Ministry of Environment and Water, Bulgaria

# Risk Management Option Analysis Conclusion Document

**Substance Name: Formic acid**

**EC Number: 200-579-1**

**CAS Number: 64-18-6**

**Authority: Bulgarian Competent Authority**

**Submitted by: Ministry of Environment and Water**

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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 a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

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 Bulgarian Competent 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 Bulgarian Competent Authority. In case the Bulgarian Competent 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 Bulgarian Competent Authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

The preparation of RMO Analysis by the Bulgarian Competent Authority commenced in April 2016. Following a communication with the lead registrant during the course of RMOA, the consorcium informed BG CA about its intention to update the CSR and the exposure scenarios. The lead Registrant, has updated twice the Chemical Safety Report for Formic acid which extended the RMOA process till May 2017.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

## 1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

The table below summarizes the completed or ongoing regulatory processes regarding Formic acid.

***Table 1: Completed or ongoing processes***

| | | |
|---|---|---|
| RMOA | ☒ Risk Management Option Analysis (RMOA) | |
| REACH Processes | Evaluation | ☐ Compliance check, Final decision |
| | | ☐ Testing proposal |
| | | ☐ CoRAP and Substance Evaluation |
| | Authorisation | ☐ Candidate List |
| | | ☐ Annex XIV |
| | Restri -ction | ☐ Annex XVII[2] |
| Harmonized C&L | ☒ Annex VI (CLP)<br>Process is ongoing. | |
| Processes under other EU legislation | ☐ Plant Protection Products Regulation<br>Regulation (EC) No 1107/2009 | |
| | ☒ Biocidal Product Regulation<br>Regulation (EU) 528/2012 and amendments<br>Process is ongoing. | |
| Previous legislation | ☐ Dangerous substances Directive<br>Directive 67/548/EEC (NONS) | |
| | ☒ Existing Substances Regulation<br>Regulation 793/93/EEC (RAR/RRS) on the evaluation and control of the risks of existing substances | |

[2] Please specify the relevant entry.

| | |
|---|---|
| (UNEP) Stockholm convention (POPs Protocol) | ☐ Assessment |
| | ☐ In relevant Annex |
| Other processes/ EU legislation | ☒ Other (provide further details below)<br>Regulation (EC) No 2006/15/EC on Indicative Occupational Exposure<br>Regulation (EC) No 1223/2009 on cosmetic products. |

## Proposal for Harmonized Classification in Annex VI of the CLP

Formic acid (CAS n 64-18-6) was classified as corrosive to the skin with specific concentration ranges under Dir. 67/548/EEC, and this was transferred into CLP Annex VI, GHS classification.

Formic acid is a biocidal active substance and during its evaluation under the Biocidal Product Regulation (BPR, Regulation (EU) 528/2012), applications have been submitted for the approval of Formic acid as a biocidal active substance. During its evaluation the MS competent authority concluded that the current harmonized classification was no longer up to date. New hazard classes are proposed in the CLH report, while the previous ones are retained.

The MS Competent Authority submitted (17 November 2016) a CLH report - Proposal for Harmonized Classification and Labelling based on Regulation (EC) No 1272/2008 (CLP), Annex VI, Part 2. CLH-report was made in the context of Biocidal Product Regulation (EU) No 528/2012.

***Table 2: Proposed harmonized classification and labelling according to the CLP criteria***

| | Index No | International Chemical Identification | EC No | CAS No | Classification | | Labelling | | | Specific Conc. Limits, M-factors |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Hazard Class and Category Code(s) | Hazard statement Code(s) | Pictogram, Signal Word Code(s) | Hazard statement Code(s) | Suppl. Hazard statement Code(s) | |
| Dossier submitters proposal | 607-001-00-0 | Formic acid ... % | 200-579-1 | 64-18-6 | **Add** Flam. Liq. 3 | H226 | GHS02 | H226 | - | C≥99% |
| | | | | | **Add** Acute Tox. 4 (oral) | H302 | GHS07 | H302 | - | |
| | | | | | **Add** Acute Tox. 3 (Inhalation - vapour) | H331, EUH071 | GHS06 | H331 | - | |
| | | | | | **Add** Eye Dam./Irrit. 1 | H318 | GHS05 Danger | H318 | - | C≥10% |

## 2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

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

## 3. NO ACTION NEEDED AT THIS TIME

Formic acid is a high production volume chemical (100,000 – 1,000,000 tpa) with a high dispersive use.
The main health concerns are related to the corrosive effect of Formic acid. Eye contact may cause severe burns and loss of vision. Contact with the skin may cause severe burns which may be delayed in onset. Formic acid vapor is irritating to the skin, eyes, nose, throat and respiratory tract, causing irritation, coughing, chest pain and dyspnea. Swelling of the throat and accumulation of fluid in the lungs (shortness of breath, cyanosis, expectoration and cough) may occur.

The main concern that arose during the manual screening and triggered the RMOA analysis was related to the workers' and consumers' safety. They were based on the wide dispersive use and RCR values close to 1 calculated for different workers' scenarios and for long-term consumer use. The sMSCA proposed RMOA as the best regulatory process to follow for Formic acid.

During the RMOA analysis the lead Registrant, has updated twice the Chemical Safety Report for Formic acid. The updats were as follow:

- CSR 2016: the Exposure assessment and related risk characterization in the CSR 2014 have been reassessed and the RCRs for all contributing scenarios for long-term inhalation exposure have been re-calculated, using EasyTRA 4.1.0. The re-calculated RCRs were well below <1, hence the concerns regarding workers and consumers identified in CSR 2014 have not been confirmed.
- CSR 2017: The evaporation model for consumer exposure estimation and an additional contributing scenario for bathroom cleaning sprays for modelling inhalation exposure among the different use phases (spray and evaporation model) have been performed and included The calculated RCRs were well bellow 1, thus Formic acid poses no risk for the human health.

Further, after a recommendation from BG CA in the updated CSR 2017, for the exposure scenarios: ES 2 (PROC 5, 8a, 9), ES 7 (PROC 10, 11, 13, 19), ES 8 (PROC 7) and ES 9 (PROC 8a, 10, 11, 13, 19) the lead Registrant has added the following statements regarding respiratory protection: "*In case no good general ventilation is present: Wear suitable respiratory protection with adequate effectiveness*."

## Conclusion

Based on the available information, ongoing harmonized CLP process, the risk reduction measures already implemented and as well as newly proposed and accepted by the Registrant, the analysis concludes that Formic acid does not represent unacceptable risk to workers, consumers or to the environment. The Bulgarian Competent Authority considers therefore that there is no need for further regulation of Formic acid for the time being.