Safety assessment of tetra-methyl bisphenol F diglycidyl ether (TMBPF-DGE) for use in coating in canned food packaging materials

Summary and Introduction

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Summary

1. Tetra-methyl bisphenol F diglycidyl ether (TMBPF-DGE) is a mixture of mono- and diglycidyl ether and TMBPF-DGE oligomers, derived from the reaction of tetramethyl bisphenol F (TMBPF) with epichlorohydrin. TMBPF-DGE is further processed to form an epoxy resin and polymer dispersion, which is then used as a component in coatings in canned food packaging materials, in contact with all food types (beverages included).

2. TMBPF-DGE contains epoxy (glycidyl) groups and as such is intended to be reactive. However, reactivity is negligible in the finished (cured) coating where it is incorporated into the polymer backbone. While TMBPF-DGE derived epoxy groups remaining in the resin may react with food constituents, no interactions with food substances after polymerisation are anticipated.

3. A worst-case approach was applied using extraction and quantification of TMBPF-DGE, its hydrolysis products and the total number of epoxy groups to assess possible exposure. Migration into acetonitrile was considered a worst case-

scenario.

4. When estimating the worst-case dietary exposure to TMBPF-DGE, the hydrolysis and chlorinated products that form during the manufacturing process and application to light metal food packaging coating materials need to be considered. Hence, all TMBPF-DGE monomer derivatives were included in the total concentration used in the dietary exposure assessment.

5. TMBPF-DGE was genotoxic in vitro but while uncertainties remain over the potential ability to induce polyploidy, TMBPF-DGE was overall considered negative for mutagenicity or genotoxicity in vivo. However, when considering the other toxicological endpoints, Members of the FCMJEG and COT did not think it appropriate to formalise a health-based guidance value (HBGV) due to the lack of a long term/chronic toxicity study and other database deficiencies. The available 28-day study, while informative, did not include all the endpoints in a long term/chronic study.

6. Overall, when considering all available information, the available data did not identify a safety concern for the usage of TMBPF-DGE in can coatings. Hence, the Committees did not see any scientific reason to apply restrictions to the usage of TMBPF-DGE.

Introduction

7. Towards the end of 2021 the UK Food Standards Agency (FSA) policy team received a request by the food contact can coating sector to assess the suitability of tetra-methyl bisphenol F diglycidyl ether (TMBPF-DGE) for use in coatings in canned food packaging materials.

8. EFSA had not carried out an assessment of TMBPF-DGE and this necessitated national authorities to consider the safety and use of TMBPF-DGE as an epoxy in can coatings. In 2022, the Dutch Authorities included TMBPF-DGE in their revision of the Dutch Commodities Act (Warenwet), allowing it to be used as a coating in canned food packaging subject to specific restrictions. In accordance with mutual recognition principles, goods lawfully placed on the market within an EU member state can be freely placed on the market within Northern Ireland (NI). This does not apply to Great Britain (GB), which would have to reach its own conclusion. TMBPF-DGE is being suggested as a possible replacement for bisphenol A (BPA) in can coatings, with several global brands already marketing cans coated with TMBPF-DGE-based polymers in the European Union (EU). Manufacturers are now intending to apply the coating to cans destined for the GB market and a decision

is therefore required to determine whether TMBPF-DGE should be allowed to be used in the GB market under similar conditions.

9. Given that there is no legislative framework in place for the assessment of substances in can coatings nor the ability to create or amend a positive list at present, the suitability of TMBPF-DGE was assessed outside the FSA/FSS (Food Standards Scotland) regulated products approvals process. The FSA policy team therefore does not anticipate formal authorisation of TMBPF-DGE but would take into account the finalised risk assessment in their risk management considerations. The objective will be to ensure that it appropriately sets out operator requirements and expectations.

10. The information provided to the FSA on TMBPF-DGE was considered by the Joint Expert Group on Food Contact Materials (FCMJEG), the Committee on Toxicity of Chemicals, Consumer Products and the Environment (COT) and the Committee on Mutagenicity (COM), for their specific expertise.