Submitted via email and regulations.gov

May 14, 2024

Michal Freedhoff, PhD.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
US Environmental Protection Agency

RE: **Agriculture and Green Industry Stakeholder Comments on the 2024 Draft Risk Evaluation for Formaldehyde Prepared Under the Toxic Substances Control Act; Docket ID Number EPA-HQ-OPPT-2023-0613**

Dear AA Freedhoff:

The undersigned organizations appreciate the opportunity to provide comments to the EPA Science Advisory Committee on Chemicals (SACC), the EPA Office of Pollution Prevention and Toxics (OPPT), and the EPA Office of Pesticides Programs (OPP) on the 2024 Draft Risk Evaluation for Formaldehyde (Draft Formaldehyde Risk Evaluation) prepared under the Toxic Substances Control Act (TSCA).[1] When final, the risk evaluation will be used by EPA to inform potential future regulations under TSCA.

The undersigned organizations represent a diverse array of national trade associations across the manufacturing, food, horticulture, and agricultural sectors of the economy, and we are writing to express our concerns regarding the Draft Formaldehyde Risk Evaluation, both with regard to its inconsistency with TSCA requirements and the implications that this proposal, if finalized, would have on U.S. and global food production.

Formaldehyde is a naturally occurring substance composed of carbon, hydrogen, and oxygen. It is already regulated by OSHA[2] which establishes permissible exposure limits for workers and requirements for training, monitoring workplace exposure, and establishes requirements to implement engineering and work practice controls to limit exposure to formaldehyde. Formaldehyde plays a vital role in enhancing the storage, handling, and environmental performance of critical fertilizer inputs essential for U.S. and global food production.

EPA's draft formaldehyde risk evaluation and its reliance on a faulty IRIS assessment are inconsistent with the actual use of formaldehyde within the fertilizer and agricultural sector and not based on sound science as required by TSCA, including the reforms enacted in 2016, which ensure that decisions related to chemical evaluation and regulation are grounded in rigorous scientific methodologies, and consistent with the best available science.

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[1] The Draft Risk Evaluation is available at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-formaldehyde, and supporting information is also available at: https://www.regulations.gov/docket/EPA-HQ-OPT-2023-0613/document.

[2] 29 CFR 1910.1048.

The draft evaluation does not, for example, include the comprehensive evaluation of peer-reviewed studies and international assessments required by TSCA.

Additionally, EPA's reliance on the draft IRIS assessment is a fatal flaw and violates statutory requirements for best available science. Reliance on the draft IRIS assessment has resulted in EPA proposing an overly conservative occupational exposure value and overly conservative exposure assessments.

If EPA finalizes an occupation exposure limit of 11 parts per billion (ppb) for formaldehyde[3], it would have severe economic repercussions and significant impacts on nitrogen availability domestically. EPA correctly acknowledges the challenges with designing an implementable regulatory occupational exposure limit when the draft occupational exposure value is below the concentrations found in half of residential settings across the US.[4] For context, EPA's draft occupational exposure value is approximately 30 times lower than the recently established European Binding Occupational Exposure Limit of 300 ppb.[5] It's critical EPA revise or remove the draft occupational exposure value, to finalize an implementable risk evaluation that does not result in bans or unachievable workplace standards.

We are also concerned with the Occupational Exposure Assessment's inaccurate descriptions of fertilizer manufacturing, product characteristics, and application. Constructive and actionable comments aimed at better informing EPA of fertilizer manufacturing practices and fertilizer use have been submitted to this docket by The Fertilize Institute. It's critical that those submissions are used to revise inaccuracies of the draft evaluation, specifically the occupational exposure scenarios and unreasonable risk determination.

Three distinct nitrogen fertilizers could be directly impacted by this draft evaluation. Urea, a nitrogen fertilizer essential for domestic and global agriculture, relies on formaldehyde-based additives in its production process. Nearly 25% of all nitrogen consumed domestically is urea[6] and almost 50% of nitrogen consumed globally is urea.[7] Any restrictions on formaldehyde could disrupt the U.S. and global fertilizer market, national food security, and impact plant nutrition, and healthy greenspaces. Formaldehyde is also essential in the production of ureaform fertilizers (slow-release solid urea and urea Triazone liquid slow-release fertilizers), which are enhanced-efficiency fertilizers that decrease nitrogen losses via leaching and GHG emissions. The manufacturing conditions of these products chemically ensure, that formaldehyde additives irreversibly react resulting in final products with unique chemical identities that do not contain free formaldehyde.

Furthermore, implementing such restrictions could necessitate costly infrastructure overhauls for both fertilizer production and application processes, imposing financial burdens on stakeholders across the agricultural and green industries. The logistical challenges of transitioning to alternative

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3 EPA, *Draft Human Health Risk Assessment for Formaldehyde,* March 2024, at 142.

4 *Id.*

5 Directive (EU) 2019/983 of the European Parliament and of the Council of 5 June 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

6 2017 Commercial Fertilizers Report.

7 International Fertilizer Association, TFI Calculations.

fertilizers could lead to diminished yields and economic losses for farmers, posing risks to domestic and global food production and to plant nutrition.

Given the critical importance of formaldehyde in fertilizer production and use and its implications for agricultural productivity and food security, we urge the EPA to ensure that the formaldehyde risk evaluation is conducted thoroughly and transparently, in accordance with the TSCA and based on sound science along with consideration of the real-world impacts on stakeholders throughout the agricultural supply chain.

Thank you for considering our concerns. We stand ready to provide any additional information or assistance to support a balanced and science-based approach to chemical regulation under TSCA.

Sincerely,

The Fertilizer Institute

Agricultural Retailers Association

American Farm Bureau Federation

Association of Equipment Manufacturers

Golf Course Superintendents Association of America (GCSAA)

International Fresh Produce Association

National Association of Landscape Professionals

National Association of State Departments of Agriculture

Ohio AgriBusiness Association

RISE (Responsible Industry for a Sound Environment)

The Lawn and Horticultural Products Working Group (LHPWG)

USA Rice

Virginia Agribusiness Council

cc: Jeff Morris PhD (EPA OPPT), Anita Pease (EPA OPP), Anna Lowit PhD (EPA OPPT), and Monique Perron PhD (EPA OPP), Rod Synder (EPA OARA)