RESPONDENT'S EXHIBIT 5

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DCPA Final Work Plan
Registration Review

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Case # 0270

Approved By:

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Date

Introduction

This is the Environmental Protection Agency's (EPA's) *Final Work Plan* for the registration review of DCPA. This work plan includes the expected registration review timeline. No public comments were received concerning the ***Preliminary Work Plan*** in the ***Summary Document***, which was posted in the DCPA registration review docket (EPA-HQ-OPP-2011-0374. The ***Summary Document*** provided information on what EPA knows about the pesticide and what additional risk analyses and data or information the Agency believes are needed to make a registration review decision.

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. Changes in science, public policy, and pesticide use practices will occur over time. 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. The public phase of registration review begins when the initial docket is opened for each case. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

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.

Comments Received on Preliminary Work Plan

No comments were received during the 60-day public comment period on the planned human health and ecological risk assessments discussed in the ***Preliminary Work Plan***. EPA specifically solicited comments on several specific topics, but no information was received from any source during the comment period that concerned these topics.

Anticipated Risk Assessment and Data Needs

The Agency anticipates requiring data considered necessary to update and refine comprehensive assessments of the human health and ecological risks associated with the use of DCPA. An endangered species risk assessment will be conducted as part of the updated and refined

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

ecological risk assessment. Below is a summary of the issues relevant to the registration review of DCPA and the data the Agency anticipates requiring.

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.

[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

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.

- 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 # 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 # 850.2300 Avian reproduction
- Guideline # 850.4225 & 4250 Seedling emergence and vegetative vigor, 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

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 # 835.2120 Hydrolysis
- 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 # 850.1730 Fish bioconcentration
- Guideline # 850.1735 Whole sediment, acute invertebrates, freshwater
- Guideline # 850.1740 Whole sediment, acute invertebrates, marine
- 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 Agency has created the following estimated timeline for the completion of the registration review for DCPA.

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

Summary of Comments and Agency Responses

No comments were received during the comment period on the DCPA Preliminary Work Plan.

Next Steps

The Agency plans to issue a Data Call-in (DCI) for DCPA in 2012. The information received in response to this DCI will be used to conduct the planned human health, ecological risk, and endangered species assessments for DCPA.

Summary of Data Needs for the Registration Review of DCPA

Guideline Number	Data Requirement	Test Substance	Estimated Timeframe (months)
Environmental Fate			
835.4300	Aerobic aquatic metabolism	DCPA	24
835.6100	Terrestrial field dissipation		24
Toxicity to aquatic animals			
850.1010	Acute toxicity, freshwater invertebrates	DCPA	12
850.1025	Acute toxicity, oyster (shell deposition)		12
850.1035	Acute toxicity, mysid		12
850.1075	Acute toxicity, freshwater and estuarine/marine fish		18
850.1300	Aquatic invertebrate life-cycle, freshwater		12
850.1350	Aquatic invertebrate life-cycle estuarine/marine		12
850.1400	Fish early life-stage		12
850.1735	Whole sediment, acute invertebrates, freshwater		12
850.1740	Whole sediment, acute invertebrates, marine		12
Toxicity to terrestrial animals			
850.2100	Acute avian oral, passerine species	DCPA	12
850.2300	Avian reproduction		24
Special Study	Avian inhalation toxicity, passerine species		12
Toxicity to plants			
850.4225	Tier II Plant toxicity – Seedling Emergence	DCPA	12
850.4250	Tier II Plant toxicity – Vegetative Vigor		12
850.4400	Tier I/II Plant toxicity (*Lemna spp.*)		12
850.5400	Tier I/II Algal toxicity		12
Environmental fate			
835.1230	Adsorption/desorption	TPA (metabolite)	12
835.1240	Leaching		12
835.2120	Hydrolysis		12
835.2240	Aqueous photolysis		12
835.4100	Aerobic soil metabolism		24
835.4200	Anaerobic soil metabolism		24
835.4300	Aerobic aquatic metabolism		24
835.4400	Anaerobic aquatic metabolism		24
835.6100	Terrestrial field dissipation		24

Guideline Number	Data Requirement	Test Substance	Estimated Timeframe (months)
Toxicity to aquatic animals			
850.1010	Acute toxicity, freshwater invertebrates	TPA (metabolite)	12
850.1025	Acute toxicity, oyster (shell deposition)		12
850.1035	Acute toxicity, mysid		12
850.1075	Acute toxicity, freshwater and estuarine/marine fish		12
850.1300	Aquatic invertebrate life-cycle, freshwater		12
850.1350	Aquatic invertebrate life-cycle estuarine/marine		12
850.1400	Fish early life stage freshwater & estuarine/marine		12
850.1730	Fish bioconcentration		12
850.1735	Whole sediment, acute invertebrates, freshwater		12
850.1740	Whole sediment, acute invertebrates, marine		12
Toxicity to plants			
850.4225	Seedling emergence, Tier II	TPA (metabolite)	12
850.4400	Aquatic vascular plant growth-*Lemna spp.* Tiers II		12
850.5400	Algal toxicity test, Tier I/II		12
Residue chemistry			
860.1300	Nature of the residue: poultry	DCPA	24
860.1340	Residue analytical method: livestock commodities		24
860.1380	Storage stability		24
860.1480	Meat/milk/poultry/eggs: ruminants		24
860.1900	Field accumulation in rotational crops		36
Toxicology			
870.3465	Subchronic inhalation toxicity study—28 day	DCPA	12
870.6200	Neurotoxicity battery (acute and subchronic studies)		12
870.7800	Immunotoxicity		12
Special Study	Comparative thyroid study		12