

BRIEFING

Comments on the ECHA's draft recommendation to include Melamine in the authorisation list of REACH.

16 May 2024

HEAL strongly supports the inclusion of melamine in the Authorisation List of REACH. Melamine is a substance recognised as being toxic for human health and the environment. It is also recognised as a substance being persistent which does not readily biodegrade, and it is very mobile creating a potential for widespread contamination of the water environment. Moreover, uses in food contact materials is identified as one of the most significant sources of human exposure to melamine. As regard human health effects melamine is classified under CLP as STOT RE 2 and Carcinogenic category 2 due to its urinary tract toxicity and it is also classified as reprotoxic category 2 given the testicular and sperm effects identified in experimental animals.

Melamine is used in very high volumes in a multitude of different industrial and consumer products. Melamine is used in products including building materials (flooring walls, plywood, adhesives, paints, coatings, flame retardants etc), textiles, fertilisers, cosmetics, personal care products, stain and water-resistant clothing, detergents, fragrances, electrical and household appliances, and plastic products including reusable plastic tableware and toys.

Melamine was added to the Candidate List for authorisation on 17 January 2023 after it was identified as a substance meeting the criteria of Article 57(f) of Regulation (EC) 1907/2006 as it is a substance for which there is scientific evidence of probable serious effects to the environment and human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH.

The inclusion of melamine in the authorisation list is therefore urgent to respond to the serious human and environmental health concerns raised by melamine. Due its use in a broad range of application, including wide-dispersive uses and uses in articles, no uses of melamine should be exempted from the authorisation requirement in order to reduce the exposure use of EU citizens to this toxic chemical.

HEAL comments on the following aspects open for consultation:

1. Shorter transition periods

As a result of the identification of melamine as a SVHC in accordance with Article 57(f) of REACH as it is a substance for which there is scientific evidence of probable serious effects to the environment and human health, ECHA has recommended to include melamine in Annex XIV. **This is a welcome and long-overdue inclusion, and should be held to the shortest timeline possible, namely 18 months for the latest application date and 18 months after the latest application date for the sunset date for all uses.**

For more information:

Basile Ghesquiere
basile@env-health.org
www.env-health.org



2. “Uses” or “categories of uses” exempted from authorisation requirement.

HEAL reiterates its support for a decision based on intrinsic hazard properties of melamine, which are very concerning for human health and the environment and therefore **we support not to recommend exemptions for any uses of melamine from the authorisation requirement.** Uses of melamine that are the most significant to human exposure are of particular concern.

- **Food Contact materials:** Annex XV dossier identifies uses of melamine in food contact materials as one of the most significant sources of human exposure. There are a great many safer, melamine-free materials appropriate for FCM, such as tableware, and **no uses of melamine should therefore be exempted from the authorisation requirement in FCM.**
- **Flame retardants:** Annex XV dossier also identifies articles containing melamine as flame retardant as a significant source of human exposure. There is a critical need to assess the actual efficacy from use of flame retardants and open flame tests compared with other non-hazardous fire safety interventions. In fact, a report from the EU commission supports the conclusion that non-flammability requirements such as open flame tests are not indicative of real-life scenarios and these requirements have little bearing on fire safety overall [1]. Instead, flame retardants may actually be compounding the injuries and harms associated with exposure to toxic fumes and smoke during a fire that contain such hazards as carbon monoxide, cyanide, dioxins and furans [2]. **We therefore urge ECHA to take this information into account when assessing any request for exemption of melamine from the authorisation requirement in relevant uses.**

3. Combined exposures

Melamine can be metabolised to a group of potentially harmful derivatives including cyanuric acid, (CYA), ammeline (AMN), and ammelide (AMD). Further, research has shown that co-exposures to cyanuric acid and melamine exacerbate kidney toxicity compared to exposure to one compound by itself. Cyanuric acid and other derivatives are often used together with melamine in industrial and consumer products, leading to increased risk of potential harm. Thus, combined exposures are a major concern.

The dossier cites compelling evidence of increased risk in relation to co-exposures to melamine and its derivatives such as the Sathyanarayana et al. (2019) [3] study which found statistically significant associations amongst individuals with higher exposures to melamine and cyanuric acid in combination and kidney injury markers. Another study not mentioned in the dossier looked at melamine and cyanuric acid in foodstuffs and estimated daily intakes (EDI). It found children’s EDI were 5-10 times higher than in adults, with dairy, meat, and cereal products accounting for over 80% of contaminated dietary exposures [4]. These findings suggest that these substances are ubiquitous in many products and environments and certain vulnerable populations may be exposed at higher levels on a daily basis.

Melamine is also often used in the production of formaldehyde-based resins for plastic production, which we believe further supports its inclusion in Annex XIV. Melamine and formaldehyde are classified as category 2 and 1B carcinogen respectively. The uncertainties of combined exposure effects of these two harmful substances commonly used in tandem, add further arguments in favour of the inclusion in the authorisation list.

Conclusion

Melamine was added to the Candidate List for authorisation on 17 January 2023 after it was identified as a substance meeting the criteria of Article 57(f) of Regulation (EC) 1907/2006 as it is a substance for which there is scientific evidence of probable serious effects to the environment and human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH.

It is therefore high time to phase out this substance and to authorize its use only where there are no available alternatives in order to reduce adverse effects of melamine on health and the environment. It is now for the ECHA Member State Committee to decide whether melamine should be included in the authorisation list of REACH.

NOTES:

[Click here](#) to read HEAL's full comments on the inclusion of melamine in the authorisation list SVHC identification proposal for melamine (submitted on 7 May 2024).

- [1] Arcadis EBRC, 2011. Report for European Commission (DG Health and Consumers) - Evaluation of data on flame retardants in consumer products – Final report 17.020200/09/549040
- [2] Page, J. et al. (2023). A new consensus on reconciling fire safety with environmental & health impacts of chemical flame retardants. *Environment International* 173. <https://doi.org/10.1016/j.envint.2023.107782>
- [3] Sathyanarayana, S., et al. (2019). Melamine and cyanuric acid exposure and kidney injury in US children. *Environmental Research*. DOI: 10.1016/j.envres.2018.10.038.
- [4] Zhu, H., Kannan, K. (2019). Melamine and cyanuric acid in foodstuffs from the United States and their implications for human exposure. *Environ Int*. Doi: 10.1016/j.envint.2019.104950.
- [5] Zhu, H., Kannan, K. (2019). Melamine and cyanuric acid in foodstuffs from the United States and their implications for human exposure. *Environ Int*. Doi: 10.1016/j.envint.2019.104950.

View HEAL's comments on the SVHC identification proposal for Melamine: <https://www.env-health.org/why-melamine-should-be-added-to-reachs-blacklist-of-harmful-chemicals/>

Basile Ghesquiere

Senior Policy and Advocacy Officer Health and Chemicals

Health and Environment Alliance (HEAL)

E-mail: basile@env-health.org

Health and Environment Alliance (HEAL)

Avenue des Arts 7/8

1210 Brussels, Belgium

Tel: +32 (0)2 329 00 80

E-mail: info@env-health.org



The Health and Environment Alliance (HEAL) is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution, and raise awareness on the benefits of environmental action for health.

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As an alliance, HEAL brings independent and expert evidence from the health community to EU and global decision-making processes to inspire disease prevention and to promote a toxic-free, low-carbon, fair and healthy future.

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