

**BEFORE THE
CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION
STATE OF CALIFORNIA**

In the Matter of the Accusation Against: DPR Case No. R-19-001

DOW AGROSCIENCES LLC

9330 Zionsville Road
Indianapolis, IN 46268
CA registration numbers 62719-72-ZA,
62719-79-ZA, 62719-220-ZA, 62719-220-
ZC, 62719-301-AA, 62719-575-AA, 62719-
591-AA, 62719-615-AA, and SLN CA-
040026

NOTICE OF DEFENSE

Respondent.

In response to the Accusation by the California Department of Pesticide Regulation (the "Department"), and pursuant to Section 11506 of the California Government Code, Respondent Dow AgroSciences LLC ("Dow AgroSciences") specifically denies the allegations of fact and conclusions of law set forth in the Accusation, objects to the Accusation upon the ground that it does not state acts or omissions upon which the agency may proceed, and hereby responds to each paragraph of the Accusation as follows:

PARTIES

1. Complainant brings this Accusation solely in his official capacity as the Acting Director of the California Department of Pesticide Regulation (the "Department").

ANSWER: Dow AgroSciences has insufficient information with which to admit or deny the allegations in paragraph 1.

2. Respondent Dow AgroSciences LLC ("Dow") is a Delaware limited liability company with its principal place of business in Indianapolis, Indiana.

ANSWER: Dow AgroSciences admits the allegations in paragraph 2.

REGISTRATIONS

3. On or about December 27, 2004, the Department issued a registration for a special

local need under United States Code, title 7, section 136v(c) to Dow for a pesticide product containing chlorpyrifos called "Lorsban 75WG" for "Control of Cabbage Aphid Infesting Brassica (Cole) Leafy Vegetables." This registration has a California registration number of SLN CA-040026. This registration remains in effect today.

ANSWER: Dow AgroSciences admits the allegations in paragraph 3.

4. On or about January 23, 2014, the Department issued a registration to Dow for a pesticide product containing chlorpyrifos called "Hatchet." This registration has a California registration number of 62719-220-ZC. The Department has annually renewed that registration, and the registration remains in effect today.

ANSWER: Dow AgroSciences admits the allegations in paragraph 4.

5. On or about January 23, 2014, the Department issued a registration to Dow for a pesticide product containing chlorpyrifos called "Lorsban-4E." This registration has a California registration number of 62719-220-ZA. The Department has annually renewed that registration, and the registration remains in effect today.

ANSWER: Dow AgroSciences admits the allegations in paragraph 5.

6. On or about February 6, 2014, the Department issued a registration to Dow for a pesticide product containing chlorpyrifos called "Cobalt Advanced." This registration has a California registration number of 62719-615-AA. The Department has annually renewed that registration, and the registration remains in effect today.

ANSWER: Dow AgroSciences admits the allegations in paragraph 6.

7. On or about February 12, 2014, the Department issued a registration to Dow for a pesticide product containing chlorpyrifos called "Cobalt." This registration has a California registration number of 62719-575-AA. The Department has annually renewed that registration, and the registration remains in effect today.

ANSWER: Dow AgroSciences admits the allegations in paragraph 7.

8. On or about February 12, 2014, the Department issued a registration to Dow for a pesticide product containing chlorpyrifos called "Lock-On Insecticide." This registration has a California registration number of 62719-79-ZA. The Department has annually renewed that

registration, and the registration remains in effect today.

ANSWER: Dow AgroSciences admits the allegations in paragraph 8.

9. On or about February 20, 2014, the Department issued a registration to Dow for a pesticide product containing chlorpyrifos called "Lorsban 75WG." This registration has a California registration number of 62719-301-AA. The Department has annually renewed that registration, and the registration remains in effect today.

ANSWER: Dow AgroSciences admits the allegations in paragraph 9.

10. On or about February 21, 2014, the Department issued a registration to Dow for a pesticide product containing chlorpyrifos called "Dursban 50W in Water Soluble Packets." This registration has a California registration number of 62719-72-ZA. The Department has annually renewed that registration, and the registration remains in effect today.

ANSWER: Dow AgroSciences admits the allegations in paragraph 10.

11. On or about March 8, 2017, the Department issued a registration to Dow for a pesticide product containing chlorpyrifos called "Lorsban Advanced." This registration has a California registration number of 62719-591-AA. The Department has annually renewed that registration, and the registration remains in effect today.

ANSWER: Dow AgroSciences admits the allegations in paragraph 11.

JURISDICTION

12. Food and Agricultural Code section 12825 provides that the Department may cancel the registration of any pesticide product for specified grounds after a hearing.

ANSWER: Paragraph 12 of the Accusation states a conclusion of law, which Dow AgroSciences neither admits nor denies.

STATUTORY AND REGULATORY PROVISIONS

Registration

13. "Every manufacturer of, importer of, or dealer in any pesticide, except a person that sells any raw material to a manufacturer of any pesticide or a dealer or agent that sells any pesticide that has been registered by the manufacturer or wholesaler, shall obtain a certificate of registration from the department before the pesticide is offered for sale." (Food & Agr. Code, § 12811.)

ANSWER: Dow AgroSciences admits that this language in paragraph 13 is the text of the cited section of the Food and Agriculture Code.

14. "Every registration expires on December 31st of each year except when renewal is applied for within one month thereafter in the manner which is provided for registration." (Food & Agr. Code, § 12817.)

ANSWER: Dow AgroSciences admits that this language in paragraph 14 is the text of the cited section of the Food and Agriculture Code.

15. "A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 136a of this title for all purposes of this subchapter, but shall authorize distribution and use only within such State." (7 U.S.C. § 136v(c)(1).)

ANSWER: Dow AgroSciences admits that this language in paragraph 15 is the text of the cited section of the United States Code.

Continuous Evaluation

16. "The director shall endeavor to eliminate from use in the state any pesticide that endangers the agricultural or nonagricultural environment, is not beneficial for the purposes for which it is sold, or is misrepresented. In carrying out this responsibility, the director shall develop an orderly program for the continuous evaluation of all pesticides actually registered. [¶] Before a substance is registered as a pesticide for the first time, there shall be a thorough and timely evaluation in accordance with this section. Appropriate restrictions may be placed upon its use including, but not limited to, limitations on quantity, area, and manner of application. All pesticides for which renewal of registration is sought also shall be evaluated in accordance with this section. [¶] The director may establish specific criteria to evaluate a pesticide with regard to the factors listed in Section 12825. The department may establish performance standards and tests that are to be conducted or financed, or both conducted and financed, by the registrants, applicants for registration, or parties interested in the registration of those pesticides." (Food & Agr. Code, § 12824.)

ANSWER: Dow AgroSciences admits that this language in paragraph 16 is the text of the cited section of the Food and Agriculture Code.

Cancellation

17. "Pursuant to Section 12824, the director, after hearing, may cancel the registration of, or refuse to register, any pesticide:

- (a) That has demonstrated serious uncontrollable adverse effects either within or outside the agricultural environment.
- (b) The use of which is of less public value or greater detriment to the environment than the benefit received by its use.
- (c) For which there is a reasonable, effective, and practicable alternate material or procedure that is demonstrably less destructive to the environment.
- (d) That, when properly used, is detrimental to vegetation, except weeds, to domestic animals, or to the public health and safety.
- (e) That is of little or no value for the purpose for which it is intended.
- (f) Concerning which any false or misleading statement is made or implied by the registrant or his or her agent, either verbally or in writing, or in the form of any advertising literature.
- (g) For which the director determines the registrant has failed to report an adverse effect or risk as required by Section 12825.5.
- (h) If the director determines that the registrant has failed to comply with the requirements of a reevaluation or to submit the data required as part of the reevaluation of the registrant's product.
- (i) That is required to be registered pursuant to the federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec. 136 et seq.) and that is not so registered.

In making a determination pursuant to this section, the director may require those practical demonstrations that are necessary to determine the facts." (Food & Agr. Code, § 12825.)

ANSWER: Dow AgroSciences admits that this language in paragraph 17 is the text of the cited section of the Food and Agriculture Code.

18. "If the director has reason to believe that any of the conditions stated in Section 12825 are applicable to any registered pesticide and that the use or continued use of that pesticide constitutes an immediate substantial danger to persons or to the environment, the director, after notice to the registrant, may suspend the registration of that pesticide pending a hearing and final decision. If an accusation pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code is not filed within 10 days from the date of the notice, the suspension shall be

terminated." (Food & Agr. Code, § 12826.)

ANSWER: Dow AgroSciences admits that this language in paragraph 18 is the text of the cited section of the Food and Agriculture Code.

19. "The director may cancel a certificate of registration, or, refuse to issue certification to any manufacturer, importer, or dealer in any pesticide that repeatedly violates any of the provisions of this chapter or the regulations of the director. [¶] The proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. The director has all the powers that are granted therein." (Food & Agr. Code, § 12827.)

ANSWER: Dow AgroSciences admits that this language in paragraph 19 is the text of the cited section of the Food and Agriculture Code.

Restricted Materials

20. "The director shall, by regulation, designate and establish as necessary to carry out the purposes of this division, a list of restricted materials based upon, but not limited to, any of the following criteria:

- (a) Danger of impairment of public health.
- (b) Hazards to applicators and farmworkers.
- (c) Hazards to domestic animals, including honeybees, or to crops from direct application or drift.
- (d) Hazard to the environment from drift onto streams, lakes, and wildlife sanctuaries.
- (e) Hazards related to persistent residues in the soil resulting ultimately in contamination of the air, waterways, estuaries or lakes, with consequent damage to fish, wild birds, and other wildlife.
- (f) Hazards to subsequent crops through persistent soil residues." (Food & Agr. Code, § 14004.5.)

ANSWER: Dow AgroSciences admits that this language in paragraph 20 is the text of the cited section of the Food and Agriculture Code.

21. Chlorpyrifos, when labeled for the production of an agricultural commodity, is designated as a restricted material. (Cal. Code Regs., tit. 3, § 6400, subd. (e).)

ANSWER: Dow AgroSciences admits the allegations in paragraph 21.

22. A restricted material may only be used by or under the supervision of a certified applicator and under a permit issued by a County Agricultural Commissioner. (Food & Agr. Code, §§ 14006.5, 14015; *see also* Cal Code Regs., tit. 3, §§ 6400-44 [limitations and permit system for restricted materials].)

ANSWER: Paragraph 22 of the Accusation states a conclusion of law, which Dow AgroSciences neither admits nor denies.

Toxic Air Contaminant

23. "For purposes of this article, 'toxic air contaminant' means an air pollutant that may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health." (Food & Agr. Code, § 14021, subd. (b).)

ANSWER: Dow AgroSciences admits that this language in paragraph 23 is the text of the cited section of the Food and Agriculture Code.

24. "A pesticide shall be identified as a toxic air contaminant if its concentrations in ambient air are greater than the following levels (for the purposes of this Section, a threshold is defined as the dose of a chemical below which no adverse effect occurs): [¶] (a) For pesticides which have thresholds for adverse health effects, this level shall be ten-fold-below the air concentration which has been determined by the director to be adequately protective of human health. [¶] (b) For pesticides which do not have thresholds for adverse health effects, this level shall be equivalent to the air concentration which would result in a ten-fold lower risk than that which has been determined by the director to be a negligible risk." (Cal. Code Regs., tit. 3, § 6864.)

ANSWER: Dow AgroSciences admits that this language in paragraph 24 is the text of the cited section of the California Code of Regulations.

25. After review by the Office of Environmental Human Health Assessment ("OEHHA"), the California Air Resources Board ("ARB"), and the independent Scientific Review Panel, followed by notice and comment rulemaking, and pursuant to Food and Agricultural Code sections 14022 and 14023, the Department listed chlorpyrifos as a toxic air contaminant effective April 1, 2019. (Cal. Code Regs., tit. 3, § 6860, subd. (a).)

ANSWER: Dow AgroSciences admits that chlorpyrifos was listed by the Department as a toxic air contaminant effective April 1, 2019. Dow AgroSciences denies the remaining allegations in paragraph 25, in particular that a meaningful notice and comment rulemaking occurred and also that any Scientific Review Panel is "independent."

26. "For those pesticides for which a need for control measures has been determined pursuant to subdivision (e) or (f) of Section 14023 and pursuant to provisions of this code, the director, in consultation with the agricultural commissioners, air pollution control districts, and air quality management districts in the affected counties, shall develop control measures designed to reduce emissions sufficiently so that the source will not expose the public to the levels of exposure that may cause or contribute to significant adverse health effects." (Food & Agr. Code, § 14024, subd. (a).) These control measures may include cancellation of registrations. (*Id.*, § 14024, subd. (b)(6)) The Department "shall adopt control measures to protect human health" within two years. (*Id.*, § 14024, subd. (c)(1).)

ANSWER: Dow AgroSciences admits that the quoted language in paragraph 26 is text of the cited section of the Food and Agriculture Code. The remaining statements in paragraph 26 constitute conclusions of law, which Dow AgroSciences neither admits nor denies.

CAUSE FOR CANCELLATION

27. Chlorpyrifos (O,O-diethyl-O-3,5,6-trichloro-2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate pesticide. Chlorpyrifos operates by inhibiting the functions of the nervous system. This is how it kills insects. Acute exposure can have similar effects on humans, resulting in symptoms such as sweating, salivation, vomiting, diarrhea, low blood pressure and heart rate, seizures, and death. These effects are caused by the inhibition of an important enzyme in both insects and mammals called acetylcholinesterase.

ANSWER: Dow AgroSciences denies the allegations in paragraph 27. Chlorpyrifos is an organophosphate insecticide and like other organophosphates, its insecticidal action is due to inhibition of the enzyme cholinesterase which regulates the neurotransmitter acetylcholine in the nervous system of the insect. The US EPA along with major regulatory agencies globally evaluate potential risk to humans and regulate chlorpyrifos based on red blood cell cholinesterase inhibition

(RBC ChEI) which is a sensitive and protective endpoint since RBC ChEI in itself causes no known physiological effect and occurs well below levels which could cause brain ChE inhibition. The acute exposure effects claimed in paragraph 27 only would result from over-exposures such as poisonings, and would not result from exposures under labeled use conditions.

28. Historically, the Department has analyzed and mitigated the human health effects of chlorpyrifos by focusing and relying on data relating to acetylcholinesterase inhibition caused by chlorpyrifos exposure.

ANSWER: Dow AgroSciences denies the allegations in paragraph 28.

29. Recent research has shown that chlorpyrifos also causes development neurotoxicity in children and sensitive populations at exposure levels substantially lower than those that induce overt toxicity or inhibit acetylcholinesterase activity. Developmental neurotoxicity effects include adverse effects on cognition, attention span, motor control, anxiety, and the structure of the brain.

ANSWER: Dow AgroSciences denies the allegations in paragraph 29. Single epidemiology studies cannot determine causation. Although many hypothesis-generating research publications have appeared in the literature, comprehensive, weight-of-evidence evaluations of the full body of information have consistently found that adverse effects cannot be attributed to chlorpyrifos at concentrations below which AChEI (i.e., cholinesterase inhibition) occurs (i.e., the current EPA regulatory endpoint). Moreover, the purported neurodevelopmental outcomes have been over-generalized across the epidemiology studies. The specific results are not reproduced across all studies, which undermines the validity of any hypothesis of a link between neurodevelopment effects and chlorpyrifos exposures. An examination of results in total across the epidemiology studies does not support and even counters such a hypothesis.

In addition, the U.S. Environmental Protection Agency (“EPA”) concluded in its July 2019 Final Order (denying a petition to revoke federal approvals for chlorpyrifos) that the shortcomings of the data from these epidemiology studies raise issues that direct against using the data for risk assessment at this time (EPA, 2019). EPA cited as a critical scientific/regulatory shortcoming, the lack of any meaningful raw data from these studies which they consider to be the centerpiece of the question of increased sensitivity of the young to potential neurotoxic effects of chlorpyrifos and for

any susceptibility of the developing brain to chlorpyrifos. EPA noted that despite repeated requests, researchers of these studies have not provided the underlying raw data needed to allow the EPA and others to independently verify the validity and reliability of the published results (EPA, 2019). At the same time the scientific validity of the conclusions of these epidemiology studies has been challenged, the scientific evidence related to chlorpyrifos and other pesticides in that same class (organophosphates) is growing. Newer findings from epidemiology studies do not support the hypothesis of possible linkages between neurodevelopmental effects and exposure to chlorpyrifos.

Weight-of-evidence evaluations along with study citations have been included in multiple comments submitted by Dow AgroSciences (2018, 2017). *See, e.g.*, Dow AgroSciences LLC's Response to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos (August 27, 2018) <https://www.regulations.gov/document?D=EPA-HQ-OPP-2007-1005-0526> (Appendix 1); Dow AgroSciences. 2018. Dow AgroSciences Comments for March 2, 2018 and Response to Questions Raised during January 23, 2018 California Air Resources Board Scientific Review Panel's Discussion of Chlorpyrifos as a Toxic Air Contaminant (February 26, 2018). Dow AgroSciences, LLC. Indianapolis, IN (Appendix 2); Dow AgroSciences. 2017. Dow AgroSciences Comments for California Air Resources Board Toxic Air Contaminant (TAC) Scientific Review Panel on Chlorpyrifos (January 9, 2018). Dow AgroSciences, LLC., Indianapolis, IN (Appendix 3); US EPA. 2019. Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order. FRL# 9997-06. Docket ID: EPA-HQ-OPP-2007-1005. www.regulations.gov. Issued July 18, 2019 (Appendix 4).

30. In 2016, 2017, and 2018, five *in vivo* animal studies were published in peer-reviewed journals that analyzed the developmental neurotoxicity effects of chlorpyrifos. The lowest observed effect levels (the lowest dose at which there is an observed toxic effect) or no observed effect levels (the highest dose at which there is not an observable toxic effect) of these studies were much lower -- up to ten times lower -- than those in studies focused only on acetylcholinesterase inhibition effects. These recent *in vivo* animal studies, along with epidemiological studies, formed the basis for the Department's evaluation of chlorpyrifos as a toxic air contaminant -- which was conducted in consultation with OEHHA and ARB, and was reviewed by the Scientific Review Panel -- and for

the establishment of developmental neurotoxicity as the critical endpoint for chlorpyrifos.

ANSWER: Dow AgroSciences denies the allegations in paragraph 30. Dow AgroSciences disagrees with the contention that 5 *in vivo* studies published from 2016 to 2018 reported effects at doses up to 10 times lower than the threshold for cholinesterase inhibition, specifically red blood cell (RBC) cholinesterase inhibition (ChEI). The claims of neurodevelopmental effects in laboratory animal studies below the threshold for cholinesterase inhibition are not supported after review of the scientific data. None of the 5 studies cited as supportive of this view measured RBC cholinesterase inhibition and doses used in these studies are above the true threshold for RBC ChEI. Moreover, the inference that the threshold for cholinesterase is 1 mg/kg/day is erroneous, as guideline GLP studies have consistently demonstrated the threshold for RBC ChEI is well below this level and the USEPA has established, based on benchmark dose modeling, that the dose level associated with 10% RBC ChEI is 0.06 mg/kg/day. Finally, there are no known reported neurodevelopmental effects/outcomes in studies that are below the threshold associated with 10% RBC ChEI and this point of departure and threshold continues to be protective of all toxicities, including neurodevelopmental toxicity. Dow AgroSciences has commented previously on this point on multiple occasions (Dow AgroSciences 2019, 2018, 2017). *See, e.g.*, Dow AgroSciences LLC's Response to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos (August 27, 2018) <https://www.regulations.gov/document?D=EPA-HQ-OPP-2007-1005-0526> (Appendix 1); Dow AgroSciences. 2019. Dow AgroSciences Additional Comments on Toxicology Studies cited in California Department of Pesticide Regulation. Final Toxic Air Contaminant Evaluation of Chlorpyrifos. Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders. July 2018. Dow AgroSciences July 2019. (Appendix 5); Dow AgroSciences. 2018 Dow AgroSciences Comments for California Air Resources Board Toxic Air Contaminant (TAC) Scientific Review Panel on Chlorpyrifos. (Pages 10-11). (January 9, 2018). Dow AgroSciences LLC, Indianapolis, IN. (Appendix 3); Dow AgroSciences. 2018. Dow AgroSciences Comments for March 2, 2018 and Response to Questions Raised during January 23, 2018 California Air Resources Board Scientific Review Panel's Discussion of Chlorpyrifos as a Toxic Air Contaminant. (page 4) (February 26, 2018). Dow AgroSciences LLC., Indianapolis, IN

(Appendix 2); Dow AgroSciences. 2017. Dow AgroSciences LLC's Comments on 2016 Notice of Data Availability, Revised Human Health Risk Assessment and Refined Drinking Water Assessment for Chlorpyrifos (EPA Docket: EPA-HQ-OPP-2015-0653), (Pages 13-18, 30-33, and Appendix D) (January 17, 2017). Dow AgroSciences, LLC., Indianapolis, IN. (Appendix 6).

31. In 2017, the Developmental and Reproductive Toxicant Identification Committee, a group of expert scientists appointed by the Governor under Proposition 65, independently reviewed whether or not chlorpyrifos has been clearly shown by scientifically valid testing according to generally accepted principles to cause developmental toxicity and thus should be listed under Proposition 65. Their unanimous decision was to list chlorpyrifos as a chemical known to the State of California to cause developmental toxicity.

ANSWER: Dow AgroSciences denies the allegations in paragraph 31. Dow AgroSciences disagrees with the listing of chlorpyrifos as a Proposition 65 developmental toxicant. Under Proposition 65 a substance is subject to listing as a developmental toxicant if, based on the weight of scientific evidence, it has been "clearly shown through scientifically valid testing according to generally accepted principles to cause . . . reproductive toxicity." Cal. Health & Safety Code § 254249.8(b). The epidemiology studies considered by the DARTIC for the listing of chlorpyrifos under Proposition 65 do not provide sufficient evidence in humans that chlorpyrifos causes developmental toxicity and the animal studies considered by DARTIC do not provide sufficient evidence in experimental animals (mammals) that chlorpyrifos causes developmental toxicity; and neither the epidemiology studies nor the animal studies provide limited evidence or suggestive evidence in humans that chlorpyrifos causes developmental toxicity. Dow AgroSciences has provided extensive comment on the basis for why this listing is not supported by a weight of evidence review related to chlorpyrifos exposure and neurodevelopmental toxicity (Dow AgroSciences 2019, 2017). *See, e.g.*, Dow AgroSciences. 2019. Dow AgroSciences Comments on OEHHA Proposed Amendments to Section 25805(b), Specific Regulatory Levels: Chemicals Causing Reproductive Toxicity. Maximum Allowable Dose Levels for Chlorpyrifos (Oral, Inhalation, and Dermal Exposures). Dow AgroSciences LLC. July 7, 2019 (Appendix 7); Dow AgroSciences. 2017. Evaluation of the Data for Chlorpyrifos Pursuant to the DART Criteria. 2017.

Why the Weight of Evidence Does Not Support Listing Chlorpyrifos as a Developmental Toxicant Under Proposition 65 (pages 35-69). Dow AgroSciences LLC. October 24, 2017 (Appendix 8).

32. In June 2018, the Department submitted and presented its toxic air contaminant evaluation findings for chlorpyrifos to California's Scientific Review Panel. OEHHA also prepared and submitted findings to the Scientific Review Panel, which supported identifying chlorpyrifos as a toxic air contaminant and establishing developmental neurotoxicity as the critical endpoint for chlorpyrifos. The Scientific Review Panel held public meetings to consider the information on December 13, 2017, January 23, 2018, March 2, 2018, June 12, 2018, and July 30, 2018.

ANSWER: Dow AgroSciences denies the allegations in paragraph 32. A rigorous evaluation of the science does not support the listing of chlorpyrifos as a Toxic Air Contaminant nor the purported basis behind this listing, specifically the contention that developmental neurotoxicity serves as the critical endpoint for the listing. Dow AgroSciences has previously submitted extensive comments on why RBC ChEI is protective against all other toxicities and effects, and why allegations that there are effects reported below a level associated with 10% RBC ChEI are not scientifically valid. A full discussion and evaluation of the science is given in previous submissions (Dow AgroSciences 2018, 2017, 2016). *See, e.g.*, Dow AgroSciences LLC's Response to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos (August 27, 2018) <https://www.regulations.gov/document?D=EPA-HQ-OPP-2007-1005-0526> (Appendix 1); Dow AgroSciences. 2018. Dow AgroSciences Comments for March 2, 2018 and Response to Questions Raised during January 23, 2018 California Air Resources Board Scientific Review Panel's Discussion of Chlorpyrifos as a Toxic Air Contaminant. (pages 2-4) (February 26, 2018). Dow AgroSciences LLC., Indianapolis, IN (Appendix 2); Dow AgroSciences. 2017. Dow AgroSciences LLC's Comments on 2016 Notice of Data Availability, Revised Human Health Risk Assessment and Refined Drinking Water Assessment for Chlorpyrifos (EPA Docket: EPA-HQ-OPP-2015-0653), (Pages 13-18, 30-33, and Appendix D) (January 17, 2017). Dow AgroSciences, LLC., Indianapolis, IN (Appendix 6); Dow AgroSciences. 2016. Dow AgroSciences Response to EPA's: Chlorpyrifos; Tolerance Revocations; Proposed Rule and EPA Analysis of the Small Business Impacts of Revoking Chlorpyrifos Food Tolerances. Docket: EPA-HQ-OPP-2015-0653, (Pages 24-

27, 38-51) (January 4, 2016). Dow AgroSciences, LLC., Indianapolis, IN (Appendix 9).

33. The Department issued its "Final Toxic Air Contaminant Evaluation of Chlorpyrifos and Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders" ("Risk Characterization Document") in July 2018. The Department thoroughly evaluated the developmental neurotoxicity effects of chlorpyrifos in the Risk Characterization Document.

ANSWER: Dow AgroSciences denies the allegations in paragraph 33, in particular that the Department thoroughly evaluated the developmental neurotoxicity effects of chlorpyrifos in the Risk Characterization Document. Based on a scientific evaluation of the "Risk Characterization Document" cited above, Dow AgroSciences disagrees with the contention that chlorpyrifos is a neurodevelopmental toxicant and furthermore with the listing of chlorpyrifos as a Toxic Air Contaminant. A thorough weight-of-evidence review of all available information, including independent reviews and guideline compliant studies required for registration, does not support an allegation of adverse effects below the current regulatory endpoint of RBC ChEI (Dow AgroSciences, 2018). *See, e.g.*, Dow AgroSciences LLC's Response to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos (August 27, 2018) <https://www.regulations.gov/document?D=EPA-HQ-OPP-2007-1005-0526> (Appendix 1); Dow AgroSciences. 2018. Dow AgroSciences Comments on California Department of Pesticide Regulation (CDPR) Proposal to Amend Section 6860 of Title 3, California Code of Regulations (3 CCR); Proposed Regulatory Action to Designate the Pesticide Chemical Chlorpyrifos as a Toxic Air Contaminant (TAC) in Subsection (a) Pursuant to Food and Agricultural Code (FAC) Section 14023 (November 2, 2018). Dow AgroSciences, LLC., Indianapolis, IN (Appendix 10).

34. The Scientific Review Panel provided its formal findings to the Department after its July 30, 2018 meeting. Those findings included that "[t]he estimated bystander exposures to Chlorpyrifos are at levels that cause concern about the associated health risks." The Scientific Review Panel concluded that the Department's assessment of developmental neurotoxicity risks from chlorpyrifos was "based on sound scientific knowledge, and represents a balanced assessment of our current scientific understanding." The Scientific Review Panel recommended that chlorpyrifos be listed as a toxic air contaminant based on the Department's assessment of developmental neurotoxicity

risks.

ANSWER: Dow AgroSciences denies the allegations in paragraph 34. Based on a rigorous evaluation of the science, Dow AgroSciences disagrees with the statement that “estimated bystander exposures to Chlorpyrifos are at levels that cause concern about the associated health risks.” As presented in November 2, 2018, Dow AgroSciences comments to the SRP (Dow AgroSciences, 2018a; *see* sections IV and V), the hypothetical bystander exposure scenario and assessment includes significant overestimation bias. This scenario has not been validated, and available air monitoring data do not support or corroborate estimated air concentrations. Further discussion of the science is presented in Dow AgroSciences comments (February 28, 2018b) to the SRP; specifically, sections V through X. Key refinements are available, but have not been included by CDPR, for the bystander exposure assessment, including accounting for inhalation and/or respirable fractions of the particulate matter presumably available for potential inhalation resultant from primary spray drift. *See, e.g.,* Dow AgroSciences LLC's Response to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos (August 27, 2018) <https://www.regulations.gov/document?D=EPA-HQ-OPP-2007-1005-0526> (Appendix 1); Dow AgroSciences. 2018a. Dow AgroSciences Comments on California Department of Pesticide Regulation (CDPR) Proposal to Amend Section 6860 of Title 3, California Code of Regulations (3 CCR); Proposed Regulatory Action to Designate the Pesticide Chemical Chlorpyrifos as a Toxic Air Contaminant (TAC) in Subsection (a) Pursuant to Food and Agricultural Code (FAC) Section 14023. November 2, 2018. Dow AgroSciences, LLC., Indianapolis, IN (Appendix10); Dow AgroSciences. 2018b. Dow AgroSciences Comments for March 2, 2018 and Response to Questions Raised during January 23, 2018 California Air Resources Board Scientific Review Panel's Discussion of Chlorpyrifos as a Toxic Air Contaminant. (February 26, 2018). Dow AgroSciences LLC., Indianapolis, IN (Appendix 2).

35. In November 2018, the Department released revised interim recommended permit conditions for chlorpyrifos to County Agricultural Commissioners. Those recommendations became effective January 1, 2019 and include prohibiting aerial applications, limiting uses to critical uses, and requiring buffer zones of one quarter mile. Buffer zones are the area that surrounds a pesticide

application block in which certain activities are restricted for a specified period of time.

ANSWER: Dow AgroSciences denies the allegations in paragraph 35. Based on the science and refined exposure methodology, Dow AgroSciences disagreed with the basis for the proposed permit conditions. The conditions were overly restrictive and resulted from use of toxicological endpoints not supported by a full evaluation of the science and unrefined, unrealistic exposure assessments. The following key concerns and issues have been raised by Dow AgroSciences in previous comments related to CDPR estimates of exposure and which do not appear to have been fully considered even though refinements which would produce more realistic estimates of potential risk are feasible and have been available to CDPR (Dow AgroSciences 2018a,b,c,d; 2017a,b; 2016). CDPR's assessment misinterprets key toxicological points and the exposure assessment lacks refinement. CDPR's assessments therefore significantly over-estimate potential exposure and risk. Refinements discussed in these and previous comments demonstrate acceptable levels of risk and Margins of Exposure (MoE) with approved use patterns and the endpoint based on RBC ChEI. Previous Dow AgroSciences comments show scientifically that the drift scenario is hypothetical, and not validated. Also, CDPR's hypothetical, modeled results do not accurately reflect real world detections in air and over-predict the probability of exposures. Multiple years of air sampling in California show chlorpyrifos detections are infrequent. In sampling, focused in high pesticide use areas, detections were infrequent and when detected, most of those detections were trace levels at or above the limit of detection, but below a quantifiable limit. The sampling data are orders of magnitude lower than spray drift air concentrations predicted in CDPR's assessments. *See, e.g.,* Dow AgroSciences. 2018. Dow AgroSciences Comments on California Department of Pesticide Regulation (CDPR) Proposal to Amend Section 6860 of Title 3, California Code of Regulations (3 CCR); Proposed Regulatory Action to Designate the Pesticide Chemical Chlorpyrifos as a Toxic Air Contaminant (TAC) in Subsection (a) Pursuant to Food and Agricultural Code (FAC) Section 14023 (November 2, 2018) (Appendix 10); Dow AgroSciences. 2018b. Dow AgroSciences Comments on Draft Air Monitoring Network Results (2011 to 2017) for Chlorpyrifos. (August 28, 2018). Dow AgroSciences LLC. Indianapolis, IN (Appendix 11); Dow AgroSciences. 2018. Dow AgroSciences Comments for March 2, 2018 and Response to Questions Raised during January 23, 2018 California

Air Resources Board Scientific Review Panel's Discussion of Chlorpyrifos as a Toxic Air Contaminant. (February 26, 2018). Dow AgroSciences LLC., Indianapolis, IN (Appendix 2); Dow AgroSciences. 2018d. Dow AgroSciences Comments for California Air Resources Board Toxic Air Contaminant (TAC) Scientific Review Panel on Chlorpyrifos. (January 9, 2018). Dow AgroSciences LLC., Indianapolis, IN (Appendix 3); Dow AgroSciences. 2017a. Dow AgroSciences Comments on Draft Air Monitoring Network Results for 2016 for Chlorpyrifos. (October 3, 2017). Dow AgroSciences LLC., Indianapolis, IN (Appendix 14); Dow AgroSciences. 2017b. Dow AgroSciences Response to California Department of Pesticide Regulation's Draft Evaluation of Chlorpyrifos as a Toxic Air Contaminant: Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders. Dated: August 18, 2017. (October 2, 2017). Dow AgroSciences LLC., Indianapolis, IN (Appendix 12); Dow AgroSciences. 2016. Dow AgroSciences Response to Chlorpyrifos Risk Characterization Document Spray Drift, Dietary and Aggregate Exposures to Residential Bystanders. (March 28, 2016). Regulatory Sciences and Regulatory Affairs, Dow AgroSciences LLC. Indianapolis, IN (Appendix 13).

36. On May 28, 2019, after consultation with OEHHA, ARB, the California Department of Food and Agriculture, and local air pollution control districts and air quality management districts, the Department issued a Risk Management Directive for chlorpyrifos, based on its July 2018 Risk Characterization Document for chlorpyrifos and the Scientific Review Panel's review of the 2018 Risk Characterization Document and findings. The Risk Management Directive set the reference concentration and reference dose for chlorpyrifos, which define the levels at or below which exposure to chlorpyrifos would have negligible risk to human health.

ANSWER: Dow AgroSciences denies the allegations in paragraph 36. Based on an evaluation of the science, Dow AgroSciences disagrees with the basis for and derivation of the reference concentration and reference dose based on presumptive neurodevelopment-related effects. In contrast, the recognized toxicological endpoint of Cholinesterase Inhibition remains scientifically-valid and a conservative regulatory endpoint protective of all other toxicities including possible neurodevelopmental effects. Dow AgroSciences has provided extensive scientific comments related to this topic (Dow AgroSciences 2018a,b,c; 2017a,b; 2016).

While comments made in both CDPR's Final Toxic Air Contaminant Evaluation of Chlorpyrifos and Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders" ("Risk Characterization Document") and at the 2018 meetings of the California Air Resources Board Toxic Air Contaminant Scientific Review Panel on Chlorpyrifos purported that animal studies demonstrate neurodevelopmental effects at exposures less than the current regulatory endpoint of RBC ChEI, these assertions are scientifically incorrect and contrary to the weight of scientific evidence and studies cited in these and previous Dow AgroSciences comments. A more thorough examination of these studies, along with other studies conducted according to strict regulatory standards, show there is no compelling or consistent evidence to support the contention that neurodevelopmental outcomes occur at exposures below where AChEI occurs.

And in the July 18, 2019 Final Order (EPA, 2019), EPA noted that both EPA and FIFRA SAP have also consistently cited the lack of robustness of the available data for deriving a point of departure (POD) based on neurodevelopmental effects given (1) the absence of a clear mechanism of action for chlorpyrifos in the developing brain, (2) dosing regimes in *in vivo* studies that differ from internationally accepted protocols; and (3) the lack of any meaningful raw data from the epidemiology studies which have been cited as central to the hypothesis of any link between chlorpyrifos exposures and neurodevelopmental effects. EPA therefore retained RBC ChEI as the scientifically-valid regulatory endpoint. *See, e.g.*, Dow AgroSciences LLC's Response to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos (August 27, 2018) <https://www.regulations.gov/document?D=EPA-HQ-OPP-2007-1005-0526> (Appendix 1); Dow AgroSciences. 2018a. Dow AgroSciences Comments for California Air Resources Board Toxic Air Contaminant (TAC) Scientific Review Panel on Chlorpyrifos. (January 9, 2018). Dow AgroSciences LLC., Indianapolis, IN (Appendix 3); Dow AgroSciences. 2018b. Dow AgroSciences Comments for March 2, 2018 and Response to Questions Raised during January 23, 2018 California Air Resources Board Scientific Review Panel's Discussion of Chlorpyrifos as a Toxic Air Contaminant. (February 26, 2018). Dow AgroSciences LLC., Indianapolis, IN (Appendix 2); Dow AgroSciences. 2018c. Dow AgroSciences Comments on California Department of Pesticide

Regulation (CDPR) Proposal to Amend Section 6860 of Title 3, California Code of Regulations (3 CCR); Proposed Regulatory Action to Designate the Pesticide Chemical Chlorpyrifos as a Toxic Air Contaminant (TAC) in Subsection (a) Pursuant to Food and Agricultural Code (FAC) Section 14023 (November 2, 2018). Dow AgroSciences, LLC., Indianapolis, IN (Appendix 10); Dow AgroSciences. 2017a. Dow AgroSciences Comments on Draft Air Monitoring Network Results for 2016 for Chlorpyrifos. (October 3, 2017). Dow AgroSciences LLC., Indianapolis, IN (Appendix 14); Dow AgroSciences. 2017b. Dow AgroSciences Response to California Department of Pesticide Regulation's Draft Evaluation of Chlorpyrifos as a Toxic Air Contaminant: Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders. Dated: August 18, 2017. (October 2, 2017). Dow AgroSciences LLC., Indianapolis, IN (Appendix 12); Dow AgroSciences. 2016. Dow AgroSciences Response to Chlorpyrifos Risk Characterization Document Spray Drift, Dietary and Aggregate Exposures to Residential Bystanders. March 28, 2016. Regulatory Sciences and Regulatory Affairs, Dow AgroSciences LLC. Indianapolis, IN (Appendix 13); US EPA. 2019. Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order. FRL# 9997-06. Docket ID: EPA-HQ-OPP-2007-1005. www.regulations.gov. Issued July 18, 2019 (Appendix 4).

37. The Department calculated a reference concentration of 4.05 micrograms per cubic meter for inhalation exposure to chlorpyrifos and a reference dose for aggregate exposure of 0.0001 milligrams per kilogram per day for dietary exposure to chlorpyrifos based on developmental neurotoxicity risks, taking into account uncertainties about translating these animal effects to human effects as well as uncertainties about heightened effects on children and other sensitive populations through the use of standard uncertainty factors.

ANSWER: Dow AgroSciences denies the allegations in paragraph 37. Dow AgroSciences disagrees with the basis of the reference concentration and the reference dose. Dow AgroSciences also disagrees with their derivation. In contrast, values derived using a validated human physiologically-based pharmacokinetic model, based on cholinesterase inhibition are available and scientifically robust. *See* comments and related Dow AgroSciences submissions described in Dow AgroSciences response to paragraph 36 of the Accusation (above).

38. One human health risk is due to inhalation, incidental hand-to-mouth, and dermal

exposures to chlorpyrifos when it is applied by way of ground application (that is, "drift"). At the reference concentration calculated by the Department, the inhalation risks from drift caused by the vast majority of chlorpyrifos applications can only be minimized to an acceptable level using buffer zones greater than a quarter mile, distances which are not required by the product labels or recommended by the Department's interim recommended permit conditions. Aerial applications of chlorpyrifos would also result in unacceptable exposure from drift, but should not occur under the Department's interim recommended permit conditions.

ANSWER: Dow AgroSciences denies the allegations in paragraph 38. Dow AgroSciences has repeatedly provided scientific comments on the hypothetical and conservative, even unrealistic, nature of the bystander exposure scenarios and presumed exposure pathways and routes (Dow AgroSciences 2018a,b,c,d; 2017a,b; 2016). The CDPR assessments, including the Final Toxic Air Contaminant Evaluation of Chlorpyrifos and Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders" ("Risk Characterization Document"), have misinterpreted key toxicological points and the exposure assessments have lacked refinement. The CDPR assessments therefore significantly over-estimate potential exposure and risk. Previous comments submitted by Dow AgroSciences do not appear to have been fully considered and further refinements to the bystander exposure assessment, although feasible and scientifically-justified, were not made prior to listing as a Toxic Air Contaminant or release of CDPR's Final Toxic Air Contaminant Evaluation of Chlorpyrifos and Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders" ("Risk Characterization Document"). *See, e.g.,* Dow AgroSciences LLC's Response to Objections to EPA's Denial of Petition to Revoke All Tolerances and Cancel All Registrations for Chlorpyrifos (August 27, 2018) <https://www.regulations.gov/document?D=EPA-HQ-OPP-2007-1005-0526> (Appendix 1); Dow AgroSciences. 2018a. Dow AgroSciences Comments on California Department of Pesticide Regulation (CDPR) Proposal to Amend Section 6860 of Title 3, California Code of Regulations (3 CCR); Proposed Regulatory Action to Designate the Pesticide Chemical Chlorpyrifos as a Toxic Air Contaminant (TAC) in Subsection (a) Pursuant to Food and Agricultural Code (FAC) Section 14023. (November 2, 2018). Dow AgroSciences LLC., Indianapolis, IN (Appendix 10); Dow

AgroSciences. 2018b. Dow AgroSciences Comments on Draft Air Monitoring Network Results (2011 to 2017) for Chlorpyrifos. (August 28, 2018). Dow AgroSciences LLC. Indianapolis, IN (Appendix 11); Dow AgroSciences. 2018c. Dow AgroSciences Comments for March 2, 2018 and Response to Questions Raised during January 23, 2018 California Air Resources Board Scientific Review Panel's Discussion of Chlorpyrifos as a Toxic Air Contaminant. (February 26, 2018). Dow AgroSciences LLC., Indianapolis, IN (Appendix 2); Dow AgroSciences. 2018d. Dow AgroSciences Comments for California Air Resources Board Toxic Air Contaminant (TAC) Scientific Review Panel on Chlorpyrifos. (January 9, 2018). Dow AgroSciences LLC., Indianapolis, IN (Appendix 3); Dow AgroSciences. 2017a. Dow AgroSciences Response to California Department of Pesticide Regulation's Draft Evaluation of Chlorpyrifos as a Toxic Air Contaminant: Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders. Dated: August 18, 2017. (October 2, 2017). Dow AgroSciences LLC., Indianapolis, IN (Appendix 12); Dow AgroSciences. 2017b. Dow AgroSciences Comments on Draft Air Monitoring Network Results for 2016 for Chlorpyrifos. Dated October 3, 2017. Dow AgroSciences LLC., Indianapolis, IN (Appendix 14); Dow AgroSciences. 2016. Dow AgroSciences Response to Chlorpyrifos Risk Characterization Document Spray Drift, Dietary and Aggregate Exposures to Residential Bystanders. (March 28, 2016). Regulatory Sciences and Regulatory Affairs, Dow AgroSciences LLC. Indianapolis, IN (Appendix 13).

39. Because of these inhalation risks, the use of the pesticide products registered by Dow named Cobalt, Cobalt Advanced, Hatchet, Lock-On Insecticide, Lorsban 75WG, Lorsban Advanced, and Lorsban-4E, and the special local needs registration for Lorsban 75WG for Control of Cabbage Aphid Infesting Brassica (Cole) Leafy Vegetables are detrimental to public health, and cancellation of those registrations is appropriate under Food and Agricultural Code section 12825, subdivision (d).

ANSWER: Dow AgroSciences denies the allegations in paragraph 39. As discussed fully in the Dow AgroSciences comments to paragraphs 29-38 of the Accusation (above), a thorough evaluation of the science does not support the statement that the listed pesticide products are “detrimental” to public health and does not support the cancellation of those products.

40. Another human health risk is due to dietary ingestion of chlorpyrifos that remains on agricultural produce as a residue after application of chlorpyrifos products. The amount of residue that remains on some commonly consumed agricultural produce after application of chlorpyrifos is well above the reference dose calculated by the Department when taking into account consumption of the produce.

ANSWER: Dow AgroSciences denies the allegations in paragraph 40. Based on an evaluation of the science, Dow AgroSciences disagrees that dietary ingestion of chlorpyrifos residues results in exposure that are unsafe. CDPR's dietary (and aggregate) assessment is based on a point of departure (POD) not supported by a full evaluation of the science, as discussed extensively in the Dow AgroSciences comments to paragraphs 29-39 of the Accusation (above). It is the use of this point of departure (POD), and not the actual residues, which drive the scientifically-invalid claim of dietary exposures above the reference dose. As recent as the CDPR's August 19, 2017 "Draft Evaluation of Chlorpyrifos as a Toxic Air Contaminant: Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential Bystanders" dietary exposures were found not to exceed the RBC ChEI endpoint, which according to EPA's July 18, 2019 Final Order remains the scientifically-valid regulatory endpoint and is accepted by regulatory agencies globally. *See, e.g.,* US EPA. 2019. Chlorpyrifos; Final Order Denying Objections to March 2017 Petition Denial Order. FRL# 9997-06. Docket ID: EPA-HQ-OPP-2007-1005. www.regulations.gov. Issued July 18, 2019 (Appendix 4).

41. Because of these dietary risks (separate or together from [sic] the inhalation risks), the use of the pesticide products registered by Dow named Hatched, Lorsban 75WG, Lorsban Advanced, and Lorsban-4E are detrimental to public health, and cancellation of those registrations is appropriate under Food and Agricultural Code section 12825, subdivision (d).

ANSWER: Dow AgroSciences denies the allegations in paragraph 41.

42. The product Dursban 50W in Water Soluble Packets does not have any uses that are proper under the product label registered with the Department and the Department's interim recommended permit conditions, and cancellation of that registration is appropriate under Food and Agricultural Code section 12825, subdivision (e).

ANSWER: Dow AgroSciences denies the allegations in paragraph 42

PRAYER

WHEREFORE, based on the responses provided in this Notice of Defense, Dow AgroSciences requests that the remedy sought in the Accusation (namely, cancellation of the product registrations listed below) be denied.

- Cobalt Advanced (CA # 62719-615-AA)
- Dursban 50W in Water Soluble Packets (CA # 62719-72-ZA);
- Hatchet (CA # 62719-220-ZC);
- Lock-On Insecticide (CA #62719-79-ZA);
- Lorsban 75WG (CA # 62719-301-AA);
- Lorsban Advanced (CA # 62719-591-AA);
- Lorsban-4E (CA # 62719-220-ZA); and
- the special local needs registration for Lorsban 75WG for Control of Cabbage Aphid Infesting Brassica (Cole) Leafy Vegetables (CA SLN # CA-040026).

Respondent reserves the right to amend and/or supplement this Prayer.

Dated: September 20, 2019

Respectfully submitted,

By: 

Warren U. Lehrenbaum
Amy B. Symonds
CROWELL & MORING LLP
Attorneys for DOW AGROSCIENCES, LLC