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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-19-011

15 **MAKHTESHIM AGAN OF NORTH**  
16 **AMERICA, INC.**

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

17 3120 Highwoods Boulevard, Suite 100  
18 Raleigh, NC 27604  
CA registration numbers 66222-19-AA,  
66222-19-ZA, 66222-233-AA

19 Respondent.  
20

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

24 **PARTIES**

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

27 2. Respondent Makhteshim Agan of North America, Inc. (sometimes doing business and  
28 herein referred to as “ADAMA”) is a Delaware corporation with its principal place of business in

1 Raleigh, North Carolina.

2 **REGISTRATIONS**

3 3. On or about December 18, 2013, the Department issued a registration to ADAMA for  
4 a pesticide product containing chlorpyrifos called “Quali-Pro Chlorpyrifos 4E.” This registration  
5 has a California registration number of 66222-19-ZA. The Department has annually renewed that  
6 registration, and the registration remains in effect today.

7 4. On or about June 22, 2016, the Department issued a registration to ADAMA for a  
8 pesticide product containing chlorpyrifos called “Chlorpyrifos 4E AG.” This registration has a  
9 California registration number of 66222-19-AA. The Department has annually renewed that  
10 registration, and the registration remains in effect today.

11 5. On or about July 2, 2018, the Department issued a registration to ADAMA for a  
12 pesticide product containing chlorpyrifos called “Vulcan.” This registration has a California  
13 registration number of 66222-233-AA. The Department has annually renewed that registration,  
14 and the registration remains in effect today.

15 **JURISDICTION**

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

18 **STATUTORY AND REGULATORY PROVISIONS**

19 *Registration*

20 7. “Every manufacturer of, importer of, or dealer in any pesticide, except a person that  
21 sells any raw material to a manufacturer of any pesticide or a dealer or agent that sells any  
22 pesticide that has been registered by the manufacturer or wholesaler, shall obtain a certificate of  
23 registration from the department before the pesticide is offered for sale.” (Food & Agr. Code, §  
24 12811.)

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

28 *Continuous Evaluation*

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

14           *Cancellation*

15           10.   “Pursuant to Section 12824, the director, after hearing, may cancel the registration of,  
16 or refuse to register, any pesticide:

- 17                   (a) That has demonstrated serious uncontrollable adverse effects either within or  
18                   outside the agricultural environment.
- 19                   (b) The use of which is of less public value or greater detriment to the environment  
20                   than the benefit received by its use.
- 21                   (c) For which there is a reasonable, effective, and practicable alternate material or  
22                   procedure that is demonstrably less destructive to the environment.
- 23                   (d) That, when properly used, is detrimental to vegetation, except weeds, to domestic  
24                   animals, or to the public health and safety.
- 25                   (e) That is of little or no value for the purpose for which it is intended.
- 26                   (f) Concerning which any false or misleading statement is made or implied by the  
27                   registrant or his or her agent, either verbally or in writing, or in the form of any  
28                   advertising literature.

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

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

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

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

10 11. “If the director has reason to believe that any of the conditions stated in Section  
11 12825 are applicable to any registered pesticide and that the use or continued use of that pesticide  
12 constitutes an immediate substantial danger to persons or to the environment, the director, after  
13 notice to the registrant, may suspend the registration of that pesticide pending a hearing and final  
14 decision. If an accusation pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of  
15 Division 3 of Title 2 of the Government Code is not filed within 10 days from the date of the  
16 notice, the suspension shall be terminated.” (Food & Agr. Code, § 12826.)

17 12. “The director may cancel a certificate of registration, or, refuse to issue certification  
18 to any manufacturer, importer, or dealer in any pesticide that repeatedly violates any of the  
19 provisions of this chapter or the regulations of the director. [¶] The proceedings shall be  
20 conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division  
21 3 of Title 2 of the Government Code. The director has all the powers that are granted therein.”  
22 (Food & Agr. Code, § 12827.)

23 *Restricted Materials*

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

- 27 (a) Danger of impairment of public health.  
28 (b) Hazards to applicators and farmworkers.

1 (c) Hazards to domestic animals, including honeybees, or to crops from direct  
2 application or drift.

3 (d) Hazard to the environment from drift onto streams, lakes, and wildlife sanctuaries.

4 (e) Hazards related to persistent residues in the soil resulting ultimately in  
5 contamination of the air, waterways, estuaries or lakes, with consequent damage to  
6 fish, wild birds, and other wildlife.

7 (f) Hazards to subsequent crops through persistent soil residues.” (Food & Agr.  
8 Code, § 14004.5.)

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

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

15 *Toxic Air Contaminant*

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

19 17. “A pesticide shall be identified as a toxic air contaminant if its concentrations in  
20 ambient air are greater than the following levels (for the purposes of this Section, a threshold is  
21 defined as the dose of a chemical below which no adverse effect occurs): [¶] (a) For pesticides  
22 which have thresholds for adverse health effects, this level shall be ten-fold below the air  
23 concentration which has been determined by the director to be adequately protective of human  
24 health. [¶] (b) For pesticides which do not have thresholds for adverse health effects, this level  
25 shall be equivalent to the air concentration which would result in a ten-fold lower risk than that  
26 which has been determined by the director to be a negligible risk.” (Cal. Code Regs., tit. 3, §  
27 6864.)

28 18. After review by the Office of Environmental Human Health Assessment

1 (“OEHHA”), the California Air Resources Board (“ARB”), and the independent Scientific  
2 Review Panel, followed by notice and comment rulemaking, and pursuant to Food and  
3 Agricultural Code sections 14022 and 14023, the Department listed chlorpyrifos as a toxic air  
4 contaminant effective April 1, 2019. (Cal. Code Regs., tit. 3, § 6860, subd. (a).)

5 19. “For those pesticides for which a need for control measures has been determined  
6 pursuant to subdivision (e) or (f) of Section 14023 and pursuant to provisions of this code, the  
7 director, in consultation with the agricultural commissioners, air pollution control districts, and air  
8 quality management districts in the affected counties, shall develop control measures designed to  
9 reduce emissions sufficiently so that the source will not expose the public to the levels of  
10 exposure that may cause or contribute to significant adverse health effects.” (Food & Agr. Code,  
11 § 14024, subd. (a).) These control measures may include cancellation of registrations. (*Id.*, §  
12 14024, subd. (b)(6).) The Department “shall adopt control measures to protect human health”  
13 within two years. (*Id.*, § 14024, subd. (c)(1).)

#### 14 **CAUSE FOR CANCELLATION**

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

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

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

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

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

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

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

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

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

15           29. On May 28, 2019, after consultation with OEHHA, ARB, the California Department  
16 of Food and Agriculture, and local air pollution control districts and air quality management  
17 districts, the Department issued a Risk Management Directive for chlorpyrifos, based on its July  
18 2018 Risk Characterization Document for chlorpyrifos and the Scientific Review Panel’s review  
19 of the 2018 Risk Characterization Document and findings. The Risk Management Directive set  
20 the reference concentration and reference dose for chlorpyrifos, which define the levels at or  
21 below which exposure to chlorpyrifos would have negligible risk to human health.

22           30. The Department calculated a reference concentration of 4.05 micrograms per cubic  
23 meter for inhalation exposure to chlorpyrifos and a reference dose for aggregate exposure of  
24 0.0001 milligrams per kilogram per day for dietary exposure to chlorpyrifos based on  
25 developmental neurotoxicity risks, taking into account uncertainties about translating these  
26 animal effects to human effects as well as uncertainties about heightened effects on children and  
27 other sensitive populations through the use of standard uncertainty factors.

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



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

8 32. Because of these inhalation risks, the use of the pesticide products registered by  
9 ADAMA named Quali-Pro Chlorpyrifos 4E, Chlorpyrifos 4E AG, and Vulcan are detrimental to  
10 public health, and cancellation of these registrations is appropriate under Food and Agricultural  
11 Code section 12825, subdivision (d).

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

17 34. Because of these dietary risks (separate or together from the inhalation risks), the use  
18 of the pesticide products registered by ADAMA named Quali-Pro Chlorpyrifos 4E, Chlorpyrifos  
19 4E AG, and Vulcan are detrimental to public health, and cancellation of these registrations is  
20 appropriate under Food and Agricultural Code section 12825, subdivision (d).

### 21 **PRAYER**

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

- 25 1. Cancelling the following registrations, effective immediately:
- 26 • Quali-Pro Chlorpyrifos 4E (CA # 66222-19-ZA);
  - 27 • Chlorpyrifos 4E AG (CA # 66222-19-AA); and
  - 28 • Vulcan (CA # 66222-233-AA);

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2. Taking such other and further action as deemed necessary and proper.

Dated: August 14, 2019



VAL DOLCINI  
Acting Director  
California Department of Pesticide  
Regulation  
State of California  
*Complainant*

OK2019900180