Annex C - Assessment of Exposure

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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.

Daily dose

Commercial Product Name	Form	Composition	recommended by
			vendor or website
Seven Seas Pregnancy	Tablet	Ginger extract 10 mg	1 tablet a day.
Seven Seas Pregnancy Plus	Tablet, capsule	Ginger extract 10 mg	One tablet and one
Follow-On	capsule		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
		Ginger (Zingiber officinale)	
		Root Powder 150 mg,	
Solgar	Capsules	Standardised Ginger (Zingiber	1-2 capsules
		officinale) Root Powdered	daily
		Extract (5% ginger gingerols)	
		300 mg	

Capsules	Ginger (Zingiber officinale) Root Powder 500 mg. Ginger (Zingiber officinale) Root Powdered Extract (4:1) 5 mg.	-	
Capsules	Ginger Root 540 mg	2 capsules daily	
Capsules	Ginger Root 500 mg	No data.	
Capsules	Ginger (root) (std. to 5% gingerols, 12.5 mg) 250 mg	1-3 daily	
Capsules	Ginger root (concentrate) (Zingiber officinale) 500 mg	1 daily	
Capsule	Ginger Root 14,400 mg (provided by 120 mg of a 120:1 extract) providing 24 mg gingerols	1 daily	
Tablets	Ginger Extract 12000 mg	1-2 tablets daily	
Capsule	Ginger 12:1 Extract	1-2 tablets daily	
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	
	Capsules Capsules Capsules Capsule Tablets Capsule Capsule	CapsulesPowder 500 mg. Ginger (Zingiber officinale) Root Powdered Extract (4:1) 5 mg.CapsulesGinger Root 540 mgCapsulesGinger Root 500 mgCapsulesGinger (root) (std. to 5% gingerols, 12.5 mg) 250 mgCapsulesGinger root (concentrate) (Zingiber officinale) 500 mgCapsulesGinger Root 14,400 mg (provided by 120 mg of a 120:1 providing 24 mg gingerolsTabletsGinger Extract 12000 mgCapsuleGinger Icat for the stract (Zingiber officinale) Sol mgTabletsGinger Icat for the stract (Zingiber officinale) Sol mgTabletsGinger Extract 12000 mgCapsuleGinger Icat for the stract (Zingiber officinale) Sol mgTabletsGinger Icat for the stract (Zingiber officinale) Sol mgTabletsGinger Icat for the stract (Zingiber officinale) Sol mgCapsuleGinger Icat for the stract for the stractCapsuleGinger Icat for the stract for the stractCapsuleGinger Icat for the stract for the stractCapsuleGinger Icat for the stract for the stract for the stractCapsuleGinger Icat for the stract for the st	

Ginger Ext	ract (Zingiber
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Now Foods Capsules	Capsules	officinale) (Root) (Standardized to min. 5% Gingerols) 250 mg:	1-3 capsules daily	
Superfood World		Ginger Powder (Zingiber		
		officinale) (Root) 225 mg		
Viridian		One vegetarian capsule		
	Capsules	provides: Certified organic	1-3 capsules daily	
Ginger		Ginger root 400 mg	·	

Table 2: Sample of ginger supplements in liquid and powder forms commercially available

			Daily dose
Commercial			recommended
Product	Form	Composition	by
Name			vendor or website
			1-2 ml, 2-3 times
		Zingiber officinale, Alcohol, Water.	Daily
Indigo Herbs	Tincture	e Extraction Ratio: 1:3, Alcohol	20 drops from the
		Volume: 25%	glass dropper
			equals ~ 1ml

Nature's Answer	Tincture	Ginger (Zingiber 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)

			0.2ml to 0.4ml
			three times a da
			in a little water.
Organic Herbal		herb to pure grain alcohol of 1:3. a 1ml is the equivalent of 333mg of dried ginger root. W	Children 6-12
Remedies	Tincture		years old 0.1ml to
			0.2ml three times a
			day
Biovea	Tincture	Fresh Organic Ginger (root) (667	30 drops (~ 1 ml), 1-3 times daily
		mg per 1 ml serving)	or
			as needed

		15 drops, 3 times
		daily Max 60 drops
		per day unless
Epigenar Tinctu	Purified water, organic alcohol,	otherwise advised.
	Tincture organic ginger (Zingiber officinale)	Children aged 4-
	(amounts not specified)	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		
	Form	Composition
product name		

Border Biscuits Dark Chocolate & Ginger Ground ginger $\,$ Ground ginger 1.5 %

		Candied Stem Ginger (17%)
Sainsbury's Stem Ginger Cookies, Taste the Difference	Stem ginger	(Australian Stem Ginger, Sugar);
		ginger powder
		Candied Stem Ginger (13%)
Sainsbury's Dark Chocolate & Ginger Cookies, Taste the Difference	Stem ginger	(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	No data.	Ginger (0.5%),

		Organic gluten free oat flour
		(33%), organic coconut oil (24%),
		organic coconut flower sugar,
Rhythm 108 Lemon, Ginger & Chia Biscuit Share Bag	Dried ginger powder	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 concentrat	38% organic and high-quality ginger, organic ^e 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	No Data.	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
		Fermented Ginger Root Extract (Water, Glucose
Fentimans Ginger Beer	Drink	Syrup, Ginger Root, Pear Juice Concentrate,
		Yeast); Natural Flavourings (Ginger, Lemon,
		Capsicum)
Cawston Press Apple & Ginger Juice	Juice	1% Ginger Extract
Pukka Lemon Ginger & Manuka Tea	Теа	Ginger Root (32%)
Twinings Epicod Cingor Too	Too	Ginger Root* (70%), Liquorice Root* (15%),
Twinings Spiced Ginger Tea	Теа	Cinnamon* (10%), Cloves* (5%)
		Kombucha (Filtered Water, Cane Sugar*, Green
No.1 Kombucha Ginger & Turmeric	Tea drink	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%),	
MOJU Ginger Juice Shot 60ml	Juice	Liquorice Root 17.2g fresh ginger root'. Apple, Ginger Root (25%), Lemon, Antioxidant: Ascorbic Acid	
		Apple Juice (54%), Carrot Juice (15%), Ginger	
Innocent Shots Ginger Kick, Kicking	Juice shot	Juice (10%), Red Pepper Juice, Lemon Juice,	
Ginger & Spicy Turmeric 100ml		Orange Juice, Jalapeño Pepper Juice, Turmeric	
		Juice (0.2%), Vitamin D	
Plenish Organic Ginger Immunity Juice Shot	Juice shot	Apple, Ginger (20%), Lemon, Apple Cider Vinegar	
		(7%), Acerola Cherry Powder	

		Carrot Juice* (30%), Orange Juice*, Ginger Juice*
Lo Bros Organic Kombucha Gut Shot Ginger		(25%), Kombucha (14%) (Filtered Water,
	Juice shot	Kombucha Culture*, Green Tea*, Oolong Tea*,
		Raw Sugar*), Lemon Juice Concentrate", Living
		Cultures
		Carbonated Spring Water, Sugar, Lemon Juice
Belvoir Ginger Beer	Drink	from Concentrate, Fresh Root Ginger Infusion 2%,
		Pressed Ginger Juice, Ginger Extracts, Lemon
		Extract, Capsicum Extract
		Water, Sorrel Cordial (Water, Sugar, Sorrel Flower
		(3%), Acid: Citric Acid), Rum Flavouring, Natural
Grace Tropical Rhythms Sorrell	Drink	Sorrel Powder (0.13%), Ginger Emulsion (Water,
Ginger		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.

Source	Range of daily exposures (g/day)	Range of daily exposures (g/kg bw/day)	Mean acute exposure* (g/day)	Mean acute exposure* (g/kg bw/day)	97.5 ^{cm} percentile	97.5 th percentile acute exposure* (g/kg bw/day)	chro
Food ^a	No data.	No data.	1.7	0.026	11	0.16	0.55
Drinks (Including tea and shots) ^{b1,b}	0.5 - 32.5	0.0071 - 0.46	No data.	No data.	No data.	No data.	No da
Supplements c	⁵ 0.010 - 24	0.00014 - 0.34	No data.	No data.	No data.	No data.	No da

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.

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 from drinks and supplements was over double those estimated from 97.5th percentile acute consumption from food.

10. 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> <u>Galangal & Golden Turmeric</u> <u>Tea Bags</u>	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.
Pret's Sparkling Ginger Beer Pret A Manger	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.

Supplement	Maternal supplement?	Form of ginger	Recommended dose per person/day	d Daily Consumptior (g/kg bw)*	Notes
<u>Seven Seas</u> Pregnancy - 28 tablets	Yes	Ginger extract 10 mg	0.010 g	0.00014	No data.
<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	No data.

<u>Boots Naturals</u> <u>Ginger 60</u> <u>Tablets</u>	No	Dried ginger root 1.2 g	1.2 g	0.017	No data.
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	No data.
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	No data.
<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	No data.
GINGER 250mg 120 Vegetarian Capsules by BIOVEA	No	Ginger root	0.75 g	0.011	No data.

Jarrow Formulas Ginger (100 Capsules)	No	Ginger root concentrate	1.5 Q	0.021	No data.
<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	No data.
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)

Bates, B.; Cox, L.; Nicholson, S.; Page, P.; Prentice, A.; Steer, T.; Swan, G. (2016) Available at: <u>National Diet and Nutrition Survey Results from Years 5 and 6</u> (combined) of the Rolling Programme (2012/2013 – 2013/2014)

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