Exposure Assessment

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84. *Echinacea* is not used as a food commodity on its own or in recipes for cooking, but there are tea and honey products, found from online sources, supplemented with *Echinacea* and *Echinacea* extracts (Appendix B, Table 7) and these could be consumed as part of the general diet. Data from the National Diet and Nutrition Survey (NDNS) (Bates *et al*., 2014, 2016, 2020; Roberts *et al*., 2018)

on acute herbal and fruit tea consumption and honey among women of childbearing age (16-49 years) may provide an indicator of *Echinacea* intake from these foods during pregnancy. The acute consumption scenario is considered because *Echinacea* products are likely to be consumed for a short period of time during an episode of cold/flu during pregnancy. The NDNS does not provide data for pregnant or lactating women, so while data is based on women of childbearing age, this may not necessarily be representative of the maternal diet. It is also worth noting that some of the *Echinacea* containing tea products advise pregnant or lactating women to consult a healthcare professional prior to using the product. The *Echinacea*-containing honey states that it is suitable for pregnant or breastfeeding women, whilst the lozenges contain no warnings. Like tablets and capsules, lozenges are solid dosage forms, but they are specifically designed to dissolve or disintegrate slowly in the mouth and are formulated with a flavoured or sweetened base.

85. The NDNS data indicate that women of childbearing age consume a mean of 520 mL/person/day or 1,500 mL/person/day at the 97.5th percentile of herbal and fruit tea at the acute consumption level (Table 3). The consumption of herbal and fruit tea has been used as a proxy for the consumption of *Echinacea* tea. Information from *Echinacea* tea products available suggests preparing the teacup with 227-250 mL hot water and consumption recommendations vary between 2-6 cups per day (Appendix B, Table 7). Based on the *Echinacea* content of the tea products, (Table 7, Appendix B) that would provide 144 - 1005 mg *Echinacea* per cup of tea, assuming 100% extraction efficiency. Taking the NDNS data for the consumption of herbal and fruit teas into consideration and the assumption that a cup of *Echinacea* tea will be prepared with 250 mL water, this would equate to the consumption of 6 cups of *Echinacea* tea per day at the 97.5th percentile by women of childbearing age. This corresponds to an estimated acute exposure of 864 to 6,030 mg of *Echinacea* per day at the 97.5th percentile, resulting from the consumption of *Echinacea* tea.

Table 3: Acute consumption of herbal and fruit tea (as consumed), as a proxy for *Echinacea* tea consumption (without recipes)

Consumers (n)^	**Mean (mL/person /day)**	**97.5th percentile (mL/person /day)**	**Mean (mL/kg/ bw/day)**	**97.5th percentile (mL/kg bw/day)**

364	520	1,500	8.0	23

*Rounded to 2 significant figures.

^Based on women of childbearing age (16-49 years).

86. The NDNS data on honey consumption (Table 4) suggests that women of childbearing age have a mean acute consumption of honey of 15 g/person/day honey or 48 g/person/day at the 97.5th percentile. *Echinacea* honey products contain 0.4-2.1 mg *Echinacea* per 1 g honey (Appendix B, Table 7). This corresponds to an estimated acute exposure of 19 to 101 mg of *Echinacea* per day at the 97.5th percentile, resulting from the consumption of *Echinacea* honey.

Table 4: Acute consumption of honey as a proxy for *Echinacea* honey consumption (without recipes)

Consumers (n)^	**Mean (g/person /day)**	**97.5th percentile (g/person /day)**	**Mean (g/kg/ bw/day)**	**97.5th percentile (g/kg bw/day)**
293	15	48	0.23	0.75

*Rounded to 2 significant figures.

^Based on women of childbearing age (16-49 years).

87. *Echinacea* supplements available online include solid dosage forms (tablets and capsules; Appendix B, Table 8) and oral liquids (solutions and tinctures; Appendix B, Table 9). Most of these supplements advise consulting a healthcare provider prior to using them during pregnancy/breastfeeding or state that they are not suitable for use during these periods. In addition, some of the supplements recommend short-term use only (5 days to several weeks). For products with herbal blends or unclear directions, the daily *Echinacea* dose is difficult to determine. Where extracts are specified, tablets/capsules provide 130–700 mg dry herb extract (equivalent to 1,300–7,000 mg herb). Products with dried plant parts contain 400–3,600 mg herb or 500–3,200 mg root. Fewer oral liquid products were found, and some lacked clear composition or usage

instructions. Available liquids deliver 500–1,500 mg herb extract or 600–3,000 mg dried herb daily.

88. The *Echinacea* products for oral use with THR from the MHRA include tablets, capsules, oral solutions, tinctures and oromucosal spray (Appendix B, Table 13). The most common are tablets and capsules containing dry extract of *E. purpurea* root, with daily doses of 143–429 mg (equivalent to 858–3,000 mg root). Preparations from dried pressed juice of *E. purpurea* herb provide 176–352 mg daily (equivalent to 3.5–9.8 g fresh herb). A comparison between the THR products and the EMA monographs in terms of species used, preparations and doses can be found in Table 14, Appendix B. There is no evidence to suggest that THR products and *Echinacea* food supplements are taken together during pregnancy, and the assumption is that this is unlikely, especially since the THR products advise against use in pregnancy in their patient information leaflets. In addition, the regulation of THR products is a remit of the MHRA and the *Echinacea* exposure from licensed herbal *Echinacea* products is therefore not considered in the combined exposure scenarios.

89. Pregnant women may consume *Echinacea* through various sources, including herbal teas, honey, lozenges, and food supplements such as tablets, capsules, and oral liquids. The FSA's Exposure Team estimated *Echinacea* intake during pregnancy under different worst-case scenarios, combining these products. The combined exposure values (Tables 8-11 Appendix B) are based on recommended doses from product labels for food supplements (tablets, capsules, lozenges and oral liquids) and estimated intakes from NDNS consumption data for herbal tea, honey and lozenges. Table 5 presents acute exposure estimates from individual products, while Table 6 shows minimum and maximum combined exposures. Results indicate that combined use of foods and food supplements could reach *Echinacea* (as dried herb/root) intakes of up to 13,000 mg/day.

Table 5: Estimated minimum and maximum acute exposures to Echinacea (as dried root/herb) from individual Echinacea containing products

Echinacea containing food/food supplement	**Estimated exposure to *Echinacea* (mg/day)**
Tea	860 – 6,000

Honey	19 - 100
Lozenges	40
Tablets/capsules	400 – 3,600
Oral liquids	600 – 3,000

*Rounded to 2 significant figures.

Table 6: Estimated minimum and maximum acute exposures to Echinacea (as dried root/herb) based on combined consumption of Echinacea products

Number of *Echinacea* products consumed per day	**Minimum estimated exposure to *Echinacea* (mg/day)**	**Maximum estimated exposure to *Echinacea* (mg/day)**
2	60	9,600
3	460	13,000
4-5	1,100	13,000

*Rounded to 2 significant figures.