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

Disclaimer*: Comments provided during the consultation are made available as submitted by the commenting parties. It was in 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.*

Substance name: *N*-(hydroxymethyl)acrylamide
CAS number: 924-42-5
EC number: 213-103-2

The substance is proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH Regulation: Carcinogenic (Article 57a); Mutagenic (Article 57b)

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

General comments on the SVHC proposal

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses

Specific comments on the justification

Number / Date	Submitted by (name, submitter type, country)	Comment	Responses
5600 2022/04/14	ANSES (The French Agency for Food, Environmental and Occupational Health & Safety), National Authority,	ANSES supports the proposal of identification of N-(hydroxymethyl)acrylamide as SVHC according to articles 57a and 57b. The substance is covered by index number 616-230-00-5 of Regulation b(EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) based on their hazard classification carcinogenicity category 1B (hazard statement H350: "May cause cancer") and germ cell mutagenicity	Thank you for your support.

	France	category 1B (hazard statement H340: "May cause genetic defects").	
5601 2022/04/19	European Environmental Bureau (EEB), International NGO, Belgium	The EEB supports the proposal submitted by Sweden to identify N-(hydroxymethyl)acrylamide as a Substance of Very High Concern due to its Carcinogenicity (REACH article 57(a)) and Mutagenicity (REACH article 57(b)). The substance has a harmonised classification in the CLP regulation as Carcinogen cat. 1 B, Mutagen cat. 1B and STOT RE 1. RAC agreed already in 2018 on the harmonised classification and the substance was included in CLP in 2020. The inclusion of this substance in the Candidate List is urgently needed, four years after the consensus reached by EU experts on its carcinogenic and mutagenic properties. The substance is registered under REACH at 1.000 - 10.000 tpa and has 525 notifiers in CLP. It may be used as a substitute for acrylamide given its structural similarity. Therefore, the substance should be added to the Candidate List to prevent regrettable substitution and additional regulatory risk management measures need to be considered in analogy to acrylamide.	Thank you for your 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	Responses