COT Evaluations

In this guide

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Statement on the Safety of Ginger Supplement Use in Pregnancy (COT/2025/01)

In 2019 the Scientific Advisory Committee on Nutrition (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. To support this, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) were asked to review the risks of toxicity from chemicals in the maternal diet.

In May 2021, the COT considered the potential effects of ginger and ginger supplements during pregnancy and lactation and reviewed the available data on

toxicity to the mother, effects on the development of the fetus or embryo, and possible interactions with drugs, as well as data on potential exposure to ginger.

Ginger (*Zingiber officinale*) is a flowering tropical plant originating in Southeast Asia. Ginger is commonly consumed as a spice in food or as a supplement. It is taken as fresh root, dried root powder and capsule (encapsulated dried powder) forms, as a liquid extract, preserved in syrup or sugar, and as a tea.

Ginger is growing in popularity as a natural remedy as it has been reported to modify the immune system to help the body respond to illness, and also to alleviate motion sickness and post-operative nausea and vomiting. Consuming ginger is one of the ways suggested by the NHS and NICE guidelines that might alleviate mild to moderate nausea and vomiting in pregnancy. It has also been used as a dietary supplement and a traditional remedy in many cultures for this and other purposes.

Several ginger supplements are commercially available, with varying amounts of ginger. In addition to this, concentrated ginger shots (liquid form), containing large amounts of pressed ginger, are becoming increasingly popular. The differences in composition of these supplements add uncertainty to estimates of the amount of ginger being consumed.

Generally, consumption of ginger in a traditional culinary manner within a diet is not considered a health concern. The Committee noted that from the evidence presented, the potential for contamination of ginger with heavy metals and/or mycotoxins cannot be excluded.

The COT concluded that there is no evidence to support changing the current NHS advice to pregnant women. This suggests that eating foods or drinks containing ginger might ease symptoms of morning sickness and states that during pregnancy a person should check with a pharmacist before taking ginger supplements.

The full statement can be found on the Committees website.

Statement of advice on the risk to human health from consumption of bivalve molluscs (shellfish) harvested from UK waters associated with marine biotoxins (COT/2025/02)

1.1 The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) was asked by the Food Standards Agency (FSA) to evaluate whether emerging marine biotoxins found in shellfish harvested from United Kingdom (UK) waters may pose a risk to human health.

1.2 Marine biotoxins are naturally occurring toxic compounds produced by certain types of algae. These biotoxins can accumulate in shellfish, such as mussels and oysters, and may cause illness if consumed. The presence of some biotoxins in UK or EU waters is already known and work has begun to routinely monitor and regulate them in the UK. Others are considered “emerging marine biotoxins” because they have not previously been prevalent in UK waters but may become so due to several factors, including environmental changes, such as climate change and warming seas. These factors can alter the global distribution of marine biotoxin producing algae, increasing the likelihood that emerging marine biotoxins will be detected in UK waters and shellfish.

1.3 Groups of emerging marine biotoxins with related chemical structures and potencies have been identified through literature searches and by evaluating assessments by other authorities such as the European Food Safety Authority (EFSA) and Centre for Environment, Fisheries and Aquaculture Science (Cefas). As these biotoxins are not yet regulated or included in official monitoring programmes there is very little data on their current prevalence, levels, or distribution.

1.4 Toxicological data are also limited. As a result, the COT could not undertake a full risk assessment. Instead, the Committee developed a numerical risk-ranking approach to determine which emerging marine biotoxins could be of potential higher concern. This risk ranking approach is thus a prioritisation tool; it is not a measure of current risk to UK consumers and does not replace a formal risk assessment. The risk ranking will however support prioritisation of marine biotoxins and decision making by policy colleagues. The numerical risk ranking considered four different categories of evidence: (1) the extent to which each toxin is currently monitored; (2) the toxicological data based on animal studies; (3) documented reports of human illness or death; and (4) whether the toxin has been found in UK or European Union (EU) shellfish and waters, and if possible how frequent that occurrence is.

1.5 Using this approach, six groups of emerging marine biotoxins were successfully prioritised from highest to lowest risk: tetrodoxins (highest), palytoxins, microcystins, spirolides, brevetoxins, gymnodimines (lowest). Other toxins including azaspiracids, pteriatoxins and domoic acid analogues were also

considered but were excluded from the risk ranking due to insufficient information. A “read across” (using data from similar toxins) approach was explored to generate temporary rankings for these toxins but the Committee found this method was too uncertain to provide robust scores.

1.6 The risk ranking approach in general is limited by a lack of data, including: (1) the absence of routine monitoring programmes, meaning that in most cases it was unclear whether these emerging biotoxins are already present in UK waters or shellfish; (2) the potential underreporting of human illness, especially in cases with only mild or moderate symptoms such as diarrhoea where individuals may not seek medical attention or report their symptoms; (3) missing information on human case reports that could influence the observed effects, such as pre-existing health conditions, possible exposure to multiple biotoxins and how long symptoms of illness lasted; (4) only a limited number of toxicological data were available on these emerging marine biotoxins, preventing the derivation of health-based guidance values (HBGVs). The lack of an HBGV further limits the conclusions that can be drawn on the potential risks to public health, as it is not possible to establish what an acceptable level of exposure at which no adverse effect occurs is.

1.7 Despite the uncertainties in the database, the risk-ranking approach applied in this assessment provides a useful prioritisation tool to support decision-making. As more data becomes available, the understanding of risks associated with these marine biotoxins may evolve.

1.8 The full statement can be found on the Committees website: 2025-statements and position papers | Committee on Toxicity. A lay summary will be published in 2026.

Statement on the Effects of Mercury on Maternal Health

1.9 The Scientific Advisory Committee on Nutrition (SACN) is reviewing the scientific evidence that informs the Government’s dietary recommendations for women of childbearing age. As part of that process the COT was asked to review the risks of toxicity from certain chemicals in the maternal diet. As part of this programme of work, the possible risks from mercury in the diet of women of childbearing age was reviewed. Other chemical contaminants and excess nutrients will be considered separately.

1.10 Mercury occurs naturally in the earth’s crust, chiefly as mercury (II) sulfide and is released into the environment from both natural and man-made sources. In the environment, mercury undergoes complex transformations and cycles between atmosphere, land, and aquatic systems where it can enter the food chain. Mercury exists in different forms, but evaluations show the most important form in relation to diet is methylmercury (MeHg), which accumulates in fish, especially large long-lived species such as shark, swordfish, and tuna. Other foods may contain mercury, but that it is usually in the form of inorganic mercury which is much less toxic, and the available data indicates that exposure to that form is insignificant.

1.11 The main concern with MeHg is its ability to affect the nervous system. MeHg can cross the placenta and the blood–brain barrier, so exposure during pregnancy may affect the developing brain of the foetus. MeHg also has bioaccumulative properties and a long half-life in the body, meaning that exposure before pregnancy can contribute to levels during pregnancy. Developmental and behavioural effects in children, including learning and coordination difficulties, have been observed at high exposure levels, in addition to increased risk of pregnancy complications such as preeclampsia and premature birth. For this reason, pregnant and breastfeeding women are considered sensitive groups.

1.12 Current UK advice already recommends that women who are pregnant or trying to conceive should avoid eating shark, swordfish, marlin, raw shellfish, and uncooked cold-smoked or cured fish, and limit oily fish to two portions per week and tuna steaks to no more than two per week. Following this dietary advice greatly reduces exposure to the harmful effects of MeHg.

1.13 In 2012 EFSA set health-based guidance values for MeHg (1.3 micrograms per kilogram of body weight per week) and inorganic mercury (4 micrograms per kilogram of body weight per week). COT reviewed UK exposure data from food, water, air, and soil. Even in high-consumption scenarios, the estimated combined exposures were below these guidance values. This means that, for most women and their babies, the risk from mercury in the diet is low.

1.14 In summary, mercury is present in the environment and can enter the diet, mainly through consumption of fish or shellfish. While MeHg can be harmful to the developing child’s nervous system, current UK dietary advice provides effective protection and women of childbearing age should continue to follow this advice.

1.15 The full statement and lay summary can be found on the Committees website: 2025- statements and position papers | Committee on Toxicity.

Citrinin

1.16 The Scientific Advisory Committee on Nutrition (SACN) is reviewing the evidence that relates to the Government's dietary recommendations for women of childbearing age. The COT was asked to review the risks of toxicity from certain chemicals in the maternal diet. The following evaluation sets out the advice of the COT on whether UK exposures to citrinin would pose a risk to maternal health, i.e. adversely affect maternal outcomes during pregnancy, childbirth and up to 24 months after delivery.

1.17 Citrinin is a toxic substance produced by several species of fungi. It occurs mainly in grains but is also found in other products of plant origin e.g. beans, fruits, fruit and vegetable juices, herbs and spices as well as in spoiled dairy products. Its occurrence is generally due to the growth of fungi during the storage of crops after harvest.

1.18 In 2014, the Food Standards Agency (FSA) carried out a survey, the Total Diet Study, to calculate the background exposure of UK consumers to various chemicals, including citrinin, from the whole diet and to determine trends in exposure. Animal-derived foods were included in the Total Diet Study, but citrinin was not detected in any of the animal-derived food products analysed. Carryover of citrinin from animal feed into animal-based foods is not, therefore, considered in this assessment.

1.19 Citrinin has also been reported as a contaminant in certain fermentation products such as red yeast rice (RYR). However, the majority of packaging of RYR supplements either states that the product is not suitable for children and/or women who are pregnant or breast feeding or recommends that these groups should consult a general practitioner prior to consumption; RYR supplements are not, therefore, considered in this assessment.

1.20 Experimental studies in animals have linked citrinin to kidney and liver toxicity. In the kidney, the main adverse effects following citrinin administration were degeneration and tissue death, which were observed in all species tested. In the liver, a significant decrease in liver weight as a fraction of body weight (relative liver weight) has been reported.

1.21 Data from cell and animal studies also suggest that citrinin may be associated with reproductive toxicity, including adverse effects on the developing foetus during pregnancy. In experimental studies, however, these effects usually occur at doses that cause harm, including kidney damage, in the pregnant female. This suggests that any effects on the developing offspring are secondary to maternal toxicity. Animal studies also suggest that citrinin can cross the placenta, although there is limited evidence to support this.

1.22 No epidemiological or human case report studies specific to the UK population were available. However, studies from non-UK countries (Belgium, Czech Republic, Portugal, Germany, Haiti, Bangladesh, Nigeria, Turkey, and Tunisia) that monitored citrinin levels in human urine did not indicate an association between higher maternal daily intakes of citrinin and duration of pregnancy, birth weight, birth length or head circumference at birth.

1.23 In 2012, EFSA assessed the risks to public and animal health related to the presence of citrinin in food and animal feed.

1.24 EFSA noted that citrinin does not seem to cause mutations in bacteria but that citrinin can induce chromosome changes in mammalian cells and in mice. These changes can be associated with the development of cancer.

1.25 Citrinin has been shown to cause kidney tumours in rats; however, EFSA could not predict whether citrinin might cause cancer in humans because of a lack of lifetime exposure studies in animals.

1.26 The evidence concerning potential DNA damage and the lack of human dietary exposure data led EFSA to conclude that establishing either a safety limit or following a margin of exposure approach for citrinin would not be appropriate. Instead, EFSA used the evidence from a study in rats to identify a “level of no concern” of 0.2 µg per kg body weight per day for kidney toxicity in humans. A level of no concern is not a safety limit; rather, it is a level of exposure below which there is no significant concern for adverse effects.

1.27 In 2015, the Netherlands Food and Consumer Product Safety Authority (NVWA) commissioned the National Institute for Public Health and Environment (RIVM) to find out whether any new studies on the toxic effects of citrinin had been published since 2011.

1.28 The RIVM selected two studies in rodents to identify the lowest dose of citrinin that is linked to a 5% increase in adverse effects (the Benchmark Dose Lower Confidence Limit, BMDL05). The value they calculated was 48 µg per kg

body weight per day for foetal growth restriction measured as decreased crown rump length, the length of a foetus from the top of the head to the rump (bottom), excluding the legs. This was 240 times higher than the dose set by EFSA as the level of no concern for kidney toxicity, suggesting that exposures below the level of no concern are very unlikely to cause adverse effects on foetal development and further supporting the idea that any effects on the developing offspring are likely to be secondary to maternal toxicity.

1.29 The COT agreed with EFSA's level of no concern of 0.2 µg per kg body weight per day for kidney toxicity and its justification for the recommended level. Whilst the BMDL05 derived by the RIVM was specific to reproductive effects, EFSA 's level of no concern was 240 times lower. Complying with the level of no concern would therefore provide protection against all the other forms of toxicity reported, including maternal and reproductive toxic effects, as well as adverse effects to the developing foetus during pregnancy.

1.30 Estimated exposures of women of childbearing age to citrinin were below the level of no concern set by EFSA. Therefore, the estimated exposures were not of concern for kidney or reproductive toxicity or for adverse effects to the developing foetus during pregnancy. In addition, citrinin was not detected above the lowest level that can be reliably measured in any of the food groups considered, further confirming that dietary exposure to citrinin is low and supporting the conclusion that levels of citrinin in the diet are not of concern to UK consumers.

1.31 Due to limitations in the database, the COT concluded that the risk of DNA damage or cancer cannot be ruled out. The COT agreed with EFSA and the RIVM that there is a need for further research to identify whether citrinin can damage DNA and/or increase the risk of cancer.

1.32 The full statement and lay summary can be found on the Committees website: 2025- statements and position papers | Committee on Toxicity.