RESPONDENT'S EXHIBIT 2

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DCPA Summary Document
Registration Review: Initial Docket
June 2011

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Case # 0270

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Date: 6/23/11

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This Preliminary Work Plan (PWP) and Fact Sheet summarize the Environmental Protection Agency's current position based on the following documents:

"Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment of Dimethyl 2,3,5,6-Tetrachloroterephthalate (DCPA)," May 31, 2011.

"DCPA. (Chlorthal Dimethyl). Human Health Assessment Scoping Document in Support of Registration Review," March 27, 2011.

"BEAD Chemical Profile for Registration Review: DCPA (078701)," January 10, 2011.

"DCPA-Chlorthal-dimethyl (078701), Screening Level Usage Analysis (SLUA)," August 18, 2010.

"Appendix A: Food/Feed & Non-Food/Non-Feed Uses [of DCPA] Considered in Registration Review Work Planning," December 1, 2010.

These documents are posted in the docket EPA-HQ-OPP-2011-0374 at www.regulations.gov.

I. PRELIMINARY WORK PLAN—DCPA

Introduction

The Food Quality Protection Act of 1996 mandated a registration review program**.** All pesticides distributed or sold in the United States (U.S.) generally must be registered by the Environmental Protection Agency (EPA or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at www.epa.gov/oppsrrd1/registration_review/.

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of DCPA.

DCPA is a chlorinated benzoic acid or phthalate pre-emergence herbicide. It is registered for use on a variety of crop and non-crop sites, including corn, soybean, cole crops, cucurbits, peppers, herbs, and non-residential turf and ornamentals. DCPA is used to control annual grasses and certain annual broadleaf weeds. It was first registered in the U.S. in 1958. A Reregistration Eligibility Decision was issued for DCPA in 1998[1], and tolerances were reassessed in 2005[2]. The presence in technical-grade DCPA of one dioxin congener and hexachlorobenzene (HCB) , both manufacturing impurities of toxicological significance has been documented in earlier Agency decisions and documents and in the public literature.

Anticipated Risk Assessment and Data Needs

The Agency expects to require data for use in updating and refining the ecological risk assessment for DCPA (including an endangered species risk assessment) and the human health risk assessment.

[1] http://www.epa.gov/oppsrrd1/REDs/0270red.pdf
[2] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2005-0024-0005

Ecological risk

- The most recent ecological risk assessment for DCPA was conducted in 2009[3]. The assessment was prompted by a lawsuit brought by the Center for Biological Diversity (CBD), filed in April 2002 (CBD v. EPA, Case No.: 02-1580-JSW [JL])[4]. The CBD alleged that the Agency failed to comply with the Endangered Species Act by not ensuring that the registration of 66 pesticide active ingredients, including DCPA, would not affect the California red-legged frog (CRFL), a federally-listed threatened species.

- On February 20, 2009, the Agency submitted a risk assessment and effects determination to the U.S. Fish and Wildlife Service (FWS) for the CRLF and its designated critical habitat relative to the use of DCPA in California. The Agency also requested the initiation of formal consultation with FWS. A "likely to adversely affect" determination was made for all uses of DCPA. The determination is supported by the finding of direct effects on the terrestrial phase CRLF from exposure to the parent DCPA and product impurities, direct effects on the aquatic phase CRLF resulting from exposure to DCPA and the degradate tetrachloroterephthalic acid (TPA), indirect effects to the aquatic and terrestrial prey bases (plants and animals), and indirect effects to the aquatic and terrestrial habitat (plants). Modification to designated critical habitat is expected, primarily due to changes in the food sources for juvenile and adult CRLFs, and effects to terrestrial and aquatic plants of designated critical habitat are also expected. The Agency will consider any Reasonable and Prudent Alternatives and Measures that may be included in FWS's future responses to the Agency's request for consultation on the CRLF.

- The most recent nation-wide ecological risk assessment was conducted in 1998, in support of the DCPA Reregistration Eligibility Decision (RED). The non-turf uses of DCPA were determined to be eligible for reregistration. The Agency was unable to make an eligibility decision for DCPA used on turf because of acute and chronic risk concerns for a range of species. The turf decision was deferred until a benefits assessment was conducted, but the subsequent voluntary cancellation of residential uses obviated the need for that assessment. The RED specified certain risk management measures to reduce the ecological risks in the interim. These measures included:
    - Establishing certified upper limits for the concentrations of toxicologically significant impurities in DCPA products.
    - Instituting production caps for the period 1997 to 2000.
    - Eliminating fall turf uses and reducing the maximum application rate on turf.
    - Placing surface water, groundwater, and spray drift advisories on product labels.

  Not all current DCPA registrations and labels reflect these risk management measures, or with the use terminations requested by the technical registrant and subsequently accepted by the Agency. The Agency will be working with the registrants to bring the labels into compliance in advance of initiating the registration review risk assessments.

[3] http://www.epa.gov/oppfead1/endanger/litstatus/effects/redleg-frog/index.html#dcpa
[4] http://www.epa.gov/espp/litstatus/redleg-frog/rlf.htm

- On January 19, 2011, the CBD and the Pesticide Action Network North America filed another lawsuit against EPA in the U.S. District Court for the Northern District of California. The plaintiffs allege that EPA failed to undertake consultation with the National Marine Fisheries Service (NMFS) and FWS regarding the effects of over 350 pesticides, including DCPA, on over 200 listed species throughout the country (CBD, et al. v. EPA, et al., No. C 11-00293 (N.D.Cal.).

- Although the Agency has completed a species-specific determination for the CRLF, an ecological risk assessment that supports a complete endangered species determination for DCPA has not been conducted. The ecological risk assessment planned during registration review will allow the Agency to determine whether DCPA's use has "no effect" or "may affect" federally listed threatened or endangered species or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine fisheries Service (the Services), as appropriate.

For use in conducting a complete ecological risk assessment, including a full endangered species assessment, for DCPA, the Agency anticipates requiring the following data on the parent compound:

- Guideline # 835.4300 Aerobic aquatic metabolism
- Guideline # 850.1010 Acute toxicity, freshwater invertebrates
- Guideline # 850.1025 Acute toxicity, oyster (shell deposition)
- Guideline # 850.1035 Acute toxicity, mysid
- Guideline # 850.1075 Acute toxicity, freshwater and estuarine/marine fish
- Guideline # 850.1300 Aquatic invertebrate life-cycle, freshwater
- Guideline # 850.1350 Aquatic invertebrate life-cycle estuarine/marine
- Guideline # 850.1400 Fish early life stage freshwater and estuarine/marine
- Guideline # 850.1735 Whole sediment, acute invertebrates, freshwater
- Guideline # 850.1740 Whole sediment, acute invertebrates, marine
- Guideline # 850.2100 Acute avian oral, passerine species
- Guideline # 850.4100 & 4150 Vegetative vigor and seedling emergence, Tier II
- Guideline # 850.4400 Aquatic vascular plant growth-*Lemna spp.* Tier II
- Guideline # 850.5400 Algal toxicity test, Tier I/II
- Special Study: Avian inhalation toxicity, passerine species[5]

The Agency anticipates requiring the following data on TPA, the major metabolite of DCPA for use in conducting a complete ecological risk assessment, including an endangered species assessment, for DCPA:

- Guideline # 835.1230/1240 Adsorption/desorption and leaching
- Guideline # 835.1730 Fish bioconcentration
- Guideline # 835.2120 Hydrolysis

[5] The anticipated Data Call-In Notice is expected to require that the test species be the most sensitive avian species as shown by avian acute oral studies (i.e, bobwhite quail).

- Guideline # 835.2240 Aqueous photolysis
- Guideline # 835.2410 Soil photolysis
- Guideline # 835.4100 Aerobic soil metabolism
- Guideline # 835.4200 Anaerobic soil metabolism
- Guideline # 835.4300 Aerobic aquatic metabolism
- Guideline # 835.4400 Anaerobic aquatic metabolism
- Guideline # 835.6100 Terrestrial field dissipation
- Guideline # 850.1010 Acute toxicity, freshwater invertebrates
- Guideline # 850.1025 Acute toxicity, oyster (shell deposition)
- Guideline # 850.1035 Acute toxicity, mysid
- Guideline # 850.1075 Acute toxicity, freshwater and estuarine/marine fish
- Guideline # 850.1300 Aquatic invertebrate life-cycle, freshwater
- Guideline # 850.1350 Aquatic invertebrate life-cycle estuarine/marine
- Guideline # 850.1400 Fish early life stage freshwater and estuarine/marine
- Guideline # 850.1735 Whole sediment, acute invertebrates, freshwater
- Guideline # 850.1740 Whole sediment, acute invertebrates, marine
- Guideline # 850.2100 Acute avian oral, passerine species
- Guideline # 850.4150 Seedling emergence, Tier II
- Guideline # 850.4400 Aquatic vascular plant growth-*Lemna spp.* Tiers II
- Guideline # 850.5400 Algal toxicity test, Tier I/II

- The Agency anticipates assessing the toxic impurities associated with DCPA for the registration review. A large database already exists for these compounds and the Agency is not planning at this time to require any new compound-specific data for the impurities that will be involved in the assessment.

- Please refer to the document "Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment of Dimethyl 2,3,5,6-Tetrachloroterephthalate (DCPA)," May 31, 2011, for a more detailed discussion of anticipated ecological risk assessment and data needs.

Human Health Risk

- The most recent complete human health risk assessment (dietary, drinking water, occupational, and residential) for DCPA was conducted in support of the 1998 RED. An aggregate risk assessment was conducted in 2004 to support the tolerance reassessment of DCPA. Most recently, EPA conducted a screening level literature search for relevant studies.

- Tolerances established in 40 CFR § 180.185 for residues of DCPA address both crops that are treated and inadvertent residues from off-target movement of DCPA and carry-over of residues to rotational crops. The metabolites monomethyltetrachloroterephthalate (MTP) and TPA are included in the tolerance expression for DCPA. Codex has not established maximum residue limits (MRLs), but MRLs are established in Canada for several commodities.

The Agency anticipates requiring the following data for use in conducting a human health risk assessment (with dietary, water, and occupational components) for DCPA:

- Guideline # 860.1300: Nature of the residue: poultry
- Guideline # 860.1340: Residue analytical method: livestock commodities
- Guideline # 860.1380: Storage stability
- Guideline # 860:1480: Meat/milk/poultry/eggs: ruminants
- Guideline # 860.1900: Field accumulation in rotational crops
- Guideline # 870.7800: Immunotoxicity
- Guideline # 870.3465: Subchronic inhalation toxicity study—28 day
- Guideline # 870.6200: Neurotoxicity battery (acute and subchronic studies)
- Special Study: Comparative thyroid study

- Adequate toxicity data exist for the manufacturing impurities in DCPA and the Agency does not anticipate requiring any additional data on the impurities. Human health risks associated with the manufacturing impurities in DCPA were assessed at the time of the RED. The Agency will work with the registrant of technical grade DCPA to establish if and how levels of these impurities have changed since the previous assessment. Depending in part on any such changes, the Agency will determine whether or not to conduct a new assessment of the impurities in DCPA.

- Please refer to the document "DCPA. (Chlorthal Dimethyl). Human Health Assessment Scoping Document in Support of Registration Review," March 27, 2011, for a more detailed discussion of human health risk estimates and anticipated human health risk assessment and data needs.

Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its reregistration decision, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), DCPA is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a

chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. DCPA was included on that list and was issued an order to conduct the Tier 1 testing on October 29, 2009. Once all required Tier 1 and Tier 2 data have been received and reviewed, the endpoints and safety factors used for risk assessment purposes will be examined and a new risk assessment performed if necessary. For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

Timeline

The projected timeline for the DCPA registration review appears in the table below.

Projected DCPA Registration Review Timeline

Activities	Estimated Date
Opening the Docket	
Open Docket and Begin Public Comment Period	2011 – June
Close Public Comment Period	2011 – August
Case Development	
Final Work Plan	2011 – November
Issue DCI	2012 – July – Sept.
Data Submission	2014 – July – Sept.
Open Public Comment Period for Draft Risk Assessments	2016 – Jan. – March
Close Public Comment Period	2016 – April – June
Registration Review Decision	
Open Public Comment Period for Proposed Registration Review Decision	2016 – July – Sept.
Close Public Comment Period	2016 – Oct. – Dec.
Registration Review Decision and Begin Post-Decision Follow-up	2017
Total (years)	6

Guidance for Commenters; Solicitation of Information

The public is invited to comment on EPA's preliminary work plan and rationale. The Agency will carefully consider all comments, and any additional information that is provided in a timely manner, prior to issuing a final work plan for the DCPA registration review case.

Trade Irritants

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Water Quality

DCPA is identified as a cause of impairment, as defined under section 303(d) of the Clean Water Act, for one water body in California[6]. In addition, a Total Maximum Daily Load (TMDL) has been developed for DCPA in the same watershed[7]. More information on impaired water bodies and TMDLs can be found at the Agency's website[8]. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process*[9] in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to DCPA compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure, compared to the general population.

Additional Information

Stakeholders are asked to provide additional information that will assist the Agency in refining its risk assessments for DCPA, including any species-specific ecological effects determinations. The Agency particularly is interested in receiving the following information:

1. DCPA human, domestic animal, or ecological incidents not already reported to the Agency.

2. Information on or confirmation of the following use parameters for each registered use of DCPA:

Sites of application
Formulation type

[6] http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885
[7] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES
[8] http://www.epa.gov/owow/tmdl/
[9] http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm

Application methods and equipment
Maximum application rates expressed as mass ai per unit area, typical application rates
Factors affecting application rate, *e.g.*, weather, disease pressure, fresh/processed commodity
Application intervals, frequency of application, factors affecting frequency of application
Application timing (date of first application and typical application intervals) by use – national, state, and county
Maximum number of applications per year (or season, as appropriate)

3. Use or potential use distribution (*e.g.*, geographical distribution of uses, areas of greatest use).

4. General use history.

5. Median and 90th percentile reported use rates from usage data – national/state/county.

6. Sub-county use site data.

7. Usage data for non-agricultural uses (e.g., golf course turf, combination herbicide/fertilizer products, nursery stock, non-residential ornamentals/shade trees/ground covers, sod farm turf.)

8. Directly acquired county-level usage data (not derived from state level data).
Maximum reported use rate from usage data – county
Median and 90th percentile number of applications – county
Total pounds per year – county
Year the pesticide was last used in the county/sub-county area (if no longer used), and/or
Years in which the pesticide was applied in the county/sub-county area.

9. State, local or other geographic use restrictions.

10. Any adverse effects in honey bees associated with the use of DCPA products.

11. Co-formulation or tank-mixing of DCPA and other pesticides—is DCPA typically applied with other pesticides?

Next Steps

After the 60-day comment period on this PWP closes, the Agency will review and respond to comments that have been submitted in a timely manner, and then issue a Final Work Plan (FWP) for this pesticide. As indicated above, the Agency expects to issue the FWP for DCPA in November 2011.

II. FACT SHEET: DCPA Registration Review

Background Information for DCPA

- Registration review case number: 0270
- Pesticide Chemical (PC) Code: 078701
- Chemical Abstracts Service (CAS) number: 1861-32-1
- Other names: dacthal, chlorthal dimethyl, and dimethyl 2,3,5,6-tetrachloroterephthalate
- Chemical Class: chlorinated benzoic acid or phthalate
- DCPA was first registered in the U.S. in 1958.
- A RED was completed in 1998.
- In 2005, the Agency reassessed DCPA tolerances; at the same time, the residential turf and ornamental uses and several other uses of DCPA were terminated at the request of the registrant[10].
- There are two technical-grade DCPA registrations, both held by Amvac. Three registrants hold a total of eight Section 3 end-use product registrations.
- There is one active FIFRA Special Local Need 24(c) product registered with the Agency, from the state of Wisconsin, for the use of DCPA on ginseng.

Contact information

- Pesticide Re-evaluation Division: Jill Bloom; bloom.jill@epa.gov
- Registration Division: Kay Montague; montague.kathryn@epa.gov

Use & Usage Information

The Agency has conducted a Screening Level Usage Analysis (SLUA) for DCPA and characterized the use parameters for DCPA. The Chemical Profile, SLUA, and "Appendix A" (as the listing of use parameters is known) are available in the DCPA registration review docket.

- DCPA is a pre-emergence herbicide registered for use on a variety of crop and non-crop sites, including corn, soybeans, cole crops, cucurbits, onions, tomatoes, peppers, herbs, and non-residential turf and ornamentals. DCPA is used to control annual grasses and certain annual broadleaf weeds.
- Between 1998 and 2008, agricultural usage of DCPA averaged approximately 500,000 pounds on 100,000 acres.
- In 2000, approximately 1 million pounds of DCPA were used by consumers in lawn herbicides and an additional 1.8 million pounds were used in the form of herbicide/fertilizer combination products. Since that time, usage in this sector is believed to have declined as labels come into compliance with the voluntary use terminations referenced above.
- End-use products are flowable concentrates, wettable powders, and granulars.
- DCPA is typically applied at a rate of 4-6 lbs ai per acre. Products may be applied via broadcast spray (aerial or ground), chemigation, band treatment, and soil injection.

[10] http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2005-0024-0005

Application equipment includes broadcast sprayers, spreaders, shaker-cans, sprinkler irrigation, and soil injection equipment.

- The yearly maximum application amounts, maximum number of applications, and minimum retreatment intervals are not specified on all DCPA product labels. The Agency is working with the registrants to correct these deficiencies.

Recent and Related Actions

- No recent activity; no actions pending.

Manufacturing Impurities of Toxicological Concern

The Agency is aware that the manufacturing process for DCPA technical-grade material results in the formation of impurities of toxicological significance. The Agency is working with the registrant to assure that the presence of these impurities is accurately characterized in the Confidential Statement of Formula for the technical material.

Additionally, the Agency is working with the registrant to implement previously specified labeling that notes the presence of the toxic impurities in the technical formulation.

Ecological Risk Assessment Status

Refer to the supporting documents, including "Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment of Dimethyl 2,3,5,6-Tetrachloroterephthalate (DCPA)," May 31, 2011, for a discussion of the most current ecological risk and endangered species assessments.

- DCPA is relatively persistent in the environment and has a tendency to bioaccumulate in aquatic organisms.
- The metabolite TPA forms at high levels relative to parent chemical in the environment. TPA is expected to be more mobile than DCPA and be somewhat persistent in the environment. Toxicology data are available for mammals only.
- Monitoring data indicate widespread occurrence of DCPA in surface water, groundwater, drinking water, and air. DCPA and TPA are two of the most commonly found pesticides/pesticide metabolites found in water samples.
- It does not appear that acute exposure to DCPA results in mortality in freshwater or estuarine/marine fish at the limit of solubility (0.5 ppm). Chronic effects for freshwater and estuarine/marine fish are uncertain because no chronic data have been submitted.
- Definitive DCPA toxicity test data for aquatic plants are lacking because of the limited solubility of DCPA in water. Based on the number of target species and the adverse effects observed in aquatic plant toxicity studies, effects on aquatic plants can be expected at or below the limit of solubility for DCPA in water.
- The results of reproductive toxicity tests in birds are not reliable for use in a quantitative risk assessment, in part because the overall health of the test animals was compromised at the outset of testing.

- Available data from testing in rats indicate that the adverse effects associated with TPA are much milder than those for the parent and tend to occur at doses that are lower by approximately an order of magnitude. No corresponding data are available for the metabolite MTP.
- Available scientific literature will be used characterize the toxicity and risk associated with the presence of manufacturing impurities in DCPA.

Human Health Risk Assessment Status

Past DCPA risk assessments relied in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their dermal and inhalation exposure. Many such studies, involving exposure to many different pesticides, comprise generic pesticide exposure databases such as the Pesticide Handlers Exposure Database (PHED) and the Agricultural Reentry Task Force (ARTF) Database. EPA has reviewed all the studies supporting these multi-pesticide generic exposure databases, and has found no clear and convincing evidence that the conduct of any of them was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted. All applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied, and there is no regulatory barrier to continued reliance on these studies.

Please refer to the support documents, including "DCPA. (Chlorthal Dimethyl). Human Health Assessment Scoping Document in Support of Registration Review," March 27, 2011, for a discussion of the status of the human health risk assessment. The health risk assessment conducted for the 1998 RED resulted in the following conclusions:

- In long term studies with DCPA, treated animals manifested thyroid toxicity as shown by decreased levels of thyroid hormone, microscopic thyroid changes, and increased thyroid weight. Effects on the liver were also manifested, as increased liver weight, elevated liver enzyme activity, increased cholesterol, and liver hypertrophy. It is believed that the liver effects are precursor events to the thyroid effects, with increased metabolism of thyroid hormone by the liver resulting in a compensatory stimulation of the thyroid. Effects on the kidney have also been observed.
- There were no mutagenicity concerns for DCPA, but thyroid follicular cell adenomas/ carcinomas, hepatocellular adenomas/carcinomas, and hepatocholangiocarcinomas were found in exposed rats; hepatic adenomas were found in exposed mice. DCPA is classified a Group C (possible human) carcinogen.
- Post-application risks for children to DCPA from residential applications were at a level typically associated with risks of concern. Although the RED indicated that the Agency was deferring its decision on the eligibility of the residential uses of DCPA for reregistration, these risks were addressed with the subsequent voluntary termination of residential uses of DCPA.
- Occupational risk estimates for DCPA were reduced to below the level of concern with label requirements for personal protective equipment (handlers wearing baseline clothing + gloves and dust/mist respirators) and with a Restricted-Entry Interval of 12 hours.
- The Agency concluded that DCPA does not pose a significant chronic or carcinogenic dietary risk.

Toxic impurities

- Toxic impurities reported to be present in technical-grade DCPA product were assessed at the time of the RED.
- Dietary risk estimates for the toxic impurities in DCPA were below the level of concern.
- Post-application risks for children to the toxic impurities in DCPA from residential uses were at a level typically associated with risks of concern. These risks were addressed after the RED was issued by the voluntary termination of residential uses of DCPA.
- Occupational risk estimates for the impurities were below the Agency's level of concern.

Cumulative assessment

- The Agency has not determined whether DCPA shares a common mechanism of toxicity with other chemical substances. If, in the future, the Agency determines that new information on DCPA is available that could potentially impact a cumulative risk assessment and result in a risk of concern, the Agency will revisit the need for a cumulative risk assessment.

Incident Reports

- The OPP Incident Data System (IDS) contains few incident reports citing a connection to the use of DCPA. Based on the low frequency and severity of incident cases, there does not appear to be a concern at this time that would warrant further investigation of incidents involving DCPA. The Agency will continue to monitor the incident information and, if a concern is triggered, additional analysis will be included in the risk assessment.
- The Ecological Incident Information System (EIIS, version 2.1) maintained by the Office of Pesticide Programs, and the Avian Monitoring Information System (AIMS), maintained by the American Bird Conservancy, document two incidents in which DCPA was applied in close proximity to the area in which the incidents occurred or residues of DCPA were found in affected animals. The incidents involved fish and bird kills.

Tolerances and International Harmonization

- Tolerances for DCPA are located at 40 CFR § 180.185[11].
- There are no Codex MRLs for DCPA. Canada has established MRLs for commodities from treated crops[12]. The Canadian MRLs are the same as the U.S. tolerances for the commodities they have in common, with the exception of values for collards and kale (2 ppm MRL, 5 ppm tolerance).
- During registration review, the Agency will work to harmonize tolerances and MRLs as

[11] http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?type=simple;c=ecfr;cc=ecfr;sid=701e5927a66383fe112f5dff728d547d;idno=40;region=DIV1;q1=DCPA;rgn=div8;view=text;node=40%3A23.0.1.1.28.3.19.40

[12] http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_prvd2008-18/index-eng.php

appropriate. In addition, the residue definition will be modified in accordance with current policy.

Labels

- Images of the labels of registered DCPA products can be obtained from the Pesticide Product Label System (PPLS) website at http://oaspub.epa.gov/pestlabl/ppls.home.