Introduction

In this guide

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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) (principally epigallocatechin-3-gallate (EGCG)) from all dietary sources including preparations such as food supplements and traditional infusions. The EFSA opinion, which was adopted in March 2018, was published in April 2018 (EFSA, 2018). At that time, and at the request of the Department of Health and Social Care (DHSC), who have the policy lead for food supplements in England, the Food Standards Agency's (FSA) Chemical Risk

Assessment team reviewed the EFSA opinion informally and agreed with its conclusions.

2. These conclusions were “catechins from green tea infusion, prepared in a traditional way, and reconstituted drinks with an equivalent composition to traditional green tea infusions, are in general considered to be safe according to the presumption of safety approach provided the intake corresponds to reported intakes in European Member States. However, rare cases of liver injury have been reported after consumption of green tea infusions, most probably due to an idiosyncratic reaction. Based on the available data on the potential adverse effects of GTCs on the liver, the Panel concluded that there is evidence from interventional clinical trials that intake of doses equal or above 800 mg EGCG per day taken as a food supplement has been shown to induce a statistically significant increase of serum transaminases in treated subjects compared to control.” (EFSA, 2018).

3. Following the adoption of the EFSA opinion, in December 2022, Commission Regulation (EU) 2022/2340 came into force which amended Annex III to Regulation (EC) No 1925/2006 as regards green tea extracts containing (-)-epigallocatechin-3-gallate. The Regulation set restrictions for an individual portion of a food to contain less than 800 mg of EGCG. In addition, the labels of all foods including food supplements containing EGCG at any level were required to include information on the maximum number of portions of the food for daily consumption, the content of EGCG per portion and warnings for consumers on appropriate use including a warning not to consume a daily amount of 800 mg EGCG or more.

4. The amendments to Regulation (EC) No 1925/2006 do not apply in Great Britain (GB). Under the Windsor Framework, the amendments in Regulation (EC) No 1925/2006 apply in respect of Northern Ireland. This is because Regulation (EC) No 1925/2006 is included in Annex 2 to the Windsor Framework.

5. The Nutrition Labelling Composition and Standards (NLCS) policy group has been set up under the NLCS provisional common framework, to maintain a consistent and co-ordinated policy approach across the UK (DHSC, 2020). The NLCS framework sets out arrangements for co-operation between officials in DHSC, Food Standards Scotland (FSS) (representing Scottish Government), Welsh Government (WG) and the Food Standards Agency Northern Ireland (FSANI) with regard to NLCS policy.

6. All future policy proposals relating to nutrition are considered on a four-nation basis via the NLCS policy group, with the impact assessed on the UK as a whole not just each individual nation or Great Britain (GB). The risk assessment and risk management processes of amendments to legislation (including food supplements) in scope of the provisional NLCS framework includes seeking scientific evaluation from the relevant scientific advisory committee, where appropriate.

7. Following the publication of the EFSA opinion in 2018, the UK and European food supplements industry raised a number of concerns to DHSC regarding the potential risk management measures for including GTCs (EGCG) under Article 8 of Regulation (EC) 1925/2006. These concerns were also raised to the European Commission (EC).

8. On behalf of the UK, the NLCS have requested the FSA to evaluate whether the conclusions of the 2018 EFSA opinion are still applicable considering any new data that have become available since its adoption, to enable them to consider the next steps for risk management. The EFSA 2018 evaluation pertains to GTCs and the associated cases of probable idiosyncratic hepatotoxicity, rather than a safety assessment of either GTCs or green tea infusions and extracts more generally (EFSA, 2018).

9. Following the risk assessment (which includes the domestic scientific assessment) and risk management processes set out in the NLCS Framework, the NLCS policy group will provide advice to ministers on whether any restrictions in relation to the use of EGCG in foods are in the interests for the GB market.

10. This statement presents a summary of the key findings of the EFSA Opinion and provides an update on the state of science based on the literature since the EFSA Opinion was published in 2018 up to September 2022. To determine what new literature had become available since the publication of the EFSA opinion a literature search was undertaken, focused on the safety of GTCs, related to the safety of the use of green tea extracts (GTEs) and hepatotoxicity. Databases searched included PubMed, Google Scholar and LIVERTOX using ‘green tea extract’, ‘liver injury’ and ‘hepatotoxicity’ as search terms.

11. Previous discussion papers and drafts of the COT statement are detailed in Table 1 of Annex A.