09 November 2015

COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFCATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS

Substance name: Nitrobenzene
CAS number: 98-95-3
EC number: 202-716-0

The substance is proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH Regulation: Toxic for reproduction (Article 57 c)

Disclaimer: *Comments provided during public consultation are made available as submitted by the commenting parties. It was the commenting parties own responsibility to ensure that their comments do not contain confidential information. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a substance of very high concern.*

PART I: Comments and responses to comments on the SVHC proposal and its justification

General comments on the SVHC proposal
None

Specific comments on the justification

Number / Date	Submitted by (name, submitter type, country)	Comment	Response
4491 2015/09/09	European Trade Union Confederation, Trade union, Belgium	ETUC supports the identification of Nitrobenzene as SVHC. The substance is included in the Trade Union Priority List for REACH Authorisation. See: https://www.etuc.org/trade-union-priority-list	Thank you for the support.
4502 2015/10/12	Norway, Member State	The Norwegian CA supports that nitrobenzene should be identified as a substance of very high concern and should be included in the Candidate List.	Thank you for the support.
4507 2015/10/12	Germany, Member State	The German CA supports the identification of nitrobenzene as substance of very high concern in accordance with article 57 (c) of regulation (EC) 1907/2006 (REACH).	Thank you for the support.

4524 2015/10/14	Finland, Member State	Nitrobenzene (EC 202-716-0) The Finnish CA supports the proposal to identify nitrobenzene as substances of very high concern (SVHC) according to article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as Repr. 1B (H360F: May damage fertility). The Finnish CA notes that a Risk Management Option Analysis (RMOA) Conclusion Document on nitrobenzene has been published on the ECHA website. The criteria of SVHC Roadmap 2020 for substances relevant for identification as SVHC are fulfilled for nitrobenzene. The Finnish CA considers the reasons given in the RMOA for inclusion in the candidate list are justified. The Finnish CA further considers that after inclusion of the substance in the candidate list (for eventual inclusion in the Annex XIV) it can still be further explored which risk management measures would be the most appropriate.	Thank you for the support.
4536 2015/10/15	European Trade Union Confederation, Trade union, Belgium	ETUC supports the identification of Nitrobenzene as SVHC. his substance is includes in the Trade Union priority List for REACH authorisation. See: www.etuc.org/trade-union-priority-list	Thank you for the support.
4549 2015/10/15	CHEM Trust, National NGO, United Kingdom	CHEM Trust supports inclusion of nitrobenzene in the candidate list based on its classification as 1B reprotoxic chemical. In addition, CHEM Trust would like to see a better reflection of the indications regarding the potential endocrine disrupting effects of nitrobenzene. It would be useful to add to the document that 'Inhibin is a hormone that plays a role in reproduction and given that nitrobenzene is reported to cause an increase in the secretion of this hormone, this substance might cause adverse effects on reproduction via an endocrine disruption mechanism of action.'	Thank you for the support. The potential of nitrobenzene to induce endocrine disrupting effects has been discussed in the ED Expert group via written procedure in spring 2015. In summary, no clear support has been provided for the identification of nitrobenzene as an endocrine disruptor. The majority of responses judged increased inhibin secretion as

			such as an endocrine mode of action, but stated that the available data are too limited to clearly identify nitrobenzene as endocrine disruptor. Some comments hypothesized that inhibin alteration might be secondary to a non-endocrine mode of action. In principle, substance evaluation could have been considered in order to require further testing for clarifying the endocrine disrupting effects. However, it does not seem justified to propose a substance evaluation process for this clarification, taking into consideration that this process would require considerable additional efforts, including testing and time, but would provide comparatively little additional benefits for risk management in that specific case. Nitrobenzene is already classified as Repr. 1B, and thus risk management measures could be taken on the basis of present knowledge without further delay.
4555 2015/10/15	Chemsec, International NGO, Sweden	ChemSec supports the identification of Nitrobenzene as an SVHC, which is also confirmed by the official classification as reprotoxic.	Thank you for the support.

4567 2015/10/15	Health and Environment Alliance (HEAL), International NGO, Belgium	We support the nomination of nitrobenzene to the Candidate List	Thank you for the support.

PART II: Comments and responses to comments on uses, exposures, alternatives and risks

Specific comments on use, exposure, alternatives and risks

Number / Date	Submitted by (name, submitter type, country)	Comment	Response
4529 2015/10/14	Aniline and Nitrobenzene REACH Consortium, Industry or trade association, Belgium	PROC 15 is available in the REACH dossiers for manufacturing for the intermediate use. For intermediate use there is no professional and no consumer use registered.	At this stage of the process information on the identification of nitrobenzene as SVHC is taken into account. Information on uses and exposure, will be forwarded for discussion at later stages of the authorization process (e.g. prioritization) in case the substance is identified as SVHC.