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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-19-006

15 **FMC CORPORATION**

A C C U S A T I O N

16 2929 Walnut Street
17 Philadelphia, PA 19104
CA registration numbers 279-3581-AA,
18 279-9545-ZA

19 Respondent.

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 FMC Corporation is a Delaware company with its principal place of
27 business in Philadelphia, Pennsylvania.

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1 **REGISTRATIONS**

2 3. On or about November 17, 2016, the Department issued a registration to FMC
3 Corporation (through its Agricultural Products Group) for a pesticide product containing
4 chlorpyrifos called “Bolton Insecticide.” This registration has a California registration number of
5 279-3581-AA. The Department has annually renewed that registration, and the registration
6 remains in effect today.

7 4. On or about March 14, 2017, the Department issued a registration to FMC
8 Corporation for a pesticide product containing chlorpyrifos called “Stallion Brand Insecticide.”
9 This registration has a California registration number of 279-9545-ZA. The Department has
10 annually renewed that registration, and the registration remains in effect today.

11 **JURISDICTION**

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

14 **STATUTORY AND REGULATORY PROVISIONS**

15 *Registration*

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

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

24 *Continuous Evaluation*

25 8. “The director shall endeavor to eliminate from use in the state any pesticide that
26 endangers the agricultural or nonagricultural environment, is not beneficial for the purposes for
27 which it is sold, or is misrepresented. In carrying out this responsibility, the director shall
28 develop an orderly program for the continuous evaluation of all pesticides actually registered. [¶]

1 Before a substance is registered as a pesticide for the first time, there shall be a thorough and
2 timely evaluation in accordance with this section. Appropriate restrictions may be placed upon its
3 use including, but not limited to, limitations on quantity, area, and manner of application. All
4 pesticides for which renewal of registration is sought also shall be evaluated in accordance with
5 this section. [¶] The director may establish specific criteria to evaluate a pesticide with regard to
6 the factors listed in Section 12825. The department may establish performance standards and
7 tests that are to be conducted or financed, or both conducted and financed, by the registrants,
8 applicants for registration, or parties interested in the registration of those pesticides.” (Food &
9 Agr. Code, § 12824.)

10 *Cancellation*

11 9. “Pursuant to Section 12824, the director, after hearing, may cancel the registration of,
12 or refuse to register, any pesticide:

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

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

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

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

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

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

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

27 (h) If the director determines that the registrant has failed to comply with the
28 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.)

10. “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.)

11. “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.)

Restricted Materials

12. “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

1 contamination of the air, waterways, estuaries or lakes, with consequent damage to
2 fish, wild birds, and other wildlife.

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

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

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

11 *Toxic Air Contaminant*

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

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

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

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

10 CAUSE FOR CANCELLATION

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

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

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

25 22. In 2016, 2017, and 2018, five *in vivo* animal studies were published in peer-reviewed
26 journals that analyzed the developmental neurotoxicity effects of chlorpyrifos. The lowest
27 observed effect levels (the lowest dose at which there is an observed toxic effect) or no observed
28 effect levels (the highest dose at which there is not an observable toxic effect) of these studies

1 were much lower – up to ten times lower – than those in studies focused only on
2 acetylcholinesterase inhibition effects. These recent in vivo animal studies, along with
3 epidemiological studies, formed the basis for the Department’s evaluation of chlorpyrifos as a
4 toxic air contaminant – which was conducted in consultation with OEHHA and ARB, and was
5 reviewed by the Scientific Review Panel – and for the establishment of developmental
6 neurotoxicity as the critical endpoint for chlorpyrifos.

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

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

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

25 26. The Scientific Review Panel provided its formal findings to the Department after its
26 July 30, 2018 meeting. Those findings included that “[t]he estimated bystander exposures to
27 Chlorpyrifos are at levels that cause concern about the associated health risks.” The Scientific
28 Review Panel concluded that the Department’s assessment of developmental neurotoxicity risks

1 from chlorpyrifos was “based on sound scientific knowledge, and represents a balanced
2 assessment of our current scientific understanding.” The Scientific Review Panel recommended
3 that chlorpyrifos be listed as a toxic air contaminant based on the Department’s assessment of
4 developmental neurotoxicity risks.

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

11 28. On May 28, 2019, after consultation with OEHHA, ARB, the California Department
12 of Food and Agriculture, and local air pollution control districts and air quality management
13 districts, the Department issued a Risk Management Directive for chlorpyrifos, based on its July
14 2018 Risk Characterization Document for chlorpyrifos and the Scientific Review Panel’s review
15 of the 2018 Risk Characterization Document and findings. The Risk Management Directive set
16 the reference concentration and reference dose for chlorpyrifos, which define the levels at or
17 below which exposure to chlorpyrifos would have negligible risk to human health.

18 29. The Department calculated a reference concentration of 4.05 micrograms per cubic
19 meter for inhalation exposure to chlorpyrifos and a reference dose for aggregate exposure of
20 0.0001 milligrams per kilogram per day for dietary exposure to chlorpyrifos based on
21 developmental neurotoxicity risks, taking into account uncertainties about translating these
22 animal effects to human effects as well as uncertainties about heightened effects on children and
23 other sensitive populations through the use of standard uncertainty factors.

24 30. One human health risk is due to inhalation, incidental hand-to-mouth, and dermal
25 exposures to chlorpyrifos when it is applied by way of ground application (that is, “drift”). At the
26 reference concentration calculated by the Department, the inhalation risks from drift caused by
27 the vast majority of chlorpyrifos applications can only be minimized to an acceptable level using
28 buffer zones greater than a quarter mile, distances which are not required by the product labels or

1 recommended by the Department's interim recommended permit conditions. Aerial applications
2 of chlorpyrifos would also result in unacceptable exposure from drift, but are should not occur
3 under the Department's interim recommended permit conditions.

4 31. Because of these inhalation risks, the use of the pesticide products registered by FMC
5 Corporation named Bolton Insecticide and Stallion Brand Insecticide are detrimental to public
6 health, and cancellation of these registrations is appropriate under Food and Agricultural Code
7 section 12825, subdivision (d).

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

13 33. Because of these dietary risks (separate or together from the inhalation risks), the use
14 of the pesticide product registered by FMC Corporation named Stallion Brand Insecticide is
15 detrimental to public health, and cancellation of these registrations is appropriate under Food and
16 Agricultural Code section 12825, subdivision (d).

17 34. The product Bolton Insecticide also has not been used in the past few years in
18 California, and cancellation of that registration is appropriate under Food and Agricultural Code
19 section 12825, subdivision (e).

20 **PRAYER**

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

24 1. Cancelling the following registrations, effective immediately:

- 25 • Bolton Insecticide (CA # 279-3581-AA); and
- 26 • Stallion Brand Insecticide (CA # 279-9545-ZA);

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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

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