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EPN Comments on EPA's Draft Human Health Risk Assessment for the Registration Review of DCPA

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Founded in 2017, the Environmental Protection Network (EPN) harnesses the expertise of more than 550 former 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.

EPN submits the following comments in response to the announcement by EPA of the availability of an updated Occupation and Residential Exposure Assessment (OREA) and a benefits assessment for the pesticide dimethyl tetrachlorophthalate (DCPA). As shown in the OREA and benefits assessment, not only are the risks so extraordinarily high that they cannot practically be made safe, but it appears that most uses of DCPA have low or, at best, only modest benefits. These two assessments convincingly indicate use of DCPA products, as currently labeled, does not meet the statutory standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and that EPA should move swiftly to end continued use of DCPA. Waiting for additional data or the completion of additional analyses does not appear justified. Neither would it be prudent to allow the pesticide to remain on the market during a years-long cancellation proceeding. Thus, as detailed below, EPN strongly encourages EPA to consider taking swift actions to reduce or eliminate the risks of exposure to DCPA.

I. Introduction

On May 31, 2023, EPA announced the availability of two major documents relating to the herbicide DCPA — an estimate of the risks to humans from occupational and residential exposure and an analysis of the benefits of using DCPA. These two documents are summarized in a third EPA document, the "Companion Document to the Occupational and Residential Exposure Assessment of the Registration Review of DCPA" (Companion Document). In addition, the Companion Document recounts elements of DCPA's regulatory history and identifies topics on which EPA seeks public comment.

The first document describes very serious risks to a wide range of population groups from almost all uses of DCPA. Recently received data from a Comparative Thyroid Assay (CTA) indicate that exposure of pregnant animals to DCPA caused changes in thyroid function that, in turn, could cause adverse developmental effects in the offspring. The Companion Document (p.2) offered the following description of the potential seriousness of the thyroid effects in humans:

> In humans, thyroid hormone perturbations such as those observed in the CTA can lead to health problems such as low birth weight, impaired brain development, decreased Intelligence Quotient (IQ), impaired motor skills, and decreased bone deposition.

The Companion Document (p. 7) also observed that "[t]hese effects could occur from maternal exposure occurring within a relatively short time window, are potentially irreversible, and could have long-term

consequences to offspring later in life resulting from the fetal exposure." Further, EPA compared the levels causing harm in the animal studies with human exposures expected from use of DCPA. Those comparisons showed almost every approved use produced dangerous levels of exposure that could affect the offspring of pregnant occupational handlers of DCPA, workers and residents who are exposed to DCPA post-application, as well as bystanders.

The second document, *Assessment of Dimethyl Tetrachloroterephthalate (DCPA) (PC: 078701) Use, Usage, and Benefits*, discusses the value of DCPA use on different agricultural and non-agricultural sites. In broad terms, EPA found that nearly all (~99%) use of DCPA occurs on *Brassica* vegetables (i.e., broccoli, cauliflower, cabbage) and *Alliums* (i.e., onions) (Companion Document, p. 3). The benefits assessment concluded that, for these crops, DCPA was important to the growers who applied the herbicide. But EPA also identified alternatives that could replace DCPA. More importantly, EPA reported that only 14% of broccoli is treated with DCPA, and only a very small minority of growers nationally use DCPA on cauliflower (5%), cabbage (3%), and onions (2%). Id. In short, there appear to be many other growers who can produce these crops successfully without relying on DCPA. Even though DCPA is currently registered for many other uses, "the Agency determined that DCPA has low benefits in its other registered use sites because it is rarely used, because it is not recommended for weed control in those sites, and/or because other registered preemergence herbicides are preferred in these sites" (Companion Document, p. 18).

The agency is seeking public comment on both its OREA risk assessment and its benefits assessment. Further, EPA asks for comments on risk mitigation measures. Finally, considering its significant risks and limited benefits, the agency indicates it is considering cancellation of some or all registrations of DCPA.

II. EPA Should Consider Immediate Regulatory Actions to Reduce the Risks of DCPA Exposure, Including Possible Suspension under FIFRA sec. 6(c)

The Companion Document (p.23) states that:

> Given the nature and magnitude of the potential developmental risks to occupational handlers, workers, and others exposed to residues following application, EPA has been working to determine whether there are feasible mitigation measures that can address these potential risks or whether the cancellation of the registrations of all products containing DCPA is necessary. In addition to comments on the OREA, the Agency is also seeking public input (including from the registrant, users, farmworker advocacy organizations, and the general public) on risk mitigation measures the Agency has not yet considered and on the ramifications of canceling DCPA.

Further, in its press release announcing the availability of the new DCPA risk and benefits assessments, EPA noted there is a "potential that cancellation of this pesticide could take several years to complete."

We agree with EPA's conclusion that the balance of risk and benefits for DCPA raises a very strong likelihood FIFRA requires the cessation of all use of the pesticide. For several reasons, however, we feel that the situation demands regulatory action more aggressive than cancellation. First, EPA's analyses appear very sound, and it is quite unlikely new information will contradict the conclusions in the OREA and benefits documents. Second, in the experience of several EPN volunteers who worked in EPA on pesticide regulation, the predicted levels of DCPA risk are much, much greater than normally seen for pesticides. In other risk assessments, occupational and residential Margins of Exposure (MOEs) are rarely below EPA's

target by more than a factor of 2. In contrast, the DCPA MOEs are 10 to 1,500 times lower than EPA's customary target values (Companion Document, p. 23). Third, given the amount of exposure reduction needed to reach the target level, and given EPA already requires a combination of engineering controls and personal protective equipment, it seems impossible to think there is any practical way to modify DCPA's use sufficiently to meet the FIFRA standard. Fourth, the type of harm resulting from such exposure is exceptionally concerning; developmental effects can last an entire lifetime, be severe in nature, and significantly compromise quality of life.

Waiting years to fully redress such serious risks through a cancellation proceeding would simply seem an insufficient response. Fortunately, FIFRA provides a procedure that would mitigate risks more quickly – suspension under section 6(c). The existing analyses seem sufficient to support the statutory findings required to suspend the registration of a pesticide – that an "imminent hazard" exists. An "imminent hazard" is defined as "a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment." FIFRA sec. 2(*l*). Although EPA should not lightly institute a suspension proceeding under FIFRA sec. 6(c)(1) (or emergency suspension under sec. 6(c)(3)), EPN recommends that the agency consider such a course seriously.

Given the seriousness of the potential risks posed from further exposures to DCPA, we recommend that any further sale, use, or distribution of any existing stocks of products in the hands of registrants, distributors, or users be prohibited.

In addition, EPN identifies in the next three sections of these comments other regulatory actions that EPA could take. Each of the actions would involve less administrative effort than a suspension proceeding and would address the most serious risks posed by DCPA use. In addition, some of the actions could operate in a manner that affected more uses than those that triggered the action.

III. Enforcement of EPA's 2005 Order regarding Residential Turf and Ornamental Use Labeling of DCPA Products

The Companion Document (p. 4) mentions that:

> In 2005, a use termination order for DCPA registration prohibited formulations of DCPA manufacturing use product into end-use products for use on residential sites (both turf and ornamentals) and prohibited the use of DCPA end-use products on residential turf and ornamentals, but it does not appear that the labeling for all these products includes conforming prohibitions. [footnote omitted].

While the Companion Document does not further identify the type of order that imposed the restriction, we assume that the registrant's failure to comply with the order constitutes a violation of FIFRA sec. 12(a)(2)(J) or (K).[1] If so, we encourage EPA immediately to issue a Stop Sale, Use, and Removal Order (SSURO) under FIFRA sec. 13 to any registrant of a product who has not made the required labeling

[1] If failure to comply with the "order" does not violate FIFRA sec. 12, we assume that it reflects a determination that the absence of the specified labeling text would render the product "misbranded" under FIFRA sec. 2(q)(1)(E), (F), or (G). That in turn, would mean that EPA could take enforcement action under FIFRA secs. 12(a)(1)(E) and 13.

changes and to impose significant penalties on the registrant for sale and distribution on violative products.

The need for this action is high. According to EPA's OREA risk estimates, there are extremely high developmental risks from exposure of people who apply DCPA on turf and nursery ornamentals (Companion Document, Table 2, pp. 9–12). In addition, there are also very high developmental risks from exposure of both people when they enter a site treated with DCPA and to people who enter a site onto which DCPA has drifted during application (Companion Document, Table 4, p. 17 and Table 5, pp. 17–18). Finally, it appears AMVAC, the sole registrant, has ignored the order for over 15 years.

IV. Use of FIFRA sec. 3(c)(2)(B) Authority to Require Missing Data and to Suspend Noncompliant Product Registrations

In the description of the regulatory history for DCPA, the Companion Document (p. 3) mentions that "the registrant has not submitted all required data. Accordingly, all data requirements have not been satisfied. The Agency . . . awaits ecological fate and toxicology data from the registrant as required by GDCI (a 2013 Generic Data Call-In)." The Companion Document (p. 4) also mentions that in April 2022, EPA issued a Notice of Intent to Suspend (NOITS) DCPA registrations for AMVAC's failure "to take appropriate steps to satisfy numerous GDCI data requirements." Together, these two statements suggest that, nearly a decade later, AMVAC still has not fully complied with the GCDI and that, even though it has fulfilled the GDCI requirement to provide a Comparative Thyroid Assay, AMVAC remains out of compliance with many other GDCI requirements. If correct and if EPA has not already finalized the 2022 NOITS, we strongly recommend that EPA finalize the NOITS and suspend all sale and distribution of DCPA manufacturing-use products until the registrant provides <u>all</u> required data or the agency moves to terminate registration altogether.

V. Actions to Prohibit DCPA "Handgun" Application

We strongly urge the agency to take action to prohibit the use of a mechanically pressurized "handgun" to apply DCPA liquid or wettable powder end-use formulations. People who apply DCPA using such a handgun experience some of the highest risks identified in the OREA analysis. The MOEs for handgun applications of liquids are: Golf course – 1.4; Nursery – 0.77; and Field Crop, typical – 0.065. The MOEs for handgun applications of wettable powders are: Golf course – 0.77; Nursery – 0.19; and Field Crop, typical – 0.065. When the MOE for an application is smaller than 0.1, the OREA analysis predicts that applicators using handguns will receive a level of DCPA exposure that exceeds the amount that caused adverse developmental effects in test animals. In other words, if pregnant women use a handgun to apply DCPA on typical field crops, the expected exposures seem very likely to harm their unborn children. Moreover, it appears that these adverse effects could result from relatively short-term exposures. Therefore, handgun application of DCPA over a season, or possibly even a single time, may be causing serious harm to children of pregnant applicators. Such a dire risk warrants immediate action.

We understand that the labeling of DCPA products does not specifically mention application using handguns. Nonetheless, EPA apparently has information indicating that, although uncommon, this application method is occurring because it "is not prohibited by current labeling" (Companion Document, p. 9). Ordinarily, it would be illegal to use a pesticide in a manner not specifically allowed by the product's labeling. See FIFRA sec. 12(a)(2)(G). Applying DCPA with a handgun, however, does not constitute misuse because of the flexibility permitted by FIFRA sec. 2(ee)(3). That section provides:

> The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include . . . (3) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling.

To directly address the risks to fetuses posed by their mothers' use of handgun applications, we recommend that EPA inform AMVAC that its end-use products' labeling must expressly limit the application methods to those specified on the labeling. EPA should base this direction on an express determination that such an instruction is necessary for the labeling to be adequate to protect public health. The agency should give AMVAC a reasonable period of time to modify its products' labeling after which the products would be deemed misbranded and subject to enforcement action.

These comments were developed by Penelope Fenner-Crisp, Jack Housenger, and William Jordan on behalf of EPN.