Exposure assessment

In this guide

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Exposure from ultraviolet (UV) B radiation

56. As discussed in the 2022 COT Statement on the potential effects of excess vitamin D intake during preconception, pregnancy and lactation "there are many factors affecting vitamin D formation such as season, time of day, amount of skin exposed, skin pigmentation and use of SPF sunscreen and this is reflected in the NHS Consensus Vitamin D position that states "there is still a lot of uncertainty around…how much sunlight different people need to achieve a given level of vitamin D" (NHS, 2010). Further information on serum 25(OH)D levels in multiple ethnicities with different exposure durations to UV radiation in different seasons has been discussed in the Statement on the potential effects of excess vitamin D intake during preconception, pregnancy and lactation.

57. Considering the above information, in 2022 the COT decided not to include exposure from UVB radiation in exposure assessment calculations. This was because "prolonged sunlight exposure does not lead to excess production of cutaneous vitamin D because endogenously produced pre-vitamin D3 and vitamin D3 are photolyzed to inert compounds" and that "even with prolonged irradiation in sunlight the amount of pre-vitamin D formed is limited to 12-15% of the original 7-DHC (MacLaughlin et al., 1982; Webb et al., 1988)" (SACN citing Hollick et al.,1980; MacLaughlin et al., 1982; Webb et al., 1988)".

Occurrence of calcidiol in food

58. Calcidiol, may be present in some foods of animal origin such as milk, butter, eggs, fish, meat and offal in the form of 25-hydroxycholecalciferiol (25(OH)D3) or 25-hydroxyergocalciferol (25(OH)D2). Calcidiol in the form 25-hydroxyergocalciferol has been reported in whole milk, butter and in some meat and offal (Ovesen et al., 2003; Jakobsen and Saxholt, 2009).

59. Occurrence of calcidiol in 11 food sources was reported in EFSA's 2021 paper **'Safety of calcidiol monohydrate produced by chemicals synthesis as a novel food pursuant to Regulation (EU)2015/2283'**. These levels have been summarised and can be found in Table 1.

Table 1. Foods containing calcidiol (Adapted from page 11 of EFSA, 2021).

Food	Form of calcidiol	Concentration (µg /kg)
Semi-skimmed milk	25-hydroxycholecalciferol	0.042

Whole milk	25-hydroxyergocalciferol	0.031
Butter	25-hydroxycholecalciferol,	0.96
Butter	25-hydroxyergocalciferol	0.58
Egg yolks	25-hydroxycholecalciferol	5 – 12
Salmon flesh	25-hydroxycholecalciferol	1.1
Raw trout	25-hydroxycholecalciferol	2.2
Pork cuts	25-hydroxycholecalciferol	0.7 – 1.4
Pork rind	25-hydroxycholecalciferol	3.4
Pork liver	25-hydroxycholecalciferol	4.8
Cow Kidney	25-hydroxycholecalciferol	5.1 – 9.8
Beef Liver	25-hydroxyergocalciferol	1.7

Food consumption

60. The following exposure assessments for calcidiol in food are based on consumption data from the National Diet and Nutrition Survey (NDNS) (Bates et al., 2014, 2016, 2020; Roberts et al., 2018); however, it is important to note that the NDNS does not provide data for pregnant or lactating women. Therefore, data presented below are based on women of childbearing age (16-49 years) and consumption data may not be entirely representative of the maternal diet, specifically in liver food groups due to National Health Service (NHS) recommendations that pregnant women should not consume liver or liver products (NHS, 2024). Evidence suggests that some foods and nutrients may be

under-reported to a greater extent than others, and some may be overreported, but there is no information available on the level to which different foods are misreported in the NDNS in this group.

61. Consumption data were generated for all 11 food groups in Table 1 including both whole foods and recipes; these data can be found in Annex A. Table A1 provides acute consumption data and Table A2 provides chronic consumption data. Both tables summarise the mean and 97.5th percentile consumption per food group, for women of childbearing age.

Milk

62. A search within the recipes database of the NDNS (Bates et al., 2014, 2016, 2020; Roberts et al., 2018) was conducted to retrieve both semi-skimmed milk, whole milk, and recipes containing milk which had been recorded in the survey. Other types of milk were excluded as this search was conducted based on the food groups described in Table 1.

Butter

63. Calcidiol has been detected in butter as both 25-hydroxycholecalciferol and 25-hydroxyergocalciferol (EFSA, 2021). Consumption data were retrieved for butter and recipes containing butter.

Egg Yolk

64. Both whole egg and yolk only consumption was included from the NDNS database to ensure that all egg yolk consumers were included. Foods containing egg white only were excluded from the assessment. The egg yolk makes up approximately 29.3% of the edible portion of a medium egg, and 28.7% of a large egg. The NDNS database does not specify the use of large or medium eggs therefore the figure was rounded to 29% (DH, 2012) and applied to whole eggs foods to give estimates for consumption specifically of egg yolks.

Salmon

65. Foods containing salmon in the NDNS database do not specify with or without skin, however the assumption has been made that recipes represent salmon flesh.

Trout

66. Due to a low number of consumers of trout in the NDNS database, an ‘all fish’ food group was used as proxy based on the assumption that trout is eaten in similar quantities to other types of fish such as cod and haddock.

67. It is important to note that whilst levels of Calcidiol were detected in raw trout, both canned and cooked fish and fish recipes were used within this exposure assessment as raw trout data were not available within the NDNS.

Pork

68. Calcidiol is present in in pork cuts, pork rind, and pork liver as 25-hydroxycholecalciferol. The NDNS database was used to retrieve recipes containing varying forms of pork meat including pork belly, pork loin, sausages and bacon. Within the database, pork crackling was used to represent consumption of pork rind.

Beef kidney

69. Due to a low number of consumers of beef kidney in the NDNS database, an ‘all kidney’ food group was used as proxy based on the assumption that kidney from animals such as lamb and pork would be consumed similarly.

Beef Liver

70. For women of childbearing age, within the NDNS database there are no consumers of beef liver, therefore an ‘all liver’ food group was used as proxy based on the assumption that liver from animals such as chicken and lamb would be consumed similarly.

Exposure estimates from food

71. An exposure assessment was conducted using food groups and occurrence levels presented in Table 1 only. A summary of exposure estimates for each food at its corresponding occurrence level of calcidiol can be found in Table 2 and 3. Table 2 provides acute exposure estimates to calcidiol from food, and Table 3 provides chronic exposure estimates, for women of childbearing age. In these tables, acute and chronic exposures are presented for both mean and 97.5th percentile groups on a per person and per kilogram bodyweight basis.

Table 2: Estimated acute exposure to Calcidiol from food for women of childbearing age (16-49 years).

Food Groups	**Type of Calcidiol**	**Level(s) detected (µg/kg)**	**Number of consumers**	**Mean (µ g/person/day)***	**P97.5 (µ g/person/day)***
Semi-skimmed milk	25-hydroxycholecalciferol	0.042	2083	0.0085	0.026
Whole milk	25-hydroxyergocalciferol	0.031	1333	0.0041	0.017
Butter	25-hydroxycholecalciferol	0.96	1736	0.015	0.049
Butter	25-hydroxyergocalciferol	0.58	1736	0.0092	0.029
Egg yolk	25-hydroxycholecalciferol	5.0 - 12.0	2128	0.17- 0.41	0.46 -1.1
Salmon	25-hydroxycholecalciferol	1.1	375	0.087	0.22
Trout	25-hydroxycholecalciferol	2.2	168	0.17	0.52
Pork cuts	25-hydroxycholecalciferol	0.7 - 1.4	1406	0.049 - 0.099	0.15 - 0.3
Pork rind	25-hydroxycholecalciferol	3.4	69	0.053	0.21

Pork liver	25-hydroxycholecalciferol	4.8	68	0.096	0.26
Cow Kidney	25-hydroxycholecalciferol	5.1 - 9.8	17**	0.077 - 0.15	0.14 - 0.27
Beef Liver	25-hydroxyergocalciferol	1.7	96	0.063	0.21

*Rounded to 2 s.f.

** Consumption or exposure estimates made with a small number of consumers may not be accurate. Where the number of consumers is less than 60, this should be treated with caution and may not be representative for a large number of consumers.

Table 3: Estimated chronic exposure to Calcidiol from food for women of childbearing age (16-49 years).

Food Groups	**Type of Calcidiol**	**Level(s) detected (µg /kg)**	**Number of consumers**	**Mean (ug/person/day)***	**P97.5 (ug/person/da**
Semi-skimmed milk	25-hydroxycholecalciferol	0.042	2083	0.0048	0.017
Whole milk	25-hydroxyergocalciferol	0.031	1333	0.002	0.01
Butter	25-hydroxycholecalciferol	0.96	1736	0.0066	0.024

Butter	25-hydroxyergocalciferol	0.58	1736	0.004	0.014
Egg yolks	25-hydroxycholecalciferol	5.0 - 12.0	2128	0.066 - 0.16	0.2 - 0.47
Salmon	25-hydroxycholecalciferol	1.1	375	0.025	0.059
Trout	25-hydroxycholecalciferol	2.2	168	0.047	0.16
Pork cuts	25-hydroxycholecalciferol	0.7 - 1.4	1406	0.016 - 0.033	0.057 - 0.11
Pork rind	25-hydroxycholecalciferol	3.4	69	0.015	0.053
Pork liver	25-hydroxycholecalciferol	4.8	68	0.028	0.09
Cow Kidney	25-hydroxycholecalciferol	5.1 - 9.8	17**	0.02 - 0.038	0.038 - 0.073
Beef Liver	25-hydroxyergocalciferol	1.7	96	0.017	0.06

*Rounded to 2 s.f.

** Consumption or exposure estimates made with a small number of consumers may not be accurate. Where the number of consumers is less than 60, this should be treated with caution and may not be representative for a large number of consumers.

Milk

72. Acute exposure estimates derived for 25-hydroxycholecalciferol in semi-skimmed milk at a concentration of 0.042 µg/kg are 0.0085 µg/day and 0.026 µg/day mean and 97.5th percentile values, respectively. Chronic exposure estimates are 0.0048 µg/day and 0.017 µg/day mean and 97.5th percentile values, respectively.

73. Acute exposure estimates derived for 25-hydroxyergocalciferol in whole milk at a concentration of 0.031 µg/kg are 0.0041 µg/day and 0.017 µg/day mean and 97.5th percentile values, respectively. Chronic exposure estimates are 0.002 µg/day and 0.01 µg/day mean and 97.5th percentile values respectively.

Butter

74. Calcidiol in butter was detected as 25-hydroxyergocalciferol at a concentration of 0.58 µg/kg and as 25-hydroxycholecalciferol at a concentration of 0.96 µg/kg and.

75. At a concentration of 0.58 µg/kg acute exposures were 0.0092 µg/day and 0.029 µg/day mean and 97.5th percentile values, respectively. At a concentration of 0.96 µg/kg, acute exposure estimates are 0.015 µg/day and 0.049 µg/day mean and 97.5th percentile values, respectively.

76. Chronic exposure estimates at a concentration of 0.58 µg/kg are 0.004 µg/day and 0.014 µg/day mean and 97.5th percentile values, respectively. At a concentration of 0.96 µg/kg, exposure estimates are 0.0066 µg/day and 0.024 µg/day mean and 97.5th percentile values, respectively.

Egg yolk

77. In egg yolk, 25-hydroxycholecalciferol was detected at a range of 5.0 to 12 µg/kg. Acute exposure estimates range from 0.17 to 0.41 µg/day and 0.46 to 1.1 µg/day mean and 97.5th percentile values, respectively. Chronic exposure estimates range from 0.066 to 0.16 µg/day and 0.2 to 0.47 µg/day mean and 97.5th percentile values, respectively. The highest exposure to calcidiol from food was noted from egg yolks.

Salmon

78. Acute exposure estimates to 25-hydroxycholecalciferol in salmon at a level of 1.1 µg/kg are 0.087 µg/day and 0.22 µg/day mean and 97.5th percentile values, respectively. Chronic exposure estimates are 0.025 µg/day and 0.059

µg/day mean and 97.5th percentile values, respectively.

Pork

79. 25-hydroxycholecalciferol was detected at a range of 0.7 to 1.4 µg/kg in pork cuts, 3.4 µg/kg in rind (crackling), and 4.8 µg/kg in pork liver.

80. Acute mean exposures range from 0.049 to 0.099 µg/day in pork cuts, 0.053 µg/day in rind (crackling), and 0.096 µg/day in pork liver. Acute exposure estimates at the 97.5th percentile range from 0.15 to 0.3 µg/day in pork cuts, 0.21 µg/day in rind (crackling), and 0.26 µg/day in pork liver.

81. Chronic mean exposures range from 0.016 to 0.033 µg/day in pork cuts, 0.015 µg/day in rind (crackling), and 0.028 µg/day in pork liver. Chronic exposure estimates at the 97.5th percentile range from 0.057 to 0.11 µg/day in pork cuts, 0.053 µg/day in rind (crackling), and 0.09 µg/day in pork liver.

Beef

82. 25-hydroxycholecalciferol was detected in beef kidney at a range of 5.1 to 9.8 µg/kg, whilst 25-hydroxyergocalciferol was detected at a level of 1.7 µg/kg in beef liver.

83. Acute mean exposures range from 0.077 to 0.15 µg/day in beef kidney, and 0.063 µg/day in beef liver. Acute exposure estimates at the 97.5th percentile range from 0.14 to 0.27 µg/day in beef kidney, and 0.21 µg/day in beef liver.

84. Chronic mean exposures range from 0.02 to 0.038 µg/day in beef kidney, and 0.017 µg/day in beef liver. Chronic exposure estimates at the 97.5th percentile range from 0.038 to 0.073 µg/day in beef kidney, and 0.06 µg/day in beef liver.

Total exposure estimates from food sources

85. Estimated total exposures to calcidiol from 11 food sources (Table 1), in women aged 16-49 years, are presented in Tables 3 and 4 below. Due to a range of occurrence values for some food groups, these data have been presented as minimum and maximum exposure estimates. Exposure data from food sources containing calcidiol will be compared to the ACNFP TUL of 40 µg/day and the level EFSA established as safe (i.e., up to 10 µg/day.

Table 3. Estimated total acute exposure to calcidiol from food sources (excluding supplements) in women aged 16-49 years.

Total calcidiol exposure** (food sources)	Mean (µg/person/day)*	P97.5 (µg/person/day)*	Mean (µg/kg bw/day)*	P97.5 (µg/kg bw/day)*
Minimum	0.19	0.5	0.0028	0.008
Maximum	0.4	1.1	0.006	0.017

*Rounded to 2 s.f.

** Determined from a distribution of consumption of any combination of categories, rather than by summation of the respective individual mean / 97.5th percentile consumption value for each of the 11 food categories.

86. Women of childbearing age are estimated to have minimum acute calcidiol exposures of 0.19 and 0.5 µg/day for mean and 97.5th percentile consumption, respectively. Maximum acute exposures are 0.4 and 1.1 µg/day for mean and 97.5th percentile consumption, respectively.

Table 4. Estimated total chronic exposure to calcidiol from food sources (excluding supplements) in women aged 16-49 years.

Total calcidiol exposure** (food sources)	Mean (µg/person/day)*	P97.5 (µg/person/day)*	Mean (µg/kg bw/day)*	P97.5 (µg/kg bw/day)*
Minimum	0.082	0.24	0.0012	0.0038
Maximum	0.17	0.52	0.0025	0.0081

* Rounded to 2 s.f.

**Determined from a distribution of consumption of any combination of categories, rather than by summation of the respective individual mean / 97.5th percentile consumption value for each of the 11 food categories.

87. Women of childbearing age are estimated to have minimum chronic exposures of calcidiol at 0.082 and 0.24 µg/day mean and 97.5th percentile values, respectively. Maximum expsoures are 0.17 and 0.52 µg/day mean and 97.5th percentile values, respectively.

Exposure estimates from supplements

88. Calcidiol is currently available in supplemental form and may be used in future food fortification (Guo et al., 2017). Calcidiol is present in supplements in the form of calcifediol or 25(OH)D (Biondi et al., 2017).

89. Supplements aimed at adults were identified using online sources which supplied calcidiol in doses ranging from 10 to 20 µg/day. No supplements containing calcidiol were identified that were specifically aimed at pregnant and breast-feeding women.

90. Estimate calcidiol exposures from calcidiol-containing supplements are presented in Table 5. These exposure estimates assume that a 70.3 kg female between the ages of 16 to 49 consumes the supplement at the recommended dose for adults. The bodyweight of 70.3 kg was determined as the mean bodyweight of all females of childbearing age (16 to 49 years) within years 1-11 of the NDNS database.

91. The limited number of calcidiol-containing supplements available on the market are presented in Table 5, some of which are not available in the UK, but are able to be ordered online from international stores.

Supplement	Calcidiol concentration per serving (µg)	Serving size (tablets/day)	Calcidiol exposure (µg/kg bw/day)**
VitamoreD - Vitamin D3 as Calcifediol	10	1	0.14

D.velop Tablets Adult	20	2	0.28
D.velop Gummies Adult	10	2	0.14
Bioclinic Naturals Opti Active D	10	1	0.14
Vitamin D DPrev Active	10	1	0.14

Table 5. Calcidiol exposure estimates for women of childbearing age consuming calcidiol-containing supplements*

* based on a bodyweight of 70.3kg.

** Rounded to 2 s.f.

92. The supplements listed in Table 5 are generally aimed at adults although it should be noted that pregnant women may consume these supplements as many individuals are unaware of their pregnancy at the time and may consume calcidiol-containing supplements that are of higher potency than vitamin D2 and D3 supplements.

93. The estimated calcidiol exposures from calcidiol-containing supplements range from 10 to 20 µg/day, which is equivalent to 0.14 to 0.28 µg/kg bw/day.

Total exposure estimates from food and supplements combined

94. Total exposure estimates to calcidiol from food and supplement sources combined in women aged 16-49 years are presented in Tables 6 and 7 below. For acute exposure estimates, total exposure from food sources (Table 2) was summed with exposure data from dietary supplements (Table 5). For chronic exposure estimates, total exposure from food sources (Table 4) was summed with exposure data from dietary supplements (Table 5).

95. To calculate the minimum total exposures in Tables 6 and 7, the lowest supplement exposure (10 µg/person/day or 0.14 µg/kg bw/day) was summed with the minimum exposures from food (Tables 4 and 5) for both mean and 97.5th percentile consumption. To calculate the maximum total exposures as seen in Tables 6 and 7, the highest supplement exposures from Table 5 (20 µg/person/day or 0.28 µg/kg bw/day) were summed with the maximum exposures from food (Tables 3 and 4) for both mean and 97.5th percentile consumption.

Table 6. Estimated total acute calcidiol exposure from food sources combined with supplements in women aged 16-49 years.

Total calcidiol exposure (food + supplements)	**Mean (ug/person/day)***	**P97.5 (ug/person/day)***	**Mean (µg/kg bw/day)***	**P97.5 (µg/kg bw/day)***
Minimum	10	11	0.14	0.15
Maximum	20	21	0.29	0.3

* Rounded to 2 s.f.

96. Minimum total acute calcidiol exposures from all dietary sources including supplements, for women aged 16-49 years, are 10 µg/day and 11 µg/day for mean and 97.5th percentile consumption, respectively. Maximum total acute exposures from all dietary sources including supplements are 20 µg/day and 21 µg/day mean and 97.5th percentile, respectively.

Table 7. Estimated total chronic calcidiol exposure from food sources combined with supplements in women aged 16-49 years.

Total calcidiol exposure (food + supplements)	**Mean (ug/person/day)***	**P97.5 (ug/person/day)***	**Mean (µg/kg bw/day)***	**P97.5 (µg/kg bw/day)***
Minimum	10	10	0.14	0.14

Maximum	20	21	0.28	0.29

* Rounded to 2 s.f.

97. Minimum total chronic calcidiol exposure from all dietary sources including supplements amongst women aged 16-49 years is 10 µg/day for both mean and 97.5th percentile groups. Maximum total chronic exposures from all food sources are 20 µg/day and 21 µg/day mean and 97.5th percentile values, respectively. Exposure to calcidiol from dietary sources are minor relative to exposure from supplements.