Malachite green (MG) has been used globally in aquaculture but is not registered for use in food-producing animals in the European Union. The European Commission requested EFSA to evaluate whether a reference point for action (RPA) of 2 lg/kg for the sum of MG and its major metabolite leucomalachite green (LMG) is adequate to protect public health. Available occurrence data were not suitable for a reliable exposure assessment. The hypothetical dietary exposure was calculated, considering the RPA as occurrence value for all types of fish, fish products and crustaceans. Meandietary exposure across different European dietary surveys and age classes would range from 0.1 to 5.0 ng/kg body weight (bw) per day. For high and frequent fish consumers, the exposure would range from 1.3 to 11.8 ng/kg bw per day. Both MG and LMG induced formation of DNA adducts in livers of rats and/or mice, and of micronuclei in mice. LMG also induced cII transgene mutations in mouse liver. MG caused a small, not dose-related, increase in thyroid gland follicular adenomas and carcinomas, and of mammary gland carcinomas in female rats. LMG caused an increase in hepatocellular adenomas and carcinomas in female mice. Both MG and LMG may be considered as carcinogenic and as genotoxic in vivo. A lower 95% confidence limit for a benchmark response of 10% extra risk (BMDL10) of 13 mg/kg bw per day for hepatocellular adenomas and carcinomas was selected as reference point for neoplastic effects. For non-neoplastic effects, a lower 95% confidence limit for a benchmark response of 5% extra risk (BMDL05) of 6 mg/kg bw per day was selected for the effect of MG on liver weight and of LMG on body weight. The margins of exposure were 1.1 \times 10^6 or greater for neoplastic effects and 4.9 \times 10^5 or greater for non-neoplastic effects. The CONTAM Panel concluded that it is unlikely that exposure to food contaminated with MG/LMG at or below the RPA of 2 lg/kg represents a health concern.