Meeting

Annex C Assessment of Exposure

1. The relative proportions of the active components of ginger – gingerols, shogaols and curcumin occur in varying proportions, depending on the variety of rhizome and the area of cultivation.

2. Many ginger supplements (Tables 1 and 2) are recommended to support digestive and joint health, alleviate nausea, upset stomach, and travel sickness. Currently, two commercially available pregnancy supplements – 'Seven Seas Pregnancy' and 'Seven Seas Pregnancy Plus Follow On' – contain 10 mg ginger extract.

Table 1. Sample of ginger supplements in capsule and tablet form commerciallyavailable.

Commercial Product Name	Form	Composition	Daily dose recommended by vendor or website
Seven Seas Pregnancy	Tablet	Ginger extract 10 mg.	1 tablet a day.
Seven Seas Pregnancy Plus Follow-On	Tablet, capsule	Ginger extract 10 mg.	One tablet and one capsule/ day.
Supplemented	Tablet	Ginger Extract 3,000 mg (20:1).	1-2 tablets daily.
Good n Natural	Capsule	Powdered root 550 mg.	2 capsules daily.

Woods Supplements	Tablet	Ginger extract 500 mg.	1 tablet daily.
Solgar	Capsules	Ginger (Zingiber officinale) Root Powder 150 mg, Standardised Ginger (Zingiber officinale) Root Powdered Extract (5% ginger gingerols) 300 mg.	1-2 capsules daily.
Solgar	Capsules	Ginger (Zingiber officinale) Root Powder 500 mg. Ginger (Zingiber officinale) Root Powdered Extract (4:1) 5 mg.	1-3 capsules daily.
Swanson	Capsules	Ginger Root 540 mg.	2 capsules daily.
Bio Health	Capsules	Ginger Root 500 mg.	NA
Biovea	Capsules	Ginger (root) (std. to 5% gingerols, 12.5 mg) 250 mg.	1-3 daily.
Jarrow Formulas	Capsules	Ginger root (concentrate) (Zingiber officinale) 500 mg.	1 daily.
Jarrow Formulas Nature's Best	Capsules Capsule	•	1 daily. 1 daily.
-		(Zingiber officinale) 500 mg. Ginger Root 14,400 mg (provided by 120 mg of a 120:1 extract)	-

ALPHA01	Capsules	Ginger root powder 1100 mg.	2 capsules daily.
	Tablet	Ginger Extract 12,000 mg (20:1) standardised to 600mg 12,000 mg.	1-2 tablets daily.
Now Foods Capsules Superfood World	Capsules	Ginger Extract (Zingiber officinale) (Root) (Standardized to min. 5% Gingerols) 250 mg: Ginger Powder (Zingiber officinale) (Root) 225 mg.	1-3 capsules daily.
Viridian Ginger	Capsules	One vegetarian capsule provides: Certified organic Ginger root 400 mg.	1-3 capsules daily.

Table 2: Sample of ginger supplements in liquid and powder forms commerciallyavailable.

Commercial Product Name	Form	Composition	Daily dose recommended by vendor or website
Indigo Herbs	Tincture	Zingiber officinale, Alcohol, Water. Extraction Ratio: 1:3, Alcohol Volume: 25%.	1-2 ml, 2-3 times daily 20 drops from the glass dropper equals ~ 1ml.
Nature's Answer	Tincture	Ginger (Zingiber e officinale) root extract: 145 mg.	1 ml (28 drops) three times per day.

Herb Pharm	Tincture	Ginger rhizome (Zingiber officinale) extract 598 mg (Extraction rate 140 mg herb per 0.7 ml).	"1 full squeeze of the dropper bulb to 2 oz. of water or juice, 2 - 5 times per day.
Indigo Herbs	Powder	100% Pure Zingiber officinale Powder.	1/3 teaspoon powder in water 3 times a day. (1 tsp = 3g)
Organic Herbal Remedies	Tincture	herb to pure grain alcohol of 1:3. 1ml is the equivalent of 333mg of dried ginger root. W.	0.2ml to 0.4ml three times a day in a little water. Children 6-12 years old 0.1ml to 0.2ml three times a day.
Biovea	Tincture	Fresh Organic Ginger (root) (667 mg per 1 ml serving).	30 drops (~ 1 ml), 1-3 times daily or as needed.
Epigenar	Tincture	Purified water, organic alcohol, organic ginger (Zingiber officinale) (amounts not specified).	15 drops, 3 times daily Max 60 drops per day unless otherwise advised. Children aged 4-15 years, 3 times daily, one drop per number of years of age.

Consideration of ginger from other sources

3. In addition to supplements, pregnant women may also consume ginger as part of their general diet to various degrees. There are anecdotal reports of women using ginger products such as ginger biscuits and ginger ale, to alleviate morning sickness and nausea. Some may use these in combination with juice shots or tinctures.

Table 3: Sample of ginger-containing foods commercially available.

Commercial product name	Form	Composition
Border Biscuits Dark Chocolate & Ginger	Ground ginger	Ground ginger 1.5 %.
Sainsbury's Stem Ginger Cookies, Taste the Difference	Stem ginger	Candied Stem Ginger (17%) (Australian Stem Ginger, Sugar); ginger powder.
Sainsbury's Dark Chocolate & Ginger Cookies, Taste the Difference	Stem ginger	Candied Stem Ginger (13%) (Australian Stem Ginger, Sugar); ginger powder.
Nairn's Wheat Free, Ginger Biscuits	Stem ginger	Stem Ginger (6.4%) (Stem Ginger, Sugar); Ground Ginger.
Sainsbury's Ginger Nut Biscuits, SO Organic	Powdered ginger	Ginger Powder (0.6%).
Nooro Lemon + Ginger CBD Bar	NA	Ginger (0.5%).
Rhythm 108 Lemon, Ginger & Chia Biscuit Share Bag	Dried ginger powder	Organic gluten free oat flour (33%), organic coconut oil (24%), organic coconut flower sugar, organic almonds, organic chia seeds (5%), organic lemon zest (1.3%), organic lemon oil, organic ginger powder (0.4%).

Table 4: Ginger containing teas, juices and drinks commercially available.

Commercial Product Name	Form	Composition
Gimber	liquid concentrate	38% organic and high-quality ginger, organic lemons, herbs and spices.
Moju	liquid	Apple, Ginger Root (25%), Lemon, Antioxidant: Ascorbic Acid.
James White Drinks Organic Ginger Zinger Shot 70ml	liquid	Organic Apple Juice (73%), Organic Ginger Juice (27%), Water, Antioxidant: Ascorbic Acid.
James White Drinks Organic Xtra Ginger Zinger Shot 70ml	liquid	Organic Apple Juice (59.5%), Organic Ginger Juice (40%), Organic Chilli Flavouring (0.5%), Antioxidant: Ascorbic Acid.
Twinings Lemon & Ginger Tea	Теа	Ginger Root* (37%), Natural Lemon Flavouring with Other Natural Flavourings (25%), Lemongrass*, Blackberry leaves*, Lemon Peel, Sweet Fennel*, Natural Ginger Flavouring with Other Natural Flavourings (3.5%).
Pukka Organic Ginger, Galangal & Golden Turmeric Tea	Теа	Ginger Root (52%).
Belvoir Ginger Cordial		Pressed Ginger Juice 2%, Ginger Extracts.
Old Jamaica Ginger Beer	Drink	Ginger root extract.

Fever Tree Ginger Beer Light	Drink	Ginger Root, Natural Ginger Flavouring with other Natural Flavourings.
Fentimans Ginger Beer	Drink	Fermented Ginger Root Extract (Water, Glucose Syrup, Ginger Root, Pear Juice Concentrate, Yeast); Natural Flavourings (Ginger, Lemon, Capsicum).
Cawston Press Apple & Ginger Juice	Juice	1% Ginger Extract.
Pukka Lemon Ginge & Manuka Tea	r Tea	Ginger Root (32%).
Twinings Spiced Ginger Tea	Теа	Ginger Root* (70%), Liquorice Root* (15%), Cinnamon* (10%), Cloves* (5%).
No.1 Kombucha Ginger & Turmeric	Tea drink	Kombucha (Filtered Water, Cane Sugar*, Green Tea*, Live Kombucha Cultures), Ginger Juice* (1.5%), Ginger* (0.14%), Turmeric* (0.14%), Black Pepper*.
Teapigs Lemon & Ginger Tea Bags	Теа	Ginger (65%), Lemongrass, Lemon Peel (5%), Liquorice Root.
MOJU Ginger Juice Shot 60ml	Juice	17.2g fresh ginger root'. Apple, Ginger Root (25%), Lemon, Antioxidant: Ascorbic Acid.
Innocent Shots Ginger Kick, Kicking Ginger & Spicy Turmeric 100ml	Juice shot	Apple Juice (54%), Carrot Juice (15%), Ginger Juice (10%), Red Pepper Juice, Lemon Juice, Orange Juice, Jalapeño Pepper Juice, Turmeric Juice (0.2%), Vitamin D.

Plenish Organic Ginger Immunity Ju Juice Shot	uice shot	Apple, Ginger (20%), Lemon, Apple Cider Vinegar (7%), Acerola Cherry Powder.
Lo Bros Organic Kombucha Gut Shot Ju Ginger	uice shot	Carrot Juice* (30%), Orange Juice*, Ginger Juice* (25%), Kombucha (14%) (Filtered Water, Kombucha Culture*, Green Tea*, Oolong Tea*, Raw Sugar*), Lemon Juice Concentrate", Living Cultures.
Belvoir Ginger Beer D	Drink	Carbonated Spring Water, Sugar, Lemon Juice from Concentrate, Fresh Root Ginger Infusion 2%, Pressed Ginger Juice, Ginger Extracts, Lemon Extract, Capsicum Extract.
Grace Tropical Rhythms Sorrell D Ginger	Drink	Water, Sorrel Cordial (Water, Sugar, Sorrel Flower (3%), Acid: Citric Acid), Rum Flavouring, Natural Sorrel Powder (0.13%), Ginger Emulsion (Water, Ginger Flavouring (.006%), Acid: Citric Acid, Capsicum, Stabilisers: Acacia Gum, Ester Gum), Colour: E129.

Background Exposure from the diet

Exposure estimates based on the NDNS

4. Table 5 provides exposure estimates for women of childbearing age (16 - 49 years) from years 1 - 8 of the NDNS survey (Bates *et al.*, 2014; 2016; Roberts *et al.*, 2018). The NDNS (Bates *et al.*, 2014; 2016; Roberts *et al.*, 2018) does not provide data for pregnant or lactating women so while data is based on women of childbearing age, this data may not necessarily be representative of the maternal diet. The food group used for the exposure assessment consisted of all foods within the NDNS database which contained ginger (raw, powdered etc) except for alcoholic beverages. Mean chronic ginger exposure from the diet of women aged 16 - 49 years old was 0.0083 g/kg bw/day, and at a 97.5th percentile consumption

was 0.058 g/kg bw/day.

5. Table 5 indicates the contribution of ginger to the diet of women aged 16-49 years is low, therefore, the main contributor to exposure for some could be from supplement use. This may vary however according to country of origin. For example, ginger is used more and in larger quantities in foods in Asian, African and Caribbean communities.

6. The NDNS does not provide data for pregnant women, therefore there would be uncertainty as to whether this give an accurate reflection of exposure during pregnancy, especially in women who will use ginger drinks and teas or foods such as ginger biscuits to alleviate symptoms of pregnancy associated sickness.

7. TOX/2021/26 demonstrated that the potential risks arising from exposure to ginger from food can be considered low compared to exposure from supplements, which are available at much higher doses due to the concentrated nature of supplements and shots.

8. The Committee highlighted that assumptions would have to be made on how many products, such as ginger shots, were consumed per day. The Committee noted that, as it is commonly understood that ginger suppresses morning sickness, it could not be ruled out that pregnant women would be using the supplements in this way. Diet plus supplement exposure would need to be considered, as well as diet plus shots depending on the exposure period of concern.

Consumption of ginger from food sources

9. The FSA Exposure team have sourced information on Ginger intake in women of childbearing age from food. Due to the limited information on consumption amounts of supplements and drinks in pregnant women, exposure was estimated based on the compositional information and usage information in widely available supplements and information on concentrated drinks. Full details of the ginger sources are given in Table 1 - 4.

Table 5: Estimated ginger exposures from a variety of sources in women aged 16- 49 years old.

Commodity	dailv	daily exposures (g/kg	Mean acute exposure* (g/day)	acute exposure* (g/kg	97.5" percentile acute exposure*	acute	chro
Food ^a	NA	NA	1.7	0.026	11	0.16	0.55
Drinks (Including tea and shots) ^{b1,b}	0.5 - 32.5	0.0071 - 0.46	NA	NA	NA	NA	NA
Supplements c	0.010 - 24	0.00014 - 0.34	NA	NA	NA	NA	NA

1This assumes only one serving is consumed per day.

a Data obtained from the National Diet and Nutrition surveys years 1-8 calculated from women of a childbearing age (16-49 years)

(Bates et al., 2014; 2016; Roberts et al., 2018).

b Data obtained online from retailers, see Appendix 1 for further details.

c Data obtained online from retailers, see Appendix 1 for further details.

*Rounded to 2 significant figures.

10. Table 5 provides exposure estimates for women of childbearing age - (16 - 49 years) 1 from years 1 - 8 of the NDNS survey (Bates *et al.*, 2014; 2016; Roberts *et al.*, 2018). The NDNS (Bates *et al.*, 2014; 2016; Roberts *et al.*, 2018) does not provide data for pregnant or lactating women so while data is based on women of childbearing age, this data may not necessarily be representative of the maternal diet. The food groups used for the exposure assessment consisted of all foods within the NDNS database which contained ginger (raw, powdered etc) except for alcoholic beverages. Mean acute ginger exposure from the diet of women aged 16-49 years old was 0.026 g/kg bw/day, and at a 97.5th percentile

consumption was 0.16 g/kg bw/day. The corresponding mean and 97.5th percentile chronic exposure was 0.0083 and 0.058 g/kg bw/day. The upper value of the range of exposure from drinks and supplements was over double those estimated from 97.5th percentile acute consumption from food.

11. As the NDNS does not provide data for pregnant women, there would be uncertainty as to whether the data in Table 1 are an accurate reflection of consumption during pregnancy. This uncertainty also extends to data presented for drinks and supplements, as the patten of consumption during pregnancy to alleviate symptoms of sickness is unknown.

Further Information

Table 6: Ginger content in shots, teas and other drinks.

Shots	Notes
<u>Ginger Shot Pret A Manger</u>	Contains 25% ginger in 110 ml shot, equivalent to 27.5 g fresh ginger.
Innocent Shots Ginger Kick, Kicking Ginger & Spicy Turmeric 100ml	Contains 10% ginger juice in 100 ml shot, equivalent to 10 g fresh ginger.
Hot Shot Pret A Manger	Contains 2.5% ginger in 110 ml, equivalent to 2.75 g fresh ginger.
James White Drinks Organic Xtra Ginger Zinger Shot 70ml	Contains 26% organic ginger juice in 70 ml, equivalent to 18.2 g fresh ginger.
James White Drinks Organic Xtra Ginger Zinger Shot	Contains 40% organic ginger juice in 70 ml, equivalent to 28 g of fresh ginger.
MOJU Ginger Shots (12x60ml)	Contains 17.2 g of ginger in a 60 ml shot.

<u>BumbleZest Ginger Turmeric</u> <u>Drink</u>	Contains 16% ginger juice in 60 ml shot, equivalent to 9.6 g of fresh ginger.
Teas	Notes
<u>Myrtle & Maude - Morning</u> <u>Sickness Herbal Tea -</u> <u>Peppermint & Ginger for</u> <u>Nausea Relief</u>	Contains 25% ginger in each tea bag. Assuming that each bag is approximately 2 g, they will contain 0.5 g of dried ginger.
<u>Pukka Lemon, Ginger and</u> <u>Manuka Honey 20 Herbal Tea</u> <u>Sachets 40g</u>	Each tea bag contains ginger root 32%. Assuming each bag is 2 g, they will contain 0.64 g of dried ginger.
<u>Twinings Lemon & Ginger 20</u> <u>Tea Bags</u>	Each tea bag contains 37% ginger root. Assuming each bag is 2 g, they will contain 0.74 g of dried ginger.
<u>Pukka Organic Ginger,</u> Galangal & Golden Turmeric Tea Bags	Contains 52% ginger root. For a 2 g tea bag, this is equivalent to1 g of dried ginger.
<u>Twinings Spiced Ginger 20</u> <u>Tea Bags</u>	Contains 70% ginger root. For a 2 g tea bag, this is equivalent to 1.4 g of dried ginger root.
<u>Lemon & Ginger Herbal Tea </u> <u>teapigs</u>	Contains 65% ginger. For a 2 g tea bag, this is equivalent to 1.3 g of dried ginger.
Other drinks	Notes
<u>Ginger Kombucha Pret A</u> <u>Manger</u>	Contains 2.2% ginger in 250 ml, equivalent to 5.5 g fresh ginger.

<u>Belvoir Fruit Farms Ginger</u> <u>Cordial</u>	Contains 11% fresh root ginger infusion and 2% pressed ginger juice in a 500 ml product. This is equivalent to 65 g fresh ginger and 32.5 g in a 250 ml serving.
Pure Pret Sparkling Ginger	Contains 1% ginger juice in 330 ml, equivalent to

3.3 g of fresh ginger.

Please note the different forms of ginger (i.e., gingerols, ginger extract, dried ginger root, fresh ginger) which may not be directly comparable.

Table 7: Consumption of ginger from supplements.

Beer | Pret A Manger

Supplement	Maternal supplement?	Form of ginger	Recommended dose per person/day	Daily Consumption (g/kg bw)*	Notes
<u>Seven Seas</u> <u>Pregnancy - 28</u> <u>tablets</u>	Yes	Ginger extract 10 mg	0.010 g	0.00014	NA
<u>Boots</u> <u>Pregnancy</u> <u>Essential</u> <u>Vitamins 90</u> <u>Tablets</u>	Yes	Ginger root extract 58.5 mg	0.05 9g	0.00084	NA
<u>Boots Naturals</u> Ginger 60 <u>Tablets</u>	No	Dried ginger root 1.2 g	1.2 g	0.017	NA

Boots Pharmaceuticals DIGESTION SUPPORT TRAVEL with added Ginger 30 Capsules	No	Ginger Root Extract to 345 mg and Ginger root - 750 mg	0.35 g extract + 0.75 g ginger root	0.005 + 0.011	NA
Good n Natural Ginger Root Capsules 550mg Holland & Barrett	No	Ginger root	1.1 g	0.016	2 capsules daily
<u>Ginger 3000mg</u> <u>Tablets –</u> <u>Supplemented</u>	No	Ginger extract	6.0 g	0.085	NA
<u>Solgar Ginger</u> <u>Root Extract (60</u> <u>Veg Caps)</u>	No	Ginger root powder + Ginger root extract	0.15 g + 0.30 g	0.0021 + 0.0043	NA
GINGER 250mg 120 Vegetarian Capsules by BIOVEA	No	Ginger root	0.75 g	0.011	NA
Jarrow Formulas Ginger (100 Capsules)	No	Ginger root concentrate	1.5 Q	0.021	NA

<u>High Strength</u> <u>Ginger Root</u> <u>Capsules </u> <u>Nature's Best</u>	No	24 mg gingerols equivalent to 14.4 g fresh ginger	14.4 g	0.20	NA
Ginger 12000mg x 120 Tablets Nausea - Stomach Settler - Aids Digestion Neulife Health & Fitness	No	Ginger extract 600 mg equivalent to 12 g fresh ginger-		0.34	1-2 capsules a day
<u>Lifeplan Ginger</u> <u>Root 1000mg</u> <u>90 Tablets</u>	No	Ginger Extract (equiv. herb powder 1000 mg) 50 mg	2 g	0.028	2 tablets/day

*Consumption per body weight based on recommended dose rounded to 2 significant figures.

is calculated from the daily recommended intake and the average body weight of women aged 16- 49 years (70.3kg).

^Indicates whether the supplement is marketed specifically to pregnant or breastfeeding women.

Please note the different forms of ginger (i.e., gingerols, ginger extract, dried ginger root, fresh ginger) which may not be directly comparable.

References

Bates, B.; Lennox, A.; Prentice, A.; Bates, C.; Page, P.; Nicholson, S.; Swan, G. (2014) Available at: <u>National Diet and Nutrition Survey Results from Years 1, 2, 3</u> and 4 (combined) of the Rolling Programme (2008/2009 – 2011/2012).

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