Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

# Risk Management Option Analysis Conclusion Document

## Tetrahydrofuran (THF) in consumer products

**Substance Name: Tetrahydrofuran**
**EC Number: 203-726-8**
**CAS Number: 109-99-9**

**Authority: DE CA (aMSCA)**
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# Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether further regulatory management measures are needed.
An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

## 1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Tetrahydrofuran (THF) was subject to two targeted dossier evaluations[1], which were concluded by ECHA without a decision.

Furthermore, THF was subject to a substance evaluation (SEv) by the German CA (DE CA) in 2013. A decision[2] was sent to the Registrants in 2015 and the SEv was concluded in 2017[3].

THF has a harmonised classification as Flam. Liq. 2 (H225), Carc. 2 (H351), STOT SE 3 (H335; C ≥ 25 %) and Eye Irrit. 2 (H319, C ≥ 25 %).

**Assessment of regulatory needs (ARN):**

In 2021, **ECHA** initiated a screening assessment in a **regulatory strategy of a group including THF (Group Name: Cyclic ethers**). For THF, no need for further EU regulatory risk management was identified[4].

## 2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information.

| **Conclusions** | **Tick box** |
|---|---|
| Need for follow-up regulatory action at EU level: | x |
| *Harmonised classification and labelling* | x |
| *Identification as SVHC (authorisation)* | |
| *Restriction under REACH* | x |
| *Other EU-wide regulatory measures* | |
| Need for action other than EU regulatory action | |
| No action needed at this time | |

## 3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

The initial concern that led to the preparation of this RMOA was based on open questions regarding the safe use of THF-containing consumer products. These questions originated from the SEv of THF by the German CA (2013). Risks for consumers could not be ruled out based on the generic information available during the SEv and a deeper understanding of products used by consumers and their respective exposure scenarios was considered

[1] https://echa.europa.eu/de/information-on-chemicals/dossier-evaluation-status/-./dislist/substance/100.003.389; accessed 17. August 2022

[2] https://echa.europa.eu/documents/10162/835e9e08-4884-6bca-1f46-4f202b3ef9bf; accessed 17. August 2022

[3] https://echa.europa.eu/documents/10162/ddee5811-405d-e609-ed17-e50cae51f2ed; accessed 17. August 2022

[4] https://echa.europa.eu/documents/10162/fa738b95-ee66-de41-2bc7-b499754750f1; accessed 17. August 2022

necessary. This RMOA including the consultation to obtain detailed product information was performed to determine whether the use of products containing THF poses a health risk to consumers, and whether, respectively which, further risk management measures are necessary to protect consumers.

Obtained information suggests that even though THF has a harmonised classification as suspected carcinogen (Carc. 2), the substance is used at very high concentrations in glues that are used by consumers indoors. It is also noted that numerous C&L notifiers do not self-classify THF as Carc. 2, despite its harmonised classification for this hazard class. Hence, it is concluded a Carc. 2 classification cannot be considered an appropriate protective regulatory measure for consumer safety.

Using conservative assumptions, potential uncontrolled risks (RCRs > 1) could not be ruled out for any of the examined exposure scenarios for THF-containing glues used indoors by consumers. The evaluated uncertainties do not allow for an exclusion of a realistic health risk for consumers, as besides worst-case also conservative scenarios were assessed. Therefore, further (regulatory) action is considered necessary.

## 3.1 Harmonised classification and labelling

THF has a harmonised classification as Flam. Liq. 2 (H225), Carc. 2 (H351), STOT SE 3 (H335; C ≥ 25 %) and Eye Irrit. 2 (H319, C ≥ 25 %). However, it is noted that numerous C&L notifiers do not self-classify THF accordingly, particularly regarding the classification for Carc. 2.

It was stated in the SEv conclusion document that the current harmonised classification of THF as per Annex VI of Regulation (EC) 1272/2008 (CLP) does not fully cover the classification/labelling that would result based on a full evaluation of the whole available toxicological database.

In particular, it should be considered to change the current classification from Eye lrrit. 2 (H319) to Eye Dam. 1 (H318) and to add the following additional classification: Acute Tox 4 (H302), STOT SE 3 (H336), EUH019 and EUH066.

Nevertheless, it is noted that these endpoints do not belong to the endpoints usually being subject to harmonised classification (Article 36(1) of CLP Regulation).

So far, the recommended classification reported in the SEv conclusion document has not been fully taken into account by industry. Therefore, the preparation of a new Annex VI dossier for harmonised classification is considered beneficial. **It is noted, however, that this classification is not crucial to manage the potential risks for consumers identified in this RMOA.**

## 3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

For THF requirements laid down in Article 57 a) - f) are not fulfilled. For this reason, an inclusion in the candidate list and subsequently in Annex XIV is not foreseen and not considered a possible risk management option at this point.

### 3.3 Restriction under REACH

Based on the information currently available it is concluded that a restriction is the most appropriate risk management option, as the specific THF-containing products for which health risks for consumers were identified can be addressed and managed by this measure, while other THF containing products which may not pose a risk to consumers can be excluded.

Appropriate restriction options should be considered, e.g. i) restricting/banning THF in glues for indoor uses by consumers or ii) limiting the maximum THF concentration in glues used by consumers indoors. The latter may in some cases also lead to complete substitution of THF, as the minimum concentration for ensuring technical function may be above such a designated concentration limit. Further information is needed to clarify whether a reduction of THF concentrations may be feasible with regard to its technical function. Such information may be obtained in a call for evidence.

Regarding both options i) and ii), the specific conditions of the restriction, availabilities of suitable non-risk alternatives and potential socio-economic impacts need careful consideration.

## 4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

| Follow-up action | Date for follow-up | Actor |
|---|---|---|
| Preparation of a CLH dossier | TBD | TBD |
| Preparation of a restriction proposal | TBD | DE CA |