

**Recommendation no. 14
of the BPC Ad hoc Working Group on Human Exposure**

**Default human factor values for use in exposure
assessments for biocidal products**

**(revision of HEEG opinion 17 agreed at the
Human Health Working Group III on 12 June 2017)**

Document history		
Version	Changes	Date
1	First version	Endorsed at TM II 2013
2	<p>Changes to the document:</p> <ul style="list-style-type: none"> • Inclusion of age category from 2 to < 6 years old in Appendixes A and B • Clarification in Appendix A for the age groups for adults. • The neck surface area has been included in all age groups, in Appendix A. • The trunk surface area for adults has been updated to incorporate the neck surface area. • Correction of total arms surface area for toddlers. • The surface area of the head for children has been updated. • A clarification for the derivation of default values for the body part surface areas for infants and children has been included in Appendix A. The surface area of legs includes the splitting of "thighs" and "lower legs" for all age groups. • A comment that face and scalp each compose 50% of head surface area and that the upper surface of the feet composes 50 % of the feet has been included. • Reference to Boniol et al., (2008) and to Taylor et al., 1941 have been included. 	12 May 2017

1. Introduction

This Recommendation is to promote a harmonised approach to biocide exposure assessment across Member States. Appendix A gives the agreed list of default human factors for the 'infant', 'toddler', 'child' and 'adult' (irrespective of gender) to be used in exposure/risk assessments for biocidal products.

The original HEEG Opinion Number 17 has been revised and converted into an Ad hoc Working Group - Human Exposure (HEAdhoc) recommendation in order to revise surface areas for different body parts and to include clarifications and additional references following discussion within HEAdhoc.

2. Background

- (a)** In review of available data, the NEGH Final Report ('Existing Default Values and Recommendations for Exposure assessment – A Nordic Exposure Group Project 2011) concluded that the US EPA data was the most valid. The data in Appendix A and Appendix B are based on those from the US EPA Exposure Factors Handbook (2011 Issue), which are derived from US EPA Analysis of NHANES 1999-2006. The values for body weights and body surface areas are 25th percentile values; those for females providing a worse-case exposure assessment.
- (b)** The data points in the US EPA Exposure Factors Handbook are often for a series of human age groups. For biocides assessment it would be laborious, and in fact unnecessary, for exposure assessments to determine exposures for all age groups. Therefore, in this Recommendation, in order to provide a snapshot of exposure to the human population as a whole, four representative groups have been selected: for bodyweight and body part surface area - infant (based on female 6 to <12 months old); toddler (based on female 1 to <2 years); child (based on female 2 to <6 years); child (based on female 6 to <11 years); and adult (based on female 30 to <40 years old). The inhalation rates are based on the age groups: infant (0 to <1 years old); toddler (2 years); child (3 to <6 years old); child (6 to <11 years), and for the adult (long-term exposure: 31 to 51 years old – for short-term exposure, see 2 (d)(ii) below).
- (c)** For an assessment, an Assessor would need to determine which representative group(s) is (are) at risk in a particular exposure scenario. For some scenarios, in some circumstances – an exposure assessment for one of the groups might allay concerns for the other three groups, and consequently for the human population as a whole. If so, and if explained in the assessment, actual exposure and risk calculations for the other three age groups might not need to be undertaken.

In particular for the infant and toddler, their behavioural characteristics will influence the route, frequency and degree of exposure. Definitions of both groups are given below to aid decision making.

- i) Definitions of infant:

- child who is at least 6 weeks old but less than 12 months old (Age Group Definitions – Minnesota Statutes 245A.02, subd. 19, 2016 on <https://www.revisor.mn.gov/statutes/?id=245A.02&year=2016#stat.245A.02.21>);
- child under 12 months old (http://www.proz.com/kudoz/English/education_pedagogy/1148644-infant_x_toddler.html);
- child in earliest period of life, especially before he/she can walk (<http://www.thefreedictionary.com/infant>);
- child who is in the earliest stage of extra uterine life, a time extending from the first month after birth to approximately 12 months of age, when the baby is able to assume an erect posture (<http://medical-dictionary.thefreedictionary.com/infant>)

From these definitions it is reasonable to infer that 'infants' cannot walk or crawl extensively away from the place they are put to explore their environment. An 'infant' could touch surfaces which are within reach or within a very limited distance if the infant has some crawling ability. However for airborne residue (e.g., in a room where residues are volatilising from a treated surface) an infant could potentially inhale the volatised residue for the whole of the period the infant is in the treated area.

ii) Definitions of toddler:

- 'toddling' is the kind of unsteady walking associated with young children (http://www.proz.com/kudoz/English/education_pedagogy/1148644-infant_x_toddler.html);
- child who is at least 12 months old but less than 24 months old (Age Group Definitions – Minnesota Statutes 245A.02, subd. 19 2016 on <https://www.revisor.mn.gov/statutes/?id=245A.02&year=2016#stat.245A.02.21>);
- child between 12 and 36 months of age. During this period of development the child acquires a sense of autonomy and independence through the mastery of various specialized tasks such as control of body functions, refinement of motor and language skills (<http://medical-dictionary.thefreedictionary.com/toddler>);
- when children learn to walk, begin to explore their environment (<http://extension.illinois.edu/babysitting/age-toddler.cfm>).

From these definitions it is reasonable to infer that 'toddlers' can crawl/walk away from the place they are put and move to explore their environment. For example, a toddler, held by an adult, could learn to play on a treated climbing frame. For the purposes of this document a 'toddler' will be considered to be in the age range 1 to <2 years old.

(d) Inhalation Rates

(i) There are no recommended 25th percentile values for either short-term or long-term inhalation exposure presented in the US EPA Exposure Factors Handbook (September 2011), only mean and 95th percentile values. Therefore, mean values have been adopted for the infant, toddler and child with short-term inhalation rates based on 'moderate intensity' of activity. [A 'moderate intensity' of activity being defined as:

- Fast walking, 3.3 to 4 miles per hour, and slow running, 3.5 to 4 miles per hour (page 5-8, Table 5-6 of USEPA Exposure Factors Handbook August 1997);
- and specifically for children, play (page 5-9, Table 5-7 of USEPA Exposure Factors Handbook August 1997);

- For adults, 'moderate intensity activity' includes for males, mowing, wood working, yard work (page 5-9, Table 5-7 of USEPA Exposure Factors Handbook August 1997), and for all adults heavy indoor cleanup, performance of major indoor repairs/alterations and climbing stairs (page 5-18, Table 5-16 of USEPA Exposure Factors Handbook August 1997.)

(ii) For the adult, the default short-term inhalation rate is 1.25 m³/hour; this value is retained as it has been universally used to date in biocidal product assessments and to have harmonization with other EU regulatory frameworks. It is understood 1.25 m³/hour derives from a paper by Taylor (Taylor C., American Journal of Physiology November 30 1941, 135: 27-42). From the paper, a value of pulmonary ventilation of 1.7 m³/hour was the average value of a worker (man) performing light work; litres per minute were measured and extrapolated to one hour. This makes this value of 1.7 m³/hour very conservative as the light work is not performed continuously. The value of 1.25 m³ tends to be used in industry for one hour (8m³ for ten hours) and falls within the measured limits. This rate takes into account that work resulting in faster breathing is not continuous, which is probably more the case nowadays than in 1941. Thus 1.25 m³ is considered sufficiently conservative value, especially for women; using 1.7 m³/hour for persons of 60 kg would be unrealistic.

(e) There may be situations where one or more of these default values do not make sense. In such cases, deviations from the agreed values may be used, but such deviations will need to be thoroughly justified in the assessment.

(f) It is recognised every issue yet to be met in exposure assessment cannot be foreseen. As exposure assessments progress, the suitability of the human factor default values in this Recommendation can be determined and if relevant can be amended; also, other human parameters/factors can be added.

3. References

Boniol M., Verriest J.-P., Pedeux R., and Dore J.-F.. Proportion of Skin Surface Area of Children and Young Adults from 2 to 18 Years Old. Journal of Investigative Dermatology. 2008; 128: 461-464.

Final NEGH Report: 'Existing Default Values And Recommendations for Exposure assessment – A Nordic Exposure Group Project 2011' published by the Nordic Council of Ministers, Ved Stranden 18, 1061 København K; TemaNord 2012:505; ISBN 978-92-893-2316-1.

Taylor C., American Journal of Physiology November 30 1941, 135: 27-42.

US-EPA, Human Factors Handbook (2011 Issue). EPA/600/R-090/052F Sept 2011/www.epa.gov

APPENDIX A: BODY WEIGHTS AND BODY PART SURFACE AREAS¹

DEFAULT VALUES FOR BODY WEIGHT AND BODY PART SURFACE AREAS FOR THE INFANT, TODDLER, CHILD AND ADULT					
	INFANT (< 1 year old) irrespective of gender <i>(based on data from female 6 to <12 months old)</i>	TODDLER (1 to <2 years old) irrespective of gender <i>(based on data from female 1 to <2 years old)</i>	CHILD (2 to < 6 years old) irrespective of gender <i>(based on data from female 2 to <6 years old)</i>	CHILD (6 to < 12 years old) irrespective of gender <i>(based on data from female 6 to <11 years old)</i>	ADULT irrespective of gender <i>(body weight based on data from female 30 to <40 years old: total and body parts surface areas are based on data from females >21 years old)</i>
Body weight	8 kg	10 kg	15.6 kg	23.9 kg	60 kg
Body Part Surface Areas**					
Hands (palms and backs of both hands)	196.8 cm²	230.4 cm²	330.9 cm²	427.8 cm²	820 cm²
Arms (both)	Upper = 352.6 cm² Lower = 229.6 cm² Total = 582.2 cm²	Upper = 412.8 cm² Lower = 268.8 cm² Total = 681.6 cm²	Upper = 573.5 cm² Lower = 371.7 cm² Total = 945.2 cm²	Upper = 772.8 cm² Lower = 496.8 cm² Total = 1269.6 cm²	Upper = 1141.2 cm² Lower = 1128.8 cm² Total = 2270 cm²
Head (face and scalp each compose 50% of head surface area)	344.4 cm²	403.2 cm²	523.6 cm²	531.3 cm²	1110 cm²
Trunk (bosom, neck, shoulders, abdomen, back, genitals and buttocks)	Neck = 155.8 cm² Total = 1689.2 cm²	Neck= 182.4 cm² Total = 1977.6 cm²	Neck = 240.3 cm² Total = 2774.4 cm²	Neck = 248.4 cm² Total = 3624.8 cm²	Neck = 230 cm² Total = 5940 cm²

¹ The individual body parts surfaces areas have been calculated with empirically derived formulas. These formulas were then applied to a population measured for body weight and height. Since specific parameters were used in the formulas describing each individual body part and the total body surface area as a whole, adding up the surface areas of the individual body parts results in a slight deviation to the total body surface area.

	INFANT (< 1 year old) irrespective of gender <i>(based on data from female 6 to <12 months old)</i>	TODDLER (1 to <2 years old) irrespective of gender <i>(based on data from female 1 to <2 years old)</i>	CHILD (2 to < 6 years old) irrespective of gender <i>(based on data from female 2 to <6 years old)</i>	CHILD (6 to < 12 years old) irrespective of gender <i>(based on data from female 6 to <11 years old)</i>	ADULT irrespective of gender <i>(body weight based on data from female 30 to <40 years old: total and body parts surface areas are based on data from females >21 years old)</i>
Legs (both lower legs and thighs)	Lower legs = 459.2 cm² Thighs = 582.2 cm² Total = 1041.4 cm²	Lower legs = 537.6 cm² Thighs = 681.6 cm² Total=1219.2 cm²	Lower legs = 748.0 cm² Thighs = 1049.5 cm² Total=1797.5 cm²	Lower legs = 1090.2 cm² Thighs = 1651.4 cm² Total = 2741.6 cm²	Lower legs = 2132 cm² Thighs = 3198 cm² Total = 5330 cm²
Feet (both. It is assumed that the upper surface of the feet composes 50% of the feet surface area)	246 cm²	288 cm²	428.4 cm²	604.9 cm²	1130 cm²
Total body surface area	4100 cm²	4800 cm²	6800 cm²	9200 cm²	16600 cm²
<p>* Table 7-12 in in US EPA/ Exposure Factors Handbook, Nov 2011 (data based on US EPA 1985, and NHANES 2005-2006) informs that the 25th percentile surface area for adult <u>male</u> forearms is 1320 cm² which equates to 6.8 % of the 25th percentile for the total body surface area for the male (19300 cm²). Therefore, it is assumed that the 25th percentile for the surface area of the forearms for females also equates to 6.8 % of the female 25th percentile for the total body surface area. Thus for the adult female, the surface area of both forearms is calculated to be 16600 x 6.8/100 = 1128.8 cm².</p>					
<p>** The default values for the body part surface areas for infants (based on female 6 to <12 months old) have been derived based on the proportion (%) of skin surface area for girls (age 2 years) from Table 2 in Boniol et al., 2008. The default values for the body part surface areas for child (based on female 6 to <11 years old) has been derived based on the average proportion (%) of skin surface area for girls age 6 to 12 years from Table 2 in Boniol et al., 2008.</p>					

APPENDIX B: SHORT- AND LONG-TERM INHALATION RATES

SHORT-TERM EXPOSURE VALUES FOR INHALATION²	
Infant - (< 1 year old) irrespective of gender: <i>based on data from 0 to <1 years old</i>	0.84 m³/h
Toddler - (1 to <2 years old) irrespective of gender: <i>based on data from 1 to < 2 years old</i>	1.26 m³/h
Child - (2 to < 6 years old) irrespective of gender: <i>based on data from 3 to <6 years old</i>	1.26 m³/h
Child - (6 to < 12 years old) - irrespective of gender: <i>based data from 6 to <11 years old</i>	1.32 m³/h
Adult - irrespective of gender: <i>see 2 (d)(ii) above</i>	1.25 m³/h

LONG-TERM EXPOSURE VALUES FOR INHALATION³	
Infant - (< 1 year old) irrespective of gender: <i>based on data from 0 to <1 years old</i>	5.4 m³/24-hour day
Toddler - (1 to <2 years old) irrespective of gender: <i>based on data from 1 to <2 years old</i>	8 m³/24-hour day
Child - (2 to < 6 years old) irrespective of gender: <i>based on data from 3 to <6 years old</i>	10.1 m³/24-hour day
Child - (6 to < 12 years old) irrespective of gender: <i>based on data from 6 to <11 years old</i>	12 m³/24-hour day
Adult - irrespective of gender: <i>based on data from 31 to <41 years old or 41 to <51 years old</i>	16 m³/24-hour day

² For short-term inhalation rates infants, toddlers and children values have been derived from Table 6-2 from the EPA Exposure Factors Handbook, considering moderate intensity of activity. For adults the short-term inhalation rate is derived from paper by Taylor C., 1941. The short-term inhalation rates should be used when the scenario considered exposed people as active, and does not include rest and/or sleep periods.

³ The long-term inhalation rates values are derived from Table 6-1 from the EPA Exposure Factors Handbook.