

COT Conclusions

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128. The aim of this statement was to assess whether any new literature had been published on the hepatotoxic potential of GTEs since the adoption of the EFSA opinion on GTCs in 2018, that would affect the conclusions drawn by EFSA.

129. Data from human studies remain inconsistent, with incidences of hepatotoxicity occurring at a variety of doses, formulations and treatment duration. Recent evidence suggests this hepatotoxicity may be a result of individual idiosyncratic responses. The human data also suggest that it can prove difficult to determine the amounts of GTE (and thus EGCG) present in the supplements taken. Furthermore, there remains uncertainty in the extent of the contribution of other compounds, that may be present in the same GTE formulation such as PAs, to hepatotoxicity.

130. While some new studies have become available, it appears further studies are needed to elucidate factors contributing to potential green tea induced hepatotoxicity, which it seems may at least in part, be idiosyncratic, and be affected by multiple factors including genetic factors, nutrient and fasting state, and possibly general liver health.

131. Additional information on the nature of the idiosyncratic response, susceptibility factors and on the incidence of affected individuals, would be required to enable more informed guidance to be given by the Committee.

132. 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 sensitive individuals could still experience adverse effects below this dose due to an idiosyncratic reaction.

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