

1 XAVIER BECERRA, State Bar No. 118517
 Attorney General of California
 2 SUSAN S. FIERING, State Bar No. 121621
 Supervising Deputy Attorney General
 3 DENNIS RAGEN, State Bar No. 106468
 HEATHER C. LESLIE, State Bar No. 305095
 4 LAURA J. ZUCKERMAN, State Bar No. 161896
 Deputy Attorneys General
 5 1515 Clay Street, 20th Floor
 P.O. Box 70550
 6 Oakland, CA 94612-0550
 Telephone: (510) 879-1299
 7 Fax: (510) 622-2270
 E-mail: Laura.Zuckerman@doj.ca.gov
 8 *Attorneys for Defendants Dr. Lauren Zeise,*
Director, Office of Environmental Health Hazard
 9 *Assessment, and Xavier Becerra, Attorney General*
 10 *of the State of California*

11 IN THE UNITED STATES DISTRICT COURT
 12 FOR THE EASTERN DISTRICT OF CALIFORNIA

15 **NATIONAL ASSOCIATION OF WHEAT**
 16 **GROWERS ET AL.,**
 17 Plaintiffs,
 18 v.
 19 **LAUREN ZEISE, IN HER OFFICIAL**
 20 **CAPACITY AS DIRECTOR OF THE**
 21 **OFFICE OF ENVIRONMENTAL**
 22 **HEALTH HAZARD ASSESSMENT; AND**
 23 **XAVIER BECERRA, IN HIS OFFICIAL**
 24 **CAPACITY AS ATTORNEY GENERAL**
 25 **OF THE STATE OF CALIFORNIA,**
 Defendants.

Civil Action No. 2:17-CV-02041-WBS-EFB
ANSWER OF DR. LAUREN ZEISE,
DIRECTOR OF THE OFFICE OF
ENVIRONMENTAL HEALTH HAZARD
ASSESSMENT AND XAVIER
BECERRA, ATTORNEY GENERAL OF
THE STATE OF CALIFORNIA TO
FIRST AMENDED COMPLAINT

Courtroom: 5
 Judge: The Honorable William B.
 Shubb
 Trial Date: None set.
 Action Filed: November 15, 2017

26 Defendants Dr. Lauren Zeise, Director of Office of Environmental Health Hazard
 27 Assessment and Xavier Becerra, Attorney General of the State of California (jointly the “State
 28 Parties”) hereby respond to the First Amended Complaint filed by Monsanto Company, and the

1 National Association of Wheat Growers et al. (jointly “Plaintiffs”).

2 1. The State Parties deny that any warning under Proposition 65 is false, misleading
3 and highly controversial. The State Parties lack information or belief sufficient to admit or deny
4 the remaining allegations of this paragraph and, on that basis, deny them.

5 2. The State Parties lack information or belief sufficient to admit or deny the
6 allegations of this paragraph concerning glyphosate and, on that basis, deny them. The remainder
7 of the allegations are Plaintiffs’ characterizations of law and require no response. To the extent a
8 response is deemed required, OEHHA denies the allegations.

9 3. The allegations of this paragraph are Plaintiffs’ characterizations of the conclusions
10 of other entities, which speak for themselves and require no response. To the extent that a
11 response is required, the State Parties admit that a program within the Office of Health Hazard
12 Assessment (“OEHHA”) that establishes non-regulatory goals for contaminants in drinking water
13 concluded in 1997 and 2007, based on the evidence they reviewed at those times, that glyphosate
14 “is unlikely to pose a cancer hazard to humans,” and established a public health goal for the
15 chemical based on non-cancer health effects. OEHHA denies that the discussion in the public
16 health goal document has any relevance to the issues before this Court. Except as expressly
17 admitted herein, the State Parties deny the remainder of the allegations of this paragraph.

18 4. The State Parties admit that OEHHA listed glyphosate as a carcinogen under
19 Proposition 65 on July 7, 2017 under the Labor Code Listing mechanism of Proposition 65 based
20 on a determination by IARC that there is sufficient evidence from scientific studies in animals of
21 glyphosate’s carcinogenicity, strong mechanistic evidence, and limited evidence in scientific
22 studies in humans that glyphosate is “probably carcinogenic to humans.” The remainder of the
23 allegations of this paragraph are the Plaintiffs’ characterization of the law and require no
24 response. To the extent that a response is deemed required, OEHHA denies the allegations of this
25 paragraph.

26 5. Denied.

27 6. The State Parties admit that OEHHA does not independently review the scientific
28 validity of the IARC determination and that the listing is “ministerial” as long as the IARC

1 determination meets the requirements of California Health and Safety Code section 25249.8(a)
2 and California Code of Regulations, title 27, section 25904. (“27 CCR”.) The State Parties admit
3 that private enforcers are entitle to 25% of any penalty assessed under Proposition 65. Except as
4 expressly admitted herein, OEHHA denies the remainder of the allegations of this paragraph.

5 7. Denied.

6 8. Denied.

7 9. The State Parties lack information or belief sufficient to admit or deny the allegations
8 of this paragraph and, on that basis, deny them.

9 10. The State Parties lack information or belief sufficient to admit or deny the allegations
10 of this paragraph and, on that basis, deny them.

11 11. The State Parties lack information or belief sufficient to admit or deny the allegations
12 of this paragraph and, on that basis, deny them.

13 12. The State Parties lack information or belief sufficient to admit or deny the allegations
14 of this paragraph and, on that basis, deny them.

15 13. The State Parties lack information or belief sufficient to admit or deny the allegations
16 of this paragraph and, on that basis, deny them.

17 14. The State Parties lack information or belief sufficient to admit or deny the allegations
18 of this paragraph and, on that basis, deny them.

19 15. The State Parties lack information or belief sufficient to admit or deny the allegations
20 of this paragraph and, on that basis, deny them.

21 16. The State Parties lack information or belief sufficient to admit or deny the allegations
22 of this paragraph and, on that basis, deny them.

23 17. The State Parties lack information or belief sufficient to admit or deny the allegations
24 of this paragraph and, on that basis, deny them.

25 18. The State Parties lack information or belief sufficient to admit or deny the allegations
26 of this paragraph and, on that basis, deny them.

27 19. The State Parties lack information or belief sufficient to admit or deny the allegations
28 of this paragraph and, on that basis, deny them.

1 20. The State Parties lack information or belief sufficient to admit or deny the allegations
2 of this paragraph and, on that basis, deny them.

3 21. The State Parties lack information or belief sufficient to admit or deny the allegations
4 of this paragraph and, on that basis, deny them.

5 22. The State Parties lack information or belief sufficient to admit or deny the allegations
6 of this paragraph and, on that basis, deny them.

7 23. The State Parties admit that Dr. Lauren Zeise, the Director of OEHHA and the
8 highest ranking administrative officer, is sued in her official capacity, and that OEHHA has
9 offices in Sacramento and Oakland. Except as expressly admitted herein, the State Parties deny
10 the remainder of the allegations of this paragraph.

11 24. Admitted.

12 25. This paragraph is Plaintiffs' statement of the law and requires no response. To the
13 extent that a response is deemed required, the State Parties deny the allegations of this paragraph.

14 26. This paragraph is Plaintiffs' statement of the law and requires no response. To the
15 extent that a response is deemed required, the State Parties admit that Defendants are located
16 within this District. Except as expressly admitted herein, the State Parties deny the remaining
17 allegations of this paragraph.

18 27. This paragraph is Plaintiffs' statement of the law and requires no response. To the
19 extent that a response is deemed required, the State Parties admit that federal law regulates the
20 sale and use of pesticides and the labeling of food products to some extent. Except as expressly
21 admitted herein, the State Parties deny the allegations of this paragraph.

22 28. This paragraph is Plaintiffs' statement of the law and of the content of particular
23 documents, which speak for themselves, and requires no response. To the extent that a response
24 is deemed required, the State Parties deny the allegations of this paragraph.

25 29. This paragraph is Plaintiffs' statement of the law and requires no response. To the
26 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

27 30. This paragraph is Plaintiffs' statement of the law and requires no response. To the
28 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

1 31. This paragraph is Plaintiffs’ statement of the law and requires no response. To the
2 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

3 32. The State Parties lack information or belief sufficient to admit or deny the allegations
4 of this paragraph and, on that basis, deny them.

5 33. The State Parties lack information or belief sufficient to admit or deny the allegations
6 of this paragraph and, on that basis, deny them.

7 34. The State Parties lack information or belief sufficient to admit or deny the allegations
8 of this paragraph and, on that basis, deny them.

9 35. The State Parties lack information or belief sufficient to admit or deny the allegations
10 of this paragraph and, on that basis, deny them.

11 36. The State Parties deny that glyphosate has been recognized as a “safe” herbicide by
12 OEHHA. The State Parties lack information or belief sufficient to admit or deny the remaining
13 allegations of this paragraph and, on that basis, deny them.

14 37. The State Parties lack information or belief sufficient to admit or deny the allegations
15 of this paragraph and, on that basis, deny them. To the extent that this paragraph contains
16 quotations from an EPA document, that document speaks for itself, and requires no response.

17 38. The State Parties lack information or belief sufficient to admit or deny the allegations
18 of this paragraph and, on that basis, deny them. To the extent that this paragraph contains
19 quotations from an EPA document, that document speaks for itself and requires no response.

20 39. The State Parties lack information or belief sufficient to admit or deny the allegations
21 of this paragraph and, on that basis, deny them. To the extent that this paragraph contains
22 quotations from a document, that document speaks for itself and requires no response.

23 40. The State Parties lack information or belief sufficient to admit or deny the allegations
24 of this paragraph and, on that basis, deny them. To the extent that this paragraph contains
25 quotations from a document, that document speaks for itself and requires no response.

26 41. The State Parties lack information or belief sufficient to admit or deny the allegations
27 of this paragraph and, on that basis, deny them. To the extent that this paragraph contains
28 quotations from a document, that document speaks for itself and requires no response.

1 42. The State Parties lack information or belief sufficient to admit or deny the allegations
2 of this paragraph and, on that basis, deny them. To the extent that this paragraph contains
3 quotations from a document, that document speaks for itself and requires no response.

4 43. The State Parties deny that OEHHA has concluded that glyphosate is non-
5 carcinogenic for purposes of Proposition 65. OEHHA admits that one of its programs unrelated
6 to Proposition 65 reviewed the health effects of glyphosate based on the scientific information
7 available at that time, including some of the same studies relied on by IARC, and stated that, for
8 purposes of establishing a non-regulatory public health goal for glyphosate, the program
9 determined there was insufficient evidence of carcinogenicity to use as a basis for the public
10 health goal.

11 44. The State Parties admit that IARC is an agency of the United Nations World Health
12 Organization and is based in Lyon, France; that it convenes Working Groups of international
13 scientific experts who review the scientific evidence and reach conclusions and prepare
14 Monographs concerning the cancer hazard posed by different substances; and that it is not a
15 regulator. Except as expressly admitted herein, the State Parties deny the remainder of the
16 allegations of this paragraph.

17 45. Denied.

18 46. The State Parties lack information or belief sufficient to admit or deny the allegations
19 of this paragraph and, on that basis, deny them. To the extent that this paragraph contains
20 quotations from a document, that document speaks for itself and requires no response.

21 47. The State Parties lack information or belief sufficient to admit or deny the allegations
22 of this paragraph and, on that basis, deny them. To the extent that this paragraph contains
23 quotations from a document, that document speaks for itself and requires no response.

24 48. The State Parties lack information or belief sufficient to admit or deny the allegations
25 of this paragraph and, on that basis, deny them. To the extent that this paragraph characterizes
26 the content of another document, that document speaks for itself and requires no response.

27
28

1 49. The State Parties lack information or belief sufficient to admit or deny the allegations
2 of this paragraph and, on that basis, deny them. To the extent that this paragraph contains
3 quotations from a document, that document speaks for itself and requires no response.

4 50. The State Parties lack information or belief sufficient to admit or deny the allegations
5 of this paragraph and, on that basis, deny them. To the extent that this paragraph contains
6 quotations from a document and characterizes the content of a document, that document speaks
7 for itself and requires no response.

8 51. Denied.

9 52. This paragraph is Plaintiffs' characterization of media articles concerning glyphosate,
10 which speak for themselves and require no response. To the extent a response is deemed
11 required, the State Parties deny the allegations of this paragraph.

12 53. This paragraph is Plaintiffs' characterization of a media article concerning
13 glyphosate, which speaks for itself and requires no response. To the extent a response is deemed
14 required, the State Parties deny the allegations of this paragraph.

15 54. The State Parties admit that OEHHA personnel wrote the statement quoted in a letter
16 in 2002, but deny that the characterization of that statement by Plaintiffs' is accurate. The State
17 Parties lack information or belief sufficient to admit or deny the remaining allegations of this
18 paragraph and, on that basis, deny them.

19 55. This paragraph is Plaintiffs' statement of the law and requires no response. To the
20 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

21 56. This paragraph is Plaintiffs' statement of the law and requires no response. To the
22 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

23 57. This paragraph is Plaintiffs' statement of the law and requires no response. To the
24 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

25 58. This paragraph is Plaintiffs' statement of the law and requires no response. To the
26 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

27 59. The State Parties admit that OEHHA has described its process for listing chemicals
28 pursuant to the Labor Code Listing mechanism (Health & Saf. Code, § 25249.8, subd. (a)), as

1 “ministerial.” The remainder of the allegations of this paragraph are Plaintiffs’ statement of the
2 law and require no response. To the extent a response is deemed required, the State Parties deny
3 the allegations of this paragraph.

4 60. This paragraph is Plaintiffs’ statement of the law and requires no response. To the
5 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

6 61. This paragraph is Plaintiffs’ statement of the law and requires no response. To the
7 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

8 62. This paragraph is Plaintiffs’ statement of the law and requires no response. To the
9 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

10 63. The allegations of this paragraph are Plaintiffs’ statement of the law, which require no
11 response. To the extent that a response is deemed required the State Parties admit that the
12 Attorney General of California has a history of enforcing Proposition 65’s warning requirement.
13 Except as expressly admitted herein, the State Parties deny the remainder of the allegations of this
14 paragraph.

15 64. The allegations of this paragraph are Plaintiffs’ statements of the law, which require
16 no response. To the extent a response is deemed required the State Parties deny the allegations of
17 this paragraph.

18 65. The allegations of this paragraph are Plaintiffs’ statements of the law, which require
19 no response and Plaintiffs’ characterization of a media article, which requires no response. To the
20 extent a response is deemed required, the State Parties deny the allegations of this paragraph.

21 66. The allegations of this paragraph are Plaintiffs’ statements of the law, which requires
22 no response. To the extent a response is deemed required, defendants deny the allegations of this
23 paragraph.

24 67. The allegations of this paragraph are Plaintiffs’ quotations from a dissenting opinion
25 in a court of appeal decision, which requires no response. To the extent a response is deemed
26 required, the State Parties deny the allegations of this paragraph.

27
28

1 68. The allegations of this paragraph are Plaintiffs' characterization of statements made
2 in media articles, which speak for themselves and require no response. To the extent a response
3 is deemed required, defendants deny the allegations of this paragraph.

4 69. The State Parties admit that a number of Proposition 65 lawsuits have been filed and
5 that parties have sometimes provided sixty-day notices shortly after the warning requirement goes
6 into effect. Except as expressly admitted herein, the State Parties deny the remainder of the
7 allegations of this paragraph.

8 70. The State Parties admit that on July 7, 2017 glyphosate was listed under Proposition
9 65 as a chemical known to the state to cause cancer based on IARC's determination that there was
10 sufficient evidence of carcinogenicity in animal studies and limited evidence of carcinogenicity in
11 human studies. Except as expressly admitted herein, the State Parties deny the remainder of the
12 allegations of this paragraph.

13 71. The State Parties admit the approximately 9,183 comments were filed in response to
14 the NOIL, both for an against listing the chemical, and that the language quoted by Plaintiffs from
15 the NOIL is accurate. To the extent that the allegations characterize the NOIL, that document
16 speaks for itself, and requires no response. Except as expressly admitted herein, the State Parties
17 deny the remainder of the allegations of this paragraph.

18 72. The State Parties lack information or belief sufficient to admit or deny the allegations
19 of this paragraph and, on that basis, deny them.

20 73. Denied.

21 74. The State Parties admit that certain foods are permitted to contain glyphosate residues
22 under federal law and that businesses that expose individuals to glyphosate must either provide a
23 warning or be prepared to demonstrate that the exposure does not cause a significant risk of
24 cancer as defined by the regulations. Except as expressly admitted herein, the State Parties deny
25 the remaining allegations of this paragraph.

26 75. The State Parties lack information or belief to admit or deny the allegations of this
27 paragraph and, on that basis, deny them.

28

1 76. The State Parties lack information or belief to admit or deny the allegations of this
2 paragraph and, on that basis, deny them.

3 77. Denied.

4 78. The State Parties lack information or belief to admit or deny the allegations of this
5 paragraph and, on that basis, deny them.

6 79. The State Parties deny that any Proposition 65 warning for exposure to glyphosate
7 that may be provided by a particular business is false and highly controversial. The State Parties
8 lack information or belief to admit or deny the remaining allegations of this paragraph and, on
9 that basis, deny them.

10 80. The State Parties lack information or belief to admit or deny the allegations of this
11 paragraph and, on that basis, deny them.

12 81. The State Parties lack information or belief to admit or deny the allegations of this
13 paragraph and, on that basis, deny them.

14 82. The State Parties lack information or belief to admit or deny the allegations of this
15 paragraph and, on that basis, deny them.

16 83. The State Parties lack information or belief to admit or deny the allegations of this
17 paragraph and, on that basis, deny them.

18 84. The State Parties lack information or belief to admit or deny the allegations of this
19 paragraph and, on that basis, deny them.

20 85. The State Parties lack information or belief to admit or deny the allegations of this
21 paragraph and, on that basis, deny them.

22 86. The State Parties deny that any Proposition 65 warning for exposures to glyphosate
23 that may be provided by a particular business is false and highly controversial or that Plaintiffs
24 will be injured. The State Parties lack information or belief to admit or deny the remaining
25 allegations of this paragraph and, on that basis, deny them.

26 87. The State Parties deny that Proposition 65 creates “unreasonable litigation risk.” The
27 State Parties lack information or belief to admit or deny the remaining allegations of this
28 paragraph and, on that basis, deny them.

1 88. Denied

2 89. Denied.

3 90. The State Parties deny that a Proposition 65 warning for exposures to glyphosate that
4 may be provided by a particular business would be “false speech” or “false warnings.” The State
5 Parties lack information or belief to admit or deny the remaining allegations of this paragraph
6 and, on that basis, deny them.

7 91. Denied.

8 92. The foregoing paragraphs are incorporated by reference as if set forth in full herein.

9 93. The allegations of this paragraph are the Plaintiffs’ statement of law and require no
10 response. To the extent that a response is deemed required, the State Parties deny the allegations
11 of this paragraph.

12 94. The allegations of this paragraph are the Plaintiffs’ statement of law and require no
13 response. To the extent that a response is deemed required, the State Parties deny the allegations
14 of this paragraph.

15 95. The allegations of this paragraph are the Plaintiffs’ statement of law and require no
16 response. To the extent that a response is deemed required, the State Parties deny the allegations
17 of this paragraph.

18 96. Denied.

19 97. Denied.

20 98. Denied.

21 99. Denied.

22 100. Denied.

23 101. Denied.

24 102. Denied.

25 103. Denied.

26 104. Denied.

27 105. The foregoing paragraphs are incorporated by reference as if set forth in full herein.

28

1 106. The allegations of this paragraph are the Plaintiffs' statement of law and require no
2 response. To the extent that a response is deemed required, the State Parties deny the allegations
3 of this paragraph.

4 107. Denied

5 108. Denied.

6 109. Denied.

7 110. The allegations of this paragraph are the Plaintiffs' statement of law and require no
8 response. To the extent that a response is deemed required, the State Parties deny the allegations
9 of this paragraph.

10 111. Denied.

11 112. The State Parties lack information or belief to respond to the allegations of this
12 paragraph and, on that basis, deny them.

13 113. Denied.

14 114. The allegations of this paragraph are the Plaintiffs' statement of law and require no
15 response. To the extent that a response is deemed required, the State Parties deny the allegations
16 of this paragraph.

17 115. The allegations of this paragraph are the Plaintiffs' statement of law and require no
18 response. To the extent that a response is deemed required, the State Parties deny the allegations
19 of this paragraph.

20 116. Denied.

21 117. Denied.

22 118. The foregoing Paragraphs are incorporated by reference as if set forth in full herein.

23 119. The allegations of this paragraph are the Plaintiffs' statement of law and require no
24 response. To the extent that a response is deemed required, the State Parties deny the allegations
25 of this paragraph.

26 120. Denied.

27 121. The State Parties admit that glyphosate was listed as a carcinogen under Proposition
28 65 because it met the requirements for listing pursuant to Health and Safety Code, section

1 25249.8(a) and California Code of Regulations, title 27, section 25904, based on IARC's
2 determination in the March 2015 Monograph that there was sufficient evidence in animals that
3 IARC causes cancer and glyphosate is "probably carcinogenic to humans." The State Parties
4 admit that OEHHA did not conduct an independent assessment of the studies concerning
5 glyphosate for purposes of the listing. Except as expressly admitted herein, the State Parties deny
6 the remainder of the allegations of this paragraph.

7 122. Denied.

8 123. Denied.

9 124. Denied.

10 125. Denied.

11 **AFFIRMATIVE DEFENSES**

12 1. As and for a first affirmative defense, the State Parties state that the claims against
13 some or all of the State Parties are barred by the Eleventh Amendment.

14 2. As and for a second affirmative defense, the State Parties state that glyphosate was
15 listed by OEHHA on July 7, 2017, and any challenge to the listing is therefore moot.

16 3. As and for a third affirmative defense, the State Parties allege that OEHHA's listing
17 of glyphosate as a chemical known to the State to cause cancer is in all respects in accordance
18 with law.

19 4. As and for a fourth affirmative defense, the State Parties allege that the complaint
20 fails to state a cause of action upon which relief can be granted.

21 5. As and for a fifth affirmative defense, the State Parties allege that the matter is not
22 ripe, that there is therefore no case or controversy as required by Article III of the United States
23 Constitution, and that the Court therefore has no jurisdiction over the matter.

24 6. As and for a sixth affirmative defense, the State Parties allege that the Plaintiffs
25 cannot meet the standard for a preliminary or permanent injunction.

26 7. As and for a seventh affirmative defense, the State Parties allege that this Court
27 should exercise its discretion not to take jurisdiction of this matter under the Declaratory
28 Judgment Act.

