October 2015

ATTACHMENT H

Part 201 Generic Exposure Assumption Values Update

TECHNICAL SUPPORT DOCUMENT

SUBJECT: BODY WEIGHT (BW)

MDEQ Introduction

MDEQ contracted SRC, Inc. to evaluate and update the exposure assumptions and fate and transport values, consistent with the Collaborative Stakeholder Advisory (CSA) recommendations. This work is a component of the DEQ's comprehensive cleanup criteria update and is incorporated in the calculations of the health-based cleanup values. The CSA recommendations pertinent to exposure assumptions and fate and transport values are presented in the Decision Framework for Determination of Exposure Values (CSA, 2014). To satisfy the "best available information" requirement of the Framework, SRC followed the Framework's process for evaluating data against the Data Quality Objectives (DQOs) and selecting the values for their recommendations. Refer to the CSA Report (2014) and Cleanup Criteria and Screening Levels Development and Application Resource Materials Section 4.3.

Background

This Technical Support Document (TSD) describes the process used to update generic exposure assumption values for body weight (BW) for use by Michigan Department of Environmental Quality (MDEQ) in deriving Part 201 generic cleanup criteria. The TSD follows the Decision Framework for Updating the Michigan Part 201 Generic Cleanup Criteria Exposure Assumptions (TAG, 2014). As outlined in the Decision Framework, the update process involves searching for Michigan-specific data pertinent to each exposure assumption, revised U.S. Environmental Protection Agency (EPA) exposure assumptions, and other sources of relevant data (e.g., state and federal government agencies, published literature), and evaluating both the existing and any new information against the Data Quality Objectives (DQOs) provided in the Decision Framework.

To identify new information pertinent to each exposure assumption, the following search process was followed. First, Michigan government agencies and select research universities were contacted to determine if relevant data could be provided. Second, exposure parameters recommended by U.S. EPA's most recent (2011) Exposure Factors Handbook and U.S. EPA's (2014) Office of Solid Waste and Emergency Response (OSWER) were considered. Third, searches of the published scientific literature for data or analyses specific to Michigan or to the

U.S. as a whole were conducted. U.S. EPA (2011) performed comprehensive searches of scientific literature and other data sources, and indicated that the document included literature published through July, 2011. For the purpose of this TSD, searches of the published literature were restricted to papers published in 2009 or later. An earlier date than 2011 was selected to ensure that no papers published near the time of completion of the 2011 document were missed. Fourth, websites for U.S. governmental organizations were searched for readily accessible data relevant to the exposure assumptions. Fifth, selected state (including Illinois, Indiana, Minnesota, Ohio, Wisconsin, California, Oregon, Washington, Texas, and Massachusetts) and international (Health Canada and Environment Canada, Ontario Ministry of the Environment, European Commission Joint Research Centre [ECJRC], and the European Centre for Ecotoxicology and Toxicology of Chemicals [ECETOC]) environmental agency websites were searched to identify default exposure assumptions used by these agencies.

The TSD describes the results of each of the searches and the evaluation of new, relevant information against the DQOs. The DQOs in the framework (TAG, 2014) address the following:

- Relevant and applicable to Michigan;
- Clear and comprehensive;
- Sound and credible;
- Transparent and objective; and
- Certainty.

The 2005 exposure assumptions and new relevant information were evaluated against the DQOs and given a rating of high, medium, or low; an explanation of the ratings is provided as Appendix A of this document. Based on the ratings, the data or information that best meets the DQOs are recommended as the basis for updated values.

The algorithms used by MDEQ to derive Part 201 generic cleanup criteria employ a combination of central tendency and upper percentile estimates for exposure parameters. Specifically, in accordance with U.S. EPA guidance (1992), central tendency values are used for life span, body weight, and surface area, while high-end values are used for exposure duration, exposure frequency, soil ingestion rate, and soil adherence factor. Thus, the recommendations for BW presented in this TSD are based on central tendency values.

Introduction

This TSD consists of one section. Table 1 below provides a comparison of the MDEQ (2005) and 2015 updated values for BW.

Table 1. Summary of 2005 and 2015 updated MDEQ values for BW (kg)

	2005 MDEQ value	2015 Updated BW
$BW_{ages <2}$ = Body weight: ages < 2	NV	9.6
$BW_{ages 2-<6}$= Body weight: ages 2 to <6	NV	17
$BW_{ages birth-<6}$ = Body weight: ages birth to <6	15	15
$BW_{ages 6-<16}$= Body weight: ages 6 to <16	NV	44
$BW_{ages 16-<EDr}$= Body weight: ages 16 to <EDr[a]	NV	77
$BW_{ages 6-<EDr}$= Body weight: ages 6 to <EDr[a]	70	65
BW_{adult}= Body weight: adult	70	80
BW_{nrdev}= Body weight: nonresidential, developmental toxicant		
1st trimester	NV	76
2nd trimester	NV	73
3rd trimester	NV	80
All trimesters	NV	75

[a]EDr is exposure duration for the residential scenario. MDEQ (2005) used 30 years for EDr (and thus $BW_{ages 6-30}$ and $BW_{ages 16-30}$), while the 2015 updated value for EDr is 32 years.
NV = no value

Section 1. Body Weights (BW)

1.1. Introduction

By risk assessment convention, exposure to chemical substances is normalized to BW. For residential exposure scenarios, MDEQ uses BWs for specific age groups corresponding to ages of particular susceptibility to exposure (e.g., soil ingestion) or effects (e.g., carcinogenicity from mutagenic compounds). For nonresidential exposure scenarios, the adult BW (or pregnancy BW for pregnant worker) is used.

1.2. MDEQ (2005) Value

1.2.1. Description of MDEQ (2005) Value

MDEQ (2005) recommended a BW of 15 kg for young children (<1 to 6 years old) and a BW of 70 kg for youth and adults age 6+ years for the residential scenario and for adults in a nonresidential exposure scenario. These BWs represent central tendency estimates and are based on the U.S. EPA (1989) Exposure Factors Handbook and U.S. EPA (1991). U.S. EPA (1989) indicated that the original analysis of BW was reported in U.S. EPA (1985); the latter document indicated that the BW values were estimated using data from National Health and Nutrition Examination Survey (NHANES) II. NHANES, conducted annually by the National Center for Health Statistics (NCHS) within the Centers for Disease Control and Prevention (CDC), began in the 1960s to assess the health and nutritional status of children and adults in the U.S. Beginning in 1999, the survey became a continuous program with data collection every 2 years. NHANES is a national survey in which a sample of the U.S. population answers

questions regarding health and nutrition and undergoes a medical examination that includes measurement of BW. NHANES is intended to sample a broad distribution of the population, and subjects include children of all ages as well as pregnant women and other adults.

1.2.2. Evaluation of Data Quality Objectives

The BW values recommended by MDEQ (2005) were evaluated using the Part 201 DQOs. A summary of the evaluation follows.

Relevance and applicability to Michigan (g*eographic, temporal, and demographic representativeness*). NHANES II was conducted between 1976 and 1980 and was designed to represent the non-institutionalized civilian population of the United States; BWs were measured at various times of day and in different seasons. Moffatt et al. (1980) compared BWs measured in adults 1978 in Michigan with national averages from NHANES I (1971-1974). When compared to the data from NHANES I, BWs of Michigan men and women were on average 1.8 and 1.2 kg (respectively) higher than the national male population, and BWs of Michigan women were 1.2 kg higher than the national female population. Whether the BW disparity between BWs in Michigan and the U.S. population observed by Moffatt et al. (1980) persisted through the timeframe of the NHANES II survey is not known; thus, the representativeness of the national estimates used by MDEQ (2005) is unclear. However, the data upon which the MDEQ (2005) BW values are based were collected ~35 years ago, and BWs of U.S. residents have changed over time. Rating: Low.

Clarity and comprehensiveness (completeness of method and data reporting, completeness of literature search). The information considered by U.S. EPA (1985, 1989) as potentially relevant to the selection of BW values appears to be comprehensive, and the document provides a thorough discussion of the basis for the values recommended. U.S. EPA (1985, 1989) did not indicate the number of nonrespondents in the NHANES II survey, but did use sample weights to adjust for nonresponse. Rating: Medium.

Soundness and credibility (*adequacy of approach; intrinsic sources of bias; sample size*). U.S. EPA (1985) described the NHANES II survey used as the basis for BW values reported therein and in U.S. EPA (1989). As described by U.S. EPA (1985), NHANES II collected BW data on 20,322 subjects; the number of children sampled was not reported. Because children and adults classified as living at or below poverty level were assumed to be at special risk of nutritional problems, they were sampled at substantially higher rates than the general population. Because of the biased sampling design, the data were weighted to ensure that the resulting statistics reflected the true distribution of persons across socioeconomic strata in the United States. BWs were measured during examination by trained medical professionals using calibrated self-balancing scales that mechanically printed weights rounded to quarter-pound

intervals onto a permanent record. U.S. EPA (1985) performed statistical analyses of sample-weighted BWs; the sample weights addressed individual selection probability, adjustments for nonresponse, and post-stratification adjustments. Rating: High.

Transparency and objectivity (availability of supporting data; funding source; peer-review). U.S. EPA (1985) was a report prepared by GCA Corporation under contract to the U.S. EPA. The report does not indicate whether the analysis contained therein was subjected to peer review; presumably, it did receive internal U.S. EPA review prior to publication. The U.S. EPA (1989) Exposure Factors Handbook, which also used the BW data from U.S. EPA (1985), received both internal and external peer review. Both reports are available on the internet. NHANES II was a major program of the National Center for Health Statistics (NCHS) within the Centers for Disease Control and Prevention (CDC), which provides the funding for the survey and data collection. Rating: High.

Certainty (number and agreement of studies). The BWs used by MDEQ (2005) are based on analysis and recommendations published in U.S. EPA (1985, 1989), which were derived from the NHANES II (NCHS, 1983). U.S. EPA (1985, 1989) considered other published data on BW from the first NHANES survey as well, but only used data from the later study. Although only a single NHANES dataset was used, NHANES is a large survey intended to generate data representative of the entire U.S. Rating: Medium.

1.3. Evaluation of New Information Using Decision Framework

1.3.1. Michigan-Specific Data

1.3.1.1. Summary of Search Results

MDEQ Remediation and Redevelopment Division (RRD) was contacted by email and phone to determine if the agency was aware of research or could provide data pertinent to BWs of Michigan residents; however, the Department was not aware of research or data relevant to this exposure parameter. As discussed below, additional agencies and research universities were also contacted by email and phone to determine if any was aware of research or could provide data pertinent to BWs of Michigan residents.

Michigan Department of Community Health collects clinical measurements of BW from newborn infants' birth certificates, as well as the mother's pre-pregnancy weight. The Michigan Care Improvement Registry (MCIR), within the Michigan Department of Health and Human Services (MDHHS), models BMI data for individuals less than 18 years of age based on voluntary, self-reported height and weight information, but reporting is not mandated, and self-reported data are often unreliable. The Injury and Violence Prevention Section of MDHHS collects BW data from the Vital Records and Health Data Services Section of the Division for Vital Records and Health Statistics, but the data are only from birth and death certificates. The Lifecourse

Epidemiology and Genomics Division of the Bureau of Disease Control, Prevention and Epidemiology in MDHHS has BW data for Michigan residents, but they are self-reported data collected as part of the Michigan Behavioral Risk Factor System, the Pregnancy Risk Assessment Monitoring System, and the Youth Risk Behavior Survey. The Women, Infant and Children's (WIC's) Supplemental Nutrition Program measures BWs of low income children and their mothers who participate in the WIC program; however, these data would not necessarily be representative of all residents. The Secretary of State has self-reported BW information from drivers' licenses, but, as noted earlier, self-reported data are not reliable. Given that all of the BW data available for Michigan residents are either self-reported or not representative of the Michigan population as a whole, they are not useful for the purposes of this evaluation.

1.3.2. Most Recent EPA Recommended Value(s)

1.3.2.1. Summary of Search Results

The U.S. EPA (2011) Exposure Factors Handbook recommended mean BWs based on NHANES 1999-2006 data for a number of age groups, as shown in Table 2 below.

Table 2. Body Weights Reported in U.S. EPA (2011)

	Mean BW (kg)
Ages 0 to <1 mo	4.8
Ages 1 to <3 mo	5.9
Ages 3 to <6 mo	7.4
Ages 6 to <12 mo	9.2
Ages 1 to <2 yr	11.4
Ages 2 to <3 yr	13.8
Ages 3 to <6 yr	18.6
Ages 6 to <11 yr	31.8
Ages 11 to <16 yr	56.8
Ages 16 to <21 yr	71.6
Adult	80
Pregnant women	75
1st trimester	76
2nd trimester	73
3rd trimester	80

BW values for the age ranges used by MDEQ can be estimated from the data above by time weighting the mean BW for each age group by the duration of time spent in that age group (for example, assuming that one year is spent in the 2 to <3 year age group and three years are spent in the 3 to <6 year age group to estimate a BW for the 2 to 6 year age group); Table 3 below shows the resulting values.

Table 3. Body Weights for MDEQ Age Ranges Based on U.S. EPA (2011) Recommendations	
	Age-weighted mean BW (kg)
Ages < 2	9.6
Ages 2 to <6	17
Ages birth to <6	15
Ages 6 to <16	44
Ages 16 to <EDr	77
Ages 6 to <EDr	65
Adult	80

U.S. EPA (2014) recommended a child BW of 15 kg and adult BW of 80 kg based on data reported by U.S. EPA (2011). U.S. EPA (2014) calculated the child BW as the weighted average of BWs reported in U.S. EPA (2011) for ages birth to <6 years.

1.3.2.2. Evaluation of Data Quality Objectives

The BWs recommended by U.S. EPA (2011, 2014) were evaluated using the Part 201 DQOs. A summary of the evaluation follows.

Relevance and applicability to Michigan (g*eographic, temporal, and demographic representativeness*). The BWs recommended by U.S. EPA (2011) were based on analysis of four NHANES datasets from 1999 to 2006. As described earlier, NHANES is a nationally representative sample of the non-institutionalized civilian U.S. population. There are no data with which to assess the extent to which current BWs among Michigan residents are represented by the NHANES data from 1999 to 2006; however, these data better reflect current BWs in the U.S. than data used by U.S. EPA (1985, 1989). Rating: Medium.

Clarity and comprehensiveness (completeness of method and data reporting, completeness of literature search). The information considered by U.S. EPA (2011) as potentially relevant to the selection of BW values appears to be comprehensive, and the document provides a thorough discussion of the basis for the values recommended. The sampling design, data collection, and data analysis methods of NHANES surveys are well described[1]. U.S. EPA (2011) based its BW recommendations on the 4 latest sets of NHANES data available at the time the report was prepared. Rating: High.

[1] http://www.cdc.gov/nchs/nhanes/survey_methods.htm

Soundness and credibility (*adequacy of approach; intrinsic sources of bias; sample size*). U.S. EPA (2011) described the NHANES survey used as the basis for their BW values. As described by U.S. EPA (2011), the NHANES 1999-2006 survey consisted of a large sample size: approximately 40,000 persons of all ages, of which approximately 20,000 were children. The following subpopulations were oversampled: low-income persons, adolescents 12-19 years old, adults over 60 years of age, and African and Mexican Americans. As with previous NHANES surveys, BWs were measured during examination by trained medical professionals. U.S. EPA (2011) performed statistical analyses of sample-weighted BWs; the sample weights were developed in accordance with U.S. CDC guidance for NHANES data analysis in order to ensure that the resulting weights are representative of the entire U.S. population. Rating: High.

Transparency and objectivity (availability of supporting data; funding source; peer-review). The U.S. EPA (2011) report is available on the internet. Prior to publication, the report was reviewed internally by U.S. EPA staff, and also reviewed by a Science Advisory Board panel and an external Peer Review Panel consisting of scientists from academia, other governmental agencies, industry, and consultants. Funding for the NHANES data upon which the U.S. EPA (2011) recommendations were based is provided by the CDC. Rating: High.

Certainty (number and agreement of studies). The BWs used by U.S. EPA (2011) are based on analysis of NHANES data (1999-2006). U.S. EPA (2011) considered other published data on BW, but used data from NHANES (1999-2006) because it was more recent and provided data for all ages. Other studies available at the time used older BW data. Rating: High.

1.3.3. New Scientific Literature

A search of the open scientific literature (PubMed and ToxLine) for data on BW from studies published since 2009 was conducted. This search did not yield any potentially relevant studies of BW.

1.3.4. New Federal Information

The CDC published growth charts for U.S. infants and children in 2000 (CDC, 2000). These charts were based on data collected in the U.S. as part of the NHANES program and present percentiles of BW by age for boys and girls. Data from NHANES I, II, and III were used for this purpose; in fact, NHANES III purposely oversampled children <6 years so that growth charts in place since the 1970s could be updated. BW data forming the basis of the 2000 CDC growth charts were from 1963 to 1994. Data from NHANES III (1988-1994) were used to create CDC growth curves for children ages 2-5 months; NHANES II (1976-1980) and III were used for children ages 6-11 months; and NHANES I (1971-1974), II, and III were used for children ages 12-59 months. Specific methodologies used to develop the growth charts were described by

Kuczmarski et al. (2002). As the CDC (2000) growth charts use the same data source (NHANES) as U.S. EPA (2011, 1989, 1985), no further evaluation of this information was conducted.

The NHANES program, run by the NCHS within the CDC, has published three large surveys (NHANES I, II, and III). Since 1996, the survey has been conducted every 2 years. The U.S. EPA (2011) Exposure Factors Handbook used NHANES data from 1999-2006 to derive estimates of BWs. NHANES data collected since 2006 have not been published in a summary report that is readily available. When available, these data could be used to update or supplement the 1999-2006 BW estimates, but extensive analysis of the data would be required. According to Johnson et al. (2014), single years of NHANES data are not released as public-use data files, but are only available for analysis in the NCHS Research Data Center[2].

1.3.5. Other State and/or International Searches

1.3.5.1. Summary of Search Results

State and international agencies listed in the background to this TSD were searched for recommended BW values. Table 4 below summarizes the BW values identified in the searches. As the table shows, all states other than Massachusetts use BW values based on U.S. EPA assessments (1989, 1997, 2011) or do not report a basis for their BW values. Massachusetts (MADEP) uses BWs for children under 3 years of age based on 1976 pediatric growth charts from Massachusetts General Hospital; BWs for older children and adults were based on U.S. EPA (1989). All BWs used by Massachusetts are median values. Ontario based its BW estimates for children <1-6 years, ≤0.5 years, and 0.5-4 years on central tendency values reported in the 1997 Canadian Exposure Factors Handbook (Richardson 1997). Because the state and international values were either based on Canadian data or previous U.S. EPA (1989, 1997, 2011) exposure factors, further evaluation of DQOs for these values was not conducted.

[2] http://www.cdc.gov/rdc/

Table 4. Comparison of default state and international BW values (kg).

Exposure parameter	MI	IL	CA	MA[a]	MN[c]	WA	WI	IN[e]	OH	OR	TX	Ontario, CA[g]
$BW_{ages\ <2}$	-	-	-	10	11	-	-	9	-	15	-	8.2
$BW_{ages\ 2-<6}$	-	-	-	16	-	-	-	16	-	15	-	16.5
$BW_{ages\ birth-<6}$	15	15	15	14	15	16[d]	15	15	15	15	15	-
$BW_{ages\ 6-16}$	-	-	-	38	43	-	-	44	-	70	45[f]	32.9
$BW_{ages\ 16-30}$	-	-	-	58	70	-	-	76	-	70	70[f]	59.7
$BW_{ages\ 6-30}$	70	70	80	-	-	-	70	-	-	-	-	-
BW_{adult}	70	70	80	65[b]	70	70	70	-	70	70	70	70.7

[a]Values for ages up to 3 years based on 1976 pediatric growth charts from Massachusetts General Hospital; values for older ages from U.S. EPA(1989) (MADEP, 1995).
[b]Calculated for this TSD as the age-weighted average of median values reported by MADEP (1995) for males and females between the ages of 18 and 65.
[c]MPCA (1999) cites U.S. EPA (1997).
[d]Basis not reported in ODEQ (2010).
[e]IDEM (2012) cites U.S. EPA (2011).
[f]For ages 6-18 years and 18-30 years; basis for these values was not reported (TCEQ, 2009).
[g]For children ≤ 0.5 years (8.2 kg), 0.5 to 4 years old (16.5 kg), 5-11 years (32.9 kg), and 12-19 years (59.7 kg); cites Richardson (1997).

1.3.6. Comparison of Results of DQO Evaluations.

Table 5 provides a comparison of the DQO evaluations for the MDEQ (2005) BW values and those recommended by U.S. EPA (2011, 2014). For each DQO, the assessments have been rated low, medium, or high.

Table 5. Summary of DQO evaluation for BW (kg)

	MDEQ (2005) value	U.S. EPA (2011, 2014) recommended value
$BW_{ages\ <2}$	NV	9.6
$BW_{ages\ 2-<6}$	NV	17
$BW_{ages\ birth-<6}$	15	15
$BW_{ages\ 6-<16}$	NV	44
$BW_{ages\ 16-<EDr}$	NV	77
$BW_{ages\ 6-<EDr}$	70	65
BW_{adult}= Body weight: adult	70	80
BW_{nrdev}= Body weight: nonresidential, developmental toxicant		
1st trimester	NV	76
2nd trimester	NV	73
3rd trimester	NV	80
All trimesters		75
Relevance and applicability to Michigan	L	M
Clarity and comprehensiveness	M	H

Table 5. Summary of DQO evaluation for BW (kg)

	MDEQ (2005) value	U.S. EPA (2011, 2014) recommended value
Soundness and credibility	H	H
Transparency and objectivity	H	H
Certainty	M	H

NV = no value; H = high; M = medium; L = low

1.4. Conclusion

The U.S. EPA (2011) data best meet the DQOs for establishing generic exposure assumptions for MDEQ for BW. U.S. EPA (2011) BW values are derived from NHANES 1999-2006 data, and these are the most recent NHANES data publically available in summary form. Thus, it is recommended that weighted averages of the U.S. EPA (2011) central tendency estimates be used for the age ranges of interest to MDEQ (see Table 3 and Table 6).

Table 6. Summary of 2015 updated MDEQ values for BW

	2015 Updated BW (kg)
$BW_{ages <2}$ = Body weight: ages < 2	9.6
$BW_{ages 2-<6}$= Body weight: ages 2 to <6	17
$BW_{ages birth-<6}$ = Body weight: ages birth to <6	15
$BW_{ages 6-<16}$= Body weight: ages 6-<16	44
$BW_{ages 16-<EDr}$= Body weight: ages 16 to <EDr	77
$BW_{ages 6-<EDr}$= Body weight: ages 6 to <EDr	65
BW_{adult}= Body weight: adult	80
BW_{nrdev}= Body weight: nonresidential, developmental toxicant	
1st trimester	76
2nd trimester	73
3rd trimester	80
All trimesters	75

[a]NV = no value

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