

**EPN Comments on the Draft Human Health and Ecological Risk  
Assessment for Formaldehyde and Paraformaldehyde**

Docket No. EPA-HQ-OPP-2015-0739

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The [Environmental Protection Network](https://www.epn.org/) (EPN) harnesses the expertise of more than 650 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

### **Background**

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) mandates that EPA's Office of Pesticide Programs (OPP) revisit the registration status of currently-registered pesticides at least every 15 years. At the end of this review, when making a final registration review decision, EPA will determine whether a pesticide continues to meet the registration standard in FIFRA Section 3(c)(5), including not causing unreasonable adverse effects on the environment (and human health).

The registration review process is lengthy, complex, resource-intensive, and composed of many parts. The Draft Human Health and Ecological Risk Assessments for Formaldehyde and Paraformaldehyde, on which public comment is being solicited at the present time, is just one of those many parts. This current round of registration review for formaldehyde and paraformaldehyde is further complicated by the fact that EPA's Office of Pollution Prevention and Toxics (OPPT) is concurrently evaluating formaldehyde in its Existing Chemicals Review program established under the Toxics Substances Control Act (TSCA, as amended in 2016). That process has reached the stage where OPPT has prepared a draft Risk Evaluation (RE, a rough equivalent of OPP's Draft Human Health and Ecological Risk Assessments for Formaldehyde and Paraformaldehyde). In order to maximize the use of resources, human and otherwise, the two offices collaborated on the development of several support documents that each could use in their respective risk assessment/risk evaluation efforts. Three key documents are the *Draft Human Health Hazard Assessment* (March, 2024), the *Draft Environmental Hazard Assessment* (March, 2024), and the *Draft Chemistry, Fate and Transport Assessment* (March, 2024). Some information in other TSCA support documents also may be of value to OPP although they are focused on TSCA-related issues. OPP and OPPT also agreed to use the 2022 *Draft IRIS Assessment for Formaldehyde-Inhalation* for the selection of the Point of Departure (POD) for chronic, non-cancer effects and the Individual Unit Risk (IUR) for the estimation of cancer risks.

While collaboration between the three offices (OPP, OPPT, and ORD) was laudable, it has, quite frankly, yielded some significant and unfortunate consequences. The TSCA Science Advisory Committee on Chemicals (SACC) held a four-day meeting (May 20-23, 2024) for the purpose of conducting a scientific peer review of OPPT's Draft TSCA Risk Evaluation for Formaldehyde. A broad range of recommendations for changes were made, many of which may be relevant to the OPP draft human health and ecological risk assessments.

## EPN Comments

Unfortunately, it is unlikely that the SACC report will be issued in time for commenters to have adequate time to digest and consider it as they prepare their comments on this draft OPP document. Therefore, at this time, **EPN offers one major, albeit multi-step, recommendation: Suspend any ongoing work on the risk assessments. Wait for and seriously consider the findings and recommendations of the SACC report. Be prepared to do significant revisions. And, lastly, when the revised risk assessments are complete, reissue them for public comment.**

In the meantime, EPN is offering other comments on issues/matters not directly related to those raised during the SACC review which included the derivation of some of the non-cancer hazard values, the mode of action and dose response modeling for the carcinogenic effect and some of the exposure assumptions used in both the human health and environmental risk assessments.

### Comments on OPP's Draft Human Health Risk Assessment for formaldehyde/paraformaldehyde

#### A. EPA's Risk Assessment May Underestimate Potential Exposure

FIFRA makes clear that EPA has a responsibility to consider not only how the labeling on a registered pesticide requires the product to be used, but also how it is used in practice. Specifically, FIFRA Section 3(c)(5)(D) says EPA shall register a pesticide if, among other conclusions, it finds that “when used in accordance with widespread and commonly recognized practice it will not cause unreasonable adverse effects on the environment.” This is a separate requirement from FIFRA Section 3(c)(5)(C), which requires a separate finding that the pesticide “will perform its intended function without unreasonable adverse effects on the environment.” The findings required by the two criteria differ only in how EPA is to consider the way the pesticide is used. Subparagraph (D) expressly requires the agency to examine how users will handle the product, in contrast with subparagraph (C), which implicitly refers to how the labeling directs the user to handle the product. See also FIFRA Section 6(b), which provides that “If it appears that a pesticide . . . when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the EPA Administrator may issue a notice” of the Administrator’s intent to cancel the registration. Thus, EPN thinks that the agency must obtain and evaluate information on the actual usage of pesticide products.

Moreover, EPN asserts that EPA should assess the dietary risks posed by widespread and commonly recognized uses of a pesticide, even if those uses are not lawful. Such an assessment may show the uses cause “unreasonable adverse effects on the environment,” as defined in FIFRA sec. 2(bb). If use of formaldehyde/paraformaldehyde results in residues in food, any food containing such residues would not be “safe” under the Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408(a) because there are no tolerances or tolerance exemptions for such residues. FIFRA Section 2(bb) defines “unreasonable adverse effects on the environment” to mean “(2) any human dietary risk from residues that result from use of a pesticide in or on food inconsistent with the standard under [FFDCA Section 408].” It is important to note this definition does not limit the manner of using a pesticide only to applications that comply with the product’s labeling. Thus, EPA cannot simply dismiss the dietary risks of formaldehyde/paraformaldehyde just because residues would occur only as a result of misuse.

EPN thinks that the draft Human Health Risk Assessment (HHRA) for formaldehyde/paraformaldehyde mistakenly focuses only on how the product would be used if everyone complied with the existing labeling requirements and ignores the potential – even the likelihood – that widespread and commonly recognized practices may be occurring that lead to greater exposure and risk than EPA has estimated. To avoid ignoring such risks, EPA should conduct further assessments, including a dietary risk assessment, if necessary. The following comments identify particular aspects of the HHRA for which EPA needs to consider whether the risks may be greater because users do not comply with all applicable labeling requirements.

1. *EPA may incorrectly assume that fumigation uses do not leave residues in food or feed.*

The Executive Summary states (p. 9):

Fumigation uses are classified as nonfood because the labels require the removal of all food commodities prior to and during treatment (i.e., poultry and swine spaces, citrus packing houses, and mushroom houses, and tools and equipment of mushroom spaces) or because the commodity is not for consumption (i.e., egg hatcheries). There is no expectancy of residues from fumigation uses.

The text is unclear why EPA thinks there “is no expectancy of residues from fumigation uses.” Is this because fumigation does not leave residues or because there should be no food present on which residues from fumigation would be found? If only the latter, EPN questions whether users comply with the requirement to remove “all food prior to and during treatment.” EPN suspects that non-compliance with this difficult and onerous requirement is common, as has been well-documented for other use restrictions on pesticide products’ labeling. Should non-compliance occur, there could be additional exposure from consumption of food that is not accounted for in the dietary risk assessment.

2. *EPA may incorrectly assume that pulp and paper products treated with formaldehyde do not contact food or feed.*

The Executive Summary also states (p. 9):

Pulp and paper, and coating uses were not assessed as end use dietary exposure since the label identifies these use sites for formulation or manufacture and states that EPA Reg No. 8743-17 may not be used in products coming in direct contact with food and/or drinking water until FDA clearances for the formulation use sites (i.e., pulp and paper and coating) have been obtained. Based on the label’s note and lack of use directions, these uses were not considered as indirect dietary exposure, but merely a notification that the uses are prohibited as food uses on end use labels until appropriate FDA food contact clearances are granted.

EPN also questions the agency’s assumption that users will employ formaldehyde only in the production of pulp and paper products that do not directly contact food or drinking water. Pulp and paper products treated with formaldehyde do not necessarily bear labeling conveying to the purchasers the prohibition against using the pulp/paper products in ways that would result in direct contact with food and drinking water. Even if the products carried such labeling, that prohibition is not enforceable under FIFRA. Hence there may be indirect dietary exposures that the agency’s assessment fails to capture.

*3. EPA may wrongly assume that users who apply formaldehyde using catalyzed fumigation wear properly functioning, required personal protective equipment (PPE)*

The exposures of people conducting catalyzed fumigation (Executive Summary, p. 12) may be greater than EPA has assumed; users may not wear the required properly-fitted and properly-functioning full-face respirator with a formaldehyde cartridge (a form of PPE) when mixing or applying the product. EPA's Worker Protection Standard (WPS) contains "fit-testing" provisions designed to ensure that users can safely wear required respirators. However, at best, the WPS covers only some fumigation activities conducted using catalyzed formaldehyde, and the formaldehyde labeling does not require fit-testing. Moreover, EPN thinks that it may be common for users not to wear any respirator or wear only a respirator without a formaldehyde cartridge.

*4. EPA may be underestimating exposure from uses that exclude people from treated areas until airborne concentrations of formaldehyde fall below 0.1 ppm.*

We have concerns about whether users are able to and actually do comply with labeling requirements to monitor the airborne concentration of formaldehyde and to exclude people until the level in air falls below 0.1 ppm. As noted in the Executive Summary (p.14), the Occupational Safety and Health Administration (OSHA) has established a Permissible Exposure Limit (PEL) of 0.75 ppm. We understand the OSHA PEL must be accompanied by technology that can measure the value selected. But it is uncertain in this setting whether this technology is sufficiently sensitive to reliably measure airborne concentrations of formaldehyde below 0.1 ppm. If the technology backstopping the OSHA PEL would not work to support compliance with formaldehyde product labeling, EPA needs to assess the existence and feasibility of technology that would be adequate. And, regardless of whether the OSHA PEL technology is adequate, or some other technology is needed for pesticide purposes, EPA should evaluate whether the users of formaldehyde products are consistently using the necessary technology.

EPN strongly suspects that it may be a widespread and commonly recognized practice not to measure airborne concentrations of formaldehyde, and that users instead use only their judgment about when it would be safe to reenter treated areas. If so, there is a likelihood that, in some cases, people are allowed to enter areas containing formaldehyde residues above 0.1 ppm.

## **B. Exposures from Non-Pesticidal Sources May Not Be Adequately Accounted For**

EPN thinks that as a policy matter EPA should and, as a legal matter, possibly must consider aggregate exposure to both pesticidal and non-pesticidal uses of formaldehyde. From a policy perspective, EPA should not allow pesticidal uses under FIFRA to cause the general population to experience an unsafe aggregate exposure to the chemical from any source. If the risk of aggregate exposure would be deemed unsafe under FIFRA, the agency should not allow pesticidal uses of the chemical to make the risks greater. Further, if the pesticidal use of formaldehyde results in residues in food or feed, the FFDCA requires EPA to establish tolerances for which the agency must consider aggregate exposure to all uses of the chemical – pesticidal and non-pesticidal. As noted above, EPN thinks that both the fumigation use of formaldehyde in food establishments and its use in the production of pulp and paper products are likely to result in residues in food.

The discussion of aggregate exposure (Executive Summary, p. 11) describes situations in which individuals could receive inhalation exposures from pesticidal use through handling multiple household products treated with formaldehyde, e.g., detergent, general purpose cleaner, car interior cleaner, and air freshener. As described in the draft risk assessment, people are also exposed to other non-FIFRA sources of formaldehyde, including many other products commonly found in residential settings but subject to TSCA or other legislative mandates:

Sources of formaldehyde from TSCA conditions of use (COUs) include textiles, foam bedding/seating, semiconductors, resins, glues, composite wood products, paints, coatings, plastics, rubber, construction materials (including insulation and roofing), furniture, toys, and various adhesives and sealants. (p. 29)

In addition, the draft risk assessment notes that there are exposures to formaldehyde regulated under statutes other than FIFRA and TSCA:

Formaldehyde is also regulated by EPA under the Resource Conservation and Recovery Act as a byproduct of hazardous waste material, the Clean Water Act as a hazardous substance in surface water, and the Clean Air Act as a hazardous air pollutant. [The Office of Drinking Water has developed non-regulatory Health Advisories.] In addition to EPA regulated uses, formaldehyde is regulated [under the FFDCA] by the U.S. Food and Drug Administration (FDA) as a material preservative in cosmetic and personal care products, as an animal drug to treat bacterial and fungal infections in fisheries and hatcheries, and as a food additive. (p. 30)

Section 408(b)(2)(D)(vi) of FFDCA provides that, when considering a tolerance for a pesticide chemical, the agency “shall consider ... available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances ...”

EPN agrees with the agency that there are likely to be situations in which individuals would receive concurrent exposures to formaldehyde from both pesticide and non-pesticidal uses, as well as in the form of pollution. Although these other exposures, e.g., from TSCA or FFDCA uses, are not “pesticide chemical residues” under FFDCA sec. 201(q)(2), they clearly are “related substances” and should be included in any aggregate exposure assessment. Therefore, EPN endorses an agency aggregate exposure assessment under the FFDCA that comprehensively addresses all potential non-occupational exposures to formaldehyde and paraformaldehyde.

EPN agrees the American Healthy Home survey II (AHH II) shows that the contribution to overall exposure by pesticidal sources is relatively small compared to non-pesticidal sources. Given the ubiquity of household products that have been treated with formaldehyde, this survey likely captured the contribution of non-pesticidal uses to aggregate exposure. Since, as explained above, the FFDCA requires EPA to aggregate both pesticidal and non-pesticidal sources of formaldehyde/paraformaldehyde, EPN thinks the data from AHH II should be used as the value for aggregate exposure in EPA’s assessment.

EPN has questions, however, whether the approach used by EPA appropriately accounts for the aggregate exposure to formaldehyde/paraformaldehyde from all sources. If the AHH II values were used, the inhalation risks of aggregate exposure to the pesticidal and non-pesticidal uses of formaldehyde and

paraformaldehyde could be ~ 7.5x greater than estimated for the pesticidal uses alone<sup>1</sup>. This would translate to a cancer risk of approximately  $1 \times 10^{-4}$  and an MOE of 1, both far from EPA's target values. Since these risk values are not reported, it is unclear how EPA is considering aggregate exposure.

### **C. Formaldehyde/Paraformaldehyde Registrations Should Be Suspended**

EPA's draft risk assessment reports that registrants were required by a 2017 Generic Data Call-In (GDCI) notice to provide additional data to support the continued registration of their formaldehyde and paraformaldehyde products<sup>2</sup>. The data were due to the agency in 2019, but five years later, EPA states that the following toxicity data requirements from the GDCI have not been satisfied:

- 870.3100 – 90-Day Oral Toxicity (formaldehyde) – Unsatisfied
- 870.3700 – Prenatal Toxicity (formaldehyde) – Unsatisfied
- 870.3800 – Reproductive and Fertility Effects (formaldehyde) – Unsatisfied
- 870.4100 – Chronic Oral Toxicity (formaldehyde) – Unsatisfied
- 870.4200 – Carcinogenicity (formaldehyde) – Unsatisfied
- 870.4300 – Chronic Toxicity/Carcinogenicity (formaldehyde) – Unsatisfied
- 870.6200 – Neurotoxicity (formaldehyde) – Unsatisfied
- 870.7800 – Immunotoxicity (formaldehyde) – Unsatisfied
- 875.1400 – Inhalation Exposure – Indoor (formaldehyde) – Unsatisfied
- 875.2500 – Inhalation Exposure - Post Application (paraformaldehyde) – Unsatisfied
- SF-1218 – Nature of Residue Study (formaldehyde) – Unsatisfied
- 850.4500 – Algal Toxicity (formaldehyde and paraformaldehyde) – Unsatisfied

For several reasons, EPN strongly recommends that EPA take action to suspend all of the registrations under FIFRA sec. 3(c)(2)(B) for failure to fulfill the 2017 GDCI.

- First, the list of data requirements that have not been satisfied covers many studies that normally would be essential for conducting a comprehensive human health risk assessment of products containing a pesticide active ingredient, even those active ingredients with no food uses. These data requirements include toxicity studies of both intermediate and lifetime exposure, as well as studies of many different potential toxic effects – developmental toxicity, reproductive toxicity, carcinogenicity, immunotoxicity, neurotoxicity, and other chronic toxicity. Moreover, the unsatisfied data requirements also include key inhalation exposure studies, as well as a study on the nature of residues in food. These are serious data gaps, and the fact that so many data requirements remain unfilled seven years after the agency issued the data call-in indicates that registrants have no intention of complying with FIFRA. Suspension of the registrations under FIFRA sec. 3(c)(2)(B) appears fully justified. Failure to act may encourage other registrants to ignore their obligations under FIFRA.
- Second, the registrants of both formaldehyde and paraformaldehyde have not implemented any of the risk mitigation measures specified in the agency's 2008 Reregistration Eligibility Decision

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<sup>1</sup> EPN compared the exposure for adult lifetime daily average concentration for the general purpose cleaner use to the median of AHH II distribution.

<sup>2</sup> See Exec. Sum. p. 12.



document<sup>3</sup>. The registrants' failure for nearly 16 (!) years to take the steps necessary to prevent unreasonable adverse effects on the environment further confirms the registrants' unwillingness to comply with FIFRA. EPA should not ignore such blatant disregard by the registrants for their customers' safety.

- Third, in view of the very significant risks posed by the pesticidal uses of formaldehyde and paraformaldehyde, EPN thinks that a suspension proceeding under FIFRA sec. 3(c)(2)(B) would provide some relatively swift risk mitigation. While the risks identified in the draft HHRA may not rise to a level warranting initiation of a suspension action under FIFRA sec. 6, suspending the registrations of products that have failed to meet the data call-in requirements would stop further production of the products and fairly quickly remove products from the market.
- Finally, the usage information summarized in the draft assessment suggests that companies are moving away from using formaldehyde and paraformaldehyde. If so, there probably are already acceptable alternatives, and there would not likely be significant opposition to EPA's regulatory action under FIFRA.

EPN is not convinced by the statement in EPA's draft assessment (p. 32) that it believes that the toxicological data available in the public literature are adequate for the human health risk assessment, and therefore the data are no longer needed "at this time." The agency needs to provide stronger justification for that conclusion. (Technically, it appears the registrants still have not satisfied the toxicology requirements of the GDCI because the registrants have not presented a convincing argument that the public literature on which EPA's assessment rests is an adequate substitute for DCI- required data.) More importantly, EPA has not waived or withdrawn the GDCI's other outstanding requirements for studies of indoor and post-application inhalation exposure, as well as an algal toxicity study; these too remain unsatisfied. Further, it seems that EPA could (and probably should) issue an additional DCI to obtain ecotoxicity data to address the draft assessment's discussion of uncertainties relating to the ecological risks of formaldehyde<sup>4</sup>. Thus, EPN thinks that there are many data gaps in the database needed to assess the safety of formaldehyde for humans and non-target species. Given the registrants' history of non-compliance with 2017 GDCI requirements, EPN recommends EPA proceed with a suspension proceeding under FIFRA sec. 3(c)(2)(B) for failure to satisfy the 2017 GDCI.

#### **D. Exposures From Products That Do Not Specify Application Methods**

The draft risk assessment in section 1.6 notes that the labeling for some products does not specify the method of application. EPA asserts, correctly, that different application methods will result in different levels of exposure and possibly exposures by different routes. Therefore, EPA has directed the registrants to amend the product labeling to specify the method of application.

Given the registrants' apparent unwillingness to respond to EPA directions, EPN recommends that EPA consider two alternative approaches instead of waiting for a response.

- One possible approach for EPA would be to inform the registrant(s) that the agency will consider products misbranded under FIFRA sec. 2(q)(1)(F) unless the labeling specifies an application

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<sup>3</sup> See Table 1 – 5, pp. 27 – 28.

<sup>4</sup> pp. 86 -87

method (and precludes other methods of application). The agency should give the registrant(s) a short, but reasonable time in which to seek to amend the product's labeling. Failure to submit a timely and acceptable application would lead to an enforcement action under FIFRA sec. 12(a)(1)(E).

- A second alternative for EPA is to assess the risks associated with any allowed method of application. Then, EPA should base its proposed regulatory actions on the risks associated with the application method causing the highest exposure, and apply them to all possible alternatives. EPN notes that, under FIFRA sec. 2(ee)(3), a user may employ any method of application that is not expressly prohibited by the labeling. Thus, in practice, EPA should always be looking at the risks from application methods not listed on the labeling.
- E.** EPA should reconsider the exemption of formaldehyde/paraformaldehyde products used only as embalming fluids, and preservatives for specimens in mortuaries, hospitals, and laboratory settings.

The draft risk assessment in section 1.7 notes that a regulation promulgated under the authority of FIFRA sec. 25 in 1975 (and perhaps originally as a legacy rule from an earlier decade) exempts certain pesticidal uses of formaldehyde/paraformaldehyde from all regulatory requirements of FIFRA. Specifically, formaldehyde/paraformaldehyde products used only as embalming fluids, and as preservatives of animal tissues in mortuaries, hospitals, museums, laboratory settings, and institutions of learning are exempt. See 40 CFR 152.25(c)(1),(2). The draft risk assessment did not otherwise address these uses. Further, because these products are “pesticides,” they are not subject to regulation under TSCA or by FDA. We are also not clear about whether OSHA regulates their usage. Thus, we think there is a significant likelihood that the exposures and risks caused by these exempted uses are not regulated by any federal agency.

EPN strongly encourages EPA to assess the risks of the exempted uses. Several EPN volunteers have worked directly with formaldehyde as a preservative in laboratory settings, and they think the exposures they and others experienced from that use pattern are at least as high as the exposures found to pose significant risks by other, non-exempt pesticidal uses and by uses regulated under TSCA. We further think the exposures of people working in mortuaries and hospitals may exceed those of people using formaldehyde in laboratories. If the risks of these exempted uses are as significant as we expect, EPA should undertake rulemaking to rescind the exemption.

### **Comments on Draft Ecological Risk Assessment**

In addition to the comments on the human health risk assessment above, EPN offers the following feedback on the ecological risk assessment. EPN notes that the summary of ecological risks from the registered uses of formaldehyde and paraformaldehyde (Table ES-4 in the Executive Summary) applies only to pesticide uses. While aggregate exposure is generally focused on human health assessments, the contribution of pesticide exposures to aquatic and terrestrial organisms should, if only on a qualitative basis, consider the added impacts of those pesticide exposures on non-pesticidal uses. At a minimum, EPA should consider the impacts of both pesticide uses and non-pesticidal uses in the OPPT assessment.

In many instances, it appears that the exposure impacts from pesticide use will be localized in and around use sites for fumigation and bulb treatment in Washington State. While widespread impacts from registered pesticide uses may not be expected, risks may be greater than what is expected in this assessment in areas where formaldehyde and transformation exposures occur from other non-pesticidal uses.



The identified risks, even those identified as qualitative, should not be discounted in this assessment. While uncertainties may exist from modeling, such estimates were often compromised because of missing toxicity, exposure, and fate data. Any refinements in the ecological risk assessment should be based on studies that fill in that missing data. As noted in the comments on the human health risk assessment above, EPA issued a request for data for a number of outstanding data requirements in the 2008 Reregistration Eligibility Decision. The registrants failed to fulfill those data requirements.

### **Comments on Draft Environmental Hazard Assessment for Formaldehyde**

OPPT's draft TSCA Risk Evaluation for Formaldehyde and OPP's Registration Review Draft Risk Assessment for Formaldehyde and Paraformaldehyde both noted that, since the two programs were assessing formaldehyde on a similar timeline, collaboration on the development of certain of the support documents could maximize the use of scarce human and contract dollar resources and assure capability of use of an agreed-upon single source of scientific information, where appropriate. One such support document was the March 2024 Draft Environmental Hazard Assessment for Formaldehyde jointly developed and published by USEPA, Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT), and the Office of Pesticide Programs (OPP).

All hazard datasets used in the draft hazard assessment were screened using extensive quality control procedures approved by all involved organizations. This screening process included requirements mandated by FIFRA that the quality control procedures be conducted under, and evaluated with, a series of internationally harmonized and scientifically peer-reviewed study protocols. Our review of key datasets and other relevant source material used in the Draft Environmental Hazard Assessment for Formaldehyde finds no basis for potential conflict in handling or interpretation of hazard data between the ecotoxicity assessments presented by OPP and OPPT. There also appears to be no basis for potential conflict in determining categories of toxicity for aquatic and terrestrial organisms in EPA's draft hazard assessment of formaldehyde. Finally, given the wide-ranging and highly interactive review process conducted during the development of the draft formaldehyde hazard assessment, we suspect any problems or conflicts in the handling and interpretation of datasets by OPP, OPPT, or both organizations, are likely to be relatively minor.

We recognize that pesticidal COUs of formaldehyde and paraformaldehyde are closely regulated under FIFRA and they will differ substantially from TSCA conditions of use based on legislative constraints imposed by TSCA, as amended and revised. The differing COUs will clearly affect exposure and risk considerations but should not affect the underlying hazard assessment, which is the focus of this review.

Given the above considerations, we concluded that OPP and OPPT made similar use of hazard datasets in their respective reviews and interpretations of hazards posed by formaldehyde.