

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

Attorneys for Plaintiff/Petitioner Monsanto Company

FILED

AUG 10 2016

FRESNO SUPERIOR COURT
By _____ DEPT. 401 - DEPUTY

**SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF FRESNO**

MONSANTO COMPANY,

Plaintiff/Petitioner,

v.

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

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

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

INTRODUCTION

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

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

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

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

PARTIES

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

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

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

JURISDICTION AND VENUE

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

17. Venue is proper in this county pursuant to sections 395 and 401 of the California 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

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

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

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

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

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

40. In 2014, the U.S. EPA reaffirmed its determination that glyphosate is not carcinogenic after reviewing more than 55 epidemiological studies of glyphosate, concluding: “Our review concluded that this body of research does not provide evidence to show that glyphosate causes cancer, and it does not warrant any change in EPA’s cancer classification for glyphosate. This is the same conclusion reached in 2004 by the United Nations’ Food and Agriculture 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).

1 41. In December 2013, Germany, through its risk assessment agency, BfR, and acting as
2 the Rapporteur Member State (“RMS”) for the EU, submitted a glyphosate Renewal Assessment
3 Report to the European Food Safety Authority recommending re-approval of glyphosate for use in
4 Europe. *See* Renewal Assessment Report and Proposed Decision, Volume 1 (Revised Jan. 29,
5 2015). The Report was revised in 2014 and again in 2015 in response to comments. In the Report,
6 BfR, after investigating a large number of carcinogenicity studies, concluded that glyphosate was
7 “unlikely to pose a carcinogenic risk in humans” and that “[i]n epidemiological studies in humans,
8 there was no evidence of carcinogenicity and there were no effects on fertility, reproduction and
9 development or of neurotoxicity that might be attributed to glyphosate.” *Id.* at 35-36.

10 42. In March 2015, in response to IARC’s classification of glyphosate as a “probable
11 carcinogen,” BfR stated: “As the ‘Rapporteur Member State’ for the active substance glyphosate
12 within the framework of EU re-evaluation, the Federal Institute for Risk Assessment (BfR) was
13 responsible for the human health risk assessment and has assessed glyphosate as non-carcinogenic.”
14 BfR, *Does Glyphosate Cause Cancer?* BfR Communication No. 007/2015 (March 2015).

15 43. BfR further explained: “For this purpose, BfR has compiled the most comprehensive
16 toxicological database, presumably worldwide, for glyphosate. This database comprises hundreds
17 of studies that were performed by or on behalf of the many manufacturers of glyphosate and
18 thousands of references from the open literature. This huge amount of data makes glyphosate
19 nearly unique among the active substances in plant protection products. BfR thinks that the entire
20 database must be taken into account for toxicological evaluation and risk assessment of a substance
21 and not merely a more or less arbitrary selection of studies.” *Id.*

22 44. On November 12, 2015, the EFSA released a report entitled *Conclusion on the Peer*
23 *Review of the Pesticide Risk Assessment of the Active Substance Glyphosate*. EFSA assessed the
24 findings of the BfR and “concluded that glyphosate is unlikely to pose a carcinogenic hazard to
25 humans and the evidence does not support classification with regard to its carcinogenic
26 potential” *Id.* at 1. EFSA further concluded that “[g]lyphosate did not present genotoxic
27 potential and no evidence of carcinogenicity was observed in rats or mice.” *Id.* at 10.

28 45. At the request of the EC, EFSA also addressed IARC’s classification of glyphosate

1 as a “probable carcinogen” and set forth potential reasons for the diverging views. For example,
2 EFSA explained: “With regard to the studies on experimental animals, three of the five mice
3 studies used by the EU peer review and three of the nine studies in rats were not assessed by IARC.
4 Importantly, there is a different interpretation of the statistical analysis used to assess the
5 carcinogenic findings in the animal studies and on the use of historical control data; the EU peer
6 review considered relevant historical control data from the performing laboratory. Additionally,
7 referring to the unusually large data base available, it was considered appropriate by the EU peer
8 review to adopt consistently a weight of evidence approach.” *Id.* at 11.

9 46. In 2002, the Health and Consumer Protection Directorate-General of the EC
10 conducted a review of glyphosate for purposes of the re-registration of glyphosate for use in Europe
11 and concluded that there was “[n]o evidence of carcinogenicity.” EC, Report for the Active
12 Substance Glyphosate, Directive 6511/VI/99, at 12 (Jan. 2002).

13 47. In April 2015, the Canadian PMRA proposed to continue to register products
14 containing glyphosate for sale and use in Canada. *See* PMRA, *Proposed Re-Evaluation Decision*,
15 PRVD2015-01, Glyphosate (April 2015). In reaching this determination, the PMRA stated: “In
16 consideration of the strength and limitations of the large body of information on glyphosate, which
17 included multiple short and long term (lifetime) animal toxicity studies, numerous in vivo and in
18 vitro genotoxicity assays, as well as the large body of epidemiological information, the overall
19 weight of evidence indicates that glyphosate is unlikely to pose a human cancer risk. This is
20 consistent with all other pesticide regulatory authorities world-wide, including the most recent,
21 ongoing comprehensive re-evaluation by Germany (Rapporteur Member State for the European
22 Union) that was published for public consultation in 2014.” *Id.* at 15.

23 48. In 2004, the JMPR released a report entitled *Pesticide Residues in Food* that
24 evaluated the possible toxicological effects of glyphosate. The JMPR evaluated several long-term
25 studies of toxicity and carcinogenicity in mice and rats and found that there was no evidence of
26 carcinogenicity in either species. *See* WHO/FAO, *Pesticide Residues in Food - 2004, Part II:*
27 *Toxicological*, at 158 (2004). The JMPR concluded: “In view of the absence of a carcinogenic
28 potential in animals and the lack of genotoxicity in standard tests, the [JMPR] concluded that

1 glyphosate is unlikely to pose a carcinogenic risk to humans.” *Id.*

2 II. IARC’s Classification of Glyphosate as a Probable Carcinogen.

3 A. Overview of IARC.

4 49. IARC is a specialized cancer agency of the WHO that is based in Lyon, France.
5 IARC is funded by the governments of 25 countries, as well as by grants from various governmental
6 and non-governmental agencies around the world. The Director of IARC is selected by and reports
7 to the IARC Governing Council and usually serves for a term of five years. The Director oversees
8 the day-to-day operations of IARC, including hiring, firing, promoting, and managing IARC staff.

9 50. The IARC Governing Council is composed of the Representatives of the
10 Participating States and the Director-General of the WHO. The Participating States as of May 2015
11 included Australia, Austria, Belgium, Brazil, Canada, Denmark, Finland, France, Germany, India,
12 Ireland, Italy, Japan, Mexico, Morocco, the Netherlands, Norway, Qatar, the Republic of Korea, the
13 Russian Federation, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United
14 States. Decisions of the IARC Governing Council, including selection of the Director, are made by
15 majority vote of the Representatives of the Participating States who are present and voting, with one
16 vote per Representative. A quorum consists of a majority of such Representatives.

17 51. One of IARC’s activities is the “IARC Monograph” program. As part of this
18 program, IARC convenes groups of scientists on an ad hoc basis (“Working Groups”), selected by
19 IARC staff in an opaque, non-public process, to review and summarize scientific research on the
20 carcinogenicity of a wide range of chemicals, complex mixtures, occupational exposures, physical
21 agents, biological agents, and personal habits (collectively, “agents”). IARC publishes the
22 conclusions of these Working Groups in its monograph series, *Monographs on the Evaluation of*
23 *Carcinogenic Risks to Humans* (“*Monographs*”).

24 52. IARC’s processes and procedures are set forth generally in the Preamble to the
25 *Monographs* (the “IARC Preamble”). The IARC Preamble was last amended in January 2006.

26 53. IARC states that the objective of the Monograph program is “to prepare, with the
27 help of international Working Groups of experts, and to publish in the form of *Monographs*, critical
28 reviews and evaluations of evidence on the carcinogenicity of a wide range of human exposures.”

1 IARC Preamble at 2.

2 54. IARC explains that its focus is on cancer “hazards,” as distinct from cancer “risks.”
3 According to IARC, the “distinction between hazard and risk is important, and the *Monographs*
4 identify cancer hazards even when risks are very low at current exposure levels. . . .” IARC
5 Preamble at 2. Said differently, IARC may determine that an agent is carcinogenic to humans based
6 on studies involving doses that are orders of magnitude higher than common or even conceivable
7 levels. Thus, IARC has explained that its cancer classifications address whether an agent is
8 “capable of causing cancer under some circumstances” (*i.e.*, “hazard”), but do not consider “the
9 likelihood that cancer will occur . . . as a result of exposure to the agent” (*i.e.*, “risk”).

10 Selection of Agents for Review

11 55. According to the IARC Preamble, IARC staff select agents for review based on two
12 main criteria: “(a) there is evidence of human exposure and (b) there is some evidence or suspicion
13 of carcinogenicity.” IARC Preamble at 3. It is unknown precisely what factors IARC currently
14 applies or how IARC decides to allocate its resources in selecting one agent over others. IARC
15 staff make these determinations.

16 56. Although IARC collaborates with and accepts recommendations from others in
17 considering which agents to review, IARC (acting through its staff) exercises sole discretion in its
18 selection of agents for review. Once IARC decides to review an agent pursuant to its *Monographs*
19 program, that decision is final and is not subject to review or challenge.

20 57. IARC staff have selected a wide range of agents for consideration by the Working
21 Groups. Noteworthy examples of agents that have been reviewed and classified by IARC as
22 possible, probable, or known human carcinogens include: very hot beverages (2016), processed
23 meats (2015), cellular telephone radiation (2012), coffee (1991), aloe vera (2015), and Chinese
24 salted fish (2012). IARC’s reviews are not limited to physical substances. For example, IARC has
25 found that there are cancer hazards associated with shiftwork, and the occupations of painting and
26 firefighting (2007).

27 Selection of Working Group Members

28 58. IARC staff, in their sole discretion, select the individual scientists who will form the

1 Working Group for evaluating a particular agent (or set of agents). IARC convenes a separate
2 Working Group for each volume of the *Monographs*, which may cover a single agent or occupation,
3 several related agents or occupations, or even a diverse mix of agents and occupations. Each
4 Working Group is convened for a special purpose and has no institutional existence beyond the
5 period of time required for review of the identified agent or agents, which is usually a matter of
6 months.

7 59. IARC states that it seeks to select scientists who are knowledgeable about one or
8 more of the agents under review. As described above, however, IARC Working Groups often
9 review several agents in connection with a single volume of the *Monographs*. As a result, the
10 Working Group members often are not knowledgeable about every agent under review during the
11 Working Group session. Nevertheless, each Working Group member is permitted to participate
12 fully in the review and classification of all agents under consideration during the Working Group
13 session. Therefore, for any single agent, the majority of Working Group members may be
14 unfamiliar with the relevant science prior to participating in the Working Group.

15 60. Although the Working Group members often are affiliated with a particular
16 organization or government agency, IARC has explained that “[e]ach participant who is a Member
17 of a Working Group serves as an individual scientist and not as a representative of any organization,
18 government or industry.” IARC Preamble at 5. They are therefore unaccountable to any
19 organization, individual, or group of individuals. Each Working Group has 10 to 30 members.

20 61. IARC explains that Working Group members are selected on the basis of
21 “(a) knowledge and experience and (b) absence of real or apparent conflicts of interests.” IARC
22 Preamble at 4. IARC further explains that “[c]onsideration is also given to demographic diversity
23 and balance of scientific findings and views.” *Id.* As a result, scientific merit is not the sole
24 criterion for selection.

25 62. The decisions of IARC staff as to the composition of a Working Group are final.
26 There is no process for challenging the selection of any individual or for proposing that any other
27 individual be named to the Working Group.

28 63. IARC excludes from the Working Groups any individual who has a “real or apparent

1 conflict of interest.” Pursuant to guidelines issued by the WHO in 2004, each potential Working
2 Group participant is required to declare “any interests that could constitute a real, potential or
3 apparent conflict of interest, with respect to his/her involvement in the meeting or work, between a)
4 commercial entities and the participant personally, and b) commercial entities and the
5 administrative unit with which the participant has an employment relationship.” The conflict of
6 interest policy is restricted solely to commercial entities (*i.e.*, businesses and associations of
7 businesses) and does not apply to activist organizations, academic institutions, or other not-for-
8 profit organizations, even though such entities have agendas, perspectives, motives, and interests
9 that are not purely scientific. The IARC conflict of interest policy also does not consider issues of
10 careerism or positions advocated by individual Working Group members in the past that would
11 cause a reasonable person to doubt the Working Group member’s objectivity or willingness to
12 consider all relevant information and analysis.

13 64. The WHO defines “conflict of interest” to mean “the expert or his/her partner, or the
14 administrative unit with which the expert has an employment relationship, has a financial or other
15 interest that could unduly influence the expert’s position with respect to the subject matter being
16 considered.” As described below, however, in practice, IARC does not exclude scientists who have
17 a vested professional interest in the research being evaluated such that the individual might be
18 motivated by a desire for the results to be meaningful or unduly given weight in the analysis.

19 65. IARC excludes from the Working Groups scientists who have an affiliation with
20 industry, including those who have conducted studies on the agent at issue for regulatory purposes
21 and thus may be likely to have the greatest knowledge about the agent.

22 66. On information and belief, IARC’s practice of excluding industry-affiliated scientists
23 was a reaction to a campaign by activists and governmental entities in the late 1990s and early
24 2000s to remove industry-affiliated scientists from the Working Group panels.

25 67. For example, in December 1998, Michael F. Jacobson, Executive Director of the
26 Center for Science in the Public Interest, a prominent activist organization, wrote a letter to IARC
27 expressing concern about the Agency’s review of the artificial sweetener saccharin, asserting that
28 the committee’s membership “was dominated by numerous industry representatives and industry

1 consultants.”

2 68. On February 7, 2002, Joan Denton, the former Director of OEHHA, wrote a letter to
3 IARC expressing concern about IARC’s review of styrene. Dr. Denton explained that “[i]f
4 consultants or employees of companies that have economic interests in the outcome of whether a
5 specific substance is considered a carcinogen sit on Working Groups considering such chemicals,
6 economic considerations cannot be ruled out as influences on the outcome of the IARC
7 assessment.” Dr. Denton further noted: “Because IARC *Monographs* do not undergo public review
8 and are designed to reflect the opinion of convened experts, there is no opportunity to correct errors
9 in judgment.”

10 69. On February 12, 2002, the Natural Resources Defense Council (“NRDC”), a
11 prominent activist organization, wrote a letter to IARC expressing concern about IARC’s review of
12 styrene. The NRDC requested that IARC implement a policy that “to the extent possible panel
13 members will be chosen who do not have financial conflicts of interest of any kind (particularly
14 with the chemical industry and other business interests).”

15 70. On March 13, 2002, Jennifer Sass, a Senior Scientist at the NRDC, wrote IARC: “I
16 enjoyed our recent meeting in Washington, DC, (March 1) and am hopeful that our discussions will
17 lead IARC towards compliance with the WHO/IARC Declaration of Interests (DOI) policy.
18 Clearly, IARC’s current practice of collecting the DOI forms, but allowing all financially conflicted
19 persons to remain as voting, fully participating members of the Working Group (WG) cannot be
20 considered compliance. Further, to allow scientists who have a financial interest in the decision
21 outcome to prepare the discussion documents, or, worse, to chair the discussion groups pertaining to
22 the chemical is simply unacceptable.”

23 71. On information and belief, in response to this advocacy campaign, IARC modified
24 the manner in which it implements the WHO’s conflict of interest policy to exclude from the
25 Working Groups industry-affiliated scientists, regardless of whether their past or current affiliations
26 are disclosed.

27 72. More recently, some have criticized IARC’s focus on financial interests in evaluating
28 conflicts of interest and have suggested that “careerism” -- *i.e.*, a vested professional interest in the

1 research being evaluated such that the individual might be motivated by a desire for the results to be
2 meaningful -- is a much bigger concern that is ignored by IARC's conflict of interest review. For
3 example, one group of scientists opined that in the "field of epidemiology, the area of research
4 given the most weight in IARC decision making, the working group is often composed of
5 researchers who have a strong, if not lifelong interest in the potential carcinogenicity of the
6 exposure under consideration. . . . They are clearly not disinterested evaluators of the research
7 evidence being considered, as much of it represents their own work." Joseph K. McLaughlin *et al.*,
8 *Problems With IARC's 'Expert' Working Groups*, 40 Int'l J. of Epid. 1728 (Nov. 2011). IARC has
9 no published policy with respect to such potential influences on the decisions of its ad hoc Working
10 Groups.

11 Review Process

12 73. The IARC Preamble sets forth general principles to guide the Working Group's
13 review and classification of agents, but affords the Working Group considerable discretion to
14 disregard those guidelines, stating: "The Preamble is primarily a statement of scientific principles,
15 rather than a specification of working procedures. The procedures through which a Working Group
16 implements these principles are not specified in detail" and "remain, predominantly, the prerogative
17 of each individual Working Group." IARC Preamble at 1-2.

18 74. Once assembled, the IARC Working Group is tasked with reviewing and
19 summarizing the existing scientific literature. The Working Group does not perform any studies
20 and does not generate any new data. The Working Group is permitted, however, to reevaluate study
21 findings and to reach different conclusions than the authors of the studies reviewed. The Working
22 Group also is permitted to conduct its own meta-analyses of the scientific literature (which meta-
23 analyses would not be available for peer review or editorial comment prior to the Working Group's
24 classification determination).

25 75. Pursuant to IARC policy, the Working Group is only allowed to consider "reports
26 that have been published or accepted for publication in the openly available scientific literature,"
27 "[d]ata from government agency reports that are publicly available," and, in exceptional
28 circumstances, "doctoral theses and other material that are in their final form and publicly

1 available.” IARC Preamble at 4. Thus, studies and data submitted to regulatory authorities that are
2 not publicly available are not considered by the Working Group. For regulated chemicals of
3 significant commercial value (such as glyphosate), significant scientific studies and data often are
4 not published in the peer-reviewed literature and therefore are not considered by the Working
5 Group.

6 76. The Working Group also is not permitted to consider or cite “[n]arrative reviews,
7 commentaries, and letters that do not provide relevant original data.” Thus, the Working Group
8 does not formally consider review publications that summarize the existing scientific data on a
9 particular agent.

10 77. Each Working Group convenes for a multi-day meeting in person, usually in Lyon,
11 France. The Working Group members receive a small per diem for each day of the in-person
12 meeting, plus travel expenses. They are not otherwise compensated for participating on the
13 Working Group. Thus, Working Group members do not receive compensation for time spent
14 preparing for the in-person meeting, which might include time spent reviewing the relevant
15 scientific literature and drafting preliminary working papers.

16 78. Working Group members are usually selected approximately one year prior to the
17 multi-day meeting (although, as noted below, the timing regarding the appointment of the Working
18 Group that considered glyphosate did not follow IARC’s usual procedure). Except as noted below,
19 there is no prohibition on ex parte communications with members of the Working Group on the
20 subject agent or agents prior to this meeting; nor is there any requirement that such communications
21 be disclosed.

22 79. As described above, before the meeting, IARC staff collect the “relevant biological
23 and epidemiological data . . . from recognized sources of information on carcinogenesis, including
24 data storage and retrieval systems such as PubMed.” IARC Preamble at 5. “Meeting participants
25 who are asked to prepare preliminary working papers for specific sections are expected to
26 supplement the IARC literature searches with their own searches.” *Id.*

27 80. Six months before the meeting, the relevant literature “is sent to meeting participants
28 to prepare preliminary working papers. The working papers are compiled by IARC staff and sent,

1 prior to the meeting, to Working Group Members and Invited Specialists for review.” IARC
2 Preamble at 6. In other words, the Working Group members are expected to have reviewed the
3 relevant scientific literature and preliminary working papers -- which typically consist of thousands
4 of pages of materials -- in advance of the meeting.

5 81. At the multi-day meeting, Working Group members are divided into three subgroups
6 based on type of study: (1) cancer in humans, (2) cancer in experimental animals, and (3)
7 mechanistic and other relevant data. IARC Preamble at 19-21. The “cancer in humans” subgroup
8 and the “cancer in experimental animals” subgroup are required to classify the evidence relevant to
9 carcinogenicity from studies in humans and animals, respectively, into the following categories:
10 sufficient evidence of carcinogenicity; limited evidence of carcinogenicity; inadequate evidence of
11 carcinogenicity; and evidence suggesting lack of carcinogenicity. *Id.* The “mechanistic and other
12 relevant data” subgroup is required to classify the evidence that any carcinogenic effect is due to a
13 particular mechanism using terms such as “weak,” “moderate,” or “strong.” *Id.* at 21.

14 82. A small number of interested individuals selected by IARC staff are permitted to
15 participate in or observe the deliberations of the Working Group, but may not be permitted to
16 present data or comments to the Working Group or take part in the classification decisions. IARC
17 Preamble at 4. These individuals fall into four categories: (1) invited specialists (experts on the
18 particular subject matter who have a “real or apparent conflict of interest”), who are permitted to
19 participate in discussions but cannot draft sections of the *Monographs* that discuss cancer data nor
20 participate in the evaluations; (2) representatives of national and international health agencies;
21 (3) “observers” (selected by IARC staff from nominees with “differing perspectives”), who may be
22 afforded an opportunity to speak at the discretion of the Working Group chairs, but may not
23 participate in the evaluations nor lobby Working Group members before or during the meeting; and
24 (4) the IARC Secretariat, which includes scientists designated by IARC who can participate in all
25 discussions and may also draft text or prepare tables and analyses for the Working Group’s
26 consideration and for possible inclusion in the Monograph. *Id.* at 4-5.

27 Classification Determinations

28 83. The Working Group also is responsible for making classification determinations. A

1 substance can be classified in one of five groups: carcinogenic to humans (Group 1), probably
2 carcinogenic to humans (Group 2A), possibly carcinogenic to humans (Group 2B), not classifiable
3 as to its carcinogenicity to humans (Group 3), or probably not carcinogenic to humans (Group 4).

4 84. According to the IARC Preamble, the “objectives of the [in-person] meeting are peer
5 review and consensus.” IARC Preamble at 6. Thus, “IARC Working Groups strive to achieve a
6 consensus evaluation.” *Id.* According to IARC, “[c]onsensus reflects broad agreement among
7 Working Group Members, but not necessarily unanimity.” *Id.*

8 85. The IARC Secretariat edits and prepares the final draft of the Monograph for
9 publication. Just like the IARC staff’s selection of agents for consideration and members of the
10 Working Group, the Working Group’s classification is final and is not subject to public comment,
11 review, correction, request for reconsideration, or appeal. As Dr. Denton of OEHHHA noted, once
12 the Working Group publishes its decision, “there is no opportunity to correct errors in judgment.”

13 86. IARC is not a regulatory agency, explicitly disavows any policy- or law-making role,
14 and does not intend its determinations to carry the force of law. In particular, the preamble to each
15 of IARC’s *Monographs* -- including the *Monograph* on glyphosate -- states: “The evaluations of
16 IARC Working Groups are scientific, qualitative judgments on the evidence for or against
17 carcinogenicity provided by the available data. These evaluations represent only one part of the
18 body of information on which public health decisions may be based. Public health options vary
19 from one situation to another and from country to country and relate to many factors, including
20 different socioeconomic and national priorities. Therefore, no recommendation is given with regard
21 to regulation or legislation, which are the responsibility of individual governments or other
22 international organizations.” IARC Preamble at 3.

23 87. Other regulatory authorities have recognized that IARC is not designed nor intended
24 to be a law-making entity. For example, in January 2016, Bernhard Url, the Executive Director of
25 EFSA, responded to criticisms of EFSA’s assessment of glyphosate as non-carcinogenic in light of
26 IARC’s classification of glyphosate as a probable carcinogen (see below). Dr. Url explained: “I
27 agree that IARC carries out an important role in the screening assessment of the carcinogenic
28 potential of agents. However, we should not compare this first screening assessment with the more

1 comprehensive hazard assessment done by authorities such as EFSA, which are designed to support
2 the regulatory process for pesticides in close cooperation with the Member States in the EU.”

3 88. U.S. lawmakers also have questioned whether IARC is a reliable scientific body and
4 whether it should be receiving financial support from the U.S. government. For example, on June 7,
5 2016, U.S. Congressman Robert B. Aderholt, a member of the House Committee on Appropriations
6 and Chair of the Subcommittee on Agriculture, sent a letter to Francis S. Collins, Director of the
7 National Institutes of Health (“NIH”). Congressman Aderholt requested a briefing on the IARC
8 study of glyphosate and the standards NIH places on research funded by U.S. taxpayers.
9 Congressman Aderholt also noted that “[a]ny study by IARC, regardless of its credibility, benefits
10 from association with [NIH] and its reputation as a premier research organization. The IARC study
11 conclusions [concerning glyphosate] appear to be the result of a significantly flawed process;
12 unfortunately, because the study was funded through the NIH, the conclusions will be taken more
13 seriously than they might have been.”

14 **B. IARC’s Assessment of Glyphosate.**

15 89. In April 2014, IARC convened an Advisory Group to recommend priority agents for
16 review as part of the *Monographs* program. The Advisory Group issued a report on April 18-19,
17 2014, recommending glyphosate as a “medium” priority for review. The Advisory Group identified
18 more than 50 other agents as “high” priorities for review.

19 90. Later in 2014, IARC convened a Working Group of 17 scientists to assess the
20 carcinogenicity of glyphosate and four insecticides. According to the “Monographs News” section
21 of IARC’s website, IARC announced on March 12, 2014 that it would be reviewing glyphosate. In
22 fact, IARC did not announce the review of glyphosate until the fall of 2014.

23 a. The original, March 12, 2014 entry on IARC’s website stated: “Meeting 112
24 ‘Some Pesticides and Related Chemicals’ is announced.” The entry did not identify the pesticides
25 or related chemicals to be reviewed.

26 b. Between April 5, 2014 and July 16, 2014, the entry was updated to read:
27 “Meeting 112 ‘Some Organophosphate Insecticides’ is announced.” Glyphosate is neither an
28 organophosphate nor an insecticide. Although the entry was updated after April 5, 2014, it

1 continued to be dated March 12, 2014.

2 c. Between July 16, 2014 and September 10, 2014, the entry was updated to its
3 current form to read: "Meeting 112 'Some Organophosphate Insecticides and Herbicides:
4 Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos" is announced." Although the
5 entry was updated after July 16, 2014, it continued to be dated March 12, 2014.

6 91. The IARC announcement also included a "Call for Experts," which had a closing
7 date of July 30, 2014 (*i.e.*, likely after the announcement was modified to include glyphosate).

8 92. In March 2015, the IARC Working Group met in Lyon, France and classified
9 glyphosate as "probably carcinogenic to humans" (Group 2A). The Working Group's conclusions
10 were published in Volume 112 of IARC's *Monographs* series.

11 93. IARC, in classifying glyphosate as a "probable carcinogen," is an outlier among the
12 regulatory and scientific bodies that have evaluated the scientific data on glyphosate.

13 94. For example, IARC concluded that there was "sufficient evidence" of
14 carcinogenicity in experimental animals based on four long-term carcinogenicity studies in rodents.
15 Specifically, IARC made the following findings: (i) "[t]here was a positive trend in the incidence of
16 renal tubule carcinoma and of renal tubule adenoma or carcinoma (combined) in males in one
17 feeding study in CD-1 mice"; (ii) "there was a significant positive trend in the incidence of
18 haemangiosarcoma in male CD-1 mice" in a second feeding study of mice; and (iii) two studies in
19 rats "showed a significant increase in the incidence of pancreatic islet cell adenoma in males," and
20 "one of these two studies also showed a significant positive trend in the incidences of hepatocellular
21 adenoma in males and of thyroid C-cell adenoma in females." IARC Monograph Vol. 112 at 76.

22 95. In preparing the OEHHA Assessment in 2007, OEHHA evaluated these same four
23 long-term carcinogenicity studies in rodents (or reviews of these studies). After reviewing the data,
24 OEHHA concluded that glyphosate is "unlikely to pose a cancer hazard to humans."

25 96. As shown in the table in Appendix 1 to this Petition and Complaint, other regulatory
26 and scientific bodies (including other WHO programs), on 17 different occasions, have evaluated
27 one or more of these same long-term carcinogenicity studies in rodents. Each of these reviews has
28 reached the opposite conclusion of IARC -- namely, that the small number of tumors observed in

1 rodents subjected to treatment with glyphosate in these studies were *not* related to glyphosate.

2 **III. OEHHA's Notice of Intent to List Glyphosate.**

3 97. On September 4, 2015, OEHHA published a Notice of Intent to List glyphosate
4 pursuant to the Labor Code listing mechanism.

5 98. OEHHA explained that glyphosate met the requirements for a Labor Code listing
6 because (1) IARC classified glyphosate as a "probable carcinogen," and (2) IARC concluded that
7 there was "sufficient evidence" of carcinogenicity in experimental animals.¹ *Id.*; *see also* Cal. Code
8 Regs., tit. 27, § 25904(b) ("A chemical or substance shall be included on the list if it is classified by
9 [IARC] in its IARC Monographs series . . . as: . . . (2) Probably carcinogenic to humans (Group 2A)
10 with sufficient evidence of carcinogenicity in experimental animals . . .").

11 99. OEHHA did not make any other findings about the underlying science, and refused
12 to consider comments about the underlying science, stating: "Because these are ministerial listings,
13 comments should be limited to whether IARC has identified the specific chemical or substance as a
14 known or potential human or animal carcinogen. Under this listing mechanism, OEHHA cannot
15 consider scientific arguments concerning the weight or quality of the evidence considered by IARC
16 when it identified these chemicals and will not respond to such comments if they are submitted."

17 **IV. OEHHA's Proposed Listing of Glyphosate Pursuant to the Labor Code Mechanism** 18 **Violates the California and United States Constitutions.**

19 **A. The Labor Code Listing Mechanism Constitutes an Unlawful Delegation of** 20 **Legislative Authority.**

21 100. The Labor Code listing mechanism, as interpreted by OEHHA, violates the "non-
22 delegation doctrine" that is rooted in principles of separation of powers.

23
24 ¹ IARC also considered certain "mechanistic" data in finding glyphosate to be a "probable
25 carcinogen." Mechanistic studies are studies that attempt to identify the mechanisms through which
26 a chemical may increase the risk of cancer (*e.g.*, molecular changes in cells or DNA). IARC
27 explained that the mechanistic and other relevant data supported the classification of glyphosate in
28 Group 2A. However, these mechanistic and other studies are distinct from the animal
carcinogenicity studies and did not form a basis for IARC's finding of "sufficient evidence" of
carcinogenicity in experimental animals. As such, these studies were not relevant to OEHHA's
decision to propose listing glyphosate pursuant to the Labor Code mechanism (which turned on
IARC's finding of "sufficient evidence" of carcinogenicity in experimental animals).

1 101. An unconstitutional delegation of legislative power occurs when the Legislature (or
2 the voters by initiative): (1) leaves the resolution of fundamental policy issues to others or (2) fails
3 to provide adequate direction for the implementation of those policies. The doctrine rests upon the
4 premise that the legislative body must itself resolve the truly fundamental issues and cannot escape
5 responsibility by explicitly delegating that function to others or by failing to establish an effective
6 mechanism to assure the proper implementation of its policy decisions.

7 102. The Labor Code listing mechanism of Proposition 65, as interpreted by OEHHA,
8 leaves the resolution of fundamental policy issues -- *i.e.*, decisions about which chemicals should be
9 placed on the Proposition 65 list -- to IARC, an unelected, undemocratic, foreign body that is not
10 under the oversight or control of any California governmental entity.

11 103. The placement of a chemical on the Proposition 65 list has serious policy
12 implications: it results in regulation of that chemical under California law; it requires persons doing
13 business in California to undertake evaluations of possible exposures or discharges; and, in some
14 cases, it requires persons doing business in California to change their use of the chemical or provide
15 warnings to those who may be exposed to the chemical. *See* Cal. Health & Saf. Code §§ 25249.5,
16 25249.6.

17 104. Neither Proposition 65 nor OEHHA regulations implementing Proposition 65
18 provide any direction to IARC about how to make classification determinations. As a result, IARC
19 has complete discretion in determining how (or whether) to make classification determinations.
20 Among other things, this means that IARC has unfettered power: (i) to select chemicals for review,
21 (ii) to appoint scientists to the working groups, (iii) to remove scientists from the working groups,
22 (iv) to determine which studies/data are considered, (v) to determine which factors are considered
23 and how those factors are weighed; and (vi) to determine the process by which classification
24 decisions are made.

25 105. There are no mechanisms or procedural safeguards to ensure that IARC performs its
26 function consistent with the policy goals of Proposition 65. IARC is not a regulatory entity and thus
27 is not required or incentivized to consider and weigh competing interests, nor to consider the
28 consequences of identifying a particular chemical or substance as a carcinogen. And indeed, IARC

1 explicitly disavows any regulatory responsibility or law-making role, and thus cannot be expected
2 to consider such consequences. Moreover, IARC selects a different set of individuals, on an ad hoc
3 basis, to form the Working Group for each substance or set of substances, increasing the likelihood
4 of inconsistent and arbitrary classification determinations.

5 106. The determinations of IARC's Working Groups are not subject to public comment or
6 review by any other entity. No California or federal governmental body exercises any oversight,
7 control, or veto power over individual decisions of the IARC Working Groups. There is no appeal
8 from an IARC decision.

9 107. Nor does OEHHA substantively review IARC classification decisions. By
10 regulation, OEHHA's role is limited to ensuring that the listed substance is identified accurately and
11 that IARC has made findings about the sufficiency of the evidence (pursuant to IARC's own
12 definition of "sufficient evidence" and independent judgment as to whether that standard is met).
13 Likewise, OEHHA's regulations state explicitly that the Agency will not consider comments related
14 to the underlying scientific basis for a classification decision.

15 108. Under the Labor Code mechanism, as interpreted by OEHHA, OEHHA does not
16 have authority to reject classification decisions made by individual IARC Working Groups. Thus,
17 OEHHA has described Labor Code listings as a "ministerial" and essentially automatic process.

18 109. The absence of procedural safeguards is compounded by the fact that IARC can
19 change its procedures at any time. For example, IARC could appoint patently unqualified
20 individuals, individuals with undisclosed conflicts of interests, or individuals from backgrounds
21 biased for or against certain industries or fields. It could act by majority vote or by dictate. It could
22 be controlled by the chemical industry or by anti-industry activists with any number of agendas.

23 110. For these reasons, the Labor Code listing mechanism of Proposition 65, as applied to
24 the listing of glyphosate, violates the non-delegation doctrine.

25 **B. The Labor Code Listing Mechanism Violates Procedural Due Process.**

26 111. The Labor Code listing mechanism violates the Due Process Clauses of Article I,
27 Section 7 of the California Constitution and the Fifth and Fourteenth Amendments to the United
28 States Constitution.

1 112. Under both the California and United States Constitutions, a person, including a
2 corporation, “may not be deprived of life, liberty, or property without due process of law.”

3 113. Monsanto is a leading manufacturer of glyphosate, which is the active ingredient in
4 its Roundup® line of products. In connection with its glyphosate-based herbicides, Monsanto has a
5 property interest in, among other things, its registered trademark, its business goodwill, and its
6 reputation as a manufacturer and distributor of safe and effective herbicides. These property
7 interests already have been impaired by OEHHA’s Notice of Intent to List glyphosate, and will
8 impaired further if glyphosate is formally added to the Proposition 65 list as a chemical known to
9 the state to cause cancer.

10 114. OEHHA intends to add glyphosate to the Proposition 65 list of carcinogens pursuant
11 to the Labor Code listing mechanism based solely on IARC’s classification of glyphosate as a
12 “probable carcinogen.”

13 115. As described herein, IARC is not subject to any procedural safeguards. IARC is an
14 unelected, undemocratic, foreign body and, as such, is not accountable to the California voters.

15 116. IARC, in its sole discretion, selects ad hoc groups of scientists, chosen in a non-
16 transparent manner, to make classification determinations. IARC, again in its sole discretion,
17 excludes from its Working Groups any individual who has a “real or apparent conflict of interest,”
18 and systematically excludes scientists who have an affiliation with industry (irrespective of their
19 knowledge of or experience with the chemical or substance in question).

20 117. IARC selects a different set of individuals to form the Working Group for each
21 substance or set of substances evaluated, increasing the likelihood of inconsistent and/or arbitrary
22 classification determinations.

23 118. The determinations of IARC’s Working Groups are not subject to public comment or
24 review by any other entity. No California or federal governmental body exercises any oversight,
25 control, or veto power over individual decisions of the IARC Working Groups. There is no appeal
26 from an IARC classification decision.

27 119. OEHHA does not play any substantive role in reviewing or affirming IARC
28 classification decisions. By regulation, OEHHA’s role is limited to ensuring that the listed

1 substance is identified accurately and that IARC has made findings about the sufficiency of the
2 evidence (pursuant to IARC's own definition of "sufficient evidence" and independent judgment as
3 to whether that standard is met). Likewise, OEHHA's regulations state explicitly that the Agency
4 will not consider comments related to the underlying scientific basis for a classification decision.
5 OEHHA has described Labor Code listings as a "ministerial" and essentially automatic process.

6 120. In short, the Labor Code listing mechanism does not include sufficient procedural
7 safeguards and, as such, is overwhelmingly likely to lead to erroneous results. With respect to the
8 proposed listing of glyphosate, these procedural defects include, but are not limited to, the
9 following: (i) the classification of glyphosate was made by a group of individual scientists selected
10 by an unelected, undemocratic, foreign body through a non-transparent process; (ii) the decision of
11 the IARC Working Group was not subject to review by any other entity, and no California
12 governmental entity played any substantive role in the listing process; (iii) Monsanto (and others)
13 were not afforded an opportunity to comment substantively on OEHHA's decision to list glyphosate
14 as a carcinogen; and (iv) OEHHA has noted its intent to add glyphosate to the Proposition 65 list
15 notwithstanding the fact that OEHHA itself, in 2007, reviewed the exact same set of animal
16 carcinogenicity studies relied upon by IARC (to find "sufficient evidence" of carcinogenicity in
17 experimental animals) and determined that glyphosate is not likely to be a carcinogen.

18 121. For these reasons, the Labor Code listing mechanism, as applied to the listing of
19 glyphosate, violates the Due Process Clauses of the California and United States Constitutions.

20 C. **The Labor Code Listing Mechanism Violates Article II, Section 12 of the**
21 **California Constitution.**

22 122. The Labor Code listing mechanism of Proposition 65, as interpreted by OEHHA,
23 violates Article II, Section 12 of the California Constitution.

24 123. Article II, Section 12 of the California Constitution states: "No amendment to the
25 Constitution, and no statute proposed to the electors by the Legislature or by initiative, that names
26 an individual to hold any office, or names or identifies any private corporation to perform any
27 function or to have any power or duty, may be submitted to the electors or have any effect."

28 124. Proposition 65, including the Labor Code listing mechanism, is a statute proposed to

1 the electors by initiative.

2 125. Proposition 65 names or identifies IARC by reference to the Labor Code. IARC is a
3 “private corporation” within the meaning of Article II, Section 12 of the California Constitution.

4 126. As described above, substances classified by IARC as carcinogens are placed on the
5 Proposition 65 list following a “ministerial” and essentially automatic process. OEHHA plays no
6 substantive role in Labor Code listings, and OEHHA has no discretion to reject IARC’s
7 classifications. As such, Proposition 65 effectively identifies IARC to have a power -- *i.e.*, the
8 power to identify chemicals for placement on the Proposition 65 list.

9 127. For these reasons, the Labor Code listing mechanism, as applied to the listing of
10 glyphosate, violates Article II, Section 12 of the California Constitution.

11 **D. The Labor Code Listing Mechanism Violates the Guarantee Clause of the**
12 **United States Constitution.**

13 128. The Labor Code listing mechanism violates the Guarantee Clause (Article IV,
14 Section 4, Clause 1) of the United States Constitution, which guarantees to the citizens of each state
15 a “Republican Form of Government,” because it empowers an unelected, undemocratic,
16 unaccountable, and foreign body to make laws applicable in California.

17 129. Among the hallmarks of a “Republic Form of Government” are (1) that lawmakers
18 are accountable to the electorate for the laws they enact; (2) that laws are made in a public process;
19 (3) that laws are made by individuals who are elected or appointed with the consent of the
20 governed; and (4) that the decisions of current lawmakers may be reviewed and revised by their
21 duly elected or appointed successors in the future.

22 130. The IARC process for classifying chemicals with respect to their carcinogenicity
23 contains none of these hallmarks and yet results in the enactment of laws that apply to the conduct
24 of private parties in California, thereby violating the Guarantee Clause.

25 **E. The Labor Code Listing Mechanism Constitutes an Unlawful Amendment or**
26 **Revision of the California Constitution.**

27 131. Article 4, Section 1 of the California Constitution vests the legislative power of the
28 state of California in the California Legislature and the people (through the powers of initiative and
referendum).

132. By empowering an unelected, undemocratic, unaccountable, and foreign body to make laws applicable in California, the Labor Code listing mechanism, as interpreted by OEHHA, delegates the legislative power of the state away from the Legislature and the people, which delegation could only be accomplished through a revision (or, at a minimum, an amendment) of Article 4, Section 1 of the California Constitution pursuant to Article 18 of the California Constitution.

133. Section 25249.8(a) of the California Health & Safety Code was not adopted by the electors as an amendment or revision to the California Constitution, but as an ordinary initiative. It therefore was not lawfully adopted.

F. The Listing of Glyphosate Under Proposition 65 Violates Monsanto's Right to Free Speech.

134. The listing of glyphosate under Proposition 65 violates Monsanto's right to free speech under Article I, Section 2 of the California Constitution and the First Amendment to the United States Constitution.

135. If glyphosate is added to the Proposition 65 list, Monsanto would be required (absent assertion of a viable affirmative defense) to provide a "clear and reasonable warning" on its glyphosate-based products that communicates that glyphosate is "known to the state to cause cancer." Cal. Code Regs., tit. 27, § 25601.

136. However, OEHHA, as the "lead state agency for the assessment of health risks posed by environmental contaminants," evaluated the carcinogenicity of glyphosate in 1997 and again in 2007 and concluded that "glyphosate is judged unlikely to pose a cancer hazard to humans." Plainly, glyphosate is not "known to the state to cause cancer."

137. Likewise, IARC did not conclude that glyphosate is "known" to cause cancer in humans. Rather, IARC classified glyphosate as a "probable" carcinogen with "limited" evidence of carcinogenicity in humans.

138. As such, if glyphosate is formally listed under Proposition 65, Monsanto would be compelled to affix a false and/or misleading statement to its products. Such compelled commercial speech does not advance any legitimate or substantial government interest.

139. Accordingly, the listing of glyphosate under Proposition 65, which in turn triggers

1 the warning requirement in Cal. Code Regs., tit. 27, § 25601, violates Monsanto's right to free
2 speech under the California and United States Constitutions.

3 **V. OEHHA's Notice of Intent to List Glyphosate Will Cause Irreparable Harm.**

4 140. If not enjoined, the addition of glyphosate to the Proposition 65 list of carcinogens
5 will have an immediate and irreversible impact on Monsanto and the public.

6 141. The listing of glyphosate under Proposition 65 would adversely affect Monsanto's
7 reputation and goodwill. Such a listing would harm Monsanto's reputation by implying that its
8 glyphosate-based products may be carcinogenic, despite repeated and extensive testing and
9 determinations by regulatory authorities around the world confirming that glyphosate does not
10 cause cancer in humans.

11 142. The listing of glyphosate may also lead to consumer deselection in favor of other
12 weed control alternatives. For example, glyphosate-based herbicides are used by many municipal,
13 county, and state government agencies in California. Many of these government agencies will not
14 use products that appear on the Proposition 65 list. The Irvine Unified School District and several
15 Bay Area cities and school districts already have stopped using glyphosate-based herbicides in
16 response to OEHHA's Notice of Intent to List glyphosate. Many other government agencies in
17 California (including, for example, airports, arenas, municipal buildings, and school districts) are
18 likely to follow suit if glyphosate is formally added to the Proposition 65 list of carcinogens.

19 143. There is also a risk that other consumers, including agricultural and residential users,
20 of glyphosate-based herbicides will switch to non-glyphosate herbicide products or mechanical
21 methods of vegetation management based on unfounded fears that glyphosate causes cancer. For
22 example, food companies who purchase the commodities grown by farmers may be concerned that
23 trace amounts of glyphosate residues will result in the need for Proposition 65 warnings on food
24 products, which could greatly diminish sales of such food products. Such food companies may
25 demand that their suppliers reduce or eliminate glyphosate use in order to control such residues. A
26 number of food companies have already made inquiries of Monsanto concerning the proposed
27 listing of glyphosate by OEHHA.

28 144. If glyphosate is added to the Proposition 65 list, Monsanto also would incur

1 substantial costs in connection with potential enforcement of the Proposition 65 warning and
2 discharge requirements. These costs include expenses related to, among other things:
3 (a) redesigning product labels to include the Proposition 65 warning; (b) removing products from
4 store shelves that do not contain the warning; (c) performing additional scientific and legal analyses
5 to evaluate compliance with the Proposition 65 requirements; and (d) defending Proposition 65
6 enforcement actions.

7 145. Monsanto would not be able to recover its financial losses from OEHHA if
8 OEHHA's action in listing glyphosate is subsequently held to be unlawful because there is no legal
9 mechanism for Monsanto to do so.

10 146. OEHHA's action in listing glyphosate would also harm the public because it would
11 create unfounded consumer fear, causing farmers, government agencies, and other users of
12 glyphosate-based herbicides to switch to other products and/or processes for vegetation
13 management that may not provide the same level of safety, effectiveness, and/or reliability.

14 147. As described above, glyphosate-based herbicides are used for many important public
15 purposes, including to: (a) reduce the risk of wildfires; (b) protect and restore sensitive wildlife
16 habitats threatened by invasive, non-native vegetation; and (c) control weedy vegetation to protect
17 infrastructure, water flow, irrigation, and public safety and health. These benefits could be lost if
18 consumers and government agencies switch to less reliable weed control alternatives.

19 **FIRST CAUSE OF ACTION**

20 **(Writ of Mandate)**

21 148. Monsanto re-alleges and incorporates by reference Paragraphs 1 through 147 above
22 as if fully set forth herein.

23 149. OEHHA has a legal duty and present ability to correctly and reasonably construe and
24 apply Proposition 65 consistent with the California and United States Constitutions, both of which
25 prevent OEHHA from relying on the Labor Code listing mechanism to place glyphosate on the
26 Proposition 65 list.

27 150. OEHHA has failed to comply with its legal duty to correctly and reasonably construe
28 and apply Proposition 65 consistent with the California and United States Constitutions. OEHHA's

1 Notice of Intent to List glyphosate under Proposition 65 pursuant to the Labor Code listing
2 mechanism is contrary to and violates the California and United States Constitutions.

3 151. Monsanto has a clear, present, and legal right to OEHHA's correct and reasonable
4 construction and application of Proposition 65 consistent with the California and United States
5 Constitutions. Monsanto, as the leading manufacturer of glyphosate, has a clear and present
6 beneficial interest in ensuring that OEHHA refrains from adding glyphosate to the Proposition 65
7 list in violation of California and federal law.

8 152. Monsanto has no plain, speedy, and adequate remedy in the ordinary course of law.

9 153. Monsanto therefore requests that the Court issue a writ of mandate, pursuant to
10 section 1085 of the Code of Civil Procedure and the Court's inherent equitable powers, enjoining
11 OEHHA from adding glyphosate to the Proposition 65 list pursuant to the Labor Code mechanism.

12 **SECOND CAUSE OF ACTION**

13 **(Declaratory Relief)**

14 154. Monsanto re-alleges and incorporates by reference Paragraphs 1 through 153 above
15 as if fully set forth herein.

16 155. An actual controversy has arisen and now exists between Monsanto and OEHHA
17 concerning whether OEHHA may add glyphosate to the Proposition 65 list of chemicals known to
18 the state to cause cancer via the Labor Code listing mechanism.

19 156. Monsanto contends, and OEHHA disputes, that the Labor Code listing mechanism,
20 as applied to the listing of glyphosate, violates the California and United States Constitutions.

21 157. If OEHHA is permitted to add glyphosate to the Proposition 65 list, the public,
22 Monsanto, and other manufacturers and users of glyphosate will be irreparably harmed as described
23 herein.

24 158. Monsanto has no plain, speedy, and adequate remedy in the ordinary course of law.

25 159. Monsanto is therefore entitled to a judicial declaration of its rights and OEHHA's
26 duties under section 1060 of the Code of Civil Procedure.

1 **THIRD CAUSE OF ACTION**

2 **(Injunctive Relief)**

3 160. Monsanto re-alleges and incorporates by reference Paragraphs 1 through 159 above
4 as if fully set forth herein.

5 161. Monsanto will be irreparably harmed by OEHHA's improper addition of glyphosate
6 to the Proposition 65 list via the Labor Code listing mechanism.

7 162. The improper addition of glyphosate to the Proposition 65 list also will have an
8 immediate, serious, and adverse effect on various industries and the public, resulting from the
9 reduced selection and/or availability of beneficial products that contain glyphosate.

10 163. Monsanto has no plain, speedy, and adequate remedy in the ordinary course of law.

11 164. Monsanto is therefore entitled to preliminary and permanent injunctions prohibiting
12 OEHHA from adding glyphosate to the Proposition 65 list of carcinogens pursuant to the Labor
13 Code listing mechanism, pursuant to sections 3420 and 3422 of the California Civil Code and
14 sections 526(a)(1), (a)(4), (a)(5), and/or (b)(4) of the Code of Civil Procedure.

15 **PRAYER FOR RELIEF**

16 For the reasons set forth above, Monsanto prays for relief as follows:

17 A. That the Court issue a peremptory writ of mandate enjoining OEHHA from adding
18 glyphosate to the Proposition 65 list of carcinogens pursuant to the Labor Code listing mechanism;

19 B. That the Court issue a judicial declaration that the Labor Code listing mechanism and
20 OEHHA's regulations implementing the Labor Code listing mechanism set forth at Cal. Code
21 Regs., tit. 27, § 25904, as applied to the proposed listing of glyphosate under Proposition 65, violate
22 the California and United States Constitutions;

23 C. That the Court issue a preliminary injunction enjoining OEHHA from listing, or
24 taking any further action in listing, glyphosate as a carcinogen under Proposition 65 pursuant to the
25 Labor Code listing mechanism;

26 D. That the Court issue a permanent injunction enjoining OEHHA from listing, or
27 taking any further action in listing, glyphosate as a carcinogen under Proposition 65 pursuant to the
28 Labor Code listing mechanism;

1 E. That the Court award costs and reasonable attorneys' fees, as provided by section
2 1021.5 of the Code of Civil Procedure and other applicable law; and

3 F. That the Court grant such other and further relief as the Court deems just and proper.
4

5 Dated: August____, 2016

ARNOLD & PORTER LLP

6
7 By: _____

Trenton H. Norris

Sarah Esmaili

S. Zachary Fayne

Attorneys for Plaintiff Monsanto Company
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28

2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

APPENDIX 1

Date	Entity Considering Whether Tumors Are Related to Treatment	Were Tumors Related to Treatment?			
		Mouse 1 ⁱ	Rat 1 ⁱⁱ	Rat 2 ⁱⁱⁱ	Mouse 2 ^{iv}
1987	WHO/JMPR	No	No	-	-
1991	US EPA Cancer Classification	No	No	No	-
1991	Canada PMRA	No	No	No	-
1993	US EPA RED	No	No	No	-
1994	WHO/IPCS	No	No	No	-
1999	Japan FCS	No	No	No	-
2000	FAO Specifications	No	No	No	-
2002	EU Annex I	No	No	No	No
2004	WHO/JMPR	-	-	No	No
2005	WHO/Water Sanitation Health	No	No	No	-
2007	OEHHA	No	No	No	No
2008	US EPA Effects Determination	No	-	No	-
2010	Japan FCS	No	No	No	-
2012	US EPA Human Health Risk Assessment	No	No	No	-
2013	Australia	No	No	No	No
2015	EU Annex I Renewal (BfR)	No	No	No	No
2015	Canada PMRA Registration Rev	No	No	No	No
2015	WHO/IARC	Yes	Yes	Yes	Yes

ⁱ Knezevich, A.L. & Hogan, G.K. (1983). A chronic feeding study of glyphosate (Roundup Technical) in mice.

ⁱⁱ Lankas, G.R. & Hogan, G.K. (1981). A lifetime study of glyphosate (Roundup Technical) in rats.

ⁱⁱⁱ Stout, L.D. & Ruecker, F.A. (1990). Chronic study of glyphosate administered in feed to albino rats.

^{iv} Atkinson, C., et al. (1993). Glyphosate: 104 week dietary carcinogenicity study in mice.