

# Annex A - Exposure assessment

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41. Raspberry leaf is typically consumed during pregnancy as tea (fresh or dried leaf preparations), tablets or tinctures (EMA, 2014; Bowman et al., 2021). Different recommendations exist as to when women should commence raspberry leaf use during pregnancy; most online sources suggest taking it from the third trimester, typically as tea or tablets, while others suggest taking it from the second or even first trimester (Appendix 2).

42. While not specific to raspberry leaf, data from the National Diet and Nutrition Survey (NDNS) on chronic herbal and fruit tea consumption among women of childbearing age (16-49 years) may provide an indication of raspberry leaf tea intake during pregnancy and is displayed in Tables 1a and 1b (without recipes). The data suggest that women within this age group consume a mean of 4.5 mL/kg bw/day or 16 mL/kg bw/day at the 97.5th percentile, as consumed. This corresponds to a mean of 0.045 g/kg/bw/day herbal or fruit tea or 0.16 g/kg/bw/day at the 97.5th percentile on a dried basis.

43. Significantly, it is still unclear as to what the active components in raspberry leaf are (Bowman et al., 2021). However, some raspberry leaf components, such as polyphenolic compounds, may vary in concentration between different raspberry leaf preparations, depending on area of cultivation, in a way which may affect their bioactivity and potentially also their toxicity (Venskutonis et al., 2007). Nor does NDNS data capture consumption data for pregnant or lactating women and so while the data in Tables 1a and 1b are based on women of childbearing age, they may not necessarily be representative of the maternal diet. Therefore, consumption data for raspberry leaf tea, tablets and tinctures were also estimated during each trimester based on dose recommendations gathered from online sources by the FSA’s exposure team. These are displayed in Tables 2a and 2b.

44. Assuming that one teabag represents 2 g tea, that a single cup holds 350 mL fluid and that capsules contain 100% dried raspberry leaf, online sources suggest that raspberry leaf consumption ranges from 350-1,750 mL/person/day for tea, 16-24 mL/person/day for tinctures and 900-2,400 mg/person/day for tablets during pregnancy, as consumed. In terms of dried weight, this corresponds to 2-10 g/person/day for tea, 0.014-0.021 g/person/day for tinctures and 0.9-2.4 g/person/day for tablets.

45. A retrospective cohort study suggested that at least 3.5% of women may use a combination of raspberry leaf tea, tablets and tinctures during pregnancy (Parsons et al., 1999). Therefore, the FSA’s Exposure Team calculated consumption values for raspberry leaf during pregnancy, assuming combined use of tea, tablets and or tinctures in order to cover different worst-case exposure scenarios. These values are displayed in Table 3 and were based on online dose recommendations during the third trimester, which is when raspberry leaf appears to be taken most commonly. It is apparent that the consumption level resulting from combined use of raspberry leaf tea, tablets and tinctures may reach up to 12.421 g/person/day.

**Table 1a.** Estimated chronic consumption of herbal and fruit teas as consumed (without recipes)\*<sup>ab</sup>.

<b>Consumers (n)</b>	<b>Mean (mL/person/day)</b>	<b>97.5<sup>th</sup> percentile (mL/person/day)</b>	<b>Mean (mL/kg bw/day)</b>	<b>97.5<sup>th</sup> percentile (mL/kg bw/day)</b>	<b>Respondents population group (n)</b>
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364                      290                                      1100                                      4.5                      16                                      2556

\*Rounded to 2 significant figures.

aBased on females aged 16-49 in NDNS years 1-11.

bConversion factor of 0.99 used to convert tea from dry weight to as consumed.

**Table 1b.** Estimated chronic consumption of herbal and fruit teas dry weight (without recipes)<sup>\*ab</sup>.

<b>Consumers (n)</b>	<b>Mean (g/person/day)</b>	<b>97.5<sup>th</sup> percentile (g/person/day)</b>	<b>Mean (g/kg bw/day)</b>	<b>97.5<sup>th</sup> percentile (g/kg bw/day)</b>	<b>Respondents population group (n)</b>
364	2.9	11	0.045	0.16	2556

\*Rounded to 2 significant figures.

aBased on females aged 16-49 in NDNS years 1-11.

bConversion factor of 0.01 used to convert tea as consumed to dry weight.

**Table 2a.** Raspberry leaf-containing teas, tinctures and tablets summary table of suggested serving sizes on an as-consumed basis (data pooled from online sources in Appendix 2).

<b>Stage of pregnancy</b>	<b>Suggested serving size per day (as consumed) Tea (mL) <sup>*a</sup></b>	<b>Suggested serving size per day (as consumed) Tincture (mL)</b>	<b>Suggested serving size per day (as consumed) Capsules/tablets (mg)</b>
1 <sup>st</sup> trimester	350	N/a	N/a

2 <sup>nd</sup> trimester	700	N/a	N/a
3 <sup>rd</sup> trimester	350 - 1,750	16 - 24	900 - 2,400

\*Calculated on the assumption that 1 teabag contains approximately 2 g of tea.

aCalculated on the assumption that a large mug holds approximately 350 mL of tea.

N/a = no sources recommending consumption.

**Table 2b.** Raspberry leaf-containing teas, tinctures and tablets summary table based on dry weight of raspberry leaf consumed (data pooled from online sources in Appendix 2).

Stage of pregnancy	Suggested serving size per day (as consumed) Tea (g)*	Suggested serving size per day (as consumed) Tincture (g) <sup>a</sup>	Suggested serving size per day (as consumed) Capsules /tablets (g) <sup>b</sup>
1 <sup>st</sup> trimester	2	N/a	N/a
2 <sup>nd</sup> trimester	4	N/a	N/a
3 <sup>rd</sup> trimester	2-10	0.014-0.021	0.9 - 2.4

\*Calculated on the assumption that 1 teabag contains approximately 2 g of tea.

aCalculated on the assumption that the tincture was made 1:1 weight to volume ratio. Assumption that fresh leaf is 77.75 % moisture content of nettle leaves.

bAssumption that capsules contain 100% dried raspberry leaf tea.

**Table 3.** Combined consumption scenarios of raspberry leaf tea (dry weight) in the third trimester.

<b>Estimated consumption of dry raspberry leaf (g per day) Tea</b>	<b>Estimated consumption of dry raspberry leaf (g per day) Tincture</b>	<b>Estimated consumption of dry raspberry leaf (g per day) Capsule</b>	<b>Estimated consumption of dry raspberry leaf (g per day) Total consumed per day</b>
2-10	0.014-0.021	0.9-2.4	2.914 - 12.421
2-10	0.014-0.021	N/a	2.014 - 10.021
2-10	N/a	0.9-2.4	2.9 - 12.4
N/a	0.014-0.021	0.9-2.4	0.914 - 2.421