Risk Management Option Analysis Conclusion Document

Substance Name: Aniline

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Authority: NL

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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 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] 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

On 12/10/2011 a substance evaluation was completed on aniline. (The aniline industry could not fulfil the request on information about the formation and releases of the substance in caoutchouc industry, as the aniline industry had no access to the data of the caoutchouc industry and the caoutchouc industry had no obligations under Regulation 793/93. Therefore this data request was considered complete and the file was closed.)

A risk assessment report on aniline was completed by Germany in 2004. In 2010, a recommendation from the scientific committee on occupational exposure limits (SCOEL) for aniline was published. In 2014, a new recommendation has been published due to new studies available since 2010. The latter is still a draft for consultation with the deadline being September 1st, 2014. The current status of the 2014 recommendation is uncertain.

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

The concern for aniline relates to the possible exposure of workers and of consumers via residual amounts of aniline in consumer products and via the environment. Related to worker safety, an OEL has already be established by SCOEL leading to harmonization of the occupational exposure limit values throughout the EU. An update of the OEL is ongoing with a proposal to raise the OEL from 0.5 ppm to 2 ppm.

The exposure related data for workers and consumers in the CSR are limited, but suggest workers and consumers are currently not at risk. In the absence of recent worker related cases, there is no further information available to conclude otherwise. For consumers though, recent monitoring data performed in Germany do suggest there may be reason for concern with respect to the possible exposure to aniline in approximately 5% of the population, in particular when this higher exposed group involves more vulnerable people like elderly, children, women in their menstrual period and people with hereditary NADH-diaphorase deficiency. However, current data are insufficient to establish an abundant risk. Furthermore, the exact source and level of exposure is uncertain. Moreover, there may be a possibility that the aniline measured in the urine of those people included in the monitoring study does not result from exposure to aniline but from the degradation or metabolization of other substances. As the source of aniline exposure is unclear, restriction of aniline use under REACH is therefore not considered yet.

Regarding the environment, the measured concentration of aniline in surface water is below the PNEC (see above), and reports on adverse (health) effects (environment) due to aniline exposure have not been found (internet search). Therefore, also from the perspective of environmental concerns, the presently available data do not motivate restriction under REACH as appropriate risk management option.

Aniline was originally selected for RMOA because of its STOT RE properties that might make the substance eligible for inclusion on the Candidate list based on article 57f properties, its wide spread use, high tonnage and concern for exposure of workers, environment and the general population. Though the possible effects of aniline are juded severe, the possibility to work safely with this substance under the derived DNEL (or OEL) and the reversibility of the primary effect on MetHb formation, suggest that the hazard of aniline may not be of equivalent level of concern. Also for its properties as skin sensitizer, an ELoC is not likely to be made as Aniline is considered a weakly potent skin sensitizer. Accordingly, the available data might not be sufficient to designate aniline as an SVHC substance.

Based on the available information on aniline, it is concluded that the concern for aniline and its exposure to workers and the environment seems sufficiently controlled and there is no need for further risk management measures. The recent accident with aniline in the Netherlands indicates that exposure to Aniline might not always be sufficiently controlled, which may hint at an enforcement issue. The elevated level of MetHb in possibly 5% of the general population, does give rise to concern for consumers, possibly from the use of aniline containing articles or formulations. However, insight in the possible source(s) of exposure of consumers is needed first before further action can be decided on, which may be something that could be taken up by the Inspection responsible for food safety and consumer products. Investigating/monitoring exposure sources to consumers might be rather difficult because of the combination of primary (exposure to aniline as used in a product or article) and secondary (exposure to aniline as a metabolite of other substances) sources, and will be expensive. Since there are no direct indications that there is a health problem with aniline, such a monitoring program may not be a first priority.