

Risk Characterisation

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Curcuminoids

103. Consumption as part of the normal diet (from its use as an additive and spice) would lead to curcumin exposures that are generally within the ADI of 0 - 3 mg/kg bw, although at the upper end of the exposure range there may be a slight exceedance of the ADI, particularly for younger consumers.

104. There is high uncertainty regarding the risk from the intake of raw and powdered turmeric in high quantities for their purported health benefits. A literature review of human studies (see Annex A) suggests oral intake of curcuminoids in humans is well tolerated up to doses of 114 mg/kg bw/day, though minor symptoms of nausea or diarrhoea may occur. Longer term clinical studies summarised in this statement suggest that daily consumption of curcuminoids at concentrations at or above those found in supplements result in no adverse effects.

105. With regard to dietary turmeric supplements, a recent 2021 survey shows that a small proportion (2 from 15 samples) of the tested products would lead to high exposure of curcuminoids i.e. exposures at or above the ADI of 0 - 3 mg/kg bw. The COT concluded from previous discussions that this ADI may not be appropriate for supplements. This is because as also shown in the 2021 survey, 10 of the 15 supplements analysed contained piperine or may be otherwise formulated to increase the bioavailability of curcumin from that of the natural form. The resulting changes in the TK of the curcuminoids could potentially increase the hepatotoxicity. After a review of the current evidence, it is concluded that the claim with many supplements that piperine improves the bioavailability of curcuminoids is questionable with high uncertainty. There is very limited scientific evidence for the claimed benefits of the inclusion of piperine.

106. Regarding the curcuminoid concentrations in supplements and the safety implications of long-term intake of these based on the studies presented, it is concluded that if consumption was based on the label guidance this should not pose a significant risk to the vast majority of the population even if there is minor exceedance of the ADI. However, substantial exceedances of the ADI represent a potential health risk to humans.

107. In rare instances for some individuals, lower consumption rates may pose the risk of adverse effects particularly if other medicines are being taken concomitantly and in people with certain underlying conditions such as latent impairment of biliary function.

108. The Committee has reviewed all available data regarding the recent reports of hepatotoxicity following consumption of curcumin and have concluded that there is a link to turmeric exposure because the effects occurred upon challenge and were reversed after withdrawal. The signs are consistent with an idiosyncratic reaction.

109. Furthermore, some of the other 'novel' supplement types such as micellar, nano, and micro formulations should be assessed in further detail, with regard to their pharmacokinetics and therefore their impact on curcuminoid bioavailability. This further detail is requested regardless that they only potentially make up a likely small percentage of the supplement market at present, as they may become more popular in the future.

Contamination of raw, ground turmeric and curcumin supplements

110. Contamination of raw turmeric with Pb is a result of either production of turmeric on lead rich soil or intentional adulteration with lead chromate. It has been reported that lead chromate, a Pb-based colour, is sometimes used to enhance the appearance of turmeric. As a result, raw or ground turmeric could potentially contain high levels of Pb.

111. After the Italian incident in 2018 and 2019 (see paragraphs 15 to 17), Italy's National Institute of Health concluded that a contaminant was unlikely to be the underlying cause. Furthermore, the recent 2021 FSA-funded survey of 30 turmeric products and the 2022 survey of 70 turmeric spice powder products did not show concentrations of Pb in any of the samples above the ML of 3 mg/kg for supplements, and in only one spice powder sample, which had a Pb concentration at 2.25 mg/kg, above a recent ML set by the EU of 1.5 mg/kg. These data add to the evidence base that the hepatotoxic effects associated with taking turmeric are more likely due to the curcuminoids than heavy metal contamination. In addition, the clinical picture is not that typically observed following Pb exposure. Therefore, it is concluded that after the results of the recent product surveys, Pb contamination of turmeric products is likely not the reason for incidents such as the hepatotoxicity reported in the Italian cases. However, it is still uncertain why this incident occurred as a cluster of cases.

112. On evaluation of the other trace element concentrations from the recent study by Fera Science Ltd (Fera Science Ltd, 2022), the metal concentrations across all of the products tested were extremely variable. This can be attributed to the geographical variation of the source of the products, and/or the other varying additives within supplements. Concentrations of trace elements (metals) that are relatively higher than the average across that product type have been presented in Annex B to this statement. However, no calculated exposures for any trace elements, if taking the supplements as described on their labels, would exceed any HBGVs, where HBGVs exist.