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Abstract

n-Alkanes are substances that are not only important constituents of hydrocarbon waxes but they ubiquitously present on the surface of fruits, vegetables and plant materials in general. The recently published EFSA Eternal Scientific Report: Bioaccumulation and toxicity of mineral oil hydrocarbons in rats – specificity of different subclasses of a broad mixture relevant for human dietary exposures (Cravedi et al. 2017) provides significant new information on the response of the Fischer (F-344) rats to n-alkanes. A first important finding of this study is the observation that also the animals in the control group, i.e. those that are not exposed to the hydrocarbon mixtures that are the subject of this study, show enhanced retention of n-alkanes of natural origin that are present in the feed. (Cravedi et al 2017 Table 1). Especially remarkable is the fact that the concentration of n-alkanes found in the rat livers is nine times higher than those in the fat tissue. This is completely opposite to the situation in human livers and rat species other than F- 344 where n-alkanes are essentially absent in livers. (Barp et al 2014 Fig 3.).This clearly indicates that something atypical is happening in the F-344 rats with respect to their capability to metabolize n-alkanes, including those of natural origin. A further comparison of the hydrocarbons found in human livers with those that typically constitute a wax leads indubitably to the following conclusions: Those hydrocarbons that are found to be retained preferentially in human livers are not present in waxes, and those hydrocarbons that waxes are composed of, are not see in human livers. (Cravedi et al 2017 Fig 52 and Biederman et al 2015 Fig. 6). Hence, waxes are confirmed to be fully and easy metabolizable substances in humans, a situation that is completely opposite to the situation of F-344 rats where significant retention of wax constituents, including n-alkanes, is observed. Therefore, waxes should not be seen as part of the "MOSH" concern that is essentially triggered by the retention of hydrocarbons by human tissues. Further experimental findings in the quoted EFSA External Scientific Report allow the elucidation of the mechanism by which n-alkanes lead to the inflammatory microgranulomas that have been exclusively found in the F-344 rat livers.

The final disqualification of the F-344 rat strain as an appropriate model for assessing the human safety of waxes, and notably Low Melting Paraffin Wax (LMPW), has a number of direct and indirect consequences. First and foremost, it supports a petition requesting to allocate a new Specific Migration Limit (SML) for LMPW (FCM 93) in Annex 1 of the Plastics Regulation (EU) 10/2011. Currently, this SML is 0.05 mg/kg is based in a TIER 1 petition. Relying on the full toxicological data set, with the exclusion of those studies based on the F-344 rats, supports an SML higher than the

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Overall Migration Limit (OML). Furthermore, it finishes the unqualified use of LMPW as a generic model for predicting potential adverse effects of MOSH. Hence, low viscosity oils need be assessed by their own experimentally established No Observed Adverse Effect Levels (NOAEL's) rather than by the 19 mg/kg b.w./day that was found for LMPW in the F-344 rats. Furthermore, also the margins of exposure (MOE's) that are calculated in the EFSA Opinion of 2012 and that are based on the use of 19 mg/kg b.w. day as the Reference Point need to be revised using relevant oil rather than wax data.

References

Barp, L., Kornauth, C., Wuerger, T., Rudas, M., Biedermann, L. Reiner, A., Concin, N., Grob, K. 2014 Food and Chemical Toxicology, 72, 312-231

Biedermann, M., Barp, L., Kornauth, C., Würger, T., Rudas, M., Reiner, A., Concin, N.,Grob, K. 2015. Mineral oil in himan tissues, Part II: Characterization of the accumulated hydrocarbons by comprehensive two-dimensional gas chromatography. Science of the Total Environment 506-507, 644-655

Cravedi, J-P.,Grob, K., Nygaard U.C. and Alexander, J., 2017. Bioaccumulation and toxicity of mineral oil hydrocarbons in rats-specificity of different subclasses of a broad mixture relevant for human dietary exposure. EFSA supporting publication 2017:EN-1090

EFSA (European Food Safety Agency), 2012. Scientific opinion on mineral oil hydrocarbons in food. EFSA Journal 10 (6): 2704, 1-185