

**COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD,  
CONSUMER PRODUCTS AND THE ENVIRONMENT****Default values to be used in risk assessment in the absence of  
actual measured data****Issue**

1. The European Food Safety Authority (EFSA) recently published guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data.
2. Members are asked to consider the extent to which the EFSA guidance should be adopted in risk assessments of the COT.

**EFSA guidance on default values**

3. The EFSA opinion in Annex A provides guidance on default values and procedures to be used by EFSA in the absence of empirical data. The opinion stresses that default values should be based on existing data and should represent typical values.

***Body weights***

4. Based on data from European countries, EFSA recommended default body weight values of 70kg for adults (in contrast to the value of 60kg for adults that has commonly been used), 12 kg for young children aged 1-3 years and 5kg for infants aged 0-12 months.
5. The Secretariat uses actual body weight data when possible. For example, when using data from the National Diet and Nutritional Surveys (NDNS) to estimate dietary exposure, the Food Standards Agency (FSA) estimates are produced on a bodyweight basis for each individual in the NDNS and then the mean and high level (97.5<sup>th</sup> percentile) are calculated. If data for specific types of food are not included in the NDNS, then it might be necessary to base the exposure estimate on consumption of a portion of food. In this case, the primary calculation is on a per person basis, and this is divided by mean UK bodyweight (76 kg for adults, 41.5 kg for age 4-18 years, 14.5 kg for age 1.5-4.5 years and 8.7 kg for age 6-12 months) in order to compare with a health-based guidance value.
6. Tables 1 and 2 in Annex B show the statistics for bodyweights at different ages in the UK, for comparison with tables 1 and 3 in the EFSA opinion. These data

show that mean body weights amongst the UK survey respondents are higher than those of the combined EU data. The data in tables 1 and 2 were obtained 10 or more years ago. More recent data from the Health Survey for England 2010 show that average body weights have increased further (Annex B, tables 3 and 4).

### ***Food intake***

7. EFSA did not propose default values for total solid food intake or for acute daily total liquid intake, but recommended that a default value of 2L could be used for chronic daily total liquid intake (i.e. milk, tap water, other beverages).

8. The FSA generally uses actual data on food or liquid consumption from the NDNS, or as noted above, data on portion sizes when actual consumption data are not available.

### ***Factors for converting concentrations in feed or water to dose***

9. Toxicological studies are often conducted using a fixed concentration of chemical substance in the feed or drinking water. If the original studies did not provide data on daily dose calculated from feed or drinking water consumption then use of a conversion factor is necessary. EFSA has analysed data for feed consumption of rats and mice in order to consider whether the conversion factors originally proposed by the World Health Organization (WHO), based on data from 1954, are appropriate. Based on this analysis, EFSA confirmed the WHO feed conversion factors for chronic studies and recommended additional conversion factors for subacute and subchronic studies. EFSA also analysed data on drinking water consumption of rats and mice in order to recommend drinking water conversion factors for chronic, subacute and subchronic studies.

10. The Secretariat has commonly used the WHO conversion factors and considers that the additional factors recommended by EFSA would be useful.

### ***Uncertainty factors***

11. The COT considered the use of uncertainty factors to be used in establishing health-based guidance values in its report on variability and uncertainty in toxicology<sup>1</sup>. The EFSA recommendations are consistent with those of the COT.

### ***Rounding of figures when deriving health based-guidance values***

12. EFSA concluded that the number of significant figures expressed in reporting measure values should be determined by the precision of the analytical methodology. In contrast EFSA proposed that derived values, such as health-based guidance values, should be rounded to one or two significant figures.

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<sup>1</sup> <http://cot.food.gov.uk/cotreports/cotwgreports/cotwgvut>

**Questions on which the views of the Committee are sought**

13. Members are invited to comment on the EFSA opinion and to advise if the default values proposed by EFSA should be used in COT risk assessments.

**Secretariat  
April 2012**

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<http://www.efsa.europa.eu/en/efsajournal/doc/2579.pdf>

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**Data on bodyweights in the UK**

**Table 1. Body Weight (kg) Statistics By Age and Sex for UK Survey Populations - Adults and Elderly**

Age Range (years)	Gender	N	Mean	SD	Median	P2.5	P97.5	% ≤ 70 kg	% > 70 kg
NDNS Adults [19-64] <sup>1</sup>	♀	928	69.0	14.8	66.0	47.0	104.0	60.0	40.0
NDNS Adults [19-64] <sup>2</sup>	♂	870	84.0	14.8	82.0	61.0	115.0	16.0	84.0
NDNS Elderly Free-living [65-74] <sup>2</sup>	♀	218	66.5	12.6	66.5	43.2	92.6	68.0	32.0
NDNS Elderly Free-living [65-74] <sup>2</sup>	♂	245	78.2	12.6	76.8	55.4	105.5	24.0	76.0
NDNS Elderly Institutions [65-84] <sup>2</sup>	♀	43	57.0	9.7	54.2	38.6	77.1	92.0	8.0
NDNS Elderly Institutions [65-84] <sup>2</sup>	♂	72	66.4	13.9	63.2	42.2	98.8	68.0	32.0
NDNS Elderly Free-living [75-84] <sup>2</sup>	♀	171	64.1	11.0	63.3	42.7	87.7	72.0	28.0
NDNS Elderly Free-living [75-84] <sup>2</sup>	♂	229	74.1	11.1	72.9	53.3	95.0	37.0	63.0
NDNS Elderly Free-living [85 & over] <sup>2</sup>	♀	135	59.1	11.5	57.8	39.8	81.3	82.0	18.0
NDNS Elderly Free-living [85 & over] <sup>2</sup>	♂	85	67.3	10.2	66.2	44.4	86.9	66.0	34.0
NDNS Elderly Institutions [85 & over] <sup>2</sup>	♀	59	56.2	11.7	54.4	38.5	79.6	84.0	16.0
NDNS Elderly Institutions [85 & over] <sup>2</sup>	♂	42	65.7	11.8	64.2	46.5	92.3	69.0	31.0
NDNS Elderly Free-living [65 & over] <sup>2</sup>	♀	544	64.9	12.2	64.9	42.6	90.5	71.0	29.0
NDNS Elderly Free-living [65 & over] <sup>2</sup>	♂	559	76.5	12.4	75.6	53.6	101	30.0	70.0
NDNS Elderly Institutions [65 & over] <sup>2</sup>	♀	102	56.5	10.9	54.5	38.5	79.5	88.0	12.0
NDNS Elderly Institutions [65 & over] <sup>2</sup>	♂	114	66.1	13.0	63.5	45.2	96.8	68.0	32.0

**Table 2. Body Weight (kg) Statistics By Age and Sex for UK Survey Populations - Children and Adolescents**

Age Range (years)	Gender	N	Mean	SD	Median	P2.3	P5	P95	P97.7
NDNS Toddlers [1½ - 2½] <sup>3</sup>	♀	283	11.9	1.6	11.7	8.8	-	-	15.2
NDNS Toddlers [1½ - 2½] <sup>3</sup>	♂	294	12.6	1.6	12.6	9.4	-	-	15.9
NDNS Toddlers [2½ - 3½] <sup>3</sup>	♀	314	14.3	1.7	14.3	11.2	-	-	17.9
NDNS Toddlers [2½ - 3½] <sup>3</sup>	♂	307	14.9	1.9	14.8	11.6	-	-	19.3
NDNS Toddlers [3½ - 4½] <sup>3</sup>	♀	258	16.4	2.1	16.3	12.7	-	-	20.1
NDNS Toddlers [3½ - 4½] <sup>3</sup>	♂	251	16.6	2.1	16.8	13.1	-	-	21.0
NDNS Young persons [4-6] <sup>4</sup>	♀	202	20.0	3.5	20.0	-	16.0	24.0	-
NDNS Young persons [4-6] <sup>4</sup>	♂	213	21.0	3.6	21.0	-	16.0	26.0	-
NDNS Young persons [7-10] <sup>4</sup>	♀	253	32.0	7.5	31.0	-	22.0	42.0	-
NDNS Young persons [7-10] <sup>4</sup>	♂	288	30.0	7.6	29.0	-	22.0	39.0	-
NDNS Young persons [11-14] <sup>4</sup>	♀	259	49.0	11.2	48.0	-	33.0	61.0	-
NDNS Young persons [11-14] <sup>4</sup>	♂	268	47.0	11.8	45.0	-	32.0	64.0	-
NDNS Young persons [15-18] <sup>4</sup>	♀	241	60.0	11.8	57.0	-	45.0	75.0	-
NDNS Young persons [15-18] <sup>4</sup>	♂	222	68.0	14.8	65.0	-	48.0	86.0	-
NDNS Young persons [4-18] <sup>4</sup>	♀	955	41.0	17.4	39.0	-	18.0	63.0	-
NDNS Young persons [4-18] <sup>4</sup>	♂	991	42.0	20.3	37.0	-	19.0	71.0	-

**Notes to tables 1 and 2:** Some sample sizes for groups are small (<50) and estimates should be treated with caution

<sup>1</sup> Henderson, L., Gregory J. and Swan, G. (2002) *National Diet and Nutrition Survey: Adults Aged 19 to 64 years*. Volume 1: Types and Quantities of Foods Consumed. HMSO, London.

<sup>2</sup> Finch, S., Doyle, W., Lowe, C., Bates, C. J., Prentice, A., Smithers, G. and Clarke, P. C. (1998) *The National Diet and Nutrition Survey: People Aged 65 Years and Over*. Volume 1: Report of the Diet and Nutrition Survey. HMSO, London

<sup>3</sup> Gregory, J. R., Collins, D. L., Davies, P. S. W., Hughes, J. M. and Clarke, P. C. (1995) *National Diet and Nutrition Survey: Children Aged 1½ to 4½ Years*. Volume 1: Report of the Diet and Nutrition Survey. HMSO, London.

<sup>4</sup> Gregory, J., Lowe, S., Bates, C. J., Prentice, A., Jackson, L. V., Smithers, G., Wenlock, R. and Farron, M. (2000) *National Diet and Nutrition Survey: Young People Aged 4 to 18 Years*. Volume 1: Report of the Diet and Nutrition Survey. HMSO, London.



**Table 3: Data on adult body weights from Health Survey for England 2010**

*Adults aged 16 and over with a valid weight measurement (kg)*

<b>Age (years)</b>	Mean <b>MEN</b>	Mean <b>WOMEN</b>	Mean <b>ALL ADULTS</b>
16-24	76.9	65.4	71.5
25-34	83.1	70.2	77.1
35-44	87.3	72.5	79.9
45-54	89.2	73.8	81.5
55-64	87.9	73.8	80.8
65-74	84.4	73.6	78.9
75+	80.5	66.8	72.8
<b>ALL</b>	84.6	71.2	77.9

<sup>b</sup> data have been weighted for non-response.

**Table 4: Data on adult body weights from Health Survey for England 2010**

*Children aged 0-15<sup>a</sup> with valid weight measurement (kg)*

<b>Age</b>	Mean <b>BOYS</b>	Mean <b>GIRLS</b>	Mean <b>ALL CHILDREN</b>
0	[7.9]	[7.6]	7.7
1	12.0	[11.5]	11.7
2	14.4	13.4	13.9
3	16.6	16.2	16.4
4	19.1	18.5	18.8
5	20.9	20.5	20.7
6	23.8	23.2	23.5
7	26.4	27.4	26.9
8	29.6	29.1	29.3
9	33.1	33.5	33.3
10	36.0	37.4	36.7
11	42.1	42.0	42.1
12	46.7	50.4	48.6
13	52.6	52.5	52.5
14	60.0	57.2	58.7
15	64.2	58.9	61.7
age 2-15	35.0	34.0	34.5
age 0-15	32.4	31.5	31.9

<sup>a</sup> Data in this table are based on age last birthday.

[ ] Results in brackets should be treated with caution because of the small number of subjects (below 50).

Source - <http://www.ic.nhs.uk/pubs/hse10report>