

1 TRENTON H. NORRIS (SBN 164781)
2 SARAH ESMALI (SBN 206053)
3 S. ZACHARY FAYNE (SBN 307288)
4 Arnold & Porter LLP
5 Three Embarcadero Center, 10th Floor
6 San Francisco, California 94111
7 Telephone: +1 415.471.3100
8 Facsimile: +1 415.471.3400
9 E-Mail: Trent.Norris@aporter.com

FILED

AUG 10 2016

FRESNO SUPERIOR COURT
By _____
DEPT. 401 - DEPUTY

Attorneys for Plaintiff/Petitioner Monsanto Company

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF FRESNO

11 MONSANTO COMPANY,
12
13 Plaintiff/Petitioner,

13 v.

14 OFFICE OF ENVIRONMENTAL HEALTH
15 HAZARD ASSESSMENT; LAUREN ZEISE, in
16 her official capacity as Acting Director of the
17 Office of Environmental Health Hazard
18 Assessment,

17 Defendants/Respondents.

Case No.: 16CECG00183

**MONSANTO COMPANY'S FIRST
AMENDED VERIFIED PETITION FOR
WRIT OF MANDATE AND COMPLAINT
FOR PRELIMINARY AND PERMANENT
INJUNCTIVE AND DECLARATORY
RELIEF**

Unlimited Civil Case

Dept: 401
Judge: Hon. Dale Ikeda
Trial Date: Not Assigned

20 Petitioner and Plaintiff Monsanto Company ("Monsanto") seeks a writ of mandate and
21 declaratory and injunctive relief against Defendants Office of Environmental Health Hazard
22 Assessment ("OEHHA" or the "Agency") and Lauren Zeise, in her official capacity as Acting Director
23 of OEHHA, and alleges as follows:

INTRODUCTION

25 1. This Petition and Complaint seeks a writ of mandate and declaratory and injunctive
26 relief to enjoin OEHHA from adding the herbicide glyphosate to the Proposition 65 list of
27 chemicals that are "known to the state of California to cause cancer."

28 2. Glyphosate is a widely used herbicide that is highly effective in controlling weeds in

1 agricultural, residential, aquatic, and other settings. It is marketed under a number of trade names,
2 by Monsanto and others, and is registered for use in more than 160 countries.

3 3. In the United States, glyphosate, like other pesticide products, is subject to extensive
4 regulation at both the federal and California state levels. *See generally* Federal Insecticide,
5 Fungicide, and Rodenticide Act (“FIFRA”), *codified at* 7 U.S.C. § 136 *et seq.*; Cal. Code. Reg., tit.
6 3, Div. 6 (implementing the California Food and Agricultural Code).

7 4. Numerous regulatory agencies and independent scientists have evaluated glyphosate
8 over the course of its more than forty years of use and have concluded that glyphosate does not
9 present a carcinogenic risk to humans. These regulatory and scientific bodies include, among
10 others, the U.S. Environmental Protection Agency (“EPA”), the European Commission (“EC”), the
11 European Food Safety Authority (“EFSA”), the Health Canada Pest Management Regulatory
12 Agency (“PMRA”), and the World Health Organization (“WHO”).

13 5. In 1997 and again in 2007, OEHHA itself, as the “lead state agency for the
14 assessment of health risks posed by environmental contaminants,” evaluated the carcinogenicity of
15 glyphosate for purposes of establishing a Public Health Goal for glyphosate in drinking water.
16 After reviewing the scientific data, OEHHA concluded: “Based on the weight of evidence,
17 glyphosate is judged unlikely to pose a cancer hazard to humans.”

18 6. Nevertheless, on September 4, 2015, OEHHA issued a Notice of Intent to List
19 glyphosate under Proposition 65 as a chemical “known to the state to cause cancer” pursuant to
20 OEHHA’s interpretation and application of section 25249.8(a) of the California Health and Safety
21 Code (the so-called “Labor Code listing mechanism”).

22 7. OEHHA has interpreted the Labor Code listing mechanism to require the Agency to
23 list any substance identified by the International Agency for Research on Cancer (“IARC”) as a
24 human or animal carcinogen. *See* Cal. Code Regs., tit. 27, § 25904. According to OEHHA, the
25 Agency has no discretion not to list a substance that IARC has classified as a carcinogen.
26 OEHHA’s regulations state, for example, that OEHHA “shall not consider comments related to the
27 underlying scientific basis for classification of a chemical by IARC as causing cancer.” *Id.* at
28 § 25904(c). Consequently, OEHHA has described listings under the Labor Code listing mechanism

1 as a “ministerial” and essentially automatic process.

2 8. In providing notice of its intent to list glyphosate in this manner, OEHHA relied
3 exclusively on a determination by IARC that glyphosate is a “probable carcinogen.” OEHHA
4 allowed IARC’s determination to overrule OEHHA’s opposite conclusion that glyphosate is
5 “unlikely to pose a cancer hazard to humans,” which conclusion followed OEHHA’s independent
6 review of the very same animal carcinogenicity studies relied upon by IARC to find “sufficient
7 evidence” of carcinogenicity in experimental animals. In other words, OEHHA effectively elevated
8 the determination of an ad hoc committee of an unelected, foreign body, which answers to no
9 United States official (let alone any California state official), over the conclusions of its own
10 scientific experts.

11 9. IARC’s process for classifying chemicals, such as glyphosate, as to their
12 carcinogenicity contains no inherent safeguards against arbitrary action. Indeed, IARC expressly
13 disavows any law- or policy-making role -- despite OEHHA’s virtually automatic application of
14 IARC determinations to list chemicals under Proposition 65 -- thereby misleading the public and
15 perhaps IARC panelists into underestimating the effects of IARC panel decisions.

16 10. The so-called Labor Code listing mechanism, as applied by OEHHA in proposing to
17 list glyphosate under Proposition 65, violates the California and United States Constitutions:

18 a. First, by delegating law-making authority to an unelected, undemocratic,
19 unaccountable, and foreign body without providing intelligible principles or procedural safeguards
20 to define the boundaries of that authority or prevent its arbitrary exercise, the Labor Code listing
21 mechanism, as interpreted and applied by OEHHA, violates the non-delegation doctrine that is
22 rooted in principles of separation of powers, in violation of the California Constitution.

23 b. Second, by providing for the placement of substances on the Proposition 65
24 list pursuant to a constitutionally deficient process that includes no procedural safeguards or
25 governmental oversight and that is overwhelmingly likely to lead to erroneous results, the Labor
26 Code listing mechanism, as interpreted and applied by OEHHA, violates Monsanto’s right to
27 procedural due process under the California and United States Constitutions.

28

1 c. Third, by identifying IARC to have the power to identify substances for
2 placement on the Proposition 65 list without any substantive review by OEHHA or any other
3 California governmental entity, the Labor Code listing mechanism, as interpreted and applied by
4 OEHHA, violates Article II, Section 12 of the California Constitution, which states that “no statute
5 proposed to the electors . . . by initiative” that “identifies any private corporation . . . to have any
6 power” may “have any effect.”

7 d. Fourth, by empowering an unelected, undemocratic, unaccountable, and
8 foreign body to make laws applicable in California, the Labor Code listing mechanism, as
9 interpreted and applied by OEHHA, violates the Guarantee Clause of the United States
10 Constitution, which guarantees to the citizens of every state, including California, a “Republican
11 Form of Government.” U.S. Const. Art. IV, Sec. 4, Cl. 1.

12 e. Fifth, the Labor Code listing mechanism, as interpreted and applied by
13 OEHHA, effectively empowers an unelected, undemocratic, unaccountable, and foreign body to
14 make laws applicable in California. Such a radical change to the system of government in the state
15 of California would require a revision (or, at a minimum, an amendment) to the California
16 Constitution, which is outside the reach of the initiative process by which section 25249.8(a) of the
17 California Health & Safety Code was adopted.

18 f. Sixth, the listing of glyphosate under Proposition 65 would violate
19 Monsanto’s right to free speech under Article I, Section 2 of the California Constitution and the
20 First Amendment to the United States Constitution. If glyphosate is added to the Proposition 65
21 list, Monsanto will be required to provide a “clear and reasonable warning” on its glyphosate-based
22 products that states that the products contain a chemical “known to the state to cause cancer.”
23 However, OEHHA’s scientific experts in fact reached the opposite conclusion -- namely, that
24 glyphosate is “unlikely to pose a cancer hazard to humans.” As such, the Proposition 65 warning
25 requirement, as applied to glyphosate, would compel Monsanto to affix false and/or misleading
26 statements to its products. Such compelled commercial speech does not advance any legitimate or
27 substantial government interest.

28

1 11. The listing of glyphosate would cause irreparable injury to Monsanto and the public.
2 The listing would adversely affect Monsanto's reputation for manufacturing safe and reliable
3 herbicides; would potentially result in lost sales due to consumer deselection of glyphosate-based
4 herbicides; and would require Monsanto to spend significant sums of money to re-label and re-shelf
5 its products. In addition, Monsanto would not be able to recover its financial losses from OEHHA
6 if OEHHA's action in listing glyphosate is subsequently held to be unlawful because there is no
7 legal mechanism for Monsanto to do so.

8 12. The public would be harmed as well because listing glyphosate would create
9 unfounded consumer fear, causing farmers, government agencies, and other users of glyphosate-
10 based herbicides to switch to other products and/or processes for vegetation management that may
11 not provide the same level of safety, effectiveness, or reliability.

PARTIES

12
13 13. Plaintiff Monsanto Company is a corporation headquartered in St. Louis, Missouri
14 and incorporated in the state of Delaware. Monsanto is the leading manufacturer of the herbicide
15 glyphosate, which is the main ingredient in Monsanto's Roundup® line of products.

16 14. Defendant OEHHA is the agency of the State of California designated by the
17 Governor under section 25249.12 of the California Health and Safety Code to be the lead agency
18 charged with implementing Proposition 65. Cal. Code Regs., tit. 27, § 25102(o). OEHHA has
19 offices in Sacramento and Oakland, California.

20 15. Defendant Lauren Zeise, Ph.D., is the Acting Director of OEHHA and as such is its
21 highest administrative official. Acting Director Zeise is sued solely in her official capacity.
22 OEHHA and Acting Director Zeise shall be referred to hereafter collectively as "OEHHA."

JURISDICTION AND VENUE

23
24 16. This Court has jurisdiction over this petition for writ of mandate and complaint for
25 declaratory and injunctive relief pursuant to sections 525, 526, 1060, and 1085 of the California
26 Code of Civil Procedure, and Article VI, Section 10 of the California Constitution.

27 17. Venue is proper in this county pursuant to sections 395 and 401 of the California
28 Code of Civil Procedure because this is an action against the State, or a department, officer or other

1 agency thereof, that may be commenced in the County of Sacramento, and therefore may also be
2 commenced in any county in which the California Attorney General has an office. The California
3 Attorney General has an office in this county.

4 **STATUTORY AND REGULATORY BACKGROUND**

5 18. In 1986, the California voters, by initiative, enacted the Safe Drinking Water and
6 Toxic Enforcement Act of 1986, now codified at California Health & Safety Code §§ 25249.5, *et*
7 *seq.* (“Proposition 65”). In general, Proposition 65 prohibits businesses from (i) knowingly and
8 intentionally exposing California residents to chemicals known to cause cancer or reproductive
9 toxicity without providing a clear and reasonable warning, or (ii) knowingly discharging or
10 releasing a chemical known to the state to cause cancer or reproductive toxicity into the
11 environment where the chemical passes or probably will pass into a source of drinking water. Cal.
12 Health & Safety Code §§ 25249.5 and 25249.6.

13 19. Proposition 65 requires OEHHA to publish “a list of those chemicals known to the
14 state to cause cancer or reproductive toxicity.” Cal. Health & Safety Code § 25249.8(a).

15 20. The statute provides several mechanisms by which OEHHA may place a substance
16 on the Proposition 65 list. As relevant here, the statute states that the “list shall include at a
17 minimum those substances identified by reference in Labor Code Section 6382(b)(1) and those
18 substances identified additionally by reference in Labor Code Section 6382(d).” *Id.* Section
19 6382(b)(1) of the Labor Code, in turn, identifies by reference “[s]ubstances listed as human or
20 animal carcinogens by the International Agency for Research on Cancer (IARC).”

21 21. There is ambiguity in the statutory provision at section 25249.8(a) of the California
22 Health & Safety Code as to whether it was intended to refer only to those substances classified by
23 IARC as of the enactment of Proposition 65 (a known quantity) or instead also to those substances
24 that IARC may classify in the future (an unknown quantity). The first interpretation would have
25 merely incorporated into the original Proposition 65 list a known set of substances, with no legal
26 infirmity. The second interpretation, however, would delegate to IARC the power to list chemicals
27 under Proposition 65.

28 22. OEHHA has adopted the second interpretation of Cal. Health & Safety Code

1 § 25249.8(a), and has codified that interpretation in its regulations implementing Proposition 65 at
2 Cal. Code Regs., tit. 27, § 25904. This mechanism for placing substances on the Proposition 65 list
3 by reference to determinations by IARC that were made after the enactment of Proposition 65 is
4 referred to herein as the “Labor Code listing mechanism.”

5 23. The First District Court of Appeal upheld OEHHA’s interpretation and resolved the
6 statutory ambiguity in favor of permitting OEHHA to list chemicals classified by IARC on an
7 ongoing basis. *California Chamber of Commerce v. Brown*, 196 Cal. App. 4th 233 (2011).
8 However, the parties in that case did not raise, and the Court of Appeal did not consider,
9 constitutional concerns related to the delegation of authority to an unelected, undemocratic,
10 unaccountable, foreign body. Those constitutional claims are raised for the first time in this lawsuit.

11 24. OEHHA regulations implementing the Labor Code listing mechanism state: “A
12 chemical or substance shall be included on the list if it is classified by [IARC] in its IARC
13 Monographs series on the Evaluation of Carcinogenic Risks to Humans (most recent edition), or in
14 its list of Agents Classified by the IARC Monographs, as: (1) Carcinogenic to humans (Group 1),
15 or (2) Probably carcinogenic to humans (Group 2A) with sufficient evidence of carcinogenicity in
16 experimental animals, or (3) Possibly carcinogenic to humans (Group 2B) with sufficient evidence
17 of carcinogenicity in experimental animals.” Cal. Code Regs., tit. 27, § 25904(b).

18 25. OEHHA regulations further require OEHHA to publish a notice of intent to list a
19 chemical or substance via the Labor Code listing mechanism, and to provide a 30-day public
20 comment period “on whether or not the chemical or substance has been identified by reference in
21 Labor Code section 6382(b)(1).” *Id.* at § 25904(c). OEHHA’s regulations make clear that the
22 scope of comments on a Labor Code listing is limited: “Comment is restricted to whether the
23 identification of the chemical or substance meets the requirements of this section. The lead agency
24 shall not consider comments related to the underlying scientific basis for classification of a
25 chemical by IARC as causing cancer.” *Id.*

26 **FACTUAL ALLEGATIONS**

27 **I. Glyphosate Is A Widely Used, Effective, and Safe Herbicide.**

28 **A. Overview of Glyphosate.**

1 26. Glyphosate is a broad-spectrum herbicide that is used to control weeds in a variety of
2 agricultural, residential, aquatic, and other settings. Since it was first introduced in 1974,
3 glyphosate “has become the world’s most widely used herbicide because it is efficacious,
4 economical and environmentally benign.” Stephen B. Powles, *Evolved Glyphosate-Resistant Weeds*
5 *Around the World: Lessons To Be Learnt*, 64 *Pest Management Science* 360, 360-365 (April 2008).
6 Glyphosate is marketed under a number of trade names, by Monsanto and others, and is registered
7 for use as a herbicide in more than 160 countries, including the United States.

8 27. Glyphosate is approved for use in more than 250 agricultural crop applications in
9 California. Glyphosate-based herbicides are particularly desirable in the agricultural setting
10 because of their broad-spectrum effectiveness, which allows farmers to control weeds with minimal
11 tilling of soil (a practice known as conservation tilling), thereby conserving valuable topsoil,
12 reducing soil movement into streams and other surface water, retaining soil moisture, and reducing
13 the number of trips across farm fields (which conserves time and fuel).

14 28. Glyphosate-based herbicides are also used to control vegetation in utility right-of-
15 ways, along roadsides and railways, in aquatic environments, and in residential home and garden
16 settings. In addition, glyphosate-based herbicides are used by wildlife organizations to protect and
17 restore wildlife habitats threatened by invasive, non-native vegetation. For example, a Monsanto
18 glyphosate-based herbicide was selected to control *arundo donax* (giant reed) in the Central River
19 Valley area. *Arundo donax* is a highly invasive weed that threatens California’s riparian ecosystems
20 by competing with native species, such as willows, for water.

21 29. For many of the applications for which glyphosate is used, glyphosate is the most
22 effective and reliable weed control option. For example, very few herbicides other than glyphosate
23 are approved for use in aquatic environments. Likewise, in many cases, labor-intensive, mechanical
24 means of weed control are the only available alternative to glyphosate. Mechanical alternatives are
25 even less suitable for ditch banks, steep hillsides, and many non-crop areas, which are not
26 accessible by heavy equipment (*e.g.*, mowers), and thus must be managed by hand. The use of
27 glyphosate-based herbicides in these settings reduces the risk of injury to workers who otherwise
28 must frequently enter the area to maintain mechanical control over vegetation.

1 30. Many municipal, county, and state government agencies in California use
2 glyphosate-based herbicides to manage vegetation. These agencies use glyphosate-based herbicides
3 to control weedy vegetation in order to protect infrastructure, water flow, irrigation, and public
4 safety and health. In addition, glyphosate is widely used by government agencies in California to
5 reduce the risk associated with the rapid spread of wildfires. In particular, glyphosate is used to
6 control vegetation and establish fire breaks during the wet months of the year.

7 **B. OEHHA Previously Concluded That Glyphosate Is Unlikely To Cause Cancer.**

8 31. In 1997 and again in 2007, OEHHA conducted risk assessments of glyphosate for
9 purposes of setting a public health goal (“PHG”) for glyphosate in drinking water. *See* OEHHA,
10 *Public Health Goal for Chemicals in Drinking Water: Glyphosate* (December 1997 and June 2007)
11 (collectively, the “OEHHA Assessments”).

12 32. OEHHA develops PHGs “for chemical contaminants based on the best available
13 toxicological data in the scientific literature.” 2007 OEHHA Assessment at iii.

14 33. The OEHHA Assessments were prepared by the Pesticide and Environmental
15 Toxicology Branch of OEHHA. Several OEHHA staff members and scientists contributed to the
16 evaluation of glyphosate and the corresponding technical support documents.

17 34. The OEHHA Assessments were subject to notice-and-comment rulemaking.
18 OEHHA received and responded substantively to extensive comments from the regulated
19 community and other interested parties.

20 35. As part of the OEHHA Assessments, OEHHA evaluated the carcinogenicity of
21 glyphosate. Among other things, OEHHA staff reviewed several carcinogenicity studies in which
22 glyphosate was administered to experimental animals (rats and mice). Based on its review of the
23 scientific data, OEHHA, in both 1997 and 2007, concluded that there was no evidence that
24 glyphosate causes cancer. In 2007, for example, OEHHA concluded: “Based on the weight of the
25 evidence, glyphosate is judged unlikely to pose a cancer hazard to humans.” *Id.* at 1.

26 36. Notably, OEHHA, in finding that glyphosate is unlikely to be a carcinogen,
27 considered the very same animal carcinogenicity studies that IARC relied upon in reaching the
28 conclusion that there is “sufficient evidence” of carcinogenicity in experimental animals. IARC’s

1 assessment of glyphosate is discussed in Section II.B below.

2 **C. Other Regulatory and Scientific Bodies Worldwide Have Repeatedly Concluded**
3 **That Glyphosate Is Not A Carcinogen.**

4 37. Glyphosate has been the subject of hundreds of toxicological, ecotoxicological, and
5 environmental studies over its more than forty years of use. Regulatory and scientific bodies
6 worldwide have reviewed the research on glyphosate and have repeatedly determined that there is
7 no evidence that glyphosate is carcinogenic to humans.

8 38. These regulatory and scientific bodies include, among others, the U.S. EPA, the
9 German Federal Institute for Risk Assessment (“BfR”) (acting as the Rapporteur Member State for
10 the European Union), the European Food Safety Authority (“EFSA”) (performing a peer review of
11 the BfR assessment), the European Commission (“EC”), the Canadian Pest Management Regulatory
12 Authority (“PMRA”), and the Joint FAO/WHO Meeting on Pesticide Residues (“JMPR”), which is
13 an international scientific group administered jointly by the Food and Agriculture Organization of
14 the United Nations (“FAO”) and the World Health Organization (“WHO”).

15 39. Glyphosate was first registered for use as an herbicide in the United States in 1974.
16 In 1991, the U.S. EPA conducted a peer review of glyphosate and, in 1993, approved the renewal of
17 glyphosate’s registration. The U.S. EPA concluded: “Several chronic toxicity/carcinogenicity
18 studies . . . resulted in no effects based on the parameters examined, or resulted in findings that
19 glyphosate was not carcinogenic in the study.” U.S. EPA, Registration Eligibility Decision (RED):
20 Glyphosate, EPA-738-F-93-011 (1993). The U.S. EPA has placed glyphosate in the agency’s
21 lowest cancer classification category, Category E (“evidence of non-carcinogenicity for humans --
22 based on the lack of convincing evidence of carcinogenicity in adequate studies”). *Id.*

23 40. In 2014, the U.S. EPA reaffirmed its determination that glyphosate is not
24 carcinogenic after reviewing more than 55 epidemiological studies of glyphosate, concluding: “Our
25 review concluded that this body of research does not provide evidence to show that glyphosate
26 causes cancer, and it does not warrant any change in EPA’s cancer classification for glyphosate.
27 This is the same conclusion reached in 2004 by the United Nations’ Food and Agriculture
28 Organization and affirmed this year by Germany’s pesticide regulatory officials.” Statement of
Carissa Cyran, Chemical Review Manager for the U.S. EPA Office of Pesticide Programs (2015).

