DEQ Basis of Decision and Response for a
Site-Specific Residential Direct Contact Cleanup Criterion (SSRDCC)
for Dioxins/Furans (D/F) Toxic Equivalents (TEQ) for Midland Area Soils

Revised June 1, 2012

This document describes the Michigan Department of Environmental Quality's (DEQ) analysis and decision regarding the SSRDCC for Midland Area Soils. The preliminary development of the SSRDCC was reviewed and coordinated with The Dow Chemical Company (Dow) and the U.S. Environmental Protection Agency (EPA) in conversations that lead up to Dow submitting its work plan for corrective action to address dioxin in the city of Midland. These discussions were undertaken to allow for development of the work plan on the basis of an agreed-upon action level.

This revised document includes discussion and analysis of additional information provided by the EPA during the work plan review process. This information did not result in a change of DEQ's approval of the Midland Action Level.

The DEQ has approved the 250 parts per trillion (ppt) TEQ Midland Action Level as part of the approval of the work plan. The basis of that approval is provided in the Summary section of the attached revised DEQ staff recommendation document.

Executive Summary

Cleanup criteria calculations include both exposure assumptions and toxicity values. Exposure assumptions describe how much contact a person has with contaminated media (e.g., soil, drinking water, sediments, food). Exposures vary from person to person, depending on their habits and activities. The exposure assumptions used for calculation of cleanup criteria are chosen to protect what is referred to as the "reasonable maximum exposure" in order to be protective of susceptible individuals including children. Exposure assumptions can have state-wide application (generic), be chemical specific, and/or site-specific.

Toxicity values are chemical or chemical class-specific and based on human and/or animal data that identify how much chemical causes a health-related effect. The DEQ is required by state law to consider both cancer and noncancer toxicity values. Cleanup criteria are determined on the basis of the effect (cancer or noncancer) that is most sensitive. Typically, human toxicity data are preferred over animal toxicity data.

The cancer toxicity value the DEQ considered for the Midland Area Soils SSRDCC was developed for the 1995 EPA Great Lakes Water Quality Guidance (1995 GLWQG) based on animal data.

The noncancer toxicity value considered for the Midland Area Soils SSRDCC is the 2012 EPA reference dose (RfD) based on thyroid hormone function and male reproductive function in humans exposed before and after birth.

In addition to applying the generic exposure assumptions used for other chemicals, the DEQ has considered exposure assumption changes proposed by Dow for a SSRDCC for D/F TEQ for Midland Area Soils. Although not all of the specific values proposed by Dow were accepted, the DEQ recommends changes to the following exposure assumptions:

- Soil oral bioavailability (i.e., the amount of D/F TEQ that gets into body tissues from material that is swallowed) based on the average of site-specific data in rats and young pigs;
- Soil exposure frequency (i.e., the number of days of exposure to soil) based on site-specific climate data;
- Separate soil and dust exposure with dust concentrations as a fraction of the soil concentration based on site-specific data;
- Soil dermal bioavailability (i.e., the amount of dioxin absorbed through the skin) based on average values from the published literature;
- Relative source contribution (i.e., the relative amount of exposure from soil considering exposure from other major sources such as diet) based on the most recent dietary and background exposure information and the information available for the toxicity studies.

See Tables 1 and 2 (attached) for the specific values used and the attached DEQ staff recommendations for the basis of each value.

The DEQ did not agree to the child soil ingestion rate proposed by Dow. There is no site-specific information available to support this change, and the DEQ had recently reviewed and retained the current value of 200 milligrams per day for state-wide application.

Since the noncancer RfD is based on early life exposure, a child receptor was used to calculate the noncancer cleanup value.

Based on the use of the modified exposure and toxicity values described above, the calculated cancer cleanup value is 260 ppt and the noncancer cleanup value is 260 ppt.

A recalculation of the noncancer cleanup value based on the clarification of bioavailability assumed in the development of the 2012 EPA RfD results in values of 220-230 ppt. However, the DEQ has determined that the additional conservatism of the RfD does not warrant modification of the proposed action level (since the RfD does not account for non-2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) dioxin-like chemical (DLC) exposure in the participants of the studies upon which it is based).

These calculations and the additional information provided in the attached revised DEQ staff recommendation document support a 250 ppt Midland Action Level.

The DEQ has determined, after consideration of Dow's proposal and EPA's clarification, that 250 ppt Midland Action Level is appropriate. The presumptive remedy that is approved for Midland Area Soils is based on three primary steps as laid out in the approved work plan: (1) identification of properties likely to have dioxin concentrations greater than the Midland Action Level of 250 ppt TEQ; (2) confirmation through a design sampling process whether individual residential or residential-like properties exceed the Midland Action Level; and (3) remediation, contingent on property owners' consent, through removal of the top 12 inches of soil, where practical, when the design sampling shows a property exceeds the Midland Action Level.

DEQ Staff Recommendations for a
Site-Specific Residential Direct Contact Cleanup Criterion (SSRDCC) for
Dioxins/Furans Toxic Equivalents (TEQ) for Midland Area Soils

Revised June 1, 2012

A SSRDCC for polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (D/F) has been requested by The Dow Chemical Company (Dow) for Midland Area Soils (Dow, 2010) as allowed by Condition XI.B.3.(b)(iv) of their hazardous waste management facility operating license. This document conveys staff's recommendations to DEQ management about an acceptable SSRDCC. Developing a soil direct contact criterion involves the use of both toxicity values and exposure assumptions. Toxicity values are specific to the chemical or class of chemicals and may include cancer slope factors (CSFs) or noncancer reference doses (RfD). Exposure assumptions may include generic exposure assumptions that are used for state-wide application, chemical specific, and/or site-specific assumptions. Dow has proposed some exposure assumptions changes to be considered for a site-specific criterion.

The DEQ is required, when information is available, to evaluate both cancer and noncancer risk in developing cleanup criteria for a hazardous substance. An oral CSF and a noncancer RfD value have been considered for calculating a SSRDCC for dioxin in Midland Area Soils.

Dioxin can refer to 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), dioxins and furans, or include other dioxin-like chemicals (DLCs). Four terms are used in this document:

- **Dioxin** is used as a general or umbrella term;
- **D/F**(s) refers to dioxins and furans only;
- **DLC** includes D/F and other dioxin-like chemicals such as coplanar polychlorinated biphenyls (PCBs); and
- **TCDD** refers specifically to 2,3,7,8-tetrachlorodibenzo-p-dioxin.

D/Fs and DLCs are found in mixtures and many of these chemicals act through a common mechanism(s) with both demonstrated and assumed additive toxicity. As a result a TEQ approach is used in accordance with Michigan regulations, the U.S. Environmental Protection Agency (EPA), and World Health Organization (WHO) guidance. The DEQ, Dow, and EPA have agreed with the proposal to compare the D/F TEQ (i.e., measured soil concentration) to the proposed action level. Use of the D/F TEQ is based on sampling conducted in 2010 that measured D/F and dioxin-like PCBs. That sampling found that the PCBs contributed negligibly to the TEQ (typically <2% of D/F+PCB TEQ, range 0.01-6.7%).

Toxicity Values

Cancer Slope Factor

The DEQ has used an oral CSF of 75,000 per milligram per kilogram per day (mg/kg-day^{-1}) for TCDD since 1995 for developing Part 201 cleanup criteria. This CSF was developed for 1995 EPA Great Lakes water quality guidance (GLWQG) and is based on the Kociba et al, 1978 rat study and a 1990 reevaluation of the female liver tumor classification from this study by an independent panel of pathologists. The DEQ has determined that this CSF is best available information for a SSRDCC for Midland Area Soils. The DEQ will reassess the dioxin CSF when the EPA provides a new final CSF as part of the ongoing EPA dioxin reassessment/reanalysis. The EPA has provided a draft CSF of 1,000,000 mg/kg-day^{-1} as part of the Draft EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to National Academy of Sciences (NAS) Comments (EPA 2010 Reanalysis). On August 26, 2011, the EPA's Science Advisory Board (SAB) completed a review of this document and indicated that they had significant comments that still need to be addressed by the EPA regarding the proposed CSF. On August 29, 2011, the EPA announced that it will address the SAB comments and complete the cancer portions of the reanalysis after completing the noncancer portion, but that will take some time.

NonCancer RfD or Other Equivalent Value

When information is available for multiple adverse effects of a hazardous substance, an evaluation of both cancer and noncancer adverse health effects is necessary to determine the most sensitive effect for developing cleanup criteria (§324.20120a(4)). As part of the development of the current Part 201 cleanup criteria, noncancer effects were informally evaluated to determine if they would require a cleanup criterion more restrictive than that based on the CSF. At that time, different noncancer criteria were calculated and all were less restrictive than the cancer-based criterion.

New information regarding prenatal and postnatal human effects and changes in risk assessment practices have resulted in the necessity to more closely consider the noncancer adverse effects in developing Part 201 site-specific criteria requiring the use of best available information. Based on this new information, the EPA developed a new oral RfD that was released on February 17, 2012 and posted the final noncancer assessment to the Integrated Risk Information System (IRIS). The associated toxicity assessment released at the same time is the final version of the noncancer portion of the EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to National Academy of Sciences (NAS) Comments, Volume 1 (EPA, 2012). The 2012 EPA RfD is the best available information for assessment of noncancer endpoints. In addition, when the adverse effects are related to early-life exposures, the appropriate sensitive receptor is a child. Therefore, a child receptor is used to develop the noncancer direct contact criterion based on the 2012 EPA RfD.

The noncancer value is the 2012 EPA RfD of 7.0×10^{-10} mg/kg-day from the EPA 2012 reanalysis based on two human studies demonstrating altered thyroid function

(Baccarelli et al, 2008) and impaired adult male reproductive function (Mocarelli, et al, 2008) associated with prenatal and postnatal exposure to TCDD.

The 2012 EPA RfD is based on co-critical studies in humans, Baccarelli et al, 2008 and Mocarelli et al, 2008. The Baccarelli study evaluated serum thyroid stimulating hormone (TSH) levels in neonates born to mothers who were exposed to TCDD 17-29 years prior to pregnancy during the 1976 explosion in Seveso, Italy. The adverse effect was identified as an increase in TSH levels above the WHO standard of 5 μ-units TSH per mL of serum indicating dysregulation of thyroid hormone metabolism. The Mocarelli et al study reported decreased adult sperm concentrations and decreased motile sperm counts in men who were 1-9 years old in 1976 at the time of initial exposure to TCDD from the Seveso accident.

The 2012 EPA RfD uses intake rates derived using the Emond et al human physiologically-based pharmacokinetic (PBPK) model from serum concentrations reported in the studies. For the Baccarelli et al study, the EPA used the study's regression model to estimate a maternal plasma TCDD concentration at the neonatal TSH level of concern and the Emond human PBPK model under the gestational scenario to determine the maternal intake rate lowest-observed-adverse-effect level (LOAEL) of 2.4 $x10^{-8}$ mg/kg-day. For the Mocarelli et al study, since it was not clear whether the effects were related to the peak exposure or to the average exposure, the EPA used the average of the estimated intake rates for both to derive an intake rate LOAEL of 2.0 x 10^{-8} mg/kg-day. The RfD also includes a 30x uncertainty factor, 10 for the LOAEL and 3 for within human variability.

The DEQ evaluated noncancer risk using the 2012 EPA RfD, although Dow did not include an evaluation of noncancer risk in their work plan.

Exposure Assumptions

<u>Oral Bioavailability or Ingestion Absorption Efficiency (Ae_i)</u>
Oral bioavailability is the proportion of an ingested chemical that is absorbed from the gastrointestinal tract into the bloodstream and tissues. Dow has proposed to use an oral relative bioavailability value of 0.26 or 26% based on swine data from a pilot bioavailability study conducted on a single sample to represent Midland Area Soils (Dow, 2010).

Dow proposed, and the DEQ has agreed, to consider the data from a pilot bioavailability study (Dow, 2005) in lieu of Dow conducting a full bioavailability study. This decision was made after review of the data from the pilot studies because the difference in bioavailability values did not appear to be worth the time and cost required to complete a full study.

The pilot study was designed to evaluate two animal models, Sprague-Dawley rats and juvenile swine, for measuring the bioavailability of five important D/F congeners for the

Midland Area Soils and Tittabawassee River floodplain soils to inform the design of a full study. The pilot study was to compare liver and adipose tissue D/F congener levels from soil-fed animals and control animals. The control animals had matched doses of the same congeners in either feed or corn oil vehicle. The results estimate the relative bioavailability between the soil and the vehicle dosing. Objectives were to evaluate the feasibility to detect the D/Fs in the liver and adipose tissue of both animals and evaluate the study designs including the number of animals per dose group. One soil sample each from the two areas of interest was administered for 30 days, in a soil/feed mixture for rats and in soil wrapped in a dough ball for swine. The dosing for control rats included both a feed and corn oil vehicle. The control swine were dosed with an oil vehicle in a gelatin capsule, wrapped in a dough ball.

The results of the pilot study indicated that both animal models had drawbacks. For swine, there was trouble detecting the congener concentrations for the Midland Area Soil, probably due to the rapid growth of the animals during the 30-day study period. The swine study also resulted in fairly large coefficients of variation for the bioavailability values.

The control rats also demonstrated differentially elevated enzyme activity typically induced by dioxin exposure. The studies included measurement of 7-ethoxyresorufin-O-deethylase (EROD) and methoxyresorufin-O-deethylase (MROD) associated with cytochrome P450 enzyme activity to evaluate whether or not differential enzyme induction was occurring between soil-fed and control groups. The soil-fed rats did not eat as much as expected, resulting in a lower D/F dose than the control rats. The control groups had higher EROD activity related to their higher doses than the soil-fed rats. The higher EROD induction in the controls led to speculation that the relative bioavailability estimates may be elevated since the increased metabolic activity could reflect increased elimination of the D/F congeners in the control rats. A follow-up study in rats with the Tittabawassee River floodplain soil and several dose-matched corn oil controls was designed to evaluate whether the increased EROD activity was influencing the bioavailability values (Dow, 2006). This follow-up study demonstrated that when controls with similar dose and EROD activity were used to estimate relative bioavailability, the relative bioavailability was not different from those of the pilot study for 4 of the 5 congeners. The only congener that appeared to be significantly elevated in the pilot study was 2,3,7,8-tetrachlorodibenzofuran (TCDF). TCDF has a much shorter half-life than other D/F congeners with toxic equivalency factors (TEFs), so is more likely to have increased elimination. The TCDF congener contributes an average of only 2.3% to the TEQ for 2006 Midland Area Soil samples. Since TCDF is not an important congener for the Midland area, it was not one of the congeners used in the pilot study to represent dioxin bioavailability for the Midland soil. TCDF is an important congener for the Tittabawassee River floodplain soil.

The conclusion of the follow-up study was that there appeared to be a true difference in bioavailability between the rat and swine studies. It is not clear whether the difference was due to species absorption differences or the soil dosing differences (soil within

normal feed, intermittent intake in rats, or soil within dough balls dosed twice daily, bolus intake in swine).

It is not clear which animal model, swine or rats, best represents the oral bioavailability of dioxin in soil for humans. The DEQ considers an average of the two species oral bioavailability values to be appropriate. Dow argues that the swine are a better model for human gastrointestinal function and only the swine values are appropriate.

A recent EPA report (EPA, 2010b) reviews the available information on the bioavailability of dioxins in soil. This review included the Dow rat and swine pilot and follow-up studies (Budinsky et al, 2008). The EPA's conclusions are that there is not sufficient information to determine a preferred animal model or bioassay protocol for predicting soil relative bioavailability in humans. Part of this determination is based on conflicting results between animals with increasing levels of dioxin chlorination. Rodents appear to have lower bioavailability with increasing chlorination, as would be expected. The swine appear to have higher bioavailability with increasing dioxin chlorination based on the limited swine studies available.

The stated primary purpose of the EPA, 2010b report was to evaluate whether an adjustment is necessary to account for differences in the bioavailability of dioxins in soil and the absorption of the contaminant in the test medium (ABS_{GI}) used in the critical study(s) on which the CSF and/or RfD were based (e.g., dietary exposure vs. exposure to soil). The conclusion was that this type of adjustment was appropriate, but there was not sufficient information available to establish a nationwide default value. Since the bioavailability must be evaluated relative to the test medium for the critical toxicity study, the appropriate value to use for Midland Area Soils is relative to the feed control in the rats and the dough-ball control in the swine for the current cancer slope factor.

For the 2012 EPA RfD, an absolute oral bioavailability value was used by the DEQ to calculate a Midland site-specific noncancer criterion to evaluate the Midland Action Level proposed by Dow based on calculation of a cancer criterion. In April 2012, the EPA clarified to the DEQ that the RfD was adjusted by incorporating into the physiologically-based pharmacokinetic (PBPK) model an input of 87% as the ABS_{GI} based on uptake of TCDD from corn oil measured as part of a human study (Poiger and Schlatter, 1986). The calculation for noncancer adverse effects did not include consideration of this adjustment, but assumed there was no adjustment (i.e., 100% ABS_{GI}). Further discussion of this decision is in the Summary section of this document.

One of the considerations for the bioavailability values is how to address different congeners that are contributing to the TEQ. Dow proposed to use a TEQ-weighted average from the five congeners evaluated in the bioavailability study to represent the total TEQ bioavailability. The five congener distribution of the single test soil is provided in Table 3 (attached) and compared to the average congener distribution of samples collected in 2006 for Midland Area Soils. The 2006 soil sampling was conducted to represent soil concentrations and characteristics for the design of a full bioavailability study. The five congeners in the test soil contributed 88% of the TEQ for that soil. The

congener distribution of the single test soil is not the same as the average of the 2006 soil samples. The five congeners tested for bioavailability only represent 78% of the average TEQ for the 2006 soil samples. The test soil also has a higher contribution from TCDD and 1,2,3,7,8-pentachlorodibenzo-p-dioxin (PeCDD) to the TEQ with the higher chlorinated dioxins underrepresented as compared to the average of the 2006 samples. In developing a fast analytical technique for further sampling in Midland Area Soils, Dow has determined, and DEQ concurs, that 13 of the 17 TEF congeners must be included to adequately represent the TEQ. Therefore, 22% of the TEQ typical for Midland Area Soils is not adequately represented by the bioavailability value obtained from the pilot study.

As a result of these considerations, the DEQ has adjusted the pilot bioavailability values using the following averages in sequence:

- Average of TEQ weighting from the congener distributions between the test soil and the average 2006 soil samples for both the rat relative to feed and swine relative to dough-ball control,
- Average of the reported swine values at both ½ the detection level and the detection level, and
- Average of the rat and swine averages.

The above values are displayed in Table 3. The calculations have resulted in an average TEQ weighted relative to feed bioavailability value of 0.38 or 38%. This is the recommended value for the use with the toxicity values where the test medium was feed, i.e., 1995 GLWQG oral SF. The value recommended for Midland Area Soils as best available information for oral absorption efficiency is 0.38 relative bioavailability for use with the 1995 GLWQG oral SF.

For the 2012 EPA RfD, which is based on human studies where intake doses were estimated from blood levels, the assumed test medium for the PBPK model was corn oil in humans. An absolute bioavailability value of 0.26 or 26% (Table 4) for both the rats and swine with the same considerations as above was used to evaluate the proposed Midland Action Level. Further discussion of the clarification by EPA on the human bioavailability assumption of 87% used for the PBPK model in developing the RfD is provided in the Summary section of this document.

<u>Dermal Bioavailability or Dermal Absorption Efficiency (Ae_d)</u>

Dermal bioavailability is the amount of chemical that enters the body when applied to skin. As with oral bioavailability, this value can be an absolute bioavailability value or a value relative to the vehicle used for the toxicity study that serves as the basis of a toxicity value. The generic dioxin dermal absorption efficiency in the current Part 201 rules is 0.03 or 3%. The DEQ agreed to a value of 0.0175 or 1.75% as the appropriate value for typical Michigan soils during discussions with Dow. This value was developed for soils with an f_{oc} of 0.45% (consistent with soils in Michigan) based on adjusted human AE_d values for TCDD reported as 0.0095 (0.95%) and 0.025 (2.5%) (EPA, 1991). These values were calculated from mean percents absorbed for four or five test animals or excised skin samples and, therefore, represent average values. Human *in*

vitro data from excised skin samples were adjusted using the ratio of animal *in vivo*/animal *in vitro* to derive the estimated human *in vivo* value of 0.0095 (0.95%). Animal *in vivo* data were adjusted using the ratio of human *in vitro*/animal *in vitro* to derive the estimated human *in vivo* value of 0.025 (2.5%). Both approaches are equally valid and provide estimates of average human dermal absorption efficiency for TCDD. Therefore, the DEQ suggests a midpoint value of 0.0175 (1.75%) for the dermal bioavailability (AE_d) to calculate soil direct contact criteria.

The values reported above are absolute percutaneous absorption values. As described above for the oral bioavailability, a percutaneous absorption value must be adjusted for the absorption of the contaminant from the test medium (ABS_{GI}) used in the toxicity study that serves as the basis of the oral toxicity value. This adjustment is of even greater importance for dermal absorption (EPA, 2004). The rat feed results from the pilot study were used assuming 80% absorption for the corn oil gavage to calculate an absolute bioavailability value for the feed of 0.55 (55%) as the ABS_{GI} value from the EPA dermal guidance.

The soil dermal absorption rate of 0.0175 divided by the feed absolute bioavailability value (ABS_{GI}) of 0.55 resulting in a relative bioavailability value of 0.032 (3.2%) is recommended as best available information applied to the 1995 GLWQG CSF based calculation.

The dermal absorption efficiency of 0.0175 for soil was applied to the 2012 EPA RfD based calculation. A discussion of the decision to use this soil dermal absorption rate for criterion calculations with the 2012 EPA RfD is provided in the Summary section of this document.

<u>Exposure Frequency</u>
Dow proposed using local climate data to adjust outdoor soil exposure frequency to only those days above freezing air temperature with no significant precipitation. The DEQ reviewed the original basis for the statewide default value and the available local climate data. The DEQ and EPA have typically based outdoor vs. indoor exposure on days with snow cover (e.g., >1 inch) and/or frozen soil (e.g., maximum soil temp <32° F). The DEQ accepts that these conditions define the number of days with only indoor dust exposure. The available local climate data (NOAA, 2010 and MSU, 2010) for 2005-2009 indicates the number of days with either snow cover or frozen soils (≤32°F) is 90 days (88.8-91.8 days potential range for days with missing data) resulting in 275 days when the soil is not frozen or there is less than an inch of snow cover. The default value for residential exposure is 350 days per year (accounting for 15 days per year the receptor is assumed to be away from home). The outdoor exposure for the SSRDCC would be 260 days (275-15 days spent away from home). This site-specific exposure frequency value is greater than the default value of 245 days.

Dow proposed to split the soil ingestion between outdoor soil exposure and indoor dust exposure. The soil-to-dust ratio proposed is based on a linear regression model from the University of Michigan, Dioxin Exposure Study (UMDES). The DEQ does not agree

to use the linear regression as proposed by Dow. The DEQ has previously determined that the model is confounded with collinear parameters and sampling weights, and thus would only be willing to accept the paired data without the model influences. Dow has not provided any other representation of the paired dust/soil data to the DEQ, only the model predictions. Based on the unpaired data and the model prediction, the soil-to-dust contribution appears to be in the range of 35% (model predicted) to 50% (fractional TEQ concentrations 0.30-0.54 from unpaired summary statistics). The median value (~50%) is preferred as most representative without paired soil-to-dust data. The DEQ remains willing to reconsider this prorated house dust concentration based on paired soil and dust data for the Midland Area Soils.

The DEQ considers a split between soil and dust exposure to be appropriate for both soil ingestion and dermal contact with similar adjustments to the dermal exposure frequency. Dow proposed a fifty-fifty split between soil and dust exposure that was included in the calculations for outdoor days with all of the exposure for indoor days coming from dust.

Consequently, the values recommended as best available information for Midland Area Soils are:

- Site-specific 260 outdoor exposure days per year for soil,
- 350 days per year for dust,
- half of average daily ingestion rate each for soil and dust, and
- 0.5 fractional dust concentration from soil, unless paired soil-to-dust data is provided by Dow to revise this value.

Soil Ingestion Rate for Children

Dow proposed to change the soil ingestion rate for children from 200 mg/day to 100 mg/day described as a central tendency in the 2008 EPA Exposure Factors Handbook (EFH) for children without pica or geophagy behavior. The DEQ Toxics Steering Group (TSG), Children's Environmental Health Subcommittee had recently reviewed the 200 mg/day children's soil ingestion rate for DEQ, Remediation Division (RD), and recommended retaining the 200 mg/day value. An upper bound on the central tendency for children's soil ingestion is 200-270 mg/day according to Ms. Jackie Moya, the primary author of the 2008 EPA EFH. The EPA regional screening levels continue to use 200 mg/day for the children's soil ingestion rate (<http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/usersguide.htm>). Based on this information the RD determined that the 200 mg/day value for children under the age of 6 is the best available information.

Calculation of recommended values for a Midland Area Soils SSRDCC uses the 200 mg/day soil ingestion rate value for children.

Relative Source Contribution (RSC)

Section 20120(a)(4) states: "For the noncarcinogenic effects of a hazardous substance present in soils, the intake shall be assumed to be 100% of the protective level, unless compound and site-specific data are available to demonstrate that a different source

contribution is appropriate." Part 201 provides for the application of a factor to account for "source contributions" other than the pathway under consideration in the development of soil cleanup criteria. Part 201 specifies a default value of one (100%) unless data are available to justify a chemical-specific value. Consideration of source contribution for carcinogenic effects is not provided for under Part 201.

The DEQ applies exposure data where available and of sufficient quality to choose an appropriate RSC. Data are available for DLCs primarily due to the highly toxic nature of these chemicals and public concerns related to their health effects.

The available data indicate that TCDD and related compounds are ubiquitous in the diet of U.S. residents. There are numerous studies of DLCs in dietary items including studies conducted by the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and Health Canada (HC) on dietary items, although many only included D/Fs, without dioxin-like PCBs. The FDA has used Total Diet Study (TDS) data from 2001-2004 to estimate average per capita dietary intakes of D/Fs for various age groups (FDA, 2007). Lorber et al, 2009 and Lorber et al, 2010 provided an analysis of USDA beef, pork, and poultry data and National Health and Nutrition Examination Survey (NHANES) 2001/2002 blood data for adults to evaluate trends. Although the interpretation of the trend data was difficult due to differences in methods, analytes, and detection limits between studies at different time periods, there does appear to be a downward trend in exposure levels for most DLCs and TEQ. Lorber et al, 2010 has used the most recent FDA, USDA, and HC data to update adult intake estimates to determine an average intake of 33.5 pg TEQ/day for D/Fs and PCBs for adults in the U.S. This evaluation indicates that the average dietary intake of DLCs has decreased.

<u>RSC with respect to the 2012 EPA RfD</u>
Staff recommends that it is not appropriate to use an RSC of less than one in the calculation of a criterion using the 2012 EPA RfD for the reasons described below. The 2012 EPA RfD is based on exposure to TCDD alone, since the Seveso explosion was a release of TCDD and reference toxicity values have typically been developed for TCDD. However, the available information indicates that the study populations that serve as the basis of this RfD had typical exposures to other DLCs at the time of their measured TCDD exposure.

Baccarelli et al, 2008 reported a mean maternal D/F and coplanar PCB (DFcP) TEQ of 44.8 ppt for plasma samples collected between 1992 and 1998 for a subset of the exposed mothers from Seveso. The calculated mean DFcP TEQ without TCDD is 25.9 ppt for this co-critical study. For comparison to U.S. adults in the mid 1990s and 2001/2002, Lorber et al, 2009 reported mean serum DFcP TEQ of 17.2-22.9 ppt and calculated DFcP TEQ without TCDD of 16.5-20.7 ppt. Patterson et al, 2008 reported 90th and 95th percentiles for U.S. women from the 2001-2002 NHANES data. The 90th and 95th percentile DFcP concentrations for women aged 20-39 years were 23.1 ppt and 26.4 ppt, respectively, and for women aged 40-59 years were 33.5 ppt and 46.9 ppt, respectively. From available data in Michigan, the mean and 95th percentile

values for DFcP TEQ (without TCDD) are 6.2 (5.3) ppt and 9.1 (8.0) ppt, respectively for adults from the Midland Plume,18-29 years old(n=3); 12.8 (11.5) ppt and 17.3 (15.1) ppt, respectively, for adults from the Midland Plume, 30-44 years old (N=9); 7.3 (6.6) ppt and 10.4 (7.3) ppt for adults in the Jackson/Calhoun reference area, 18-29 years old (n=16); and 13.8 (12.8) ppt and 23.3 (21.4) ppt, respectively, from the Jackson/Calhoun reference area for adults, 30-44 years old (n=66)(UMDES, 2008).

The Mocarelli et al study had only TCDD data available for their subjects due to sample volume for the individual samples. The only data for other DLCs from the appropriate time frame (soon after the 1976 explosion) are from pooled serum samples from female residents of the reference area outside the area impacted by TCDD that were analyzed for DFcP TEQ (Eskenazi et al, 2004). Two pooled serum samples were analyzed for the 0-12 year age group. The reported concentrations were 119.5 ppt and 113.6 ppt for serum DFcP TEQ and calculated DFcP TEQ without TCDD are 71.9 ppt and 80.2 ppt for this age group. These concentrations were reported as within the range of levels typical for persons tested in Europe around the same time period. Representative data for U.S. or Michigan populations were not available for comparison purposes for the age groups of interest. Based on decreases in adult serum concentrations since that time frame in the U.S. and child serum concentrations reported from elsewhere (Burns et al, 2009; Link et al, 2005; and Tohyama et al, 2011), the late 1970s Seveso reported concentrations are well above those expected for children in Midland today.

From the available data, it appears that the subjects of both the Mocarelli et al and Baccarelli et al studies had exposure to background concentrations of non-TCDD TEQ that were above, or well above, current measured or expected levels. This evaluation is supported by other data that show decreasing exposures to D/F TEQ since the 1970s. The 2012 EPA RfD is based only on TCDD exposure and did not take into account other DLC exposure in the study groups that serve as the basis for the RfD. Therefore, calculating a criterion using a RSC less than one for this RfD is not appropriate based on the information currently available and the basis of this RfD.

Summary

The DEQ is required, when information is available, to evaluate both cancer and noncancer risk in developing cleanup criteria for a hazardous substance. An oral CSF and a noncancer RfD value have been considered for calculating a SSRDCC for dioxin in Midland Area Soils.

The toxicity values and exposure assumptions used in the residential direct contact criteria calculations are presented in Table 1 for the cancer calculation and Table 2 for the noncancer calculation.

The SSRDCC uses the algorithm and, except for those identified as site-specific below, the exposure assumptions for the generic residential criteria for other chemicals pursuant to R 299.5720. Site-specific information is considered for some of the exposure assumptions in the calculation for a SSRDCC for dioxin in Midland Area Soils.

After evaluation of proposed changes to exposure assumptions for a dioxin SSRDCC, the following values are recommended as being best available information for the purpose of calculating a SSRDCC for Midland Area Soils:

- Soil oral bioavailability of 0.38 relative bioavailability and 0.26 absolute bioavailability based on site-specific information;
- Soil exposure frequency (incidental ingestion and dermal contact) of 260 outdoor days/year and dust exposure frequency of 350 days/year based on site-specific information (incidental ingestion and dermal contact for both soil and dust);
- Soil and dust each contribute half of the soil/dust exposure for the 260 outdoor days, the other 90 days are 100% dust exposure;
- Fractional concentration of TEQ for dust from soil of 0.5;
- Child soil ingestion rate of 200 mg/day based on a recent reevaluation of this generic assumption by DEQ, no change from previous generic assumption;
- Soil dermal bioavailability of 0.032 relative bioavailability and 0.0175 absolute bioavailability; and
- Relative source contribution for soil exposure to TEQ of 1 is appropriate for the 2012 EPA RfD.

In addition, a child only receptor was used to calculate the noncancer cleanup value, since the noncancer RfD is based on prenatal and postnatal early life exposures.

These recommended exposure assumptions result in a cancer value of 260 parts per trillion (ppt). The noncancer value based on human data from the 2012 EPA RfD and the recommended assumptions is 260 ppt.

As stated above in the Oral Bioavailability or Ingestion Absorption Efficiency (Ae_i) and Dermal Bioavailability or Dermal Absorption Efficiency (Ae_i) sections, EPA provided the DEQ a clarification that the 2012 EPA RfD did include an assumption of 87% oral bioavailability as part of the PBPK model. The DEQ has evaluated this information with the following considerations:

The Midland site specific noncancer criterion could be recalculated to account for this adjustment within the development of the RfD. Two approaches could be considered for this adjustment:

1. Adjust the absolute bioavailabilities (both oral and dermal) previously used for the calculation by dividing the values by the fractional absorption used in the PBPK model. This would result in a cleanup criterion of 230 ppt.
2. Use the Dow, 2005, pilot study bioavailability value relative to corn oil for the rat and the dough ball for the swine in the calculation of the noncancer oral bioavailability value. The dermal bioavailability value would be adjusted by dividing the absolute percutaneous absorption value by the fraction absorption used in the PBPK model. This would result in a cleanup criterion of 220 ppt.

The Midland Site Specific Action Level could remain as proposed based on the following considerations:

- EPA guidance recommends not making these adjustments unless the ABS_{GI} from the critical toxicity study is significantly less than 100%. Their recommended cutoff is 50%. The 87% ABS_{GI} included in the PBPK model for the 2012 EPA RfD is close to 100%, although we did adjust the bioavailability relative to feed (at 55%) for the cancer slope factor since it was close to the 50% recommended cutoff.
- The RfD is based on the exposure to TCDD alone. The study groups that are the basis of the RfD were also exposed to other DLCs. The study groups exposure to other DLCs was greater, even much greater, than has been observed or would be expected for background exposures in Midland as described in the Relative Source Contribution section of this document resulting in additional conservatism in the calculated cleanup criterion.

Based on the above considerations, the DEQ has concluded it is appropriate to approve the site-specific Midland Action Level of 250 ppt TEQ.

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Table 1. Assumptions for cancer residential direct contact criterion (DCC)

Assumptions for Cancer Risk Criteria Calculations	**Current Residential DCC (90 ppt)**	**Current Default Assumptions for Other Chemicals**	**Recommended Assumptions for SSRDCC with 1995 EPA GLWQG CSF**
Toxicity Assumptions			
Oral Cancer Slope Factor $(mg/kg\text{-}day)^{-1}$	75,000	NA – chemical specific	75,000
Target risk level	$1x10^{-5}$	$1x10^{-5}$	$1x10^{-5}$
Exposure Assumptions			
Averaging Time (years)	70	70	70
Exposure Duration (years)	30 6 (0-6 child) 24 (>6-adult)	30 6 (0-6 child) 24 (>6-adult)	30 6 (0-6 child) 24 (>6-adult)
Body Weight (kg)	15 (0-6 child) 70 (>6-adult)	15 (0-6 child) 70 (>6-adult)	15 (0-6 child) 70 (>6-adult)
Ingestion Exposure Frequency – Soil (days/year)	350*	350*	**260**
Ingestion Exposure Frequency – Dust (days/year)	NA(350)*	NA(350)*	**350**
Soil Ingestion Rate (mg/day)	200 (0-6 child) 100 (>6-adult)	200 (0-6 child) 100 (>6-adult)	200 (0-6 child) 100 (>6-adult)
Oral Bioavailability – Ingestion Absorption Efficiency (fraction)	0.5	NA – chemical specific	**0.38**[@]
Dermal Exposure Frequency – Soil (days/year)	245*	245*	**260**
Dermal Exposure Frequency – Dust (days/year)	NA(245)*	NA(245)*	**350**
Skin Surface Area (cm^2)	1820 (0-6 child) 5000 (>6-adult)	2670 (0-6 child) 5800 (>6-adult)	2670 (0-6 child) 5800 (>6-adult)
Adherence Factor (mg/cm^2)	1.0 (0-6 child) 1.0 (>6-adult)	0.2 (0-6 child) 0.07 (>6-adult)	0.2 (0-6 child) 0.07 (>6-adult)
Dermal Bioavailability – Dermal Absorption Efficiency (fraction)	0.03	NA – chemical specific	0.32 =0.0175*0.55[@]
Dust/Soil Concentration Ratio	NA(1)*	NA(1)*	**0.5**
Proportion of Outdoor Days Attributable to Dust and Soil	NA(1)*	NA(1)*	**0.5**

Bold values are based on site-specific information.
*Soil and dust exposure are not evaluated separately for generic criteria.
[@]Soil bioavailability is relative to toxicity study exposure medium (e.g., animal feed) bioavailability.

Table 2. Assumptions for noncancer residential direct contact criterion

Assumptions for NonCancer Risk Criteria Calculations	**Current Generic Assumptions for Other Chemicals**	**Recommended Assumptions for SSRDCC with 2010 Draft EPA RfD**
Toxicity Assumptions		
Oral Reference Dose (RfD - mg/kg-day)	NA – chemical specific	0.0000000007
Uncertainty Factors	NA – chemical specific	30
Exposure Assumptions		
Averaging Time (years)	30	6
Exposure Duration (years)	30 6 (0-6 child) 24 (>6-adult)	6 6 (0-6 child)
Body Weight (kg)	15 (0-6 child) 70 (>6-adult)	15 (0-6 child)
Relative Source Contribution (fraction)	NA – chemical specific (Rule 752 =0.2)	1[+]
Ingestion Exposure Frequency – Soil (days/year)	350*	**260**
Ingestion Exposure Frequency – Dust (days/year)	NA(350)*	**350**
Soil Ingestion Rate (mg/day)	200 (0-6 child) 100 (>6-adult)	200 (0-6 child)
Oral Bioavailability – Ingestion Absorption Efficiency (fraction)	NA – chemical specific	**0.26**[^]
Dermal Exposure Frequency – Soil (days/year)	245*	**260**
Dermal Exposure Frequency – Dust (days/year)	NA(245)*	**350**
Skin Surface Area (cm^2)	2670 (0-6 child) 5800 (>6-adult)	2670 (0-6 child)
Dermal Adherence Factor (mg/ cm^2)	0.2 (0-6 child) 0.07 (>6-adult)	0.2 (0-6 child)
Dermal Bioavailability – Dermal Absorption Efficiency (fraction)	NA – chemical specific (Rule 752 =0.03)	0.0175[^]
Dust/Soil Concentration Ratio	NA(1)*	**0.5**
Proportion of outdoor days attributable to Dust and Soil	NA(1)*	**0.5**

Bold values are based on site-specific information.
*Soil and dust exposure are not evaluated separately for generic criteria.
[^]Absolute bioavailability value.
[+]See text for explanation.

Table 3. Relative Bioavailability for Midland Test Soil and Animal Feed Intake

Congeners Tested	**Congener Distributions (CD)**		**Bioavailability Values**					
	Pilot Study Test Soil, CC-S-27S (n=1) % Soil TEQ	**Average 2006 Soil Samples (n=72) % Soil TEQ**	**Rat**		**Swine**			
			Soil vs. Ref. Feed		**½ D.L.**		**D.L.**	
			Liver + Adipose	**C.V.**	**Liver + Adipose**	**C.V.**	**Liver + Adipose**	**C.V.**
2,3,7,8-TCDD	49	40	43	16	18	43	22	20
1,2,3,7,8-PeCDD	25	20	55	13	24	41	34	20
1,2,3,6,7,8-HxCDD	2.7	4.6	64	11	38	55	45	32
1,2,3,4,6,7,8-HpCDD	4.3	8.3	58	10	55	32	55	32
2,3,4,7,8-PeCDF	6.7	5	50	10	32	31	41	19
Test Congeners % of Soil TEQ	88	78						
TEQ-Weighted Relative Bioavailability as % (Pilot Soil CD/ Avg. 2006 CD)			48/49		23/26		29/31	
Average Species Relative Bioavailability as %			49		27			
Average Overall Relative Bioavailability as %			38					
Average Overall Relative Bioavailability as Fraction			0.38					

Table 4. Absolute Bioavailability for Midland Test Soil

Congeners Tested	**Congener Distributions (CD)**		**Bioavailability Values**		
	Pilot Study Test Soil, CC-S-27S (n=1) % Soil TEQ	**Average 2006 Soil Samples (n=72) % Soil TEQ**	**Rat**	**Swine**	
			Soil vs. Ref. Feed	**½ D.L.**	**D.L.**
			Liver + Adipose	**Liver + Adipose**	**Liver + Adipose**
2,3,7,8-TCDD	49	40	28	15	18
1,2,3,7,8-PeCDD	25	20	32	19	27
1,2,3,6,7,8-HxCDD	2.7	4.6	37	31	36
1,2,3,4,6,7,8-HpCDD	4.3	8.3	27	44	44
2,3,4,7,8-PeCDF	6.7	5	32	25	33
Test Congeners % of Soil TEQ	88	78			
TEQ-Weighted Absolute Bioavailability as % (Pilot Soil CD/ Avg. 2006 CD)			30/30	19/21	24/25
Average Species Absolute Bioavailability as %			30	22	
Average Overall Absolute Bioavailability as %			26		
Average Overall Absolute Bioavailability as Fraction			0.26		