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11 **BEFORE THE**  
12 **CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION**  
13 **STATE OF CALIFORNIA**

14 In the Matter of the Accusation Against:

DPR Case No. R-19-002

15 **BASF CORPORATION**

**A C C U S A T I O N**

16 26 Davis Drive  
17 Research Triangle Park, NC 27709  
CA registration number 499-367-ZB

18 Respondent.

19  
20  
21 Acting Director of the California Department of Pesticide Regulation, Val Dolcini,  
22 (“Complainant”) alleges:

23 **PARTIES**

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

26 2. Respondent BASF Corporation (“BASF”) is the North American affiliate of German  
27 corporation BASF SE. BASF Corporation is incorporated in Delaware, with its principal place of  
28 business in Florham Park, New Jersey.

1 **REGISTRATION**

2 3. On or about July 9, 2014, the Department issued a registration to BASF for a  
3 pesticide product containing chlorpyrifos called “Duraguard ME Microencapsulated Insecticide.”  
4 This registration has a California registration number of 499-367-ZB. The Department has  
5 annually renewed that registration, and the registration remains in effect today.

6 **JURISDICTION**

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

9 **STATUTORY AND REGULATORY PROVISIONS**

10 *Registration*

11 5. “Every manufacturer of, importer of, or dealer in any pesticide, except a person that  
12 sells any raw material to a manufacturer of any pesticide or a dealer or agent that sells any  
13 pesticide that has been registered by the manufacturer or wholesaler, shall obtain a certificate of  
14 registration from the department before the pesticide is offered for sale.” (Food & Agr. Code, §  
15 12811.)

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

19 *Continuous Evaluation*

20 7. “The director shall endeavor to eliminate from use in the state any pesticide that  
21 endangers the agricultural or nonagricultural environment, is not beneficial for the purposes for  
22 which it is sold, or is misrepresented. In carrying out this responsibility, the director shall  
23 develop an orderly program for the continuous evaluation of all pesticides actually registered. [¶]  
24 Before a substance is registered as a pesticide for the first time, there shall be a thorough and  
25 timely evaluation in accordance with this section. Appropriate restrictions may be placed upon its  
26 use including, but not limited to, limitations on quantity, area, and manner of application. All  
27 pesticides for which renewal of registration is sought also shall be evaluated in accordance with  
28 this section. [¶] The director may establish specific criteria to evaluate a pesticide with regard to

1 the factors listed in Section 12825. The department may establish performance standards and  
2 tests that are to be conducted or financed, or both conducted and financed, by the registrants,  
3 applicants for registration, or parties interested in the registration of those pesticides.” (Food &  
4 Agr. Code, § 12824.)

5 *Cancellation*

6 8. “Pursuant to Section 12824, the director, after hearing, may cancel the registration of,  
7 or refuse to register, any pesticide:

8 (a) That has demonstrated serious uncontrollable adverse effects either within or  
9 outside the agricultural environment.

10 (b) The use of which is of less public value or greater detriment to the environment  
11 than the benefit received by its use.

12 (c) For which there is a reasonable, effective, and practicable alternate material or  
13 procedure that is demonstrably less destructive to the environment.

14 (d) That, when properly used, is detrimental to vegetation, except weeds, to domestic  
15 animals, or to the public health and safety.

16 (e) That is of little or no value for the purpose for which it is intended.

17 (f) Concerning which any false or misleading statement is made or implied by the  
18 registrant or his or her agent, either verbally or in writing, or in the form of any  
19 advertising literature.

20 (g) For which the director determines the registrant has failed to report an adverse  
21 effect or risk as required by Section 12825.5.

22 (h) If the director determines that the registrant has failed to comply with the  
23 requirements of a reevaluation or to submit the data required as part of the  
24 reevaluation of the registrant's product.

25 (i) That is required to be registered pursuant to the federal Insecticide, Fungicide, and  
26 Rodenticide Act (7 U.S.C. Sec. 136 et seq.) and that is not so registered.

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

1           9.    “If the director has reason to believe that any of the conditions stated in Section  
2 12825 are applicable to any registered pesticide and that the use or continued use of that pesticide  
3 constitutes an immediate substantial danger to persons or to the environment, the director, after  
4 notice to the registrant, may suspend the registration of that pesticide pending a hearing and final  
5 decision. If an accusation pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of  
6 Division 3 of Title 2 of the Government Code is not filed within 10 days from the date of the  
7 notice, the suspension shall be terminated.” (Food & Agr. Code, § 12826.)

8           10. “The director may cancel a certificate of registration, or, refuse to issue certification  
9 to any manufacturer, importer, or dealer in any pesticide that repeatedly violates any of the  
10 provisions of this chapter or the regulations of the director. [¶] The proceedings shall be  
11 conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division  
12 3 of Title 2 of the Government Code. The director has all the powers that are granted therein.”  
13 (Food & Agr. Code, § 12827.)

14 *Restricted Materials*

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

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

27 Code, § 14004.5.)

28

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

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

7 *Toxic Air Contaminant*

8           14. “For purposes of this article, ‘toxic air contaminant’ means an air pollutant that may  
9 cause or contribute to an increase in mortality or an increase in serious illness, or which may pose  
10 a present or potential hazard to human health.” (Food & Agr. Code, § 14021, subd. (b).)

11           15. “A pesticide shall be identified as a toxic air contaminant if its concentrations in  
12 ambient air are greater than the following levels (for the purposes of this Section, a threshold is  
13 defined as the dose of a chemical below which no adverse effect occurs): [¶] (a) For pesticides  
14 which have thresholds for adverse health effects, this level shall be ten-fold below the air  
15 concentration which has been determined by the director to be adequately protective of human  
16 health. [¶] (b) For pesticides which do not have thresholds for adverse health effects, this level  
17 shall be equivalent to the air concentration which would result in a ten-fold lower risk than that  
18 which has been determined by the director to be a negligible risk.” (Cal. Code Regs., tit. 3, §  
19 6864.)

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

25           17. “For those pesticides for which a need for control measures has been determined  
26 pursuant to subdivision (e) or (f) of Section 14023 and pursuant to provisions of this code, the  
27 director, in consultation with the agricultural commissioners, air pollution control districts, and air  
28 quality management districts in the affected counties, shall develop control measures designed to

1 reduce emissions sufficiently so that the source will not expose the public to the levels of  
2 exposure that may cause or contribute to significant adverse health effects.” (Food & Agr. Code,  
3 § 14024, subd. (a).) These control measures may include cancellation of registrations. (*Id.*, §  
4 14024, subd. (b)(6).) The Department “shall adopt control measures to protect human health”  
5 within two years. (*Id.*, § 14024, subd. (c)(1).)

### 6 **CAUSE FOR CANCELLATION**

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

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

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

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

1 reviewed by the Scientific Review Panel – and for the establishment of developmental  
2 neurotoxicity as the critical endpoint for chlorpyrifos.

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

9 23. In June 2018, the Department submitted and presented its toxic air contaminant  
10 evaluation findings for chlorpyrifos to California’s Scientific Review Panel. OEHHA also  
11 prepared and submitted findings to the Scientific Review Panel, which supported identifying  
12 chlorpyrifos as a toxic air contaminant and establishing developmental neurotoxicity as the  
13 critical endpoint for chlorpyrifos. The Scientific Review Panel held public meetings to consider  
14 the information on December 13, 2017, January 23, 2018, March 2, 2018, June 12, 2018, and July  
15 30, 2018.

16 24. The Department issued its “Final Toxic Air Contaminant Evaluation of Chlorpyrifos  
17 and Risk Characterization of Spray Drift, Dietary, and Aggregate Exposures to Residential  
18 Bystanders” (“Risk Characterization Document”) in July 2018. The Department thoroughly  
19 evaluated the developmental neurotoxicity effects of chlorpyrifos in the Risk Characterization  
20 Document.

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

1           26. In November 2018, the Department released revised interim recommended permit  
2 conditions for chlorpyrifos to County Agricultural Commissioners. Those recommendations  
3 became effective January 1, 2019 and include prohibiting aerial applications, limiting uses to  
4 critical uses, and requiring buffer zones of one quarter mile. Buffer zones are the area that  
5 surrounds a pesticide application block in which certain activities are restricted for a specified  
6 period of time.

7           27. On May 28, 2019, after consultation with OEHHA, ARB, the California Department  
8 of Food and Agriculture, and local air pollution control districts and air quality management  
9 districts, the Department issued a Risk Management Directive for chlorpyrifos, based on its July  
10 2018 Risk Characterization Document for chlorpyrifos and the Scientific Review Panel's review  
11 of the 2018 Risk Characterization Document and findings. The Risk Management Directive set  
12 the reference concentration and reference dose for chlorpyrifos, which define the levels at or  
13 below which exposure to chlorpyrifos would have negligible risk to human health.

14           28. The Department calculated a reference concentration of 4.05 micrograms per cubic  
15 meter for inhalation exposure to chlorpyrifos and a reference dose for aggregate exposure of  
16 0.0001 milligrams per kilogram per day for dietary exposure to chlorpyrifos based on  
17 developmental neurotoxicity risks, taking into account uncertainties about translating these  
18 animal effects to human effects as well as uncertainties about heightened effects on children and  
19 other sensitive populations through the use of standard uncertainty factors.

20           29. One human health risk is due to inhalation, incidental hand-to-mouth, and dermal  
21 exposures to chlorpyrifos when it is applied by way of ground application (that is, "drift"). At the  
22 reference concentration calculated by the Department, the inhalation risks from drift caused by  
23 the vast majority of chlorpyrifos applications can only be minimized to an acceptable level using  
24 buffer zones greater than a quarter mile, distances which are not required by the product labels or  
25 recommended by the Department's interim recommended permit conditions. Aerial applications  
26 of chlorpyrifos would also result in unacceptable exposure from drift, but are should not occur  
27 under the Department's interim recommended permit conditions.

28           30. Another human health risk is due to dietary ingestion of chlorpyrifos that remains on



1 agricultural produce as a residue after application of chlorpyrifos products. The amount of  
2 residue that remains on some commonly consumed agricultural produce after application of  
3 chlorpyrifos is well above the reference dose calculated by the Department when taking into  
4 account consumption of the produce.


5 31. The product Duraguard ME Microencapsulated Insecticide does not have any uses  
6 that are proper under the product label registered with the Department and the Department's  
7 interim recommended permit conditions, and cancellation of that registration is appropriate under  
8 Food and Agricultural Code section 12825, subdivision (e).

9 **PRAYER**

10 **WHEREFORE**, Complainant requests that a hearing be held on the matters herein alleged  
11 and that, following the hearing, the California Department of Pesticide Regulation issue a  
12 decision:

- 13 1. Cancelling the following registration, effective immediately:  
14 • Duraguard ME Microencapsulated Insecticide (CA # 499-367-ZB);  
15 2. Taking such other and further action as deemed necessary and proper.

16 Dated: August 14, 2019

17   
18 \_\_\_\_\_  
19 VAL DOLCINI  
20 Acting Director  
21 California Department of Pesticide  
22 Regulation  
23 State of California  
24 *Complainant*

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