

# COT evaluations - 2022

## In this guide

### [In this guide](#)

1. [About the Committees - 2022](#)
2. [COT Preface - 2022](#)
3. [COT evaluations - 2022](#)
4. [Committee Procedures - 2022](#)
5. [Ongoing Work - COT 2022](#)
6. [Other Committee Activities Joint Expert Groups and Presentations -2022](#)
7. [2022 Membership of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment](#)
8. [Committee on Mutagenicity of chemicals in Food, Consumer Products and the Environment Annual Report 2022](#)
9. [Ongoing work - COM 2022](#)
10. [COM Evaluations - 2022](#)
11. [Horizon scanning: meetings and workshops - COM 2022](#)
12. [OECD guidelines - COM 2022](#)
13. [2022 Membership of the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment](#)
14. [Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment Annual Report 2022](#)
15. [COC Ongoing Topics - 2022](#)
16. [COC Joint ongoing topics 2022](#)
17. [COC Workshop - 2022](#)
18. [Joint session - COC 2022](#)
19. [Horizon scanning - COC 2022](#)
20. [Working Groups - COC 2022](#)
21. [Guidance statements - COC 2022](#)
22. [2022 Membership of the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment](#)
23. [Annex 1 - 2022 - Terms of Reference](#)
24. [Annex 2 - 2022 - Code of Conduct for members of the COC/COM/COT](#)
25. [Annex 3 - 2022 - Openness](#)

26. [Annex 4 - 2022 - Good Practice Agreement for Scientific Advisory Committees](#)
27. [Annex 5 - 2022 - Glossary of Terms](#)

## **COT evaluations**

### **Statement on the effects of Vitamin D on maternal health**

1.1 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. The Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) was consulted, and decided that Vitamin D should be considered for a detailed risk assessment.

1.2 There are two forms of vitamin D; these are vitamin D2 (also known as ergocalciferol) and D3 (also known as cholecalciferol). Vitamin D2 can be found in plants and fungi and therefore is only available to humans via the diet. Vitamin D3 is made in human skin via ultraviolet radiation from the sun and can also be found in oil rich foods or supplements of animal origin such as cod liver oil. Vitamin D3 is reported to be about three times more potent than vitamin D2.

1.3 Both forms of vitamin D are converted in the body by the liver to analogous substances called 25-hydroxyvitamin D (25(OH)D) and the 25OHD is further converted in the kidney to analogous substances called 1,25-dihydroxyvitamin D (1,25(OH)<sub>2</sub>D); this is the active form of vitamin D.

1.4 Vitamin D (in reality two forms as described in paras 3-4) plays an important role in maintaining healthy bones by ensuring adequate uptake of calcium. It also helps maintain healthy muscles by aiding muscle contraction and helps nerves and the immune system to function. However, consuming too much vitamin D from food sources and supplements can cause adverse health effects.

1.5 Too much vitamin D in the body can lead to hypercalcaemia (higher than normal calcium levels in the blood), which can lead to hypercalciuria (higher than normal levels of calcium in urine), demineralisation of bones, kidney and cardiovascular issues. Other side effects of excess vitamin D may include vomiting, nausea, constipation and diarrhoea.

1.6 It is important to note that whilst too much vitamin D can be consumed from foods and supplements it is not possible to make too much vitamin D via ultraviolet radiation from the sun. This is because there are inbuilt biochemical mechanisms in our skin that prevent vitamin D<sub>3</sub> reaching toxic levels from exposure via skin.

## **Effects of vitamin D during pregnancy and lactation**

1.7 There is currently no information available on the adverse health effects that excess vitamin D might cause during the period preceding conception.

1.8 Information on the adverse health effects caused by excess vitamin D during pregnancy and lactation is limited, but hypercalcemia (higher than normal calcium levels in the blood) can occur during pregnancy, especially in individuals that have mutations in genes involved in vitamin D metabolism. Individuals with these mutations have experienced hypercalcemia after consuming up to 1,250 µg per month of vitamin D. Hypercalcemia during pregnancy may increase risk of fetal and neonatal morbidity. Excess vitamin D during pregnancy may also result in fetal and neonatal hypercalcemia, which can lead to adverse effects on the digestive system, behaviour and growth.

1.9 There is limited evidence for adverse health effects that could arise due to excess vitamin D exposure during lactation. However, hypercalciuria could possibly occur, with one clinical study reporting it in women that consumed supplements of 700 µg per week vitamin D. However, participants in this study had low levels of calcium before consuming the supplements that increased their levels to be in “possible hypercalciuria” range.

1.10 In 2003, the Expert Group on Vitamin and Minerals (EVM) set an intake level of 25 µg per day as the level of vitamin D that would not be expected to result in adverse health effects - i.e. a safe level of intake. More recently The European Food Safety Authority (EFSA) developed a tolerable upper limit (TUL) of 100 µg per day for the general adult population, including pregnant women. This TUL was endorsed by the COT.

1.11 This risk assessment showed that women attempting conception, pregnant and lactating women who consume vitamin D only from food (and not supplements) are very unlikely to be at risk of adverse health effects from vitamin D as their exposure levels are below the TUL of 100 micrograms per day.

1.12 Only a minority of women attempting conception, pregnant and lactating women who consume vitamin D from both food and supplements are above the TUL of 100 micrograms per day. It is important to note that this would only be of health concern if their intakes were sustained long-term. Pregnant women with mutations in the genes involved in vitamin D metabolism may be more likely to experience adverse health effects such as high blood calcium levels and high calcium levels in the urine.

1.13 Ultimately the COT concluded that consumption of higher strength vitamin D supplements alone or in combination with food can result in exceedance of the TUL and pose a potential health concern. However, consumption of lower strength supplements that are aimed at pregnant and breast-feeding women, either alone or in combination with food is very unlikely to result in excess vitamin D intake or adverse health effects related to excess vitamin D intake.

1.14 The full COT statement can be found at: [Statement 01/22 Vitamin D](#).

### **Statement on the potential effects that excess iodine intake may have during preconception, pregnancy and lactation**

1.15 The Scientific Advisory Committee on Nutrition (SACN) is currently conducting 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.

1.16 The Committee on Toxicity was consulted and decided that iodine should be considered for assessment of the risks associated with excess intake.

1.17 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 to support their review. Therefore, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) was asked to consider whether exposure to excess iodine would pose a risk to maternal health, as part of this review.

1.18 In the environment, iodine is usually found in the form of iodate salts, or in the form of organo-iodide compounds produced by algae and bacteria. Iodine is essential in the human diet because it is required for the synthesis of the thyroid hormones tri-iodo- and tetra-iodothyronine (T3 and T4 which is also known as

thyroxine). This takes place in the thyroid gland. The thyroid hormones help regulate metabolism and ensure that the heart, brain and other organs function in a healthy manner. They are also involved in brain development and bone growth especially in the fetus. The fetus is exposed to iodine via the placenta, and both maternal iodine deficiency and excess can have profound effects on both mother and offspring.

1.19 Excess iodine may lead to the occurrence of goitre in adults and children.

1.20 Goitre is a condition where a lump or swelling at the front of the neck caused by a swollen thyroid.

1.21 There are currently three health-based guidance values (HGBV) set for iodine. Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a Provisional Maximum Tolerable Daily Intake (PMTDI) of 17 µg/kg bw/day (equivalent to 1020 µg/day for a 60 kg adult) for iodine from all sources. The Expert Group on Vitamins and Minerals (EVM) set a guidance level for iodine of 15 µg/kg bw/day. The European Scientific Committee on Food (SCF) established a Upper Limit (UL) for total iodine intake of 600 µg/day.

1.22 Overall, the Committee concluded that there are no toxicological concerns at the levels of iodine exposure in the general population, however, high consumers of seaweed may be exposed to levels of iodine that could pose a toxicological risk to maternal health. Currently, available data are not sufficient to assess the applicability of the HBGVs to pregnant women, and there is a lack of exposure data in relation to pregnancy and lactation to enable a risk assessment to be performed.

The full COT statement can be found at: [Statement on the potential effects that excess iodine intake may have during preconception, pregnancy and lactation | Committee on Toxicity \(food.gov.uk\)](#).

## **Statement on the effects of excess Vitamin A on maternal health**

1.23 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. The Committee on Toxicity was consulted, and decided that Vitamin A should be considered for assessment of the risks associated with excess intake.

1.24 Vitamin A (also known as retinol) is found in foods of animal origin (such as liver, pâté and cod liver oil) and is also formed in the body when beta-carotene – the colouring matter in red and yellow, and leafy green vegetables – is broken down. The NHS lists significant food sources of vitamin A as cheese, eggs, oily fish, fortified low-fat spreads, milk, yoghurt and liver and liver products such as pâté. Significant sources of beta-carotene include vegetables such as carrots, sweet potatoes, red peppers and spinach, and some fruit such as mango, papaya and apricots.

1.25 Retinol is converted, after it is eaten, into other chemical forms that are involved in several biological functions, such as the proper growth of the fetus in pregnancy (in a form called retinoic acid) and how the retina in the eye senses light (in a form called retinal). Most of the effects of vitamin A are caused by retinoic acid, which, among other things, influences bone development and secretion of hormones from the thyroid gland and stimulates the immune system improving resistance to infections. Different chemical forms of vitamin A and synthetic substances that mimic it are also used as medicines, for example, to treat severe acne.

1.26 Although Vitamin A is vital to health and has many benefits, too much of it can cause health problems. A very high dose of vitamin A in the form of retinol can cause tiredness, joint pain, dry skin, headache, sickness, hair loss, drowsiness, liver and bone damage and sight problems. Vitamin A also accumulates in the liver and taking it over a long period of time can cause dry thickening of the skin, cracking of lips, damage to the eyes, skin reddening, hair loss, brittle bones, joint pain, lasting headache, increased pressure inside the skull and liver damage. Some, but not all, of these effects are reversible on reducing vitamin A intake.

1.27 Although it is broken down in the body to produce retinol, eating vegetables that are rich in beta-carotene, or consuming beta-carotene itself, does not result in adverse effects (except possibly high dose supplements in smokers) because less than one-third of beta-carotene from plant sources gets absorbed by the body.

1.28 Eating fat-rich food increases the absorption of vitamin A from the digestive system. The vitamin is carried on proteins in the blood to the liver, where it is stored and then distributed to the rest of the body to perform its functions. Vitamin A is excreted from the body largely in the urine, but as it accumulates in the liver, more is released in the bile, which may prevent the liver from being exposed to too much vitamin A.

## Effects of vitamin A on reproduction

1.29 Vitamin A is necessary for the proper functioning of the male and female reproductive systems, both inadequate and excessive amounts can harm the unborn fetus. The [statement on vitamin A](#) is concerned with the effects of excessive amounts of vitamin A (rather than inadequate amounts) and ill-effects from over-exposure. Excessive amounts of vitamin A can cause malformations to the fetus that include spina bifida (abnormal development of the spine), small or no eyes, harelip, cleft palate, absent or deformed ears, and deformities of limbs, kidneys, genitals, heart, thyroid gland and skeleton.

1.30 The UK Government recommends that, in order to avoid possible harm to the unborn child, pregnant women, or women thinking about having a baby or trying to conceive, should not consume liver or liver products such as paté, or supplements that contain vitamin A, including fish liver oil, unless they are advised to do so by a doctor. EFSA set a TUL for vitamin A of 3,000 µg per day for women of childbearing age, based on the risk of damage to the liver and to any unborn child. The UK Expert Committee on Vitamins and Minerals (EVM) considered that an intake greater than 1,500 µg per day was “inappropriate”, based on possible effects on bone. The World Health Organisation (WHO) recommends that vitamin A supplements should not be given to pregnant women except to prevent night blindness in places where vitamin A deficiency is a severe public health problem (which does not include the UK).

1.31 Taking food supplements, like fortified food products and vitamin pills, is the most common way for people, including pregnant women and those considering pregnancy, to be exposed to high doses of vitamin A. Scientific studies have surveyed the effects of supplements on development of the fetus in humans where women have taken higher dose supplements during pregnancy. Malformations have been seen, but as the number of women taking these supplements was low, the actual amount of vitamin A that causes deformities in humans remains uncertain.

1.32 Treatment of acne by taking tablets of the drug isotretinoin, a potent synthetic form of retinoic acid, is very effective but has raised concern as a possible cause of malformations when taken by pregnant women. Some countries, including Canada and the EU countries advise women against becoming pregnant while taking isotretinoin. But there are still a few women who become pregnant while taking this drug, putting the fetus at potential risk.

1.33 Treating acne with creams and ointments that contain forms of vitamin A and/or synthetic substances that mimic it, appears to pose a much lower level of risk to the unborn child than treatments given by mouth. However, since these preparations are also known to be able to produce the same adverse effects on the fetus as tablets, when given at a sufficiently high dose, their use is likewise not recommended during pregnancy.

1.34 Concerns have been raised about a link between isotretinoin use and an increased risk of depression and suicide. However, recent evidence suggests that having acne can itself cause depression and hence, if anything, treatment with vitamin A analogues can improve mental health. Nevertheless, as explained above, women who are pregnant or trying to conceive should avoid taking isotretinoin because of the possible risk to the fetus.

1.35 The effects of vitamin A may be affected by:

- a. Other components in the diet, including vitamins D, K, C and folate, some fats and zinc,
- b. alcohol,
- c. Medicines including antibiotics, treatments for fungal infections, drugs for epilepsy, and
- d. Chemicals in the environment including biocidal ship antifouling paints (i.e. paints that discourage growth of marine organisms) and flame retardants, for example form furniture.

1.36 One way they can do this is by affecting the rate of breakdown of vitamin A and its active products.

1.37 Consuming large amounts of beta-carotene, for example by eating a lot of carrots daily, may lead to some skin yellowing and a fall in the levels of vitamin A in the liver but, unlike intake of pre-formed vitamin A, studies on animals have shown no ill-effects of beta-carotene on their offspring.

1.38 A study showed that high intake of beta-carotene supplements, as part of a clinical trial, unexpectedly increased the incidence of lung cancer and overall mortality in smokers. However, smoking itself can damage the fetus, regardless of any additional adverse effects caused by consumption of beta-carotene, so women are anyway strongly advised against smoking during pregnancy.



1.39 In parts of Africa and south-west Asia, there is more concern about vitamin A deficiency and the harmful effects this has upon the health of unborn children. In developed countries (like the UK, USA and those in Europe), however, the concern is more about excess intake, as many people regularly consume more than the recommended daily amount, and in some cases, more than EFSA's tolerable upper limit.

1.40 EFSA has estimated that most European adults consume between 816 and 1,498 µg of retinol per day. The UK Government dietary advice, on the NHS.uk website recommends a daily vitamin A intake from food, for those aged 19 to 64, of 700 µg for men and 600 µg for women. Official estimates are that in the UK women between 16 and 49 years of age actually have an intake of between 760 and 2600 µg per day, and the small number who regularly eat liver and liver products such as pâté may consume up to 3 times this amount. Supplements containing vitamin A in the form of retinol can add 300 - 906 µg per serving. Pregnant women and women thinking about having a baby are therefore specifically warned to avoid taking supplements containing vitamin A and not to eat liver and liver products to avoid potential harm to the unborn child, unless specifically advised to do so by their Doctor. No other food provides as much vitamin A on its own, although some fortified spreads and "health foods" may, in combination, provide more than the recommended limit.

1.41 Food supplements containing beta-carotene do not have warnings against their use by pregnant women and women thinking about having a baby because this nutrient is considered low risk.

1.42 There is still a lot of uncertainty about how much vitamin A is likely to cause deformities in unborn children, therefore the COT agreed that the current UK Government advice to pregnant women and those planning pregnancy - as set out on NHS.uk website - that they should limit their intake of vitamin A to reduce this risk, remains appropriate.

1.43 The full COT statement can be found at: [Statement 04/22 Vitamin A in the maternal diet \(food.gov.uk\)](#).

## **Position paper on bamboo composites in food contact materials**

1.44 Risk assessment advice on biobased food contact materials (BBFCMs) has been increasingly requested from the Food Standards Agency (FSA), hence it was considered timely for the Committee on Toxicity of Chemicals in Food,

Consumer Products and the Environment (COT) to review the available toxicological information on BBFCMs.

1.45 The COT acknowledged the challenges and complexities associated with BBFCMs and highlighted several limitations and knowledge gaps on BBFCMs research and regulation. These included labelling, composition (including biodegradability), contamination and standardisation.

1.46 The COT undertook a more detailed review of the potential health risks of bamboo composites in Food Contact Materials (FCMs) due to the increased number of incidents reported of non-compliant bamboo composite items (e.g. coffee cups) being placed onto the European market.

1.47 Until December 2020, reports in relation to bamboo composite FCMs were predominantly related to misleading labelling on packaging and/or their advertisement, as well as incidences of formaldehyde/melamine migration levels exceeding legal limits. Since 2021, and due to the EU's conclusion that bamboo is an unauthorised additive within plastic FCMs, reports received by the FSA have predominantly been of non-compliance of plastic-bamboo FCMs in the European market. This included the advertisement of products from UK businesses on EU facing markets. No action appeared to have been taken on that basis prior to this year.

1.48 In 2019, the EFSA panel on FCMs was asked by the European Commission to assess whether the authorisation of untreated wood flour and fibres (FCM no. 96) as an additive in plastic food contact materials was still in accordance with EC Regulation 1935/2004, and also to consider whether bamboo could be considered under the scope of this authorisation. EFSA concluded that wood and bamboo should be considered distinct and each material regarded on a case-by-case basis. In addition, the food safety authorities of Belgium, Luxembourg and the Netherlands (Benelux) published a joint letter calling for the market withdrawal of bamboo-melamine plastics (NVWA, 2021a). In April 2021, the EC recommended that Member States should take stringent action on bamboo composite FCMs and set out a coordinated control plan. The UK FSA is aware of the stance by the EC and of the individual Member States and is considering an appropriate course of action based on scientific evidence.

1.49 The COT previously assessed the reports by the German Federal Institute for Risk Assessment (BfR) and the Netherlands Food and Consumer Product Safety Authority (NVWA) and noted that the BfR applied their own tolerable daily intake (TDI) of 0.6 mg/kg/day for formaldehyde whereas the NVWA and EFSA used

a lower TDI of 0.15 mg/kg/day (BfR 2020; NVWA 2021b; COT 2021c). Overall, the COT concluded that the exposure assessments were conservative but not necessarily worst-case. It was agreed that although the NVWA and BfR opinions took slightly different approaches, in general the same conclusions were reached. Based on the assessment of the BfR and NVWA reports the Committee concluded that the migration of formaldehyde and melamine from bamboo composite cups was a potential concern to human health (COT 2021c).

1.50 Due to insufficient UK data, the COT was unable to make recommendations on bamboo bio-composites FCMs. A UK study assessing the risks associated with bamboo composites and other biobased food contact materials is currently underway. The study aims to address migration levels of formaldehyde and melamine, and also the potential presence of other chemicals, such as heavy metals and pesticide residues. Data from this study is expected to be available in March 2022. Once, UK data is available, a full risk assessment will be undertaken.

1.51 The full COT statement can be found at: [COT Position Paper Bamboo Composites](#).

## **COT statement on the potential risks from cadmium in the maternal diet**

1.52 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. 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.

1.53 Cadmium is a heavy metal found widely in the environment, coming from both natural sources, such as volcanic activity, and human activities, such as the smelting of metals. Cadmium in the soil, water and air enters the human food chain through being taken up by crops, which are consumed by food animals. Once in the body, this metal accumulates over many years, where it may cause damage to the kidneys and loss of bone tissue. It can also cause cancer.

1.54 Those of childbearing age (16-49 years) can be exposed to cadmium from food, drinking water, air, dust and ingested soil. Smoking is the main non-dietary source of exposure of cadmium and can lead to a similar internal

exposure as the obtained from the diet.

1.55 In 2009, the EFSA CONTAM panel established a tolerable weekly intake (TWI) based on the adverse effect on the kidneys, to determine the level of exposure of people below which there would be no cause for concern. The TWI is defined as the amount of cadmium that can be taken in by a person every week throughout their lifetime without causing adverse effects on health. This value was very low at 2.5 micrograms (millionths of a gram) per kilogram body weight. The COT had previously concluded that the EFSA TWI for cadmium was an acceptable value to use for risk assessment.

1.56 The COT concluded that the levels of cadmium in water, soil and dust only contribute a small amount of exposure and overall, cadmium in the maternal diet does not appear to be a health concern.

1.57 The COT highlighted that the consumption data used for the exposure assessment was for women of childbearing age and therefore may not be fully representative of the maternal diet, leading to an under/overestimation of the actual exposure. The COT also noted that women who give up smoking while pregnant will still carry a higher body burden of cadmium than those who had never smoked.

1.58 The full COT statement can be found at: [Cadmium in the Maternal Diet - Introduction | Committee on Toxicity \(food.gov.uk\)](https://www.food.gov.uk/committees/cadmium-in-the-maternal-diet-introduction).

## **Statement on the potential effects of excess vitamin D intake during preconception, pregnancy and lactation**

1.59 In 2006, the European Commission established a minimum vitamin D content in infant- and follow-on formulae of 1 µg per 100 kcal (Directive 2006/141/EC). Subsequently in 2016, in Commission Delegated Regulation 2016/127, this was doubled to 2 µg per 100 kcal. This new regulation became applicable in Great Britain from the 1st of January 2021.

1.60 In order to inform discussion across the four nations on whether existing advice around vitamin D supplements remains appropriate or needed updating in light of the increase in the minimum vitamin D content of infant- and follow-on formulae, the FSA conducted an exposure assessment to determine whether this increase could result in infants (0-12 month-olds) and young children (1-4 year-olds) exceeding their tolerable upper levels (TULs).

1.61 A draft statement was prepared which provides an exposure assessment for infants and young children, regarding their vitamin D intake from infant formulae products, vitamin D supplements, and other dietary sources (including breast milk), and comparison to the relevant EFSA TULs.

1.62 The Committee concluded that the new minimum vitamin D content in infant formulae did not lead to excessive vitamin D exposure in infants or young children, as minor exceedances of their respective TULs occurred only when, in combination with other sources such as the recommended supplements, the quantities of infant formula consumed reached 1000 ml. Current NHS guidance is that supplementation is not needed if more than 500 ml infant formula is being consumed. The Committee agreed with the recently revised TUL of 35 µg/person/day for 6-12 month-olds, and also that the exposure assessment indicated that the current guidance did not give rise to any toxicological concerns.

1.63 The full COT Statement can be found at: [Vitamin D in infant formula statement](#).

## **Potential approaches to address unintentional mixture risks for future UK REACH assessments**

1.64 In September 2020, the UK Chemicals Delivery Board had agreed that the Environment Agency should prepare a report on whether the use of a mixture assessment factor (MAF) is a useful approach to address the potential risks arising from unintentional (coincidental) mixtures of chemicals under the UK REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) Regulation. Risks from intentional mixtures are already covered under the current regulatory system. This approach was also being considered by the European Union under EU REACH. Subsequently, the UK Health Security Agency (UKHSA) had agreed that they would work with the Environment Agency to prepare a joint report.

1.65 The COT considered the draft version of the joint EA/UKHSA report on this topic in March and May 2022 to review and comment on the human health aspects prior to finalisation of the report.

1.66 A number of recommendations and comments were made by the COT in March, which were addressed in the version presented in May. The COT recognised that while there were publications hypothesising that environmental mixtures of chemicals might have an additive effect, the evidence available

suggested that any potential effects were almost always driven by exposure to a small number of chemicals, even when there were a large number of substances in the mixtures considered. Similar findings had also been reported in three EFSA retrospective cumulative risk assessments of dietary exposure to mixtures of pesticide residues. The Committee noted the lack of research available to address the question of whether there was dose addition for chemicals present in a mixture at concentrations below their health-based guidance values (HBGVs). In many studies, whilst findings at effect levels were consistent with dose addition, they were also consistent with response addition (independent action). Hence, whilst dose addition might be a reasonable default at exposure levels above health-based guidance values, it was highly questionable whether this was the case at lower levels and consequently whether a MAF was needed.

1.67 Overall, the COT agreed with the conclusions of the report and in particular that there was strong scientific evidence within the report to support not adopting the use of a MAF in human health risk assessments.

1.68 The EA/UKHSA report “Evaluation of the potential approaches to risk assessment of unintentional chemical mixtures for future UK REACH assessments” was published following comments from COT and Defra’s Hazardous Substances Advisory Committee (HSAC) and is available from: [Evaluation of the potential approaches to risk assessment of unintentional chemical mixtures for future UK REACH assessments - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/114444/evaluation_of_the_potential_approaches_to_risk_assessment_of_unintentional_chemical_mixtures_for_future_uk_reach_assessments.pdf).

1.69 Contribution for update paper (2022 paper to give an indication on the level of information is available at: [Update on Advice \(food.gov.uk\)](https://www.food.gov.uk/news-updates/2022/04/2022-update-on-advice)).

## **Potential approaches to address unintentional mixture risks for future UK REACH assessments**

1.70 The EA/UKHSA report “Evaluation of the potential approaches to risk assessment of unintentional chemical mixtures for future UK REACH assessments” was published following comments from COT and Defra’s Hazardous Substances Advisory Committee (HSAC) in August 2022, and is available from: [Evaluation of the potential approaches to risk assessment of unintentional chemical mixtures for future UK REACH assessments - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/114444/evaluation_of_the_potential_approaches_to_risk_assessment_of_unintentional_chemical_mixtures_for_future_uk_reach_assessments.pdf).

1.71 In December 2022, a stakeholder workshop was hosted by Defra to discuss options for addressing unintentional mixtures under UK REACH. The report and the outputs from this workshop will be considered by Defra to inform

the development of policy options.

### **Review of potential risks of Aflatoxin in foodstuffs at the new proposed Codex Alimentarius maximum levels - RESERVED Business**

1.72 The FSA asked the Committee to review the toxicity of aflatoxins in certain foodstuffs. This item is currently reserved as it relates to developing policy.

### **Review of potential risk of Ochratoxin A in spices at the proposed Codex Alimentarius Levels (RESERVED Business)**

1.73 The FSA asked the Committee to review the toxicity of Ochratoxin A in spices. This item is currently reserved as it relates to developing policy.

### **Discussion paper on the request for assessment of a coating in canned food packaging materials**

1.74 Members discussed the information provided to the Committee on a can coating as well as the assessment and discussions of the Joint Expert Group on Food Contact Materials (FCM JEG) and sister Committee on Mutagenicity (COM). The work is ongoing, but a final assessment is expected in spring 2023. This item is reserved as the data are commercially confidential.