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

MONSANTO COMPANY,

Plaintiff,

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.

Case No.:

16 CE CG 00183

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

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Petition - Writ of Mandate
200197



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

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

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

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

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

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

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

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

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

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

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

27 c. Third, by identifying IARC to have the power to identify substances for
28 placement on the Proposition 65 list without any substantive review by OEHHA or any other

1 California governmental entity, the Labor Code listing mechanism, as interpreted and applied by
2 OEHHA, violates Article II, Section 12 of the California Constitution, which states that “no statute
3 proposed to the electors . . . by initiative” that “identifies any private corporation . . . to have any
4 power” may “have any effect.”

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

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

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

26 11. The listing of glyphosate would cause irreparable injury to Monsanto and the public.
27 The listing would adversely affect Monsanto’s reputation for manufacturing safe and reliable
28 herbicides; would potentially result in lost sales due to consumer deselection of glyphosate-based

1 herbicides; and would require Monsanto to spend significant sums of money to re-label and re-shelf
2 its products. In addition, Monsanto would not be able to recover its financial losses from OEHHA
3 if OEHHA's action in listing glyphosate is subsequently held to be unlawful because there is no
4 legal mechanism for Monsanto to do so.

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

9 **PARTIES**

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

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

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

20 **JURISDICTION AND VENUE**

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

24 17. Venue is proper in this county pursuant to sections 395 and 401 of the California
25 Code of Civil Procedure because this is an action against the State, or a department, officer or other
26 agency thereof, that may be commenced in the County of Sacramento, and therefore may also be
27 commenced in any county in which the California Attorney General has an office. The California
28 Attorney General has an office in this county.

STATUTORY AND REGULATORY BACKGROUND

1
2 18. In 1986, the California voters, by initiative, enacted the Safe Drinking Water and
3 Toxic Enforcement Act of 1986, now codified at California Health & Safety Code §§ 25249.5, *et*
4 *seq.* (“Proposition 65”). In general, Proposition 65 prohibits businesses from (i) knowingly and
5 intentionally exposing California residents to chemicals known to cause cancer or reproductive
6 toxicity without providing a clear and reasonable warning, or (ii) knowingly discharging or
7 releasing a chemical known to the state to cause cancer or reproductive toxicity into the
8 environment where the chemical passes or probably will pass into a source of drinking water. Cal.
9 Health & Safety Code §§ 25249.5 and 25249.6.

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

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

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

25 22. OEHHA has adopted the second interpretation of Cal. Health & Safety Code
26 § 25249.8(a), and has codified that interpretation in its regulations implementing Proposition 65 at
27 Cal. Code Regs., tit. 27, § 25904. This mechanism for placing substances on the Proposition 65 list
28 by reference to determinations by IARC that were made after the enactment of Proposition 65 is

1 referred to herein as the “Labor Code listing mechanism.”

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

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

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

23 FACTUAL ALLEGATIONS

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

25 **A. Overview of Glyphosate.**

26 26. Glyphosate is a broad-spectrum herbicide that is used to control weeds in a variety of
27 agricultural, residential, aquatic, and other settings. Since it was first introduced in 1974,
28 glyphosate “has become the world’s most widely used herbicide because it is efficacious,

1 economical and environmentally benign.” Stephen B. Powles, *Evolved Glyphosate-Resistant Weeds*
2 *Around the World: Lessons To Be Learnt*, 64 Pest Management Science 360, 360-365 (April 2008).
3 Glyphosate is marketed under a number of trade names, by Monsanto and others, and is registered
4 for use as a herbicide in more than 160 countries, including the United States.

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

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

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

26 30. Many municipal, county, and state government agencies in California use
27 glyphosate-based herbicides to manage vegetation. These agencies use glyphosate-based herbicides
28 to control weedy vegetation in order to protect infrastructure, water flow, irrigation, and public

1 safety and health. In addition, glyphosate is widely used by government agencies in California to
2 reduce the risk associated with the rapid spread of wildfires. In particular, glyphosate is used to
3 control vegetation and establish fire breaks during the wet months of the year.

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

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

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

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

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

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

23 36. Notably, OEHHA, in finding that glyphosate is unlikely to be a carcinogen,
24 considered the very same animal carcinogenicity studies that IARC relied upon in reaching the
25 conclusion that there is “sufficient evidence” of carcinogenicity in experimental animals. IARC’s
26 assessment of glyphosate is discussed in Section II.B below.

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

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

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

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

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

 41. In December 2013, Germany, through its risk assessment agency, BfR, and acting as

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

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

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

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

27 45. At the request of the EC, EFSA also addressed IARC’s classification of glyphosate
28 as a “probable carcinogen” and set forth potential reasons for the diverging views. For example,

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

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

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

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

1 **II. IARC's Classification of Glyphosate as a Probable Carcinogen.**

2 **A. Overview of IARC.**

3 49. IARC is a specialized agency of the WHO that is based in Lyon, France. Among
4 other activities, IARC "prepare[s], with the help of international Working Groups of experts, and ...
5 publish[es] in the form of *Monographs*, critical reviews and evaluations of evidence on the
6 carcinogenicity of a wide range of human exposures." *IARC Monographs on the Evaluation of*
7 *Carcinogenic Risks to Humans: Preamble* (2006) ("IARC Preamble") at 2.

8 50. As part of the *Monograph* process, IARC convenes ad hoc groups of scientists
9 ("Working Groups"), selected by IARC staff in an opaque, non-public process, to review and
10 summarize scientific research on the carcinogenicity of a particular substance or chemical. IARC
11 convenes a separate Working Group of individual scientists for each volume of the *Monographs*,
12 which may cover a single substance or several related substances.

13 51. IARC, in its sole discretion, selects the members of each Working Group, and
14 excludes any individual who has a "real or apparent conflict of interest." In this respect, pursuant to
15 guidelines issued by the WHO in 2004, each potential Working Group participant is required to
16 declare "any interests that could constitute a real, potential or apparent conflict of interest, with
17 respect to his/her involvement in the meeting or work, between a) commercial entities and the
18 participant personally, and b) commercial entities and the administrative unit with which the
19 participant has an employment relationship." IARC's rules for selecting members of the Working
20 Group thus exclude scientists who have an affiliation with industry, including those who have
21 conducted studies on the chemical at issue for regulatory purposes and thus may be likely to have
22 the greatest knowledge about the chemical.

23 52. Although the Working Group members often are affiliated with a particular
24 organization or government agency, IARC has explained that "[e]ach participant who is a Member
25 of a Working Group serves as an individual scientist and not as a representative of any organization,
26 government or industry." IARC Preamble at 5.

27 53. The Working Group is tasked with reviewing and summarizing the existing scientific
28 literature. Pursuant to IARC policy, the Working Group is only allowed to consider "reports that

1 have been published or accepted for publication in the openly available scientific literature,” “[d]ata
2 from government agency reports that are publicly available,” and, in exceptional circumstances,
3 “doctoral theses and other material that are in their final form and publicly available.” IARC
4 Preamble at 4. Thus, studies and data submitted to regulatory authorities that are not publicly
5 available are not considered by the Working Group. The Working Group also does not consider
6 review articles or commentaries that do not contain “new data.”

7 54. The Working Group also is responsible for making classification determinations. A
8 substance can be classified in one of five groups: carcinogenic to humans (Group 1), probably
9 carcinogenic to humans (Group 2A), possibly carcinogenic to humans (Group 2B), not classifiable
10 as to its carcinogenicity to humans (Group 3), or probably not carcinogenic to humans (Group 4).
11 The Working Group’s classification is final and is not subject to public comment, review, or appeal.

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

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

23 56. In 2014, IARC convened a Working Group of 17 scientists to assess the
24 carcinogenicity of glyphosate and four insecticides. In March 2015, the IARC Working Group
25 classified glyphosate as “probably carcinogenic to humans” (Group 2A). The Working Group’s
26 conclusions were published in Volume 112 of IARC’s *Monographs* series.

27 57. IARC, in classifying glyphosate as a “probable carcinogen,” is an outlier among the
28 regulatory and scientific bodies that have evaluated the scientific data on glyphosate.

1 58. For example, IARC concluded that there was “sufficient evidence” of
2 carcinogenicity in experimental animals based on four long-term carcinogenicity studies in rodents.
3 Specifically, IARC made the following findings: (i) “[t]here was a positive trend in the incidence of
4 renal tubule carcinoma and of renal tubule adenoma or carcinoma (combined) in males in one
5 feeding study in CD-1 mice”; (ii) “there was a significant positive trend in the incidence of
6 haemangiosarcoma in male CD-1 mice” in a second feeding study of mice; and (iii) two studies in
7 rats “showed a significant increase in the incidence of pancreatic islet cell adenoma in males,” and
8 “one of these two studies also showed a significant positive trend in the incidences of hepatocellular
9 adenoma in males and of thyroid C-cell adenoma in females.” IARC Monograph Vol. 112 at 76.

10 59. In preparing the OEHHA Assessment in 2007, OEHHA evaluated these same four
11 long-term carcinogenicity studies in rodents (or reviews of these studies). After reviewing the data,
12 OEHHA concluded that glyphosate is “unlikely to pose a cancer hazard to humans.”

13 60. As shown in the table in Appendix 1 to this Petition and Complaint, other regulatory
14 and scientific bodies (including other WHO programs), on 17 different occasions, have evaluated
15 one or more of these same long-term carcinogenicity studies in rodents. Each of these reviews has
16 reached the opposite conclusion of IARC -- namely, that the small number of tumors observed in
17 rodents subjected to treatment with glyphosate in these studies were *not* related to glyphosate.

18 **III. OEHHA’s Notice of Intent to List Glyphosate.**

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

21 62. OEHHA explained that glyphosate met the requirements for a Labor Code listing
22 because (1) IARC classified glyphosate as a “probable carcinogen,” and (2) IARC concluded that
23 there was “sufficient evidence” of carcinogenicity in experimental animals.¹ *Id.*; *see also* Cal. Code

24 _____
25 ¹ IARC also considered certain “mechanistic” data in finding glyphosate to be a “probable
26 carcinogen.” Mechanistic studies are studies that attempt to identify the mechanisms through which
27 a chemical may increase the risk of cancer (*e.g.*, molecular changes in cells or DNA). IARC
28 explained that the mechanistic and other relevant data supported the classification of glyphosate in
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

(Footnote Cont’d on Following Page)

1 Regs., tit. 27, § 25904(b) (“A chemical or substance shall be included on the list if it is classified by
2 [IARC] in its IARC Monographs series . . . as: . . . (2) Probably carcinogenic to humans (Group 2A)
3 with sufficient evidence of carcinogenicity in experimental animals . . .”).

4 63. OEHHA did not make any other findings about the underlying science, and refused
5 to consider comments about the underlying science, stating: “Because these are ministerial listings,
6 comments should be limited to whether IARC has identified the specific chemical or substance as a
7 known or potential human or animal carcinogen. Under this listing mechanism, OEHHA cannot
8 consider scientific arguments concerning the weight or quality of the evidence considered by IARC
9 when it identified these chemicals and will not respond to such comments if they are submitted.”

10 **IV. OEHHA’s Proposed Listing of Glyphosate Pursuant to the Labor Code Mechanism**
11 **Violates the California and United States Constitutions.**

12 **A. The Labor Code Listing Mechanism Constitutes an Unlawful Delegation of**
13 **Legislative Authority.**

14 64. The Labor Code listing mechanism, as interpreted by OEHHA, violates the “non-
15 delegation doctrine” that is rooted in principles of separation of powers.

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

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

26 _____
27 (Footnote Cont’d From Previous Page)

28 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 67. The placement of a chemical on the Proposition 65 list has serious policy
2 implications: it results in regulation of that chemical under California law; it requires persons doing
3 business in California to undertake evaluations of possible exposures or discharges; and, in some
4 cases, it requires persons doing business in California to change their use of the chemical or provide
5 warnings to those who may be exposed to the chemical. *See* Cal. Health & Saf. Code §§ 25249.5,
6 25249.6.

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

15 69. There are no mechanisms or procedural safeguards to ensure that IARC performs its
16 function consistent with the policy goals of Proposition 65. IARC is not a regulatory entity and thus
17 is not required or incentivized to consider and weigh competing interests, nor to consider the
18 consequences of identifying a particular chemical or substance as a carcinogen. And indeed, IARC
19 explicitly disavows any regulatory responsibility or law-making role, and thus cannot be expected
20 to consider such consequences. Moreover, IARC selects a different set of individuals, on an ad hoc
21 basis, to form the Working Group for each substance or set of substances, increasing the likelihood
22 of inconsistent and arbitrary classification determinations.

23 70. 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 decision.

27 71. Nor does OEHHA substantively review IARC classification decisions. By
28 regulation, OEHHA's role is limited to ensuring that the listed substance is identified accurately and

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

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

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

13 74. For these reasons, the Labor Code listing mechanism of Proposition 65, as applied to
14 the listing of glyphosate, violates the non-delegation doctrine.

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

16 75. The Labor Code listing mechanism violates the Due Process Clauses of Article I,
17 Section 7 of the California Constitution and the Fifth and Fourteenth Amendments to the United
18 States Constitution.

19 76. Under both the California and United States Constitutions, a person, including a
20 corporation, "may not be deprived of life, liberty, or property without due process of law."

21 77. Monsanto is a leading manufacturer of glyphosate, which is the active ingredient in
22 its Roundup® line of products. In connection with its glyphosate-based herbicides, Monsanto has a
23 property interest in, among other things, its registered trademark, its business goodwill, and its
24 reputation as a manufacturer and distributor of safe and effective herbicides. These property
25 interests already have been impaired by OEHHA's Notice of Intent to List glyphosate, and will
26 be impaired further if glyphosate is formally added to the Proposition 65 list as a chemical known to
27 the state to cause cancer.

28 78. OEHHA intends to add glyphosate to the Proposition 65 list of carcinogens pursuant

1 to the Labor Code listing mechanism based solely on IARC's classification of glyphosate as a
2 "probable carcinogen."

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

5 80. IARC, in its sole discretion, selects ad hoc groups of scientists, chosen in a non-
6 transparent manner, to make classification determinations. IARC, again in its sole discretion,
7 excludes from its Working Groups any individual who has a "real or apparent conflict of interest,"
8 and systematically excludes scientists who have an affiliation with industry (irrespective of their
9 knowledge of or experience with the chemical or substance in question).

10 81. IARC selects a different set of individuals to form the Working Group for each
11 substance or set of substances evaluated, increasing the likelihood of inconsistent and/or arbitrary
12 classification determinations.

13 82. The determinations of IARC's Working Groups are not subject to public comment or
14 review by any other entity. No California or federal governmental body exercises any oversight,
15 control, or veto power over individual decisions of the IARC Working Groups. There is no appeal
16 from an IARC classification decision.

17 83. OEHHA does not play any substantive role in reviewing or affirming IARC
18 classification decisions. By regulation, OEHHA's role is limited to ensuring that the listed
19 substance is identified accurately and that IARC has made findings about the sufficiency of the
20 evidence (pursuant to IARC's own definition of "sufficient evidence" and independent judgment as
21 to whether that standard is met). Likewise, OEHHA's regulations state explicitly that the Agency
22 will not consider comments related to the underlying scientific basis for a classification decision.
23 OEHHA has described Labor Code listings as a "ministerial" and essentially automatic process.

24 84. In short, the Labor Code listing mechanism does not include sufficient procedural
25 safeguards and, as such, is overwhelmingly likely to lead to erroneous results. With respect to the
26 proposed listing of glyphosate, these procedural defects include, but are not limited to, the
27 following: (i) the classification of glyphosate was made by a group of individual scientists selected
28 by an unelected, undemocratic, foreign body through a non-transparent process; (ii) the decision of

1 the IARC Working Group was not subject to review by any other entity, and no California
2 governmental entity played any substantive role in the listing process; (iii) Monsanto (and others)
3 were not afforded an opportunity to comment substantively on OEHHA's decision to list glyphosate
4 as a carcinogen; and (iv) OEHHA has noted its intent to add glyphosate to the Proposition 65 list
5 notwithstanding the fact that OEHHA itself, in 2007, reviewed the exact same set of animal
6 carcinogenicity studies relied upon by IARC (to find "sufficient evidence" of carcinogenicity in
7 experimental animals) and determined that glyphosate is not likely to be a carcinogen.

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

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

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

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

18 88. Proposition 65, including the Labor Code listing mechanism, is a statute proposed to
19 the electors by initiative.

20 89. Proposition 65 names or identifies IARC by reference to the Labor Code. IARC is a
21 "private corporation" within the meaning of Article II, Section 12 of the California Constitution.

22 90. As described above, substances classified by IARC as carcinogens are placed on the
23 Proposition 65 list following a "ministerial" and essentially automatic process. OEHHA plays no
24 substantive role in Labor Code listings, and OEHHA has no discretion to reject IARC's
25 classifications. As such, Proposition 65 effectively identifies IARC to have a power -- *i.e.*, the
26 power to identify chemicals for placement on the Proposition 65 list.

27 91. For these reasons, the Labor Code listing mechanism, as applied to the listing of
28 glyphosate, violates Article II, Section 12 of the California Constitution.

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

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

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

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

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

17 95. Article 4, Section 1 of the California Constitution vests the legislative power of the
18 state of California in the California Legislature and the people (through the powers of initiative and
19 referendum).

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

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

1 **F. The Listing of Glyphosate Under Proposition 65 Violates Monsanto’s Right to**
2 **Free Speech.**

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

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

10 100. However, OEHHA, as the “lead state agency for the assessment of health risks posed
11 by environmental contaminants,” evaluated the carcinogenicity of glyphosate in 1997 and again in
12 2007 and concluded that “glyphosate is judged unlikely to pose a cancer hazard to humans.”
13 Plainly, glyphosate is not “known to the state to cause cancer.”

14 101. Likewise, IARC did not conclude that glyphosate is “known” to cause cancer in
15 humans. Rather, IARC classified glyphosate as a “probable” carcinogen with “limited” evidence of
16 carcinogenicity in humans.

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

20 103. Accordingly, the listing of glyphosate under Proposition 65, which in turn triggers
21 the warning requirement in Cal. Code Regs., tit. 27, § 25601, violates Monsanto’s right to free
22 speech under the California and United States Constitutions.

23 **V. OEHHA’s Notice of Intent to List Glyphosate Will Cause Irreparable Harm.**

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

26 105. The listing of glyphosate under Proposition 65 would adversely affect Monsanto’s
27 reputation and goodwill. Such a listing would harm Monsanto’s reputation by implying that its
28 glyphosate-based products may be carcinogenic, despite repeated and extensive testing and
29 determinations by regulatory authorities around the world confirming that glyphosate does not

1 cause cancer in humans.

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

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

19 108. If glyphosate is added to the Proposition 65 list, Monsanto also would incur
20 substantial costs in connection with potential enforcement of the Proposition 65 warning and
21 discharge requirements. These costs include expenses related to, among other things:
22 (a) redesigning product labels to include the Proposition 65 warning; (b) removing products from
23 store shelves that do not contain the warning; (c) performing additional scientific and legal analyses
24 to evaluate compliance with the Proposition 65 requirements; and (d) defending Proposition 65
25 enforcement actions.

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

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

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

10 **FIRST CAUSE OF ACTION**

11 **(Writ of Mandate)**

12 112. Monsanto re-alleges and incorporates by reference Paragraphs 1 through 111 above
13 as if fully set forth herein.

14 113. OEHHA has a legal duty and present ability to correctly and reasonably construe and
15 apply Proposition 65 consistent with the California and United States Constitutions, both of which
16 prevent OEHHA from relying on the Labor Code listing mechanism to place glyphosate on the
17 Proposition 65 list.

18 114. OEHHA has failed to comply with its legal duty to correctly and reasonably construe
19 and apply Proposition 65 consistent with the California and United States Constitutions. OEHHA's
20 Notice of Intent to List glyphosate under Proposition 65 pursuant to the Labor Code listing
21 mechanism is contrary to and violates the California and United States Constitutions.

22 115. Monsanto has a clear, present, and legal right to OEHHA's correct and reasonable
23 construction and application of Proposition 65 consistent with the California and United States
24 Constitutions. Monsanto, as the leading manufacturer of glyphosate, has a clear and present
25 beneficial interest in ensuring that OEHHA refrains from adding glyphosate to the Proposition 65
26 list in violation of California and federal law.

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

28 117. Monsanto therefore requests that the Court issue a writ of mandate, pursuant to

1 section 1085 of the Code of Civil Procedure and the Court's inherent equitable powers, enjoining
2 OEHHA from adding glyphosate to the Proposition 65 list pursuant to the Labor Code mechanism.

3 **SECOND CAUSE OF ACTION**

4 **(Declaratory Relief)**

5 118. Monsanto re-alleges and incorporates by reference Paragraphs 1 through 117 above
6 as if fully set forth herein.

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

10 120. Monsanto contends, and OEHHA disputes, that the Labor Code listing mechanism,
11 as applied to the listing of glyphosate, violates the California and United States Constitutions.

12 121. If OEHHA is permitted to add glyphosate to the Proposition 65 list, the public,
13 Monsanto, and other manufacturers and users of glyphosate will be irreparably harmed as described
14 herein.

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

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

18 **THIRD CAUSE OF ACTION**

19 **(Injunctive Relief)**

20 124. Monsanto re-alleges and incorporates by reference Paragraphs 1 through 123 above
21 as if fully set forth herein.

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

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

27 127. Monsanto has no plain, speedy, and adequate remedy in the ordinary course of law.
28

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

5 **PRAYER FOR RELIEF**

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

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

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

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

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

19 E. That the Court award costs and reasonable attorneys' fees, as provided by section
20 1021.5 of the Code of Civil Procedure and other applicable law; and

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

22
23 Dated: January 21, 2016


ARNOLD & PORTER LLP

24
25 By: Trenton H. Norris
26 Trenton H. Norris
27 Sarah Esmail
28 S. Zachary Fayne
Attorneys for Plaintiff Monsanto Company

VERIFICATION

I, Christopher Martin, am Assistant Secretary of Plaintiff Monsanto Company. I have read the foregoing Verified Petition for Writ of Mandate and Complaint for Preliminary and Permanent Injunctive and Declaratory Relief ("Petition and Complaint") and am familiar with its contents. I am informed and believe that the matters set forth in the Petition and Complaint are true and on that ground allege them to be true.

I declare under penalty of perjury under the laws of the State of California that this verification is true and correct and was executed by me on January 20, 2016, in St. Louis, Missouri.



Christopher Martin
Assistant Secretary, Monsanto Company

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.