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# General Exposure Factor Inputs for Dietary, Occupational, and Residential Exposure Assessments

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# **Summary**

Exposure factors are data related to human behaviour and physiological characteristics that help determine an individual's exposure to an agent. These factors are used in combination with pesticide specific data to estimate pesticide exposure to the population. The Pest Management Regulatory Agency (PMRA) has updated a number of exposure factor inputs used in dietary, occupational, and residential exposure assessments. This was done in consideration of recent changes to the United States Environmental Protection Agency (USEPA) Exposure Factors Handbook, the Dietary Exposure Evaluation Model – Food Consumption Intake Database (DEEM-FCID), and the USEPA Standard Operating Procedures (SOPs) for Residential Pesticide Exposure Assessment. The PMRA will periodically review exposure factor assumptions to ensure that the inputs are current and relevant to the Canadian population.

The exposure factor inputs discussed in this document include body weight, food and drinking water consumption, inhalation rates, body surface area, and life expectancy. Exposure factor inputs used in incidental oral exposure assessments are also discussed. These factors are considered general exposure factors, as they are not related to pesticide activities and are commonly used across different exposure assessments.

# 1.0 Purpose

The purpose of this document is to provide an update to stakeholders on the default exposure factors used by the PMRA when calculating exposure for dietary, occupational and residential risk assessments.

# 2.0 Background

Under the *Pest Control Products Act*, the PMRA has the responsibility to protect the health of Canadians from unacceptable risks associated with pesticide use. In order to assess potential risks of pesticide use to the health of Canadians, the Agency must be able to estimate their potential exposure to pesticides and any pesticide transformation products that might be of toxicological concern. The main determinates in the exposure assessment are the properties of the pesticide and the characteristics of the exposed population. The physicochemical properties and the use pattern of the pesticide determine the availability of the pesticide in the environment. In turn, the characteristics of the population determine the susceptibility of the population to pesticide exposure from the environment. Exposure factors are data on the behavioural and physical characteristics of the population. The combined information from exposure factors and pesticide specific data allows for the estimation of the magnitude, frequency, and duration of pesticide exposure to the population.

This document provides a summary of the general exposure factors used by the PMRA in dietary, occupational, and residential exposure assessments. General or universal exposure factors refer to exposure factors that are not related to pesticide activities (for example, body weight and inhalation rate) and that are commonly used across different exposure assessments. Exposure factors related to pesticide activities (for example, transfer coefficient, application

frequency) are not discussed in this document, as their inputs may vary depending on the use pattern of the pesticide product assessed. Information related to agricultural transfer coefficients used for assessing occupational postapplication exposure to pesticides is available in Regulatory Proposal, PRO2014-02, *Updated Agricultural Transfer Coefficients for Assessing Occupational Postapplication Exposure to Pesticides*..

### **Dietary Exposure**

The dietary exposure assessment estimates human exposure from pesticides in food and drinking water. This requires the determination of the amount of pesticide residues in food and drinking water and the dietary consumption levels of the exposed population. The consumption level is an important exposure factor in the dietary exposure assessment, as the pesticide residues in the more highly consumed foods and drinks have a larger impact on the assessment. Residue estimates in drinking water can be a major dietary exposure contributor because of the high consumption level. The entire population is considered in the dietary exposure assessment, with further categorization into age and gender groups to account for different sensitivities of major identifiable subgroups, including pregnant women, infants, children, and seniors. The body weight data for the population are also used in the dietary exposure assessment to normalize exposure on a per kilogram basis. The PMRA conducts dietary exposure assessments for two exposure durations, single day or "acute" exposure, and long-term or "chronic" exposures; each assessment is calculated differently. In chronic exposure assessments, the risk assessor estimates a person's average dietary exposure over several months to a lifetime. Consequently, the central tendency measure (mean or median) of residue and consumption levels in food and drinking water are used. In acute dietary exposure assessments, the risk assessor estimates the distribution of exposures that individuals could encounter on a single day and determines the exposure to which "high-end" persons could be subjected. "High-end" is defined as a plausible estimate of exposure for those individuals at the upper end of the exposure distribution. Acute exposures are calculated by using either deterministic or probabilistic methods. Deterministic methods use high end estimates to determine residues on food commodities and generates an exposure distribution based on the consumption level of the population. The probabilistic assessment estimates the distribution of exposure people experience as the result of variations in the types and amount of foods they eat, as well as variations in the level of pesticide residue that may be present on those foods. The Agency has set a number of conditions to be considered in judging the acceptability of a probabilistic analysis for review and evaluation; these conditions relate to reproducibility and the use of sound scientific methods. Refer to the PMRA's Science Policy Notes for dietary exposure assessments (SPN2003-01, SPN2003-03, SPN2003-05) for further details. The documents can be found on the Pesticides and Pest Management portion of Health Canada's website.

### **Occupational Exposure**

The occupational exposure assessment estimates dermal and inhalation exposure to pesticide handlers who mix, load, and/or apply pesticides and to postapplication workers who work in areas treated with pesticides. Inhalation rates, body weight, and life expectancy are the general exposure factors used in occupational exposure assessments. Inhalation rates are used to determine inhalation exposure estimates. Body weight data are used to normalize exposure on a

per kilogram basis. Life expectancy inputs are used to estimate the lifetime average daily dose for occupational cancer exposure and risk assessments. The adult population and females of reproductive age groups are considered in occupational exposure assessment. Occupational exposure estimates are determined over the short-term (1 to 30 days), intermediate-term (1 to 6 months), long-term (greater than 6 months) depending on the use pattern and hazard characterization of the pesticide. A number of deterministic algorithms are used to estimate occupational exposure for different scenarios and durations. General exposure factor inputs are considered in all algorithms along with pesticide specific data.

### **Residential Exposure**

The residential exposure assessment estimates dermal, inhalation, and incidental oral exposure to pesticides used in homes, parks, on pets, and other areas such as golf courses. The general exposure factors used in the occupational exposure assessment are applied in the same manner for the residential exposure assessment. In addition to these general factors, body surface area, soil ingestion rate, hand surface area mouthed, object surface area mouthed, frequency of hand-to-mouth events, frequency of object-to-mouth events, and the saliva extraction factor are considered in residential exposure assessments. Of these, body surface area, inputs are required to estimate postapplication dermal exposure assessments, while the remaining factors are used to assess some incidental oral exposure scenarios in children. Incidental oral exposure refers to non-dietary oral exposure that could occur in young children. It includes, but is not limited to, the following pathways:

- Exposure resulting from children contacting treated surfaces (for example, turf, floor, pests) and putting their hands in their mouth ("hand-to-mouth" exposure);
- Exposure resulting from children putting objects or other toys in their mouth that had been in contact with treated surfaces ("object-to-mouth" exposure);
- Direct ingestion of pesticide residues through soil ingestion, dust ingestion or ingestion of pesticide granules.

Population groups assessed in residential exposure assessments include adults, youth, children, and females of reproductive age. Residential exposure estimates may be determined over the short-term (1 to 30 days), intermediate-term (1 to 6 months), long-term (greater than 6 months), and the entire life time. A number of deterministic algorithms are used to estimate residential exposure for different scenarios and durations. These algorithms are summarized in detail in the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments. Residential exposure estimates are combined with dietary exposure estimates to determine the aggregate exposure from a single chemical by multiple pathways and routes of exposure. Refer to the PMRA's Science Policy Notes for aggregate exposure and risk assessment (SPN2003-04) for further details. The document can be found on the Pesticides and Pest Management portion of Health Canada's website.

# **3.0** General Exposure Factor Inputs

The general exposure factor inputs used in dietary, occupational, and residential exposure assessments are discussed below. The inputs have been recently revised in consideration of the updates to the USEPA Exposure Factors Handbook, DEEM-FCID, and the USEPA SOPs for Residential Pesticide Exposure Assessments. The PMRA will periodically review exposure factor assumptions to ensure that the inputs are current and relevant to the Canadian population. As such, exposure factor inputs are subject to revisions when new data or information becomes available.

The PMRA utilizes three main reference sources for general exposure factor inputs: the USEPA Exposure Factors Handbook, the United States' National Health and Nutrition Examination Survey (NHANES), and the USEPA SOPs for Residential Pesticide Exposure Assessments. These three reference sources are related in some instances. For example, the NHANES data is reported in the Exposure Factors Handbook and is the basis for some of its recommended exposure factor inputs. In addition, many of the recommended exposure factor inputs in the Exposure Factors Handbook are subsequently adopted in the USEPA SOPs for Residential Pesticide Exposure Assessments.

Refer to Appendix I for details on the reference source and a comparison table of current and past general exposure factor inputs.

### 3.1 Body Weight

Body weight is variable within the population and is dependent on multiple factors including age, gender, genetics, diet, and physical activity. Therefore, it is necessary to normalize exposure as a function of body weight in order to estimate exposure to different population demographics. In pesticide exposure assessments, the population is divided into age and gender groups to account for physiological differences, activity scenarios, and hazard sensitivities. As such, the determination of body weights is linked to age and gender considerations of the population group. Other exposure factors, including dietary consumption and body surface area, are directly related to body weight and are considered in conjunction with body weight selection.

### **Body Weight Inputs for Occupational and Residential Exposure Assessments**

The body weight values from the 2011 USEPA Exposure Factors Handbook are used by the PMRA in occupational and residential exposure assessments. The values are based on data collected from the NHANES 1999-2006. Workers are assumed to be 80 kg in occupational exposure assessments. This is based on the mean body weight for the 16 to <81-year-old population including both males and females. For residential exposure assessments, the body weights inputs are further categorized into age and gender groups. Table 3.1.1 lists the mean body weight inputs and population groups for the occupational and residential exposure assessments. The population groups for residential exposure assessments are categorized according to the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments.

Table 3.1.1 Body Weight Inputs for Occupational and Residential Exposure Assessments

Population Group <sup>1</sup>	Mean Body Weight (kg) <sup>2</sup>
Birth to <1 month	4.8
1 to <3 months	5.9
3 to <6 months	7.4
6 to <12 months	9.2
1 to <2 years	11
2 to <3 years	14
3 to <6 years	19
6 to 11 <years< td=""><td>32</td></years<>	32
11 to <16 years	57
16 to <81 years	80
Females 11 to <51 years <sup>3</sup>	69

Both males and females are included in the population groups unless otherwise specified. Population groups categorized according to 2012 USEPA SOPs for Residential Pesticide Exposure Assessments.

### **Body Weight Inputs for Dietary Exposure Assessments**

The data from NHANES 2003-2008 is the basis for the body weight data used by the PMRA in dietary exposure assessments. The body weight data from NHANES are imbedded in the DEEM-FCID program along with the food and drinking consumption data. Further information regarding DEEM-FCID and NHANES can be found in Appendix I.

### Comparison of NHANES and Canadian Body Weight Data

Body weight data from the Canadian Community Health Survey (CCHS)<sup>1</sup> Cycle 2.2, and Canadian Health Measures Survey (CHMS)<sup>2</sup> Cycle 1 and Cycle 2 were available, in addition to the body weight data from the NHANES, and were considered for the selection of body weight inputs in the exposure assessments. Since the NHANES data contains more comprehensive data for children and allows for the use of a single database for body weight, body surface area, and food and drinking water consumption inputs, this data was considered more appropriate.

Analysis of body weight data from the three surveys indicates that NHANES mean body weight estimates are greater for all population groups than those from CCHS cycle 2.2 and CHMS cycles 1 and 2. The largest body weight difference was observed for the adult (16 to <81 years)

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Estimates from the 2011 USEPA Exposure Factors Handbook. For adults, the body weight estimates for males and females ages through 16 to <81 years were averaged to determine the estimate.

Representative body weight for females of reproductive age 13-49 years. Estimates from the USEPA Exposure Factors Handbook for females ages 11 through <51 years were averaged for the group.

The CCHS Cycle 2.2 was conducted by Statistics Canada in 2004 to provide information on dietary intake and nutritional well-being, and their key determinants, to inform and guide programs, policies and activities of federal and provincial governments. The CCHS 2.2 collected data on dietary intake, measured height and weight, and a number of other variables.

The CHMS was launched by Statistics Canada in 2007 to collect key information relevant to the health of Canadians by means of direct physical measurements such as blood pressure, height, weight and physical fitness. Two cycles of CHMS have been completed, each consisting of two-year periods. Cycle 1 collected data from March 2007 to February 2009. Cycle 2 collected data from August 2009 to November 2011.

population, with the mean body weight being 6% higher for the American NHANES 1999-2006 data as compared to CCHS cycle 2.2 when both males and females are included. For 11 to <16 year olds, the difference is 4% higher. For children 3 to <11 year olds the difference is 2 to 3% higher. Body weights for children three years and younger were not available in the Canadian databases and could not be compared to the NHANES data. Body weight data from NHANES and CHMS were not directly compared, as the population groups between the two surveys were not matched. However, inferences could be made by relating CCHS to both surveys. Body weight values from CHMS cycles 1 and 2 are higher than CCHS cycle 2.2 but lower than NHANES 1999-2006. Refer to Table 3.1.2 and 3.1.3 for the body weight data from the surveys.

In the context of other parameters included in the exposure and risk assessment and their degree of protection or conservatism, the use of the NHANES body weight data rather than the Canadian body weight data is not expected to greatly under or overestimate the health risks of pesticides to the Canadian population. In addition, the use of the NHANES body weight data is consistent with the body weight data used for the occupational and residential exposure assessment.

Table 3.1.2 CCHS Cycle 2.2 (2004) and NHANES (1999-2006) Body Weight Data

Population Group <sup>1</sup>	Mean Body Weight (kg) <sup>2</sup> CCHS (2004)	Mean Body Weight (kg) <sup>2</sup> NHANES (1999-2006)
6 to <11 months	Not available	9.2
1 to <2 years	Not available	11
2 to <3 years <sup>3</sup>	14	14
3 to <6 years	18	19
6 to <11 years	31	32
11 to <16 years	55	57
Females 11 to <51 years <sup>4</sup>	66	69
16 to <81 years	76	80

Both males and females are included in the population groups unless otherwise specified. Population groups categorized according to 2012 USEPA SOPs for Residential Pesticide Exposure Assessments.

Mean estimates for CCHS cycle 2.2 are weighted using the sample weights provided in the survey. The NHANES estimates are from the 2011 Exposure Factors Handbook. For adults, the body weight estimates for males and females ages through 16 to <81 years were averaged to determine the estimate.

CCHS has a limited sample size for the 2 to <3 year old age group with 332 samples for males and females combined. Data is not available for children 2 years and younger.

Representative body weight for females of reproductive age 13-49 years. Estimates from the Exposure Factors Handbook for females ages 11 through <51 years were averaged to determine the NHANES mean estimate.

Table 3.1.3 CCHS Cycle 2.2 (2004) and CHMS Cycle 1 (2007-2009) and 2 (2009-2011) Body Weight Data

Population Group <sup>1</sup>	Mean Body Weight (kg) <sup>2</sup> CCHS (2004)	Mean Body Weight (kg) <sup>2</sup> CHMS Cycle 1 (2007-09)	Mean Body Weight (kg) <sup>2</sup> CHMS Cycle 2 (2009-11)
3 to 5 years	18	Not available	19
6 to 11 years	33	33	33
12 to 19 years	63	63	63
20 to 39 years	74	76	76
40 to 59 years	78	79	80
60 to 79 years	76	78	78
3 to 79 years	69	Not available	71
6 to 79 years	71	72	73

Both males and females are included in the population group. Population groups categorized according to the CHMS.

### 3.2 Food and Drinking Water Consumption

The PMRA is transitioning to using the food and drinking water consumption data from the NHANES for dietary exposure assessments, which, as noted earlier, is imbedded in the DEEM-FCID program. The food and drinking water consumption data collected in the dietary intake component of the NHANES is also known as the What We Eat in America (WWEIA) component. The incorporation of consumption data into DEEM-FCID required the translation of foods-as-eaten data from NHANES WWEIA into raw agricultural food commodities. This conversion was necessary because the corresponding food residue data required to determine exposure is generally available for the raw agricultural food commodity only, as measured in supervised pesticide field trials or large scale monitoring programs. Translation of foods-as-eaten to raw agricultural food commodity is done using the FCID recipe list. For example, an apple pie weighing 100 grams is translated into 34 grams of wheat, 1 gram of milk, 15 grams of sugar from sugar beets, and 50 grams of apples. Thus far, the USEPA Office of Pesticide Programs has translated three cycles of NHANES WWEIA data (2003-2004, 2005-2006, and 2007-2008) into DEEM-FCID, with plans to incorporate an additional cycle of data (2009-10). The translated data is referred to as the WWEIA-FCID.

Further information on the consumption data can be found on the WWEIA-FCID website<sup>3</sup>. The website was built to provide an easier and more transparent way for the general public to access the consumption data in the DEEM-FCID.

Mean estimates for CCHS cycle 2.2 are weighted using the sample weights provided in the survey. Mean estimates for CHMS cycle 1 and 2 are taken from Statistics Canada survey reports. CHMS cycle did not sample for children younger than 6 years. CHMS cycle 2 did not sample for children younger than 3 years. The values are rounded to two significant figures.

The University of Maryland Joint Institute for Food Safety and Applied Nutrition (JIFSAN) built and maintains the website.

### **Comparison of NHANES and Canadian Dietary Consumption Data:**

Canadian dietary consumption data from the CCHS cycle 2.2 (2004) were available in addition to the consumption data from WWEIA. The PMRA conducted a preliminary analysis of food consumption patterns in Canada versus the US. The major food commodities in American and Canadian markets were generally similar and were available to most of the population. However, the preliminary analysis of the CCHS cycle 2.2 (2004) and NHANES-WWEIA (2003-2006) surveys indicated that the intake of processed commodities is higher in the United States while the consumption of fresh vegetables and fruits is generally higher in Canada. Overall, there were differences identified for 16% of the total number of raw agricultural commodities in the food supply; however, the nature and quality of the datasets precluded further characterization of these differences. Therefore, the United States WWEIA consumption data as part of DEEM-FCID is being adopted by the PMRA, primarily due to its larger sample size and the fact that it is a continuous survey that is more representative of current eating habits. These data enable probabilistic assessments to be conducted for acute dietary exposure assessments, have more comprehensive data for identifiable subgroups such as infants and children, and represents the most recent food consumption data available. In addition, the WWEIA data allows for the use of a single database (NHANES) for body weight, body surface area, and food and drinking water consumption inputs.

### 3.3 Body Surface Area

Body surface area inputs are required to estimate potential dermal exposure for occupational and residential postapplication activities. The transfer coefficient is the measure of the amount of surface to skin residue transfer over time for a specific activity. Transfer coefficient data are typically derived from studies that measure exposure in adult volunteers. As such, an adjustment factor is used to translate the transfer coefficient values derived from adults to other population groups that have different body surface areas (in other words, children). The adjustment factor is based on the total body surface area ratio between adults and the target population.

The total body surface area values reported in the 2011 Exposure Factors Handbook are used by the PMRA to calculate adjustment factors. These values are determined using the correlation of height and body weight data collected from the NHANES 1999-2006; the same data used for body weight inputs in occupational and residential exposure assessments. The mean body surface area values and adjustment factor for population groups are listed in Table 3.3.1. The population groups are categorized according to the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments.

**Table 3.3.1 Body Surface Area Inputs for Occupational and Residential Exposure Assessments** 

Population Group <sup>1</sup>	Mean Body Surface Area (m <sup>2</sup> ) <sup>2</sup>	Adjustment Factor
Birth to <1 month	0.29	0.15
1 to <3 months	0.33	0.17
3 to <6 months	0.38	0.19
6 to <12 months	0.45	0.23
1 to <2 years	0.53	0.27
2 to <3 years	0.61	0.31
3 to <6 years	0.76	0.39
6 to 11 <years< td=""><td>1.08</td><td>0.55</td></years<>	1.08	0.55
11 to <16 years	1.59	0.82
16 to <81 years	1.95	1
Females 11 to <51 years <sup>3</sup>	1.77	0.91

Both males and females are included in the population groups unless otherwise specified. Population groups categorized according to 2012 USEPA SOPs for Residential Pesticide Exposure Assessments.

Representative body weight for females of reproductive age 13-49 years. Estimates from the USEPA Exposure Factors Handbook for females ages 11 through <51 years were averaged for the group.

### 3.4 Inhalation Rates

Inhalation rate is the flow rate of air into the human body expressed as the volume of air inhaled per unit time. It is used in combination with pesticide air concentration data to determine inhalation exposure for occupational and residential exposure assessments. The inhalation rates used by the PMRA are based on the 2011 USEPA Exposure Factors Handbook.

These rates are categorized according to activity level and are listed in Table 3.4.1. The inputs are based on the 1997 USEPA Exposure Factors Handbook data for males and females 18 years and older. Occupational activities such as mixing and loading of pesticide containers up to 23 kg, general harvesting, and lawn treatment are considered to have light activity levels. Examples of moderate activities include application using a backpack sprayer, mixing and loading large containers (>23 kg) and harvesting using ladders. Sedentary activities include driving a tractor or piloting for aerial application. High and resting activities are generally not applicable to occupational exposure assessments for pesticides.

For residential exposure assessments, the long-term mean inhalation rates in the 2011 USEPA Exposure Factors Handbook are used. The recommendations are also adopted in the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments. The inputs are derived from multiple studies: Brochu *et al.* (2006), Stifleman (2007), USEPA (2009), and Arcus-Arth and Blasdell (2007). The selection of long-term inhalation rates vary depending on the population group. These population groups are categorized according to the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments. The population groups and inhalation rates are listed in Table 3.4.2.

Estimates from the 2011 USEPA Exposure Factors Handbook. Total body surface area values for children less than 21 years old are based on NHANES 1999-2006 data. Surface area values for adults 21 and older are based on NHANES 2005-2006 data. For adults, the body surface area estimates for males and females ages 16 through <81 years were averaged to determine the mean estimate.

**Table 3.4.1 Inhalation Rate Inputs for Occupational Exposure Assessments** 

Population	Activity	Short Term Mean Inhalation rate (m³/hour) <sup>1</sup>
Adults	Rest <sup>2</sup>	0.4
	Sedentary	0.5
	Light	1.0
	Moderate	1.6
	Heavy <sup>2</sup>	3.2

Estimates from the 1997 USEPA Exposure Factors Handbook and converted to m<sup>3</sup>/hour.

**Table 3.4.2 Inhalation Rate Inputs for Residential Exposure Assessments** 

Population Group <sup>1</sup> Long Term Mean Inhalation Rate (m³/hour) <sup>2</sup>			
6 to <12 Months	0.23		
1 to <2 years	0.33		
2 to <3 years	0.37		
3 to <6 years	0.42		
6 to <11 years	0.50		
11 to <16 years	0.63		
16 to <81 years	0.64		

Both males and females are included in the population groups. Population groups categorized according to 2012 USEPA SOPs for Residential Assessments.

# 3.5 Life Expectancy

Life expectancy is a parameter used to determine the lifetime average daily dose in occupational and residential cancer exposure and risk assessments. As pesticide exposure varies from childhood to adulthood, the exposure estimate is amortized into separate lifestages in the calculation of the lifetime average daily dose. The average daily exposure estimate for each lifestage is adjusted for the number of years in the lifestage and the life expectancy. The lifetime average daily dose is the total sum of adjusted average daily exposure estimates for all lifestages. The lifestages considered in the residential exposure assessment include children, youth, and adults. For occupational exposure assessments, the exposure is determined for the working period and assumed to be negligible for all other lifestages.

The PMRA assumes a life expectancy of 78 years based on the recommended life expectancy estimate in the 2011 USEPA Exposure Factors Handbook. The recommended value is an estimate from the study by Xue *et al.* (2010) and is the projected value for newborn males and females in 2007.

The most recent Statistics Canada data (2007–2009) indicates that the life expectancy in Canada is 81 years, which is 4% higher than the 2011 USEPA Exposure Factors Handbook recommendation. Although there is a slight difference in life expectancy between the two countries, the 2011 USEPA Exposure Factors Handbook recommendation is applied in Canadian (PMRA) exposure assessments to be consistent with the USEPA and better align the assessments

Generally not applicable to occupational exposure assessments for pesticides.

Estimates from the 2011 USEPA Exposure Factors Handbook and converted to m³/hour. For adults, the estimates for males and females ages 16 through <81 years were averaged to determine the long term mean estimate.

conducted by both agencies. In the context of other parameters included in the exposure and risk assessment and their degree of protection or conservatism, the use of the American projected life expectancy is not expected to greatly over or underestimate the health risks of pesticides to the Canadian population.

### 3.6 Exposure Factors Related to Non-Dietary Incidental Oral Exposure

The following updated general exposure factors are used in hand-to-mouth and object-to-mouth residential postapplication exposure assessments for toddlers in contact with treated surfaces, pets, and objects.

### **Saliva Extraction Factor**

The saliva extraction factor is the fraction of pesticide that may be extracted from the hand or object via saliva.

The PMRA uses the saliva extraction factor value of 0.48 or 48% from the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments, which is a mean estimate based on the study by Camann *et al.* (1996). It is noted in the 2012 USEPA SOPs that this study focused specifically on the fraction of pesticides extracted by saliva from hands and not objects. However, the data is used for object-to mouth assessments, as there are no saliva extraction data for object-to-mouth exposure.

### Hand Surface Area for Children and Fraction of Hand Area Mouthed

The hand surface area of 150 cm² is used by the PMRA. This is based on the mean surface area of one hand for 1 to <2 year olds reported in the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments. The value is calculated from the mean body surface values derived from the NHANES 1999-2006 (0.52 m² for 1 to <2 year olds) and assuming that one hand accounts for 2.75% of the total body surface area. The hand surface area to total body surface area ratio was based on estimates from the USEPA document on the Development of Statistical Distributions or Ranges of Standard Factors Used in Exposure Assessment (1985).

The PMRA assumes 12.7% of the total hand surface area is mouthed during a mouthing event. This is based on the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments. The hand-to-mouth behaviour of children was investigated in the study conducted by Leckie *et al.* (2000) via videotape. The data from the study was further analyzed by Zatarian *et al.* (2005) to quantify the fraction of hand area mouthed. A detailed explanation of the Leckie study and Zatarian analysis is found in the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments.

Using the 12.7% fraction factor with the hand surface area of 150 cm<sup>2</sup> equates to 19.05 cm<sup>2</sup> of hand surface area contact per mouthing event.

### **Surface Area of Object Mouthed**

The PMRA uses the mean surface value of 10 cm<sup>2</sup> from the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments. The value is based on data from the study by Leckie *et al.* (2000) for 2 to 5 year olds, and the assumption that the children mouth a smaller area of an object than their hand.

### Frequency of Hand-to-Mouth and Object-to-Mouth Events

The inputs for frequency of hand-to-mouth and object-to-mouths events are indicated in Table 3.6.1. Different estimates are used for outdoor and indoor scenarios. The estimates are from the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments and are derived from the mean estimates of representative datasets for children 1 to 2 years old. Refer the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments for details on the datasets.

**Table 3.6.1 Frequency of Mouthing Event Inputs for Residential Exposure Assessments** 

Scenario	Mouthing Events/Hour <sup>1</sup>
Outdoor hand to mouth exposure	13.9
Indoor hand to mouth exposure	20
Outdoor object to mouth exposure	8.8
Indoor object to mouth exposure	14

Based on the 2012 USEPA SOP for Residential Pesticide Exposure Assessments.

### **Soil Ingestion Rate**

The soil ingestion rate is defined as the amount of total soil ingested in a single day. The factor is used in residential exposure assessments to estimate incidental oral exposure to children eating soil in treated areas.

The PMRA uses the soil ingestion rate of 50 mg/day reported in the 2012 USEPA SOPs for Residential Pesticide Exposure Assessments. The value is the recommended central tendency soil ingestion rate in the 2011 USEPA Exposure Factors Handbook for children aged 1 to 6 years old and is based on data collected from multiple studies: David and Mirick (2006), Hogen *et al.* (1998), Davis *et al.* (1990), Van Wijnen *et al.* (1990), and Calabrese and Stanek (1995).

# Appendix I

### **Information Regarding Primary Reference Sources for Exposure Factors:**

USEPA Exposure Factors Handbook

The Exposure Factors Handbook contains a compendium of exposure factors data and was designed to provide recommendations on exposure factor inputs for exposure and risk assessors. The National Center for Environmental Assessment (NCEA) published the handbook in 1997 and released an updated edition in 2011. The NCEA is part of the Office of Research and Development at the USEPA. The 2011 Exposure Factors Handbook is the basis for a number of exposure factors used by the PMRA in occupational and residential exposure assessments. The 1997 edition was the main reference source for exposure factor inputs prior to the release of the 2011 edition.

National Health and Nutrition Examination Survey

The NHANES is a major program of the National Center for Health Statistics (NCHS) within the US Center for Disease Control. The survey is conducted in partnership with the United States Department of Agriculture (USDA) and was designed to assess the health and nutritional status of adults and children in the United States. The survey consists of interviews and physical examinations and is reported on a biannual cycle. Food and drinking water consumption data is collected in the dietary intake component of the survey also known as the What We Eat in America (WWEIA) component. The USEPA Office of Pesticide Programs undertook a review of consumption data used in dietary pesticide exposure assessments in 2010 and incorporated the WWEIA data collected from the NHANES into the Dietary Exposure Evaluation Model-Food Consumption Intake Database (DEEM-FCID). The DEEM-FCID is the software program used by the PMRA and USEPA to conduct dietary exposure and risk assessments for pesticides. The population demographic and body weight data from NHANES were also incorporated into the DEEM-FCID. The USEPA acquired the rights to DEEM-FCID and a public version was released in 2012-2013. Prior to the update, the data from the USDA Continuous Survey of Food Intake by Individuals (CSFII) was the basis for the consumption and body weight data in the DEEM-FCID.

USEPA Standard Operating Procedures for Residential Pesticide Exposure Assessment

The SOPs for Residential Pesticide Exposure Assessments were developed by the USEPA Office of Pesticide Programs. The first draft edition was released in 1997 and later revised in 2001. In 2012, the USEPA Office of Pesticide Programs completed a major update to the SOPs that resulted in the publication of the 2012 edition. The 2012 edition is the primary guidance document used by the PMRA for conducting residential exposure assessments. This includes the use of algorithms and exposure factor inputs reported in the SOPs. Prior to the release of the 2012 edition, the PMRA had used the exposure factor inputs reported in the 1997 SOPs and subsequent 2001 revision document. It is noted that the exposure factor inputs reported in the 2012 edition for deterministic residential exposure assessments are mostly based on the mean estimate for the target population group. This represents a change from previous exposure factor inputs reported in the 1997 and 2001 editions, which were mostly based on median estimates. Percentile exposure factors estimates are also reported in the 2012 edition; however these values

are reserved for use in probabilistic assessments. The PMRA currently conducts deterministic assessments for standard occupational and residential exposure assessments. As such, exposure factor distributions related to the occupational and residential exposure assessments are not discussed in this document. Further details on probabilistic inputs will be provided with the future development of standard procedures for probabilistic occupational and residential exposure assessment.

 Table A1
 PMRA Current and Previous Exposure Factor Inputs

General Exposure Factor	Exposure Scenario	Current Input		Previous Input	
Food Consumption <sup>1</sup>	Dietary	DEEM version 3.18 - NHANES Food Consumption and body weight data 2002-2008		DEEM version 2.14 – CFSII Food Consumption and body weight data 1994-96, 1998	
Body Weight <sup>1</sup>	Dietary	DEEM version 3.18 - NHANES Food Consumption and body weight data 2002-2008		DEEM version 2.14 – CFSII Food Consumption and body weight data 1994-96, 1998	
Body Weight <sup>2</sup>	Occupational and Residential	Group 1 to <2 year 2 to <3 year 3 to <6 year 6 to <11 year 11to <16 year 16 to <81 year (adult) Female 13 to <49 year	BW (kg) 11 14 19 32 57 80 69	Group Children Youth Adults	BW (kg) 15 39 70
Body Surface Area (BSA) <sup>3</sup>	Occupational and Residential	Group 1 to <2 year 2 to <3 year 3 to <6 year 6 to <11 year 11to <16 year 16 to <81 year (adult) Female 13 to <49 year	BSA (m <sup>2</sup> ) 0.53 0.61 0.76 1.08 1.59 1.91	Group Children Youth Adults	BSA (m <sup>2</sup> ) 0.66 1.27 1.84
Life Expectancy <sup>4</sup>	Occupational and Residential	78 years			years
Short Term Inhalation Rate (IR)	Occupational	Group: adults Activity Sedentary Light Moderate	IR (m <sup>3</sup> /hr) 0.5 1.0 1.6	Group: adults Activity Sedentary Light Moderate	IR (m <sup>3</sup> /hr) 0.5 1.0 1.6
Intermediate to Long Term Inhalation Rate (IR) <sup>5</sup>	Residential	Group 1 to <2 year 2 to <3 year 3 to <6 year 6 to <11 year 11to <16 year 16 to <81 year (adult) Female 13 to <49 year	IR (m <sup>3</sup> /hr) 0.23 0.33 0.37 0.42 0.50 0.63 0.64	Group IR Children Adults	(m <sup>3</sup> /hr) 0.36 0.55
Saliva Extraction Factor <sup>6</sup>	Residential	48%		50%	

General Exposure Factor	Exposure Scenario	Current Input		Previous Input	
Hand Surface Area Mouthed <sup>7</sup>	Residential	150 cm <sup>2</sup> (hand surface area) x 12.7% (Fraction of hand area mouthed) = 19.2 cm <sup>2</sup>		20 cm <sup>2</sup> representing the surface area of 2 to 3 fingers	
Surface Area of Object Mouthed <sup>8</sup>	Residential	$10 \text{ cm}^2 \qquad \qquad 25 \text{ cm}^2$		rm <sup>2</sup>	
Frequency of Hand to Mouth Events <sup>9</sup>	Residential	Location Outdoor Indoor	Events/hr 13.9 20	Scenario Short Term Int,-Long Term	Events/hr 20 9.5
Frequency of Object to Mouth Events <sup>10</sup>	Residential	Location Outdoor Indoor	Events/hr 8.8 14	Not Ava	ailable
Soil Ingestion Rate <sup>11</sup>	Residential	50 1	mg/day	100 m	g/day

Note: Estimates from the USEPA Exposure Factors Handbook for females ages 11 through <51 years were averaged to determine the estimate for females 13 to <49 years.

- The CSFII was the basis for the consumption and body weight data used in DEEM-FCID. The CSFII is part of the National Nutrition Monitoring and Related Research Program (NMRRP) created in 1990 by the USDA to monitor diet and nutrition in the US. The survey reported 24-hour recall of all food intakes on 2 non-consecutive days, household information, and self-reported body weights and heights. Four versions (1985-1988, 1989-1991, 1994-1996, and 1998) of CSFII were produced to focus on basic and low-income households. The last version (1998) targeted children aged 0 to 9 years in particular. DEEM-FCID version 2.14 included the 1994-1996, 1998 CSFII data. DEEM version 3.18 or latest update, incorporating NHANES food consumption data, will be adopted in 2014.
- For occupational and residential exposure assessments, the previous estimates for body weight were based on the NHANES Series II (1976-1980). The NHANES II data was included in the 1997 USEPA Exposure Factors Handbook (1997) and was the basis for the body weight inputs in the previous editions of the USEPA SOPs for Residential Pesticide Exposure Assessments. The estimate for adults was based on the median body weight of males and females 18 years and older. The estimate for youth was based on the mean of median body weights for males and females ages 10-12 year. The estimate for children was based the mean of median of body weights for males and females age three (15 kg) was used.
- The previous estimates for body surface area were based on the 1997 USEPA Exposure Factors Handbook. The estimates for adults were based on data for 18 year old males and females. The estimates for youth were based on data for 12-13 year old male and females. The estimates for toddlers were based on data for three-year-old males and females. The estimates were calculated by summing the median surface area estimates of each body part. Male and female groups were combined by taking the average for the two groups.
- <sup>4</sup> The previous estimate for life expectancy was based on American projected life expectancy for both male and females born in 1993.
- The previous estimates for intermediate- to long-term inhalation rates of children were based on the 1997 USEPA Exposure Factors Handbook. The inhalation rates for children were based on data for three- to five-year-old males and females.
- The previous estimate for the saliva extraction factor was based on the 2001 revision document for the 1997 USEPA SOPs for Residential Exposure Assessments.
- The previous estimate for hand surface area mouthed was based on the 2001 revision document for the 1997 USEPA SOPs for Residential Exposure Assessments. The estimate was corrected for the partial fraction of hand area mouthed as children do not put their entire hand in the mouth. The 20 cm<sup>2</sup> represented the surface area of 2 to 3 fingers.
- The previous estimate for surface area of object mouthed was based on the 2001 revision document for the 1997 USEPA SOPs for Residential Exposure Assessments. The estimate represented an upper percentile of the area that a toddler may mouth.
- The previous estimates for frequency of hand to mouth events was reported in the 2001 revision document for the 1997 USEPA SOP for Residential Exposure Assessments and was based on data for two to five year olds. The estimates did not differentiate between outdoor and indoor scenarios, but instead differentiated

- according to short-term and intermediate- to long-term scenarios. The 90<sup>th</sup> percentile estimate was assumed for short-term exposure scenarios and the mean estimate was assumed for intermediate- to long-term exposure scenarios.
- The frequency of object-to-mouth events was not considered in the previous exposure algorithm for object-to-mouth exposure and assessments.
- The previous estimate for the soil ingestion rate was reported in the 1997 USEPA SOPs for Residential Exposure Assessments and was based on the mean soil ingestion estimate from the Draft 1996 USEPA Exposure Factors Handbook for children aged 1 to 6 year olds.

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