment, Office of Research and Development (ORD/NCEA) issued a substantive update to its exposure assessment recommendations, *Exposure Factors Handbook – 2011 Edition (EFH 2011)*. *EFH 2011* is an externally peer-reviewed document that summarizes relevant exposure assessment data.

Following the publication of *EFH 2011*, EPA's regional risk assessors received inquiries from other EPA program offices, states, the regulated community, and other interested parties regarding the applicability of the ORD/NCEA's recommendations in *EFH 2011* for use in human health risk assessments. The OSWER Human Health Regional Risk Assessors Forum (OHHRRAF), a workgroup consisting of human health risk assessors from EPA Regions and EPA Program Offices, reviewed the recommendations in *EFH 2011* in the context of the default exposure factors used in the Superfund program and to derive Regional screening levels. As a result of a consensus-driven process, the OHHRRAF identified several Superfund-specific default exposure factors that warranted updating. OSWER Directive 9200.1-120 (*Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors*; dated February 6, 2014) incorporates and adopts the updates recommended by the OHHRRAF and updates OSWER Directive 9285.6-03.

2. Why do some of the factors recommended in OSWER Directive 9200.1-120 differ from the recommendations in the Exposure Factors Handbook – 2011 Edition (EFH 2011)?

EFH 2011 is not a Superfund-specific document; rather, it provides a summary of the latest developments in exposure science and provides recommendations for a broad range of EPA programs. The OHHRRAF developed consensus recommendations based on the context, needs, and existing health risk assessment policy/guidance for the Superfund Program, such as ensuring that the recommended exposure factors are protective of the reasonable maximum exposure (RME), consistent with the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (CERCLA) and the National Oil and Hazardous Substances Pollution Contingency Plan (NCP).

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3. Why is the updated water ingestion rate for adults 2.5 L/day and for children 0.78 L/day, instead of the values recommended in the Exposure Factors Handbook– 2011 Edition?

The recommendation in *EFH2011* is based on a 95th percentile value. OSWER Directive 9285.6-03 selected the prior default values based upon a 90th percentile value. The OHHRRAF consensus was to use the established percentile basis of exposure factors, where stated, to maintain the historic mix of upper-bound and mid-range values as indicated in the original Directive. Accordingly, the 90th percentile values were selected by OHHRRAF consensus for water ingestion rate.

4. Why hasn't the average life expectancy (lifetime) been updated to 78 years as recommended by the Exposure Factors Handbook– 2011 Edition?

The OHHRRAF has been consulting with ORD/NCEA on the appropriateness of updating this factor for purposes of calculating lifetime average daily dose. We currently understand that ORD/NCEA is re-considering its recommendation as expressed in *EFH2011*. If this consultation results in an ORD/NCEA recommendation to update this factor, additional documentation will be provided.

5. Why is 26 years recommended as the residential exposure duration when the EFH2011 recommendation is 33 years?

The ORD/NCEA-recommended exposure duration (33 years) is based on a 95th percentile value. As noted in the discussion on water ingestion, the OHHRRAF consensus was to use the established percentile basis of exposure factors, where stated, to maintain the historic mix of upper bound and mid-range values as indicated in the original Directive. The original basis for the default value for residential exposure duration was a 90th percentile value. Accordingly, the 90th percentile value (26 years) was selected by OHHRRAF consensus for residential exposure duration.

6. Why aren't age group defaults provided?

The purpose of OSWER Directive 9200.1-120 is to update and clarify the 1991 directive, which did not include age-group-specific values. Users are directed to the *Exposure Factors Handbook* – 2011 Edition as a source for age-group-specific exposure factor values, as described in *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (EPA, 2005).

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7. Why are default factors for fish ingestion and homegrown produce ingestion no longer provided?

Given the large geographic variability observed within these types of exposure values, the OHHRRAF consensus is that fish ingestion and homegrown produce ingestion values for highly exposed populations should be site specific. *EFH 2011* also recommends site-specific analysis for fish and produce consumption.

8. Will these updated exposure factors be considered in calculating Regional Screening Levels (RSLs)? How does the update of these values affect the RSLs? When will the RSL tables be updated? What should users do in the meantime?

The RSLs are updated biannually, and the next update is scheduled for May 2014. It is anticipated that the next update of the RSL tables will incorporate the updated exposure factors.

Users can use the RSL calculator to calculate updated RSLs for specific contaminants in the interim. Based on preliminary analyses performed by the OHHRRAF, changes to the default exposure factors will result in a <u>slight</u> increase to most of the medium-specific RSLs.

9. How should these updated exposure factors be weighed in Five Year Reviews?

EPA, as required by statute and as a matter of policy, reviews the remedies at certain cleanup sites every five years. To assess protectiveness of the respective remedy, the lead agency should review and evaluate the current validity of all the exposure and risk parameters upon which the original remedy selection decision was based (see *Comprehensive Five-Year Review Guidance*, OSWER Directive 9355.7-03B-P, dated June 2001). Such protectiveness assessments should consider the updated exposure factors recommended in Directive 9200.1-120.

Based on calculations performed by the OHHRRAF, updates to the default exposure factors are generally expected to result in a <u>slight</u> decrease in calculated time-weighted exposures (and, hence, risk estimates) for most chemicals. EPA recommends, however, that risk assessors evaluate and verify impacts on risk estimates on a site-specific basis.

10. Why have inhalation rates been dropped from the default exposure factors?

Human health toxicity values currently derived by the EPA Integrated Risk Information System (IRIS) for inhalation exposures (i.e., Reference Concentrations for non-cancer effects and Inhalation Unit Risk values for cancer endpoints) are based upon exposure concentrations, rather than intakes. The *Risk Assessment Guidance for Superfund, Part F* (EPA, 2009) was issued to reflect this current practice. Users are encouraged to consult *EFH 2011* to obtain inhalation rate values as needed for alternative, site-specific approaches.

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11. What if a current baseline risk assessment has been completed (or is nearing completion) using the previous default exposure factors or exposure factors from EFH 2011 other than the factors identified in this directive?

EPA recognizes that transitioning to the default exposure factors recommended in Directive 9200.1-120 will take time and that current risk assessments may have been developed using factors other than those recommended here. In the near term, EPA recommends that this discrepancy be addressed in the uncertainty section of the baseline risk assessment and the impact on the risk characterization of the exposure factors used (versus using the exposure factors in this Directive) be discussed.

It is the long-term expectation that baseline risk assessments will use the default exposure factors in in Directive 9200.1-120.

12. How was the default exposure value calculated for surface area of a child? Are the listed values correct for exposed surface area of a child and an adult worker?

For children, EPA used data in Table 7-8 of *EFH 2011* to generate age-cohort-specific ratios. For ages less than two years old, EPA used data from the nearest age.

In reviewing all surface area calculations in response to public inquiries, EPA identified that the currently recommended value should have been listed as 2,373 cm² for a child and 3,527 cm² for an adult worker. As a result Attachment 1 was updated with these corrections and two corrections to citations.

Last updated February 24, 2015