COC Ongoing Topics - 2022

In this guide

26. Annex 4 – 2022 - Good Practice Agreement for Scientific Advisory Committees
27. Annex 5 – 2022 - Glossary of Terms

Hydroxyanthracene derivatives

3.1 Following a request from UK-wide Nutrition Labelling Composition and Standards (NLCS) policy group, the UK Food Standards Agency (FSA) commissioned an independent view from the Committee on Mutagenicity (COM) on the mutagenicity of hydroxyanthracene derivates (HADs) based on consideration of the European Food Safety Authority (EFSA) 2018 opinion on HADs and any additional new data that have become available. The genotoxicity of HADs used in foods had been discussed at the COM meeting in October 2021 (see 2.17 above).

3.2 Overall, the COM agreed that the available evidence indicates that emodin, aloe-emodin, and dantron are genotoxic in vitro, namely from Ames tests. The COM agreed that the negative results from the in vivo bone marrow micronucleus assay are valid and concluded that there is reasonable evidence that there is no genotoxic effect or mechanism in vivo. Consequently, a new in vivo genotoxicity study would not be helpful. The COM considered that the reported carcinogenic effects of HADs, including those seen in the comet assay of colon cells, are caused by the high levels of irritation, inflammation, and diarrhoea. In March 2022 a discussion paper on the safety of HADs for use in food was brought for review by the COC for its opinion on the carcinogenic potential of HADs. The FSA requested that the COC review the carcinogenicity studies provided in the paper and evaluate the risk of HADs and whether a health-based guidance value (HBGV) could be derived from the information provided.

3.3 The COC agreed with the COM that HADs are not a genotoxic carcinogen in vivo. The committee suggested that while theoretically it would be possible to set an ADI, the data available was insufficient as a dose response has not been described. The COC indicated that a dose response was required in order to be able to identify a threshold or point of departure. The COC concluded that more information on the characterisation of HADs would be required for the Committee to discuss a possible HBGV and it would not be possible to set a HBGV for HADs as a single group as they are complex mixtures of different compounds that may have differing mechanisms of action. Therefore, more data would be required to make a decision as a blanket value could be misinterpreted.

3.4 Following a call to industry for new information and data, CRN UK were able to provide the FSA with a record of relevant journal articles that had not been considered in the original EFSA opinion. Following an assessment of the information provided, the Secretariat determined that one of the articles might address some of the issues raised by the Committee at the March 2022 meeting.

3.5 In July 2022 this additional article, which suggested a potential HBGV for HADs, was presented to the COC. Members indicated that as this HBGV was not based upon any new data and therefore, the value presented in the paper was based upon many different variables including different strains of animals used, different dosing regimens and various endpoints. The COC agreed that there was still insufficient data to conclude on an appropriate HBGV for HADs. It was noted that the likely levels of exposure seemed to be less than those that would be expected to cause a risk in humans, but this should be explored further with a detailed exposure analysis.

3.6 An interim position paper with the addition of dietary and dermal exposure assessment will be presented to the COC in 2023.