

EFA Opinion FGE.208 Rev1

Safety concern for *p*-mentha-1,8-dien-7-al [FL-no: 05.117]

EFA has published its Scientific Opinion on FGE.208 Rev1 related to *p*-mentha-1,8-dien-7-al [FL-no: 05.117] and 9 structurally related substances. In its opinion EFA expresses a safety concern for the representative substance *p*-mentha-1,8-dien-7-al and a potential concern for the other substances.

Today EFA has published its opinion on FGE.208 Rev1 on its website and in the EFA Journal (EFA Journal 2015; 13(7):4173) (FL/15/26). This covers a group of 10 flavouring substances of FGE.19 including *p*-mentha-1,8-dien-7-al [FL-no: 05.117] (perilla aldehyde), the representative material for testing, and 9 structurally related substances.

Previously EFA had requested additional data as a follow-up to *in vitro* data that had been submitted by Industry, specifically an *in vivo* Comet Assay (EFA opinion FGE.208: EFA Journal 2013; 11(4):3151 (FL/13/15)). Based on this request, Industry (EFA/IOFI) submitted additional data to EFA from a combined *in vivo* Micronucleus / Comet assay experiment in 2014 (17/07/14 & 14/08/14).

Review of the test data by Industry Experts and by IOFI external consultants (the Genotoxicity Testing Advisory Committee, GTAC), prior to submission to EFA, concluded that the study supported no genotoxicity concern and that the observed findings in the submitted assay were secondary to high dose liver toxicity.

Now EFA has issued its opinion in which the risk assessor interprets the data differently and concludes that there remains a genotoxicity concern for *p*-mentha-1,8-dien-7-al. The EFA-conclusion reads as follows:

*"[...] The Comet assay performed in liver shows a positive result and therefore the Panel concluded that *p*-mentha-1,8-dien-7-al [FL-no: 05.117] is genotoxic in vivo and that, accordingly, there is a safety concern for its use as flavouring substance. Since *p*-mentha-1,8-dien-7-al [FL-no: 05.117] is representative for the nine remaining substances of this subgroup 2.2 [...], there is a potential safety concern for these substances."*

This EFA opinion comes as unexpected news and is not in line with the opinion of other global experts such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the FEMA Expert Panel.

At this stage the potential risk management decision by the EU Commission is not clear, but EFA anticipates that the EU Commission will draft a measure to remove at least the representative substance (*p*-mentha-1,8-dien-7-al) from the Union List for which EFA has concluded "*there is a safety concern for its use as flavouring substance*".

Whether this will also apply to the other 9 substances is unclear at this stage. EFA notes that in today's press release EFSA states: *"EFSA's experts, therefore, indicate there is also a potential safety concern for these other substances unless further evidence proves otherwise."*

Although EFA disagrees with the data interpretation from EFSA, EFA acknowledges the consequences of this opinion with regard to the representative material *p*-mentha-1,8-dien-7-al and consequently recommends its members to start reformulating by removing this substance from their formulas without any further delay.

In case of additional questions please do not hesitate to contact the EFA Secretariat at info@efa.eu.

EFA Secretariat – 23 July 2015

Enclosure:

EFSA Opinion FGE.208 Rev1 (FL/15/26)