TOX/2020/54

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Discussion paper on the potential effects that excess iodine intake may have during preconception, pregnancy and lactation.

Introduction

1. The Scientific Advisory Committee on Nutrition (SACN) last considered maternal diet and nutrition in relation to offspring health in its reports on 'The influence of maternal, fetal and child nutrition on the development of chronic disease in later life' (SACN, 2011) and on 'Feeding in the first year of life' (SACN, 2018). In the latter report, the impact of breastfeeding on maternal health was also considered. In 2019, SACN agreed to conduct a risk assessment on nutrition and maternal health focusing on maternal outcomes during pregnancy, childbirth and up to 24 months after delivery; this would include the effects of chemical contaminants and excess nutrients in the diet.

2. SACN agreed that, where appropriate, other expert Committees would be consulted and asked to complete relevant risk assessments e.g. in the area of food safety advice. This subject was initially discussed during the horizon scanning item at the January 2020 meeting with a scoping paper being presented to the Committee in July 2020. This included background information on a provisional list of chemicals proposed by SACN. It was noted that the provisional list of chemicals was subject to change following discussion by COT who would be guiding the toxicological risk assessment process: candidate chemicals or chemical classes can be added or removed as the COT considered appropriate. The list was brought back to the COT with additional information in September 2020[1]. Following a discussion at the COT meeting in September 2020, it was agreed that papers on a number of components inclusion iodine should be prioritised. For this paper, the advice of the COT is sought on whether exposure to excess intake of iodine would pose a risk to maternal health.

3. Iodine is an essential micronutrient in the human diet, required for the production of thyroid hormones including thyroxine. These hormones are necessary for cell metabolism, growth and development at all stages of life. The most visible manifestation of iodine deficiency is goitre – an enlargement of the thyroid gland in the neck but there is concern, that in the fetus, infant, and young child, more modest changes may impair psychomotor development in the absence of overt thyroid enlargement (SACN, 2014).

[1] COT Contribution to SACN review of nutrition and maternal health: proposed scope of work and timetable. Available at: https://cot.food.gov.uk/sites/default/files/2020-09/TOX-2020-%2045%20%20Maternal%20diet%20scoping%20paper_0.pdf

4. SACN (2014) stated "Intake data from the National Diet and Nutrition Survey (NDNS) suggest that children aged ten years and younger and adults aged 19 years and older in the UK generally have adequate iodine intakes. The NDNS data for years 7 to 8 of the survey, published in 2018, showed that the median urinary iodine for women of childbearing age (16 to 49 years) was 102 µg/L with 17% of the population below 50 µg/L. While these values met the WHO criterion for adequate intake for the general population, they did not meet the criterion for iodine sufficiency in pregnant and lactating women (i.e. median urinary iodine concentration within 150-249 µg/L). However, it should be noted that pregnant and lactating women are not included in the NDNS survey.

5. This paper considers iodine intake in the population but also considers smaller groups who may be exposed to higher levels of iodine

Background

6. In the environment, iodine is usually found in the form of iodate salts or organo-iodide compounds synthesised by algae and bacteria. Iodate is reduced in the gastrointestinal tract to iodide which is the biologically active from (SACN, 2014).

Iodine function and status

7. Iodine is essential in the human diet primarily because it is required in the synthesis of the thyroid hormones tri-iodo- and tetra-iodothyronine (T3 and T4 or thyroxine). The thyroid hormones exert effects on a wide range of bodily functions such as basal metabolism, brain development and bone growth, especially in the fetus, which is exposed to iodine via the placenta, so maternal underexposure by iodine deficiency can have profound effects on both mother and offspring. Both chronic iodine deficiency and excess may lead to compensatory thyroid hypertrophy known as goitre in adults and children. Iodine deficiency in pregnancy is also associated with an increased risk of miscarriage, stillbirth and congenital abnormality. Iodine deficiency in the developing fetus can lead to cretinism, mental retardation, deaf mutism, and spastic dwarfism. Clinical features of acute iodine toxicity include vomiting and diarrhoea, seizure, delirium and collapsing. Sensitive reactions such as iodide mumps following treatment with iodine-containing medication may also occur (EVM, 2003).

Status in pregnancy

8. Thyroid function and iodine function are altered during pregnancy. In early gestation, maternal thyroid hormone production increases in response to Thyroid Stimulating Hormone (TSH), a rise in serum thyroxine-biding globulin and, possibly because of the weak TSH activity of human chorionic gonadotropin (Glinoer, 2001). It is possible that the increase in glomerular filtration rate (GFR) results in a decrease to the circulating pool of plasma iodine (Glinoer, 2007; Gaberscek and Zaletel, 2011); it is unclear if this might be migrated by increased renal retention of iodine. Additionally, any fall in plasma iodine concentrations would also be attributable, in part of least, to expansion of the plasma volume. A proportion of maternal thyroid

hormone is transferred to the fetus, as is iodine via a placental NIS (Sodium Iodide symporter) (Glinoer, 2001; Zimmermann, 2009).

9. Urinary iodine concentration (UIC) is a good indicator of short-term iodine status as >90% of dietary iodine eventually appears in urine (Rohner, 2014). A median UIC of ≤100 µg/L specifies insufficient iodine intake, a median UIC of ≥100 µg/L indicates adequate iodine intake for women who are breastfeeding their infants and children under two years of age (Harding, 2017). UIC levels of >500 µg/kg are considered excessive in pregnant women (WHO, UNICEF and ICCIDD, 2007).

10. As an alternative to UIC, Katko et al (2018) used plasma thyroglobulin (Tg) as a measure of iodine status in 164 pregnant Hungarian Women in week 16 of pregnancy, the period corresponding to major brain development. They found that UIC corresponded with daily iodine intake whereas Tg corresponded with long-term storage levels of iodine.

11. Although, iodine-deficiency is a known issue in maternal health, excess iodine intake may also occur and may potentially affect maternal health. Sources of excess iodine intake may occur via the consumption of naturally occurring iodine in water supplies, seaweed, iodine supplements, medication and milk which contains iodine resulting from feed supplements and iodophor disinfectants. Most healthy individuals are unaffected by excess iodine, however susceptible individuals such as those who have other thyroid disorders (e.g. Hashimoto's Disease, Grave' Disease) and those who are sensitive to iodine are more likely to respond adversely to excess iodine. The excessive intake of iodine during pregnancy may have an adverse effect on the fetus without affecting the mother's health. There is a correlation between excessive iodine intake during lactation and the elevation of iodine levels in breastmilk which may have an effect on neonatal health. (JECFA, 1989).

12. Sixteen healthy lactating American women with no known history of thyroid disease were administered 600 µg oral potassium iodide (KI) (456 µg iodine) after an overnight fast. Iodine measurements were taken from breastmilk and urine at baseline and hourly for 8 hours following iodine intake. All dietary iodine ingested during the study period was also measured. Baseline breastmilk and urine iodine levels were 45.5 µg/L and 67.5 µg/L, respectively. Following 600 µg KI administration, median increase in breastmilk iodine levels above baseline was 280.5 µg/L and median peak breastmilk iodine concentration was 354 µg/L. Median time to peak breastmilk iodine levels following KI administration was 6 hours (IQR 5–7). Dietary iodine sources provided an additional 36–685 µg iodine intake during the 8-hour study. It was concluded that breastmilk iodine concentrations can be interpreted in relation to recent iodine intake (Leung et al, 2012)

13. Excessive iodine dietary intake and/or iodine supplementation during pregnancy may cause adverse effects on maternal and fetal thyroid function, birth outcomes, and offspring growth and development (Le et al, 2018). Excess iodine briefly inhibits thyroid hormone synthesis through decreasing organification2 by an autoregulatory mechanism known as the acute Wolff-Chaikoff effect (Wolff et al, 1949). Healthy individuals can escape the Wolff-Chaikoff effect via downregulation of the sodium/iodide symporter in the thyrocytes, after which normal thyroid hormone synthesis restarts (Eng et al, 1999; Markou et al, 2001). Although the mechanism is

not completely understood, susceptible individuals fail to escape the Wolff-Chaikoff effect. Under 36 weeks of gestational age, the immature fetal thyroid gland is unable to escape from the acute Wolff-Chaikoff effect, making the fetus and infant more susceptible to iodine-induced hypothyroidism (Markou et al, 2001). Neonates are also more susceptible to suffer possible tracheal compression. However, it was reported that the condition may regress spontaneously postnatally after several months (SCF, 2006).

Excess iodine - human health studies

14. In some countries, including Denmark, iodine deficiency has been tackled through the mandatory iodization of all salt, including table salt and salt in bread. Monitoring instigated prior to mandatory fortification in Denmark found an increase in thyroid autoantibodies and higher levels of thyroid autoimmune disease in the 15 years following fortification (Laurberg et al, 2008; Rasmussen et al, 2008; Pedersen et al, 2011; Bliddal et al, 2015). The UK has no such fortification scheme for iodine.

15. The association of thyroid nodules (TNs)[2] and iodine intake in pregnant women was investigated. Serum and spot urine samples from 2353 pregnant women were collected. Urine iodine concentration (UIC) and creatinine (Cr) level were determined in spot urine samples, serum thyroid hormones and thyroid autoantibodies. The UIC and UIC to creatinine ratio (I/Cr ratio) was found to be significantly higher in pregnant women with TNs. Thyroglobulin, age, pre-pregnancy body mass index and iodine-excessive region were associated with TNs. The I/Cr ratio was not a significant risk factor for TNs in pregnant women in their second trimester (Gao et al, 2019).

16. The effects of high iodine intake on thyroid function in pregnant and lactating women was investigated in China. An epidemiological study was conducted among 130 pregnant women and 220 lactating women aged 19 – 40 years in areas that had a drinking water iodine content of >300 and 50-100 µg/L in Shanxi in 2014. Urinary iodine levels and blood thyroid stimulating hormone levels were examined. It was concluded that excess iodine intake might increase the risk of subclinical hypothyroidism in pregnant women and lactating women. It was suggested that iodine nutrition and thyroid function should be monitored in women, pregnant women and lactating women who live in areas with high environmental iodine. (Ren et al, 2018).

17. A cross-sectional study was performed amongst 111 lactating women in a refugee camp in Algeria who lived in areas with high and very high iodine concentrations in drinking water. Breast milk iodine concentration (BMIC), UIC and the iodine concentration in the most commonly consumed foods/drinks were measured. A 24-h dietary recall was used to estimate iodine intake. Thyroid hormones and antibodies were measured in serum. Median UIC, BMIC and iodine intake across both areas were 350 µg/L, 479 µg/L and 407 µg/day, respectively. Thyroid dysfunction and/or positive thyroid antibodies were found in 33.3% of the women, of which 18.9% had hypothyroidism and 8.1% had hyperthyroidism and

[2] Thyroid nodule (TNs): TNs are solid or fluid-filled lumps that form within the thyroid (Mayoclinic, 2020).

6.3% had positive antibodies with normal thyroid function. Elevated thyroid antibodies were in total found in 17.1% of the women. There was no difference in the distribution of thyroid dysfunction or positive antibodies between high iodine and very high iodine drink water areas. It was found that BMIC could be considered as a good indication for iodine status among lactating women. There was an association found between BMIC and thyroid dysfunction and positive antibodies, which indicated that thyroid dysfunction may be caused by an excessive iodine intake. The high prevalence of thyroid dysfunction and the chronically high intake of iodine might have adverse health consequences for the women and their children. (Akare et al, 2015).

18. A cross-sectional study of 111 children in a refugee camp in Algeria exposed to high iodine levels through breast milk with follow-up 3 years later in 289 children (76 from the baseline study) measured iodine concentrations in urine and breast milk at baseline. At follow-up, urinary iodine, and blood levels of thyroid hormones and serum thyroglobulin were measured. Excessive iodine intake (defined as urinary iodine levels of ≥300 μg/L) was identified in 88% of the group at baseline (children aged 0 – 6 months) and 72% at follow-up (3 years later). At follow-up, 24% of the study group had thyroid hormone disturbance and 9% had subclinical hypothyroidism. Children with subclinical hypothyroidism showed poorer growth and were more likely to be underweight than those without (Aakre et al, 2016).

19. Eight case reports were collected following the recall of a prenatal supplement containing excessive iodine levels in Brazil. In all cases, the infant was born with goitre. In the first case, a pregnant woman at 22 weeks' gestation was diagnosed with fetal goiter via a prenatal ultrasound. It was reported that she had taken 2 prenatal vitamin pills/day which was requested for at a local pharmacy. The maternal UIC on the 24th week of gestation was 902 μg/24 h (normal 100 – 460 μg/24 h). The prenatal vitamin was analysed and found to contain 40 mg of potassium iodide per pill. It was found that the pregnant woman was exceeding the recommended dose of 200 μg. The prenatal vitamins were discontinued. No iodine doses were reported in the remaining case reports. There were three reported cases where infants were treated with levothyroxine. Regardless of treatment, all but one returned to normal thyroid function within 4-6 months of withdrawal of the prenatal vitamin supplement. In the remaining case, normal function resumed after levothyroxine treatment for 18 months. (de Vasconcellos Thomas and Collett-Solberg, 2009).

20. There is also evidence that excessive iodine supplementation during pregnancy can increase serum TSH concentrations and thus have a negative impact on maternal thyroid function. In one observational study, pregnant women who ingested supplements containing >200 μg /d were found to be at increased risk of serum TSH elevation compared with pregnant women whose supplemental iodine intake was <100 μg/d (Rebagliato et al, 2010).

21. Eight cases of congenital goitres and hypothyroidism were reported in neonates following maternal exposure to concentrations of 12 – 1650 mg iodide/day (0.2 – 27 mg/kg bw/day). A clear casual relationship could not be demonstrated. (Carswell et al, 1970).

22. Human epidemiological studies have shown variations in the incidence of thyroid cancer, depending on the levels of iodine available in water supplies in the

areas. The type of cancer appears to differ depending on whether iodine levels are deficient or excess. Changes to the pattern of thyroid tumours have been noted after prophylaxis (EVM, 2003).

Health based guidance values

23. In 2003, the Expert Group on Vitamins and Minerals (EVM) examined iodine but were unable to set a safe upper limit (SUL). Supplemental doses of 0.5 to 1.5 mg iodine/day produced small changes in the levels of thyroid hormones (Paul et al, 1988; Chow et al, 1991; Gardner et al, 1988). The Saxena et al, 1962; Freund et al, 1966 studies indicated that the supplemental doses of 2 mg/day in addition to the dietary iodine resulted in the blockage of further iodine uptake. For the guidance level, the EVCM indicated that a level of 0.5 mg/day of supplemental iodine in addition to the background intake of 0.43 mg/day (Equivalent to 0.015 mg/kg bw/day in 60 kg adult) would be unlikely to cause adverse effects in adults based on slight alterations in serum thyroid hormone levels at supplemental doses of 0-2 mg/day in a range of human studies.

24. The Scientific Committee on Food (SCF, 2004) derived an upper limit for iodine consumption of 600 μg/day, based on the finding that biochemical changes in TSH levels and the TSH response to TRH administration were marginal and not associated with any clinical adverse effects at estimated intakes of 1700 and 1800 μg/day. The studies on which these UL estimates were based were all only of short duration, with a small number of individuals but the results were supported by a 5-year study of exposure with an iodide intake of 30 μg/kg bw/day (approximately 1800 μg iodide/day), where there was no clinical thyroid pathology. An uncertainty factor (UF) of 3 was considered adequate and provided the UL for adults The UL of 600 μg was also considered to be acceptable for pregnant and lactating women based on of lack of adverse effects at significantly higher exposures.

25. JECFA established a provisional Maximum Tolerable Daily Intake (PMTDI) of 17 μg/kg bw/day for iodine from all sources, based on an epidemiological study. 750 men and women were exposed to iodinated water in prison and consumed 1-2 mg of iodine per day for various time periods. Adverse effects were observed in four women who had previous thyroid issues before entering prison and became more symptomatic receiving the iodinated water supply. Out of 15 tested inmates, two had impaired organification of thyroidal iodine (JECFA, 1989).

Iodine exposures in maternal health

Sources of iodine exposure

Food

26. Levels of iodine have been measured in the composite food samples of the

2014 Total Diet Study (TDS) (FSA, 2016). Other sources of iodine can be found in Table A2. The richest dietary sources of iodine are fish, eggs, seafood such as seaweed and dairy products. Seaweed has been used for centuries as a staple food in Asian countries. In some Asian countries, it is customary to serve seaweed soup to new mothers (Moon et al, 2009). Seaweed consumption is also popular in people who are on a plant-based diet (EFSA, 2019). A study found that seaweed contributed largely to diets of vegans with excessive iodine intake (Eveleigh et al, 2020). EFSA conducted an analysis and risk assessment on seaweed. Estimated mean exposures to iodine ranged from 94.9 – 11, 512.3 µg/day. Estimated 95th percentile exposures to iodine ranged from 86.0 – 18,677.2 µg/day (EFSA, 2019).

Human breast milk

27. An iodine concentration of 70 µg/kg is reported for mature breast milk in DHSC (1977). This value was obtained using the pooled samples of breast milk donated by 96 mothers from different parts of Great Britain. Up to 15% of the mothers in this study took vitamin and/or iron supplements during lactation but the iodine content of the supplements, if any, was not reported. No data specifically focussing on the influence of regular use of iodine supplements on levels of iodine in breast milk of UK mothers were identified.

Cows' milk and milk products

28. Iodine-based compounds are used to clean the udders of cows during milk collection and these leach into the milk, adding to the natural levels of iodine present. Cows' milk is therefore considered to be one of the richest sources of iodine in the diet. A survey of cows' milk carried out in 1998-9 found that the overall mean iodine concentration in cows' milk was 311 µg/kg. Mean iodine concentrations were found to be lower in summer (200 µg/kg) compared to winter (430 µg/kg). The higher concentrations in winter may reflect greater use of supplemented compound feedstuffs during this period. At these levels, the COT concluded that the concentrations of iodine in cows' milk are unlikely to pose a risk to health, even in those children who are high level consumers (COT, 2000).

Drinking water

29. Iodine was detected at low levels (8 µg/L) in tap water in the 2014 TDS (FSA, 2016).

Supplement

30. Table A1 in the annex provides a list of supplements that contain iodine taken from the NDNS database. Adults are recommended a daily iodine intake of 140 µg (PHE, 2016). However, most people should be able to obtain the required amount of iodine by eating a varied and balanced diet. People who follow a strict vegan diet and do not consume any fish are advised to take an iodine supplement (NHS, 2020). The UK DRVs do not include an increment in iodine for pregnant or lactating women.

COMA advised on the premise that women of reproductive age should have customary intakes that would enable them to manage pregnancies without any need or supplements. The SACN Subgroup on Maternal and Child Nutrition (SMCN) considered there was insufficient evidence to substantiate revisions to the UK DRVs for iodine for pregnant and lactating women (SACN, 2014). No data specifically focusing on the influence of regular use of iodine supplements on levels of iodine in breast milk of UK mothers were identified.

Environmental - Dust and soil

31. Iodine levels in soil are highly variable. A median value of 5.9 mg/kg and a 90th percentile value of 14.2 mg/kg have been reported for UK soil by the British Geological Survey (BGS 2016). No specific value for dust was identified from the literature.

Air

32. According to the expert panel on Air Quality Standards, concentrations of particle bound iodine in UK air between 1996 and 2001 ranged from 0.8 x10-6 - 2.0 x 10-6 mg/m3 (DEFRA, 2006).

Medication

33. Iodine is used as a topical antiseptic, which can result in absorption through the skin. Excessive iodine intakes can occur following the ingestion of iodide-containing pharmaceuticals for the treatment of asthma, bronchitis, cystic fibrosis, chronic obstructive pulmonary disease, goitre. Iodine is also found in tropical antiseptics, mouthwashes, vaginal solutions and burn and wound treatments (SCF, 2006). Absorption in infants appears to be greater than in adults (Leung and Braverman, 2014). There are other medications that also contain iodine, which may be released metabolically into the systemic circulation.

Exposure assessment

Exposure estimates based on the TDS

34. A Total Diet Study (TDS) is described as a complementary approach to traditional monitoring and surveillance programs (EFSA, 2011). The TDS is used to calculate population dietary exposure to a range of chemicals in food and to assess the safety and/or nutritional quality of food. TDSs involve selecting, collecting and analysing commonly consumed food purchased at retail level, processing the food as for consumption, pooling the prepared food items into food groups that are representative, homogenising the pooled samples and analysing them for harmful and/or beneficial chemical substances (FSA, 2019).

35. Table 2 summarises total dietary exposures to iodine calculated using the iodine concentrations determined from food groups in 2014 Total Diet Study (TDS). The exposure assessment was carried out for women of childbearing age (16 – 49 years old) using food groups and consumption data from years 1 – 8 of the NDNS survey (Bates et al., 2014; 2016; 2018). The NDNS (Bates et al., 2014; 2016; 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. Mean chronic iodine exposures from the total diet of women aged 16-49 years old was 1.7 µg/kg bw/day and the 97.5th percentile chronic exposure was 3.7 µg/kg bw/day.

36.This TDS comprises of 27 food groups (Annex A2). The food groups making the highest contribution to iodine exposure in the TDS were milk, followed by fish and seafood. It should be noted that It has been advised that pregnant women should avoid particular types of cheese, dairy products, meat, eggs, fish and avoid drinking alcohol (NHS, 2020b). Therefore, it should be noted that pregnant or breastfeeding women may have a different diet compared to non-pregnant or breastfeeding women in the same age range as pregnant or breastfeeding women may choose to increase or decrease consumption of certain foods or drinks due to this advice.

Consumer- based and population-based exposures estimates based on foods in the Total Diet Study (TDS)

Table 2. Estimated chronic exposure for iodine from the total diet in women aged 16 – 49 years old (TDS 27 groups) (Bates et al., 2014; 2016; 2018)

Consumers (n)	Chronic exposure		Respondents in population group (n)
	Mean (µg/kg bw/day)	P97.5 (µg/kg bw/day)	
1874	1.7	3.7	1874

Exposure estimates for seaweed

37. As per paragraph 26, seaweed has been noted as a high source of iodine, particularly in people on a plant-based diet or from a culture where seaweed intake is high. For this reason, iodine levels in seaweed have been used to give exposure estimates.

38. A search within the recipes database of the NDNS (Bates et al., 2014; 2016; 2018) was conducted to retrieve seaweed and seaweed products which had been recorded in the survey. These can be seen in column one of table 3. Column three is the assumption made for the type of seaweed in each food, where it has not been specified. These assumptions were based on common uses of seaweed.

Table 3. Seaweed or seaweed-containing foods recorded in the NDNS (Bates et al., 2014; 2016; 2018)

Food as recorded in NDNS	Description of food	Assumed type of seaweed
Higher nature energy breakfast shake dry powder	Meal replacement shake	Kelp/ kombu
Laverbread	Welsh seaweed dish	Laver seaweed aka Nori
Sushi, tuna based	NA	Nori
Sushi, vegetarian	NA	Nori
Sushi, salmon based	NA	Nori
Soup with tofu and seaweed	NA	Wakame
Vecon	Vegetable stock	Kelp/ kombu
Seaweed wakame dried raw	NA	Wakame

39. It should be noted that levels of iodine vary between types of seaweed, this can be seen in the EFSA 'Analysis and Risk Assessment of Seaweed' where kelp (Saccharina latissima) had a higher iodine concentration in comparison to other seaweed species (EFSA, 2019). In this case, iodine concentration in kelp ranged from 333.0 – 4,782.2 µg/g freeze dried weight. Three other species had lower ranges of 137.8-451.2 µg/g, 105.2-961.4 µg/g and 17.2-20.8 µg/g of freeze-dried weight (fdw).

40. The different levels of iodine in different seaweeds is also apparent in Yeh et al's 'Analysis of iodine content in seaweed by GC-ECD and estimation of iodine intake' (Yeh et al, 2014) where kelp/ kombu can be compared to wakame and nori, which is more specific to the data available from the NDNS. In this case, the range for nori was 29.3 – 45.8 µg/g, for wakame 93.9 – 185.1 µg/g and for kombu 241-4921 µg/g in dried seaweed weight.

41. It was also important to consider that seaweed harvested from different countries may have varied levels of iodine, this is also illustrated by Yeh et al, 2014. 10 samples each of nori, wakame and kombu harvested from China, Japan, Korea and Taiwan were analysed with varied results (Yeh et al, 2014).

42. Another uncertainty was that seaweed consumption based on the foods in table 3 and NDNS survey data for women of childbearing age (16 – 49 years) yielded consumption data based on very few consumers (Bates et al., 2014; 2016; 2018). Exposure or consumption estimates based on very few consumers should be treated with caution, particularly 97.5th percentile estimates based on less than 60 consumers. Furthermore, as mentioned previously, the NDNS does not consider pregnant or lactating women so these estimates may not be representative of the target population. The chronic consumption estimates can be seen in table 4.

Table 4. Chronic consumption estimates of seaweed in women aged 16 – 49 years old (Bates et al., 2014; 2016; 2018)

Consumers (n)	g/ person/day*		g/kg bw/day*		Respondents in population group (n)
	Mean	P97.5	Mean	P97.5	
36	1.1	3.8	0.017	0.060	1874

*rounded to 2.s.f

43. Further to the data considered from literature in paragraphs 39 – 41, real time data was consulted. The Rapid Alert for Food and Feed (RASFF Portal) is a tool that provides information on public health warnings issued by food safety authorities and food companies. It also provides the latest information on food recall notices. Between March 2019 to August 2020, there were 37 reported incidences whereby levels of iodine were detected in seaweed samples at above the alert, recall or 'information for follow-up' level according to the RASFF Portal. The concentrations of iodine in these seaweed samples ranged from 25 µg/g to 20,620 µg/g. Countries of origin in order of contribution were: South Korea, China, Germany, Spain, Japan, Belgium and Austria. These are similar to countries from which samples were derived by Yeh et al, 2014. This range is much higher than that seen by the EFSA analysis of kelp (EFSA, 2019) and are considered to be worst-case scenario.

44. After reviewing all of the information in paragraphs 39 – 41 and tables 3 and 4, exposure estimates were calculated using NDNS seaweed consumption data and the iodine concentration range measured in 16 kelp samples by EFSA, 333.0 – 4,782.2 µg/g fdw (EFSA, 2019). Due to the various uncertainties discussed such as the varying levels of iodine in different types of seaweed and the limited consumption data available in the NDNS this was considered the most realistic scenario.

Table 5 Chronic exposure estimates using chronic consumption data from table 4 and the iodine concentration range measured in kelp by EFSA, 2019 (minimum: 333.0 µg/g fdw, maximum: 4,782.2 µg/g fdw).

µg/person/day*				**µg/kg bw/day***			
Mean		**P97.5**		**Mean**		**P97.5**	
Min	Max	Min	Max	Min	Max	Min	Max
360	5200	1300	1800	5.5	79	20	290

*rounded to 2 s.f

45. The exposure data in table 5 should be treated with caution because it is based on consumption data from a limited number of consumers, particularly the 97.5th percentile estimates. Another important caveat is that the use of unprocessed seaweed biomass is a conservative approach for exposure assessments which is likely to lead to an overestimation. The minimum and maximum seaweed iodine values are only based on 16 samples. The effects of cooking and processing as well

as bioavailability are not taken into account for this assessment as the data from EFSA 2019 is based on freeze dried samples of seaweed (EFSA, 2019).

Risk characterisation

46. In 2003, the EVM set a guidance level for iodine of 15 µg/kg bw/day that would not be expected to cause adverse effects in the majority of the population. It should be noted that this is a guidance level only as there was insufficient data from human or animal studies to establish a Safe Upper Level for iodine. Therefore, its applicability to maternal health is uncertain. The exposure estimates in Table 2 are below the guidance value. As seen in table 5, the estimated mean exposure for seaweed based on the minimum value of 333.0 µg/g fdw of iodine was 5.5 µg/kg and is below the guidance value. The estimated mean exposure for seaweed based on the maximum value of 4782.2 µg/g fdw of iodine was 79 µg/kg bw/day and is above the set guidance value. The estimated 97.5th percentile exposures for seaweed based on the minimum and maximum values of 333.0 µg/g and 4782.2 µg/g fdw iodine was 20 and 288 µg/kg bw/day, respectively. The estimated exposures are above the guidance value.

47. JECFA established a provisional Maximum Tolerable Daily Intake (PMTDI) of 17 µg/kg bw/day for iodine from all sources, based on the same longer-term studies in adults used by SCF in 2002 to support the TUL. The exposure estimates in Table 2 is below the PMTDI. As seen in table 5, the estimated mean exposure for seaweed based on the minimum value of 333.0 µg/g fdw of iodine is below the PMTDI. The estimated mean exposure for seaweed based on the maximum value of 4782.2 µg/g fdw of iodine is above the PMTDI. The 97.5th percentile exposure estimates for seaweed based on the minimum (333.0 µg/g fdw) and maximum iodine (4782.2 µg/g fdw) values are above the PMTDI.

48. The SCF established a UL of 600 µg/day for pregnant and lactating women based on of lack of adverse effects at significantly higher exposures (SCF, 2000). The exposure estimates in table 2 is below the UL. The estimated mean exposure for seaweed based on the minimum value of 333.0 µg/g fdw of iodine was below the UL. The estimated mean exposure based on the maximum value of 4782.2 µg/g fdw iodine was above the UL. The estimated 97.5th percentile exposures for seaweed based on the minimum (333.0 µg/g fdw) and maximum iodine (4782.2 µg/g fdw) values are above the UL.

Conclusions

49. Exposure to excess iodine in pregnancy may cause adverse effects on maternal and fetal thyroid function, birth outcomes, and offspring growth and development (Le et al, 2018).

50. Total dietary exposures to iodine calculated using the iodine concentrations determined from food groups in 2014 Total Diet Study (TDS). The estimated mean

chronic iodine exposure for women aged 16 – 49 years old was 1.7 µg/kg bw/day and the 97.5th percentile chronic exposure was 3.7 µg/kg bw/day. The estimated exposure values are below all the health-based guidance values. However, the NDNS (Bates et al., 2014; 2016; 2018) does not provide consumption data for pregnant or lactating women so while data is based on women of childbearing age, this data may not be representative of the maternal diet. Also, the use of a TDS survey only represents the diet of the general population and may not necessarily be a robust indicator of iodine levels in maternal health.

51. In paragraph 28 it was highlighted that seaweed consumption is popular in people who are on a plant-based diet or from a culture where seaweed intake is high. The estimated mean exposure for seaweed based on the minimum value of 333.0 µg/g fdw of iodine (Table 5) did not exceed the UL of 600 µg/day that was set for pregnant and lactating women (SCF, 2006). The estimated mean exposure for seaweed based on the maximum value of 4782.2 µg/g fdw iodine, and the estimated 97.5th percentile exposures for seaweed based on the minimum and maximum values of 333.0 µg/g and 4782.2 µg/g fdw iodine all exceeded the health based guidance values. The exposure data in table 5 should be treated with caution because it is based on consumption data from a limited number of consumers, particularly the 97.5th percentile estimates. Also, the minimum and maximum seaweed iodine values are only based on 16 samples. Another important caveat is that the use of unprocessed seaweed biomass is a conservative approach for exposure assessment which is likely to lead to an overestimation (EFSA, 2019). The effects of cooking and processing as well as bioavailability are not taken into account for this assessment as the data from EFSA 2019 is based on freeze dried samples of seaweed. The data is also just based on women of childbearing age, this data may not be representative of the maternal diet.

Questions for the Committee

Members are asked to consider the following questions:

a) Do members think that exposure to excess iodine would pose a risk to maternal health?
b) Do members think the current intakes of iodine are likely to pose a risk to the women of childbearing age, pregnant women or lactating mothers?
c) Do Members have any specific comments on seaweed?
d) Does the Committee have any further comments?

Secretariat

October 2020

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Annex A

Table A1: A list of supplements that contain iodine taken from the years 1 – 8 NDNS database (Bates et al., 2014; 2016; 2018)

Supplement name
Nutriplus micromins drops
Animal pak supplement
Higher nature advanced nutrition complex
Slimfast rtd meal replacement drink
Doterra microplex mvp food nutrient complex
Fortisip nutritionally complete supplement drink
Ensure liquid vitamin + mineral supplement
Solgar kangavites multivitamin and mineral chews
Sanatogen vital 50+ tablet only
Nutrigold supamag plus vitamin and mineral supplement
Viridian high five multivitamin and mineral supplement capsule
Ensure plus juce style
Thyroid support formula
Higher nature effervescent multivitamins and minerals
Healthspan hair and nails tablet
Biocare multivitamin and mineral tablet
Forever daily vitamins and minerals with aos complex
Vitabiotics feroglobin liquid iron supplement
Quest multivitamin and mineral supplement
Shapeworks multivitamin and mineral complex
Coral calcium supreme supplement
Higher nature true food supernutrition plus supplement
Solgar female multiple multivitamin and mineral
Bassetts active health vitamin and mineral chews
Natures plus animal parade chewable multivitamin and mineral
Lamberts health insurance plus supplement
Holland and barrett mega vita-min teens
Doterra a2z chewable
Viridian viridikid multivitamin and mineral tablets
Solo wellbeing for women supplement
Multi guard balance, multivitamin & mineral with cinnamon
Boots effervescent multivitamin and mineral supplement
Beachbody nutritionals activit
Cytoplan wholefood multivitamin and mineral
Seven seas multibionta probiotic multivitamin only
Centrum advance multivitamin and mineral
Vitabiotics visionace multivitamin and mineral
Superdrug super one multivitamin and mineral supplement
Higher nature true food wise woman supplement
Centrum advanced 50+ multivitamin & mineral supplement
Wassen magnesium-ok

Centrum women
Centrum women 50+ multivitamin-mineral supplement
Boots teenage a to z chewable multivitamins and minerals only
Vitabiotics pregnacare original
Valupak multivitamins and minerals
Holland and barrett radiance multivitamin and mineral
Forceval multivitamin and mineral
Vitabiotics pregnacare conception
Simply supplements a-z multivitamins and minerals
Vitabiotics pregnacare breastfeeding capsules
Boots complete a to z
Healthspan multivitamins and minerals '50 plus' with ginkgo
Holland and barrett abc plus tablets only
Healthspan multivitality gold a to z complete spectrum mulitvitamins and minerals
Superdrug 50+ multivitamins and minerals
Sainsburys multivitamin and mineral supplement
Sanatogen gold multivitamin and mineral tablet
Superdrug time release multivitamin and mineral tablet
Multivitamin with iron and iodine
Boots multivitamin and iron (includes other minerals)
Holland and barrett abc senior+ multivitamin and mineral
Tesco multivitamin and mineral supplement
Kirkland daily multivitamin and mineral supplement
Boots probiotic multivitamin and mineral
Superdrug a-z multivitamins and minerals
Lamberts multiguard multivitamin & mineral supplement
Wellman 50+ multivitamins and minerals
Boots general health multivitamin and mineral
Asda multivitamin and mineral supplement
Seven seas complete multivitamins (previously a-z multivitamin & mineral supplement) with ginseng
Sanatogen a-z complete multivitamin & mineral supplement
Natures best multi max advance for 50+
Boots general health 50+ multivitamins and minerals
Natures aid complete multi-vitamins & minerals antioxidant formula
Centrum performance
Healthspan multivitality for vegetarians
Healthspan multivitality 70 plus
Healthspan menoserene
Solo multi fifty-mutivitamin
Zip fit over 50s multivitamin active formula tablet
Holland and barrett ultra woman caplets
Natures way alive once daily wonem's 50+ ultra potency
Tesco multiplus pregnancy
Formula vm-75 tablets
Kelp tablets with 150 microgram iodine
Seven seas femibion healthy pregnancy capsules

Vitabiotics well woman max micronutrient, omega 3-6-9 capsule & calcium and vitamin d
Sea kelp tablets any strength
Vitabiotics perfectil multivitamin and mineral
Perfectil triple active skin, hair and nails formula
Vitabiotics menopace tablet
Nascent iodine supplement
Eniva vibe multivitamin and mineral liquid supplement

Table A2: The 27 food groups used for analysis of 26 elements in the 2014 TDS

TDS Food	Groups*
Bread	Fresh fruit
Miscellaneous cereals	Fruit products
Carcase meat	Non-alcoholic beverages
Offal	Milk
Meat products	Dairy products
Poultry	Nuts
Fish	Alcoholic drinks
Fats and oils	Meat substitutes
Eggs	Snacks
Sugars	Desserts
Green vegetables	Condiments
Potatoes	Tap water
Other vegetables	Bottled water
Canned vegetables	

*Food samples representative of the UK diet are purchased throughout the year in 24 towns covering the UK and 137 categories of foods are combined into 27 groups of similar foods for analysis.

Table A3: Estimated consumer-based chronic iodine exposure from foods in women aged 16 – 49 years old from 27 food groups in the 2014 TDS

Food group	Number of consumers				
		Mean (µg/kg bw/day)	97.5th percentile (µg/kg bw/day)	Mean (µg/kg bw/day)	97.5th percentile (µg/kg bw/day)
		LB*	UB*	LB*	UB*
Milk	1692	0.54	0.54	1.8	1.8
Fish and seafood	980	0.54	0.54	1.7	1.7

Dairy products	1540	0.20	0.20	0.71	0.71
Non-alcoholic beverages	1874	0.16	0.16	0.37	0.37
Misc cereals	1840	0.13	0.13	0.38	0.38
Eggs	970	0.18	0.18	0.53	0.53
Fruit products	958	0.14	0.14	0.50	0.50
Sugars and confectionary	1656	0.09	0.059	0.22	0.22
Tap water	1578	0.057	0.057	0.22	0.22
Meat products	1303	0.055	0.055	0.19	0.19
Desserts	700	0.093	0.093	0.28	0.28
Bread	1804	0.028	0.028	0.070	0.070
Condiments	1715	0.015	0.015	0.049	0.049
Poultry	1471	0.015	0.015	0.043	0.043
Alcoholic beverages	825	0.023	0.023	0.12	0.12
Carcass meat	1292	0.012	0.012	0.040	0.040
Snacks	1060	0.013	0.013	0.034	0.034

Potatoes	1653	0.0078	0.0078	0.020	0.020
Fats and oils	1782	0.0040	0.0040	0.012	0.012
Bottled water	669	0.0095	0.0095	0.037	0.037
Canned vegetables	785	0.0049	0.0049	0.019	0.019
Meat alternatives	129	0.0027	0.0027	0.098	0.098
Offal	76	0.0022	0.0022	0.060	0.060
Other vegetables	1756	0.0093	0.0093	0.027	0.027
Green vegetables	0	0	0.0031	0	0.011
Fresh fruit	0	0	0.0078	0	0.023
Nuts and seeds	0	0	0.0025	0	0.015

*NB. For many of the food groups the LB and UB exposure values are equal. This is because only 3 out of the 27 food groups (‘green vegetables’, ‘fresh fruit’ and ‘nuts and seeds’) had a UB iodine concentration higher than their LB concentration. See table A4.

Table A4: Iodine concentrations in 27 food groups from the 2014 TDS

Food group	Concentration (mg/kg)	
	LB*	UB*

Milk	0.26	0.26
Fish and seafood	0.81	0.81
Dairy products	0.24	0.24
Non-alcoholic beverages	0.0080	0.0080
Misc cereals	0.065	0.065
Eggs	0.38	0.38
Fruit products	0.091	0.091
Sugars and confectionary	0.16	0.16
Tap water	0.0080	0.0080
Meat products	0.067	0.067
Desserts	0.16	0.16
Bread	0.027	0.027
Condiments	0.031	0.031
Poultry	0.015	0.015
Alcoholic beverages	0.0060	0.0060

Carcass meat	0.023	0.023
Snacks	0.063	0.063
Potatoes	0.0060	0.0060
Fats and oils	0.023	0.023
Bottled water	0.0020	0.0020
Canned vegetables	0.0080	0.0080
Meat alternatives	0.052	0.052
Offal	0.075	0.075
Other vegetables	0.0070	0.0070
Green vegetables	0	0.0050
Fresh fruit	0	0.0050
Nuts and seeds	0	0.010

*rounded to 2s.f.