Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

Statement on the Hepatotoxicity of Green Tea Catechins: Lay Summary

Introduction

1. In 2017, following a series of reports of adverse effects associated with the consumption of green tea supplements, the European Commission requested the European Food Safety Authority (EFSA) to assess the available information on the safety of green tea catechins (GTCs), the key constituent of these supplements.

2. EFSA concluded that GTCs from green tea infusions prepared in a traditional way are generally considered to be safe; however, rare cases of liver damage/injury (i.e. hepatotoxicity) have been reported in those who had used supplements containing GTCs called epigallocatechin-3-gallate (EGCG). EFSA concluded that it was not possible to identify an EGCG dose from GTCs that could be considered safe. In the clinical trials that were reviewed, there was no evidence of hepatotoxicity below 800 mg of EGCG/ per day for up to 12 months. However, hepatotoxicity was reported for one specific product containing 375 mg EGCG. Doses over 800 mg EGCG/day, were shown to increase the liver enzymes that indicate liver injury, compared to control subjects.

3. The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) noted that these cases of liver damage were due to reactions that are unusual and/or unique to an individual and are related to an individual's genetic makeup. These are called "idiosyncratic" reactions, which are rare, unpredictable, and not reproducible in animals. Development of these reactions can vary markedly among individuals with dose and duration of consumption of supplements containing GTCs. The individual may not know they are susceptible before taking a supplement. This

possibility of an unexpected idiosyncratic response cannot be ruled out when using such supplements.

4. Following the adoption of the EFSA opinion, the EU Commission are proposing to restrict the use of GTCs to ensure that foods containing these substances are safe for human consumption.

5. In order to consider the next steps for risk management in the UK, the Department of Health and Social Care under the Nutrition, Labelling, Composition and Standards (NLCS) Framework, have requested the COT to evaluate whether the conclusions of the 2018 EFSA opinion are still applicable, and to review any new data that have become available since 2018. The 2018 EFSA evaluation assessed GTCs and the associated, probable idiosyncratic, reactions that are specific to liver damage/injury. It was not a general safety assessment of either GTCs or green tea infusions or extracts.

6. A ‘herbal infusion’ is the result of adding liquid to dried flowers, leaves, herbs, roots and any other parts of the plant that are in sachets or loose. Tea (*Camellia sinensis* (*C. sinensis*)) is used as a ‘herbal infusion’. An extract is a more concentrated form of a ‘herbal infusion’, e.g. green tea extract (GTE) is more concentrated than a green tea ‘herbal infusion’.

7. Different types of tea are produced from the same plant according to how they are processed. Green tea is unfermented unlike white, black and oolong teas. These undergo fermentation which lowers the levels of compounds called polyphenols, including catechins. GTCs are derived from the unfermented leaves and leaf buds of the tea plant, *C. sinensis*. Catechins are the major group of polyphenols that constitute ~20% of the total flavonoids (a subset of polyphenols) found in green tea. The production of an extract from this tea results in concentrated levels of catechins and removes other components such as caffeine (*C. sinensis* has naturally occurring caffeine).

8. Green tea, produced from the leaves of the *C. sinensis* plant, is a popular drink, consumed worldwide. Various reports on the health benefits of green tea on

different types of cancer, liver and heart disease are available in the literature. Many of these beneficial effects have been related to a particular catechin; EGCG. However, as identified by EFSA, this catechin is associated with liver toxicity.

9. The COT reviewed the literature on the potential of GTEs to cause liver toxicity which had been published since the 2018 EFSA opinion, and assessed whether the data would affect the conclusions drawn by EFSA.

10. In the studies reviewed, there was large variability in dose, composition, duration of exposure to GTE and incidence of liver toxicity as a result of consumption of green tea products. The EFSA Panel had concluded that many of the cases of liver injury were as a result of idiosyncratic reactions. Following their review of the literature, the COT agreed.

11. Overall, the COT concluded that there are no new data to suggest that EFSA's conclusion, that 800 mg/day EGCG was probably safe, is inappropriate. Although no new studies identified any effects of EGCG in humans at doses below 800 mg/day, the possibility cannot be excluded that a few individuals could still experience adverse effects below this dose due to an idiosyncratic reaction.

12. The full COT statement is available on the COT website: Statement on the Hepatotoxicity of Green Tea Catechins: https://doi.org/10.46756/sci.fsa.wii944.

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