Introduction and Background - Citrinin

In this guide

This is a paper for discussion. This does not represent the views of the Committee and should not be cited.

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, foetal 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 Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)

horizon scanning item at their January 2020 meeting with a scoping paper being presented to the COT 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. Following a discussion at the September 2020, COT agreed that papers on a number of compounds should be prioritised. The following paper provides the advice of the COT on whether exposure to citrinin would pose a risk to maternal health.

Background

3. Unless otherwise indicated, the following background information has been taken from the European Food Standards Agency's (EFSA) scientific opinion on the risks for public and animal health related to the presence of citrinin in food and feed (2012).

4. Citrinin (CIT) is a mycotoxin produced by several species of fungi of the genera *Aspergillus*, *Penicillium* and *Monascus* and is generally formed after harvest under storage conditions. It occurs mainly in grains but can also occur in other products of plant origin e.g. beans, fruits, fruit and vegetable juices, herbs and spices as well as in spoiled dairy products. In addition, CIT is found as an undesirable contaminant in red mould rice (RMR) which is used as a food preservative and colourant in Asian foods and as a supplement.

5. Experimental data indicate that CIT residues may occur in edible tissues and eggs following oral exposure of animals with highly contaminated feed materials.

Transfer of CIT from feed to meat and animal products

6. EFSA identified one study on the potential carry over of CIT from animal feeds into edible tissues and eggs (Abdelhamid and Dorra, 1990). Laying hens received feed with a CIT concentration of 100 µg/kg for 6 weeks. CIT residues of 10.4 ± 2.1 µg/kg egg yolk, 6.16 ± 1.2 µg/kg egg white, 10.3 ± 1.75 µg/kg white muscles and 9.84 ± 1.45 µg/kg red muscles were measured (Abdelhamid and Dorra, 1990). No CIT residues were detected after a withdrawal period of 2 weeks. EFSA concluded that CIT residues may occur in edible tissues and eggs following oral exposure of

animals with contaminated feed materials.

7. A more recent study by Meerpoel et al. (2020a), not included in the EFSA opinion) looked at the carry-over of CIT into animal products following the administration of CIT. For 3 weeks, pigs (n = 16) were exposed to feed containing 1 mg CIT/kg feed or to control feed (n = 4), while 2 groups of broiler chickens and laying hens (n = 8 per group) received 0.1 mg CIT/kg feed and 3 or 3.5 mg CIT/kg feed, respectively, or control feed (n = 4). CIT concentrations were quantified in plasma, kidneys, liver, muscle and eggs. CIT was detected in all collected tissues, except for muscle and egg white in hens in the lowest dose group, and egg white in hens in the highest dose group. CIT concentrations in plasma ranged from 0.1 ng/mL (laying hens in lower dose group) - 20.8 ng/mL (pigs). In tissues, CIT concentrations ranged from 0.6 (muscle) - 20.3 µg/kg (liver) in pigs, while concentrations in chickens ranged from 0.1 (muscle) - 70.2 µg/kg (liver). Carry-over ratios from feed to edible tissues were calculated by the authors as 0.1 to 2% in pigs, and between 0.1 and 6.9% in chickens, suggesting a low contribution of pig and poultry tissue-derived products towards the total dietary CIT intake for humans.

8. The carryover of CIT from feed into animal products has not been included in the exposure assessment.

Red Yeast Rice

9. CIT is an undesirable contaminant in Monascus fermentation products such as red yeast rice (RYR) also known as red mould rice (RMR), used in Asian cuisine as a food colorant and flavour enhancer. RYR contains monacolins, with monacolin K being structurally identical to lovastatin, a drug which lowers cholesterol. Hence, RYR is also used as a dietary supplement claiming to decrease plasma triglyceride and cholesterol levels (Wei et al., 2003).

10. In 2019, the maximum level (ML) for CIT in RYR preparation was reduced from 2000 µg/kg to 100 µg/kg in Commission Regulation (EC) No 1881/2006 (amendment: Commission Regulation (EU) 2019/1901). FSA Policy colleagues have confirmed that while red yeast *Monascus purpureus* is traditionally used in China as a food colouring, it is not authorised as food colour/additive under Regulation 1333/2008, including for supplements.

11. In 2017, EFSA reported that of the 92 samples of RYR food supplements tested (obtained in the EU), 37 samples (40%) were positive for CIT and three

samples exceeded the EU ML at the time of 2,000 µg/kg (EFSA, 2017). Based on the EFSA exposures it has been calculated here that 10 of the 92 samples tested would exceed the amended ML of 100 µg/kg.

12. The majority of packaging for RYR supplements states that the product is either a) not suitable for children and/or women who are pregnant or breast feeding, or b) it is recommended these groups should consult a general practitioner (GP) prior to consumption. Due to the warnings on the packaging, RYR supplements have not been considered further in this assessment.