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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-19-004

15 **DIRECT AG SOURCE, LLC**
16 30473 260th Street
Eldora, IA 50627
17 CA registration number 83222-20-AA

A C C U S A T I O N

18 Respondent.

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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 Direct AG Source, LLC is a limited liability company with its principal
27 place of business in Eldora, Iowa.

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1 **REGISTRATIONS**

2 3. On or about January 15, 2014, the Department issued a registration to Direct AG
3 Source, LLC for a pesticide product containing chlorpyrifos called “CPF 4E.” This registration
4 has a California registration number of 83222-20-AA. The Department has annually renewed
5 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 12. Chlorpyrifos, when labeled for the production of an agricultural commodity, is

1 designated as a restricted material. (Cal. Code Regs., tit. 3, § 6400, subd. (e).)

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

6 *Toxic Air Contaminant*

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

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

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

24 17. “For those pesticides for which a need for control measures has been determined
25 pursuant to subdivision (e) or (f) of Section 14023 and pursuant to provisions of this code, the
26 director, in consultation with the agricultural commissioners, air pollution control districts, and air
27 quality management districts in the affected counties, shall develop control measures designed to
28 reduce emissions sufficiently so that the source will not expose the public to the levels of

1 exposure that may cause or contribute to significant adverse health effects.” (Food & Agr. Code,
2 § 14024, subd. (a).) These control measures may include cancellation of registrations. (*Id.*, §
3 14024, subd. (b)(6).) The Department “shall adopt control measures to protect human health”
4 within two years. (*Id.*, § 14024, subd. (c)(1).)

5 CAUSE FOR CANCELLATION

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

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

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

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

1 neurotoxicity as the critical endpoint for chlorpyrifos.

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

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

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

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

28 26. In November 2018, the Department released revised interim recommended permit

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

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

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

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

27 30. Because of these inhalation risks, the use of the pesticide product registered by Direct
28 AG Source, LLC named CPF 4E is detrimental to public health, and cancellation of this

1 registration is appropriate under Food and Agricultural Code section 12825, subdivision (d).

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


7 32. Because of these dietary risks (separate or together from the inhalation risks), the use
8 of the pesticide product registered by Direct AG Sources, LLC named CPF 4E is detrimental to
9 public health, and cancellation of this registration is appropriate under Food and Agricultural
10 Code section 12825, subdivision (d).

11 **PRAYER**

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

- 15 1. Cancelling the following registration, effective immediately:
- 16 • CPF 4E (CA # 83222-20-AA);
- 17 2. Taking such other and further action as deemed necessary and proper.

18 Dated: August 14, 2019

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20 
21 VAL DOLCINI
22 Acting Director
23 California Department of Pesticide
24 Regulation
25 State of California
26 *Complainant*

27 OK2019900180