

June 18, 2024

Anita Pease, Director, Antimicrobials Division
Office of Pesticide Programs
US Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20560

ATTN: Kendall Ziner, Chemical Review Manager | ziner.kendall@epa.gov

Re: Animal Agriculture Coalition Comments on EPA's Draft Risk Assessment for Formaldehyde for FIFRA Registration Review

Docket ID No. HQ-OPP-2015-0739

Dear Sir or Madam:

On behalf of the leading national trade associations representing the poultry, swine and animal feed industries, we have been following with great interest **EPA's Office of Pesticide Program's review of formaldehyde** under the Federal Fungicide, Insecticide and Rodenticide Act (FIFRA), which is being undertaken as part of the Registration Review process while concurrently undergoing extensive review by the Office of Pollution Prevention and Toxics (OPPT) under the Toxic Substances Control Act (TSCA) risk evaluation process.

In light of this complex and dual-program review of formaldehyde by EPA, our comments today are directed primarily to the Agency's recently issued **Draft Risk Assessment (DRA) document for formaldehyde**, which includes both the draft human health and ecological risk assessment conducted in support of the pesticide active ingredients formaldehyde (PC Code 043001) and paraformaldehyde (PC Code 043002) for **FIFRA Registration Review**. However, we wish to also underscore our position and concerns regarding EPA's authority to impact the U.S. supply chain and the use of animal agriculture applications of formaldehyde under both FIFRA Registration Review and the Agency's ongoing **TSCA risk evaluation process**.

The Animal Agriculture Coalition's comments below summarize and highlight our concerns:

Essential Uses of Formaldehyde in Agricultural Applications

We have communicated to EPA on several occasions during its TSCA review process – as well as to the U.S. Department of Agriculture's Office of Policy and Pest Management – on the important uses of formaldehyde in key agriculture operations. As the agency is aware in its general overview of the industry uses in the April 10, 2024 Draft Risk Assessment and elsewhere, formaldehyde is utilized as an essential tool for the industry in several areas including, among others, as:

- pathogen control in animal feed production;
- sterilization and disinfection in egg hatcheries; and
- disinfection for live production operations on poultry farms and swine operations.

Formaldehyde-based products can be used to inactivate highly contagious viruses, such as African swine fever (ASF) and Highly Pathogenic Avian Influenza (HPAI). Credible estimates indicate that an ASF event in the U.S. could result in an economic loss of nearly \$50 billion and would be catastrophic to the nation's swine industry. In addition, the United States is in year three of an ongoing HPAI outbreak in which over 91,000,000 birds have been lost as part of what is now the most significant animal disease outbreak in the country.

Given the critical importance of these uses, we would like to briefly highlight several issues below as a starting point for discussions with EPA's Office of Pesticide Programs and USDA's Office of Pest Management Policy.

Data Deficiencies

The DRA acknowledges that it was not possible to quantitatively assess the formaldehyde exposures resulting from pesticidal uses across the occupational and other scenarios in OPP's review, and therefore the assessment is largely qualitative. Furthermore, the DRA notes that relevant data were not submitted to the Agency under the 2017 Generic Data-Call-Ins for formaldehyde and therefore data gaps remain. In view of current data gaps and the fact that relevant data were not submitted to the agency, we would like to discuss further OPP's qualitative assessment of the occupational and bystander scenarios and confirm safe current industry work practices based on product labels.

Exposure and Risk

The DRA notes that there is potential for occupational handler, bystander and ecological exposures from formaldehyde applications for poultry and swine confinement and egg hatchery applications, but current uses largely do not appear to pose relevant workforce and bystander risks. We note the following:

Egg Hatcheries: In the evaporative fumigation of eggs use category, applicator exposures are expected to be low risk because product label requirements call for ventilation and related protocols.

Poultry and Swine Operations: Risks associated with farm usage (poultry and swine confinement buildings) that have been based partly on calculating exposures using models are expected to be low risk based on well-established work practices. We would be interested in discussing with OPP certain references in the docket, such as bystander exposure calculations and ecological risks, to provide technical input and a perspective on industry safety on the farm and in key uses.

Feed Truck and Railcar Fumigation: With respect to the other two agricultural use categories of formaldehyde discussed in the document beyond egg hatcheries and housing – feed truck and railcar fumigation – we are not aware of current widespread use of formaldehyde for these disinfection applications. There appear to be effective detergent-based substitutes that are replacing formaldehyde here, and we would be interested in further discussing these uses with OPP.

Incidents

Industry's experience and familiarity with the formaldehyde applications discussed in the DRA align with the DRA's reference to zero reported incidents in recent years associated with the specific agriculture uses under review. The assessment itself describes the current use landscape as follows:

"2.1.3 Human Health Incidents | OPP Incident Data System

There are no individual incidents listed in the OPP Incident Data System for the five-year period from 2/6/2019 to 2/6/2024, when the data system was queried, that relate to the FIFRA registered uses of formaldehyde."

"3.7 Ecological Incidents

The Agency's Incident Data System (IDS) was queried on February 13, 2024, for all records over time. There were no reported ecological incidents for PC Codes 043001, 043002, or the terms formaldehyde, formalin, methylene glycol, or paraformaldehyde."

Again, these incident findings from OPP in the assessment match closely with industry's experience in the use, application and safety patterns, and was not unanticipated given the industry's long use of formaldehyde since agricultural uses were among the first registrations for formaldehyde under the FIFRA program.

Existing Mitigation Measures

With respect to how current mitigation measures are working, since EPA's 2008 formaldehyde re-registration decision, product label changes have been in place. Our knowledge of industry practices, the use of up-to-date SOPs and access to widely available training programs from the associations informs us that exposure and risk are well controlled. We would be interested in providing OPP with further information on the current level of application expertise in the industry. We are aware that mitigation measures in 2008 included certain restrictions and updates and have not been adopted.

Comment Period and Future Discussions

Our organizations have held discussions with members and experts nationwide in recent months on relevant information available for the agricultural applications reviewed and discussed in the DRA. We do not have additional specific data to provide OPP, but we would like to emphasize the industry's strong interest in working with OPP to ensure the agency not only has a sufficient technical basis for decision making on this topic but will recognize the important policy implications and industry impacts of its ongoing re-registration review, including future EPA assessment of ecological impacts and related issues.

In addition to the topics outlined above, we wish to underscore the following:

- **Scientific Expertise and USDA Engagement** – we recommend that OPP work closely with and rely on technical expertise from USDA's Office of Pest Management Policy to

ensure a thorough understanding of the status and impacts of EPA's formaldehyde decisions for agriculture.

- **Impacts from FIFRA and TSCA** – While we are concerned about unjustified and unnecessary potential FIFRA restrictions on current agriculture uses of formaldehyde, we believe that emerging, concurrent TSCA proposed restrictions on manufacturing and use could pose serious disruption and lack of availability of critical formaldehyde-based products long in use to safeguard U.S. food production.
- **Clarification on Non-TSCA Uses of Formaldehyde for Animal Agriculture** – We recently submitted comments to the TSCA evaluation docket for formaldehyde to confirm in the clearest terms possible for industry and the public that these specific downstream uses of formaldehyde-based products – including feed mill applications, egg hatcheries and flock clean out for poultry and swine – are non-TSCA uses, that these activities meet the definition of “pesticide” under FIFRA (7 U.S.C. § 136(u)) and are therefore excluded from the TSCA section 3(2) definition of “chemical substance” when manufactured, processed, or distributed in commerce for these uses. We urge the agency's FIFRA and TSCA offices to coordinate to ensure the status of formaldehyde for agricultural uses is properly communicated.

We appreciate your consideration of these comments. If you have any questions in the meantime, please contact Paul Bredwell at pbredwell@uspoultry.org.

Regards,

U.S. Poultry & Egg Association
American Farm Bureau Federation
American Feed Industry Association
National Chicken Council
National Pork Producers Council
National Turkey Federation
United Egg Producers