

Advice 14-2020 of the Scientific Committee established at the FASFC on recommendations for the risk assessment of glycidyl fatty acid esters (GE) in foodstuffs

Background and question

Glycidyl fatty acid esters (GE) are process contaminants that are formed during the refining of vegetable oils. They are hydrolyzed to glycidol in the gastrointestinal tract. Glycidol is probably carcinogenic and genotoxic. In 2017, JECFA established a BMDL₁₀ value of 2.4 mg/kg bw/day for glycidol (JECFA, 2017). No toxicological data are available for GEs.

Regulation (EU) 2018/290 sets legal maximum levels for GEs (expressed as glycidol) in vegetable oils and fats placed on the market for sale to the final consumer or for use as an ingredient in foodstuffs, in vegetable oils and fats for the production of baby food and processed cereal-based foods for infants and young children, and in processed foods for special medical purposes for infants and young children (powder or liquid).

Due to the carcinogenic and genotoxic nature of glycidol, the Scientific Committee (SciCom) is requested to propose a toxicological reference value for GEs to enable operators to carry out their own risk assessment of the presence of GEs in food. It is also requested to make recommendations to operators to reduce the levels of GEs in foodstuffs.

Method

This opinion is based on expert opinion, data available in the scientific literature, and the method of calculating a "low concern intake" developed in SciCom 15-2019. SciCom has defined a "low concern intake" of GEs (expressed as glycidol) for consumer health. To do this, the BMDL₁₀ was divided by a theoretical margin of exposure (MoE_{UF}) of 10 000. JECFA considers that an MoE of 10 000 or more can be considered that exposure to glycidol is not a public health concern.

Results and discussion

In this opinion, SciCom describes to operators how to carry out a risk assessment of the presence of GEs in food. The calculated low concern intake of GEs (0.24 µg glycidol/kg bw/day) is used as the toxicological reference value. The classical steps of a risk assessment (hazard identification, hazard characterisation, chronic exposure estimation and risk characterisation) are followed. The high and average chronic exposures of the various Belgian consumer groups (children, adults, etc.) to GEs are estimated on basis of the high and average consumption data among the different age groups of Belgian consumers, available in the EFSA Food Consumption Database (FoodEx2 system). If consumption data are not available for the Belgian consumer, the consumption data from neighboring countries (France, Netherlands, Grand Duchy of Luxembourg or Germany) may be used. Then, for risk characterization, the estimated chronic exposures are compared to the calculated "low concern intake" of GEs (0.24 µg glycidol/kg bw/day). If these are lower than the "low concern intake" of GEs, then the operator can conclude that the amount of GEs is not a public health concern. Otherwise, there is a health risk of concern.

Conclusions

SciCom calculated a low concern intake of 0.24 µg glycidol/kg bw/day. Based on this low concern intake, operators can carry out their own risk assessment or calculate an Estimated Acceptable Concentration (EAC) of GEs in a defined foodstuff. In this opinion, EAC in GEs in a number of foodstuffs are given as examples, and operators can use them.

Recommendations

SciCom recommends that operators calculate, if possible, an "Estimated Acceptable Concentration (EAC)" of GEs for each food product they produce, process and/or put on the market.

SciCom also recommends that operators apply the recommendations of the Codex Alimentarius Commission's "Code of practice for the reduction of 3-monochloropropane-1,2-diol esters (3-MCPDE) and glycidyl esters (GE) in refined oils and food products made with refined oils" (Codex Alimentarius, 2019). These recommendations aim to limit/reduce the formation and/or the presence of GEs in food in order to best protect consumer health. A translation of this document is available in the appendix.

The full text is available on this website in dutch and in french.