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7
8 UNITED STATES DISTRICT COURT
9 EASTERN DISTRICT OF CALIFORNIA

10
11 NATIONAL ASSOCIATION OF WHEAT
GROWERS; NATIONAL CORN GROWERS
12 ASSOCIATION; UNITED STATES DURUM
GROWERS ASSOCIATION; WESTERN
13 PLANT HEALTH ASSOCIATION;
MISSOURI FARM BUREAU; IOWA
14 SOYBEAN ASSOCIATION; SOUTH
DAKOTA AGRI-BUSINESS
15 ASSOCIATION; NORTH DAKOTA GRAIN
GROWERS ASSOCIATION; MISSOURI
16 CHAMBER OF COMMERCE AND
INDUSTRY; MONSANTO COMPANY;
17 ASSOCIATED INDUSTRIES OF
MISSOURI; AND AGRIBUSINESS
18 ASSOCIATION OF IOWA,

19 Plaintiffs,

20 v.

21 LAUREN ZEISE, IN HER OFFICIAL
CAPACITY AS DIRECTOR OF THE
22 OFFICE OF ENVIRONMENTAL HEALTH
HAZARD ASSESSMENT; AND XAVIER
23 BECERRA, IN HIS OFFICIAL CAPACITY
AS ATTORNEY GENERAL OF THE STATE
24 OF CALIFORNIA,

25
26 Defendants.

Civil Action No.

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

1 Plaintiffs seek declaratory and injunctive relief against Defendants Lauren Zeise and
2 Xavier Becerra, in their official capacities as Director of the California Office of Environmental
3 Health Hazard Assessment (OEHHA) and Attorney General of the State of California,
4 respectively, and allege as follows:

5 **PRELIMINARY STATEMENT**

6 1. Plaintiffs National Association of Wheat Growers, National Corn Growers
7 Association, United States Durum Growers Association, Western Plant Health Association,
8 Missouri Farm Bureau, Iowa Soybean Association, South Dakota Agri-Business Association,
9 North Dakota Grain Growers Association, Missouri Chamber of Commerce and Industry,
10 Monsanto Company, Associated Industries of Missouri, and Agribusiness Association of Iowa
11 bring this suit to prevent Defendants from mandating false, misleading, and highly controversial
12 cancer warnings concerning the herbicide glyphosate on a wide variety of food, agricultural,
13 industrial, and lawn and garden products.

14 2. Glyphosate is a broad-spectrum herbicide approved by the federal government for
15 use in more than 250 agricultural crop applications in all U.S. States. Glyphosate has been
16 subject to scientific review by the federal government repeatedly for multiple decades. It is
17 widely utilized worldwide, including throughout the U.S., in cultivation of many major crops
18 (such as corn, soybeans, canola, wheat, and oats), and in California, in cultivation of almond,
19 citrus, and cotton crops, among others. Glyphosate is regarded as one of the safest herbicides
20 ever developed. For several decades, the federal government has approved the use of glyphosate
21 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), based on extensive
22 scientific analyses of each specific use of the herbicide.¹ Likewise, the Federal Food, Drug, and
23 Cosmetic Act (FDCA) establishes scientifically-set safe food tolerance levels for herbicide
24 residues in food, and forbids misbranding food products with any false or misleading label.

25 3. EPA has repeatedly concluded under FIFRA that use of glyphosate in accordance
26

27 ¹ This Complaint uses the term “herbicide” for clarity because glyphosate is an herbicide, but
28 under federal law, herbicides, insecticides, rodenticides, and pesticides are all referred to under
the definitional term “pesticide.” 7 U.S.C. § 136(u).

1 with federal label instructions does not present any unreasonable adverse effects on human
2 health or the environment, and specifically that glyphosate *is not a carcinogen*. See *infra* ¶¶ 35,
3 36, 44. Likewise, California itself has *twice* examined glyphosate in its own reviews—in 1997
4 and in 2007—and on both occasions concluded that glyphosate is “unlikely to pose a cancer
5 hazard to humans.” *Infra* ¶ 41. The same is true for every other regulatory body worldwide that
6 has evaluated glyphosate, including regulatory agencies in Europe, Canada, New Zealand,
7 Australia, Japan, and South Korea, and the International Programme on Chemical Safety (the
8 recognized authoritative body on these issues in the World Health Organization), as well as the
9 Joint Food and Agricultural Organization and World Health Organization Meeting on Pesticide
10 Residues (JMPR). See *infra* ¶¶ 34-41, 45-48 (listing more than a dozen regulatory and scientific
11 agencies that have reviewed glyphosate and found that it is not likely to be a carcinogen).

12 4. Under California’s Proposition 65, businesses must warn Californians about the
13 presence of chemicals that are “known to the state to cause cancer.” Despite the overwhelming
14 scientific consensus that glyphosate is *not* a carcinogen, OEHHA issued a determination on July
15 7, 2017 that glyphosate has been added to the list of chemicals “known to the state to cause
16 cancer” that are subject to Proposition 65. OEHHA did not issue its Proposition 65
17 determination because OEHHA or any other California agency conducted a scientific or
18 regulatory review and reached the conclusion that glyphosate was actually carcinogenic—in fact,
19 OEHHA had previously reached the opposite conclusion. Instead, under what California refers
20 to as its “Labor Code” listing mechanism under Proposition 65, certain determinations by a
21 foreign non-governmental entity known as the International Agency for Research on Cancer
22 (IARC) *automatically* require a Proposition 65 cancer listing no matter whether the IARC
23 determination is supported by the consensus of worldwide scientific bodies or not. Indeed, a
24 listing under the Labor Code mechanism is automatically required *even if IARC is absolutely*
25 *alone in its views*, as is the case here where IARC’s conclusion is opposed by every global
26 regulatory body that has examined the issue, including OEHHA itself.

27 5. Under this framework, California has designated glyphosate as a chemical
28 “known” to cause cancer based solely on IARC’s conclusion that glyphosate is “*probably*

1 carcinogenic.” Not only does the scientific community firmly disagree with IARC’s substantive
2 conclusion, IARC’s internal process for reviewing glyphosate has also been roundly criticized.
3 *See infra* ¶¶ 49-52 (identifying multiple published reports that IARC purposely declined to share
4 critical data with its glyphosate review panel).

5 6. California has no administrative or regulatory mechanism for reviewing the
6 validity of an IARC conclusion before a Proposition 65 listing is made. Once IARC designates a
7 substance as carcinogenic, OEHHA takes the position that Proposition 65 listing is then a
8 “ministerial” task. That listing then triggers Proposition 65’s compelled speech requirements in
9 the form of consumer “warnings.” And any relevant product without an appropriate warning—
10 including consumer products, foods, and crops—will be subject to Proposition 65’s enforcement
11 mechanisms, including private strike suits filed by so-called bounty hunters, who are entitled to
12 retain one-fourth of the \$2,500 per violation per day in civil penalties that are potentially
13 available under California Health & Safety Code section 25249.12(d). Such suits are already
14 threatened regarding numerous food products that allegedly contain trace residues of glyphosate.

15 7. California’s listing of glyphosate as a carcinogen and the attendant warning
16 requirement violate the First Amendment of the U.S. Constitution by compelling Plaintiffs and
17 other entities to make false, misleading, and highly controversial statements about their products.
18 The listing and warning requirement also conflict with, and are preempted by, the FDCA, and
19 violate the Due Process Clause of the Fourteenth Amendment.

20 8. In addition to being illegal, California’s treatment of glyphosate under Proposition
21 65 threatens significant disruption to multiple of the nation’s supply chains, including the
22 nation’s food production and processing supply chains. As set forth herein, the listing threatens
23 to change the way of life for many farmers who currently rely on glyphosate herbicides as a
24 mainstay of their farming practices. It is no surprise, then, that Plaintiffs—a national coalition of
25 farming interests, food producers, glyphosate manufacturers, and others—have coalesced to
26 bring this suit. Had California conducted any sort of reasonable scientific review before taking
27 the action challenged here, it would have determined—as more than a dozen other global
28 regulatory and scientific agencies already have—that the cancer listing at issue is false and

1 inappropriate. This suit, accordingly, should be unnecessary. In addition to being enjoined,
2 Defendants should be assessed Plaintiffs' fees and costs under 42 U.S.C. § 1988(b).

3 **PARTIES**

4 9. Plaintiff National Association of Wheat Growers is a federation of twenty state
5 associations whose members are wheat farmers. The mission of the National Association of
6 Wheat Growers is to mobilize wheat farmers to advocate for beneficial policies, cultivate
7 productive relationships with partners and the public, and champion opportunities through
8 research, innovation, education, and stewardship. Members of the National Association of
9 Wheat Growers—many of whom sell their wheat into California or sell their wheat to milling
10 facilities that in turn sell into California—depend on glyphosate as a critical tool in their farming
11 practices.

12 10. Plaintiff National Corn Growers Association is a 501(c)(5) trade association
13 chartered in Iowa, with 40,000 members across the country. Most of its members are farmers
14 who use glyphosate as an important means for weed control. Members of the National Corn
15 Growers Association deliver their crops to elevators, feed mills, corn processing plants, and
16 ethanol plants, a portion of which makes its way to California.

17 11. Plaintiff United States Durum Growers Association is a national organization
18 comprised of around 175 durum wheat producers, most of which are located in North Dakota and
19 Montana, and other businesses that use and rely on durum. Durum is a specialty wheat product
20 that is used primarily for the production of semolina, the primary ingredient in pasta. The
21 purpose of the United States Durum Growers Association is to promote and address the issues
22 that affect producers of durum. Many members of the United States Durum Growers
23 Association sell their durum for incorporation into products that are sold into California.
24 Glyphosate is an integral tool for the sustainable harvesting of durum and the preservation of
25 soil.

26 12. Plaintiff Western Plant Health Association is a California based association that
27 represents the interests of fertilizer and crop protection manufacturers, distributors, and
28 agricultural retailers (including those that sell and use glyphosate) in California, Arizona, and

1 Hawaii. The Western Plant Health Association’s mission is to promote agronomically sound and
2 environmentally safe use and handling of plant health products and services for the production of
3 safe and high quality food. The association’s members comprise more than 90% of all
4 companies marketing plant nutrients, soil amendments, agricultural minerals, and crop protection
5 products in California, Arizona, and Hawaii, including glyphosate products.²

6 13. Plaintiff Missouri Farm Bureau is a collective of about 126,000 families that have
7 organized together with the goals of improving the quality of life for rural Missourians and
8 protecting Missouri’s agricultural economy. Missouri Farm Bureau has numerous members that
9 cultivate corn, soybeans, wheat, and other crops that are treated with glyphosate and sold into
10 California. Glyphosate is an integral tool in their farming activities because, among other
11 reasons, it is cost effective and facilitates environmentally friendly no-till farming that reduces
12 soil erosion.

13 14. Plaintiff Iowa Soybean Association has the mission of expanding opportunities
14 and delivering results for Iowa soybean farmers. In that capacity, the Iowa Soybean Association
15 advocates for farmers, works to increase soybean exports out of Iowa, and helps build consumer
16 confidence in today’s farm and food system. Members of the Iowa Soybean Association use
17 glyphosate on their crops, and consider the herbicide to be a critical part of their farming toolkit.
18 The crops of members of the association are incorporated into products that are sold in
19 California.

20 15. Plaintiff South Dakota Agri-Business Association is an organization of crop input
21 professionals including retailers, distributors, and manufacturers of equipment, fertilizer,
22 pesticides, and seed. For its pesticide members, Monsanto Company’s glyphosate-based product
23 Roundup® is a huge part of their market. Many clients of the association’s members apply
24 Roundup® to their pre-plant young corn and pre-harvest wheat, some of which ends up in
25 California.

26 16. Plaintiff North Dakota Grain Growers Association is the premier voice for North

27 ² Plaintiffs Western Plant Health Association and Monsanto Company join only Claim I of this
28 Complaint.

1 Dakota's wheat and barley producers. The association's mission is to educate its members and
2 represent them to increase profitability. Many of the association's members use glyphosate on
3 their wheat products (including right before harvest), a portion of which makes its way into
4 California.

5 17. Plaintiff Missouri Chamber of Commerce and Industry is Missouri's largest
6 business organization. The Missouri Chamber works with all of its member organizations to
7 protect their interests and address their concerns regarding economic and policy issues. Its
8 members include entities involved in farming and food production. Glyphosate-treated crops
9 that are produced, processed, and stored by its members are milled and refined into food, a
10 portion of which is sold in California. Further, the Missouri Chamber has members that are
11 involved in the processing and storage of crops treated with glyphosate.

12 18. Plaintiff Monsanto Company (Monsanto) is a corporation headquartered in St.
13 Louis, Missouri and incorporated in Delaware. Monsanto is the leading manufacturer of the
14 herbicide glyphosate, which is a main ingredient in Monsanto's Roundup® branded line of
15 products. Monsanto also maintains patents covering many varieties of glyphosate-tolerant crops,
16 which Monsanto has obtained federal approval to plant and market along with glyphosate itself.
17 Monsanto distributes multiple glyphosate-tolerant crops, including soybeans, corn, canola,
18 alfalfa, sugar, beets, and cotton throughout California and the United States. Monsanto and its
19 business partners also distribute glyphosate-based herbicides in California and throughout the
20 United States, including to municipal, county, and other government agencies, to control
21 vegetation in utility right-of-ways, along roadsides and railways, in aquatic environments, in
22 residential home and garden settings, and to reduce the risk associated with the rapid spread of
23 wildfires.

24 19. Plaintiff Associated Industries of Missouri is the oldest general business trade
25 association in Missouri. Its mission is to promote a favorable climate for business,
26 manufacturing, and industry by empowering its members through communications, education,
27 and advocacy. More than half of this association's members are manufacturers, many of whom
28 are in the direct business of manufacturing products that contain glyphosate. The Associated

1 Industries of Missouri also has many food producer members who produce products with trace
2 amounts of glyphosate residues, a portion of which are sold in California.

3 20. Plaintiff Agribusiness Association of Iowa is an Iowa-based organization with
4 over 1,100 members. Among other things, this organization protects the reputation of its
5 members and advances their business interests. More than half of this organization's members
6 are agricultural retailers, such as cooperatives and independent retailers who sell agronomy
7 products or who have grain storage facilities or are in the business of manufacturing. Glyphosate
8 is very important to this organization's members, many of whom sell the herbicide or use it as
9 their primary weed control product.

10 21. Defendant Lauren Zeise is the Director of OEHHA and is its highest-ranking
11 administrative officer. Director Zeise is sued in her official capacity. She performs her official
12 duties in Sacramento. Director Zeise shall be referred to as OEHHA.

13 22. Defendant Xavier Becerra is the Attorney General of the State of California and
14 the highest-ranking officer in the California Department of Justice. Attorney General Becerra is
15 sued in his official capacity. He performs his official duties in Sacramento and throughout the
16 State of California.

17 **JURISDICTION AND VENUE**

18 23. This Court has jurisdiction over this action under 28 U.S.C. § 1331, which confers
19 original jurisdiction on federal district courts over actions arising under the Constitution or laws
20 of the United States.

21 24. Venue is proper under 28 U.S.C. § 1391(b)(1) and (b)(2), because Defendants are
22 located within this district and a substantial part of the events giving rise to Plaintiffs' claims
23 occurred in this district.

24 **FEDERAL REGULATORY FRAMEWORK**

25 25. Federal law comprehensively regulates the sale and use of herbicides, including
26 their labeling and permissible presence on food. Likewise, the federal government extensively
27 regulates the labeling of food products.

28

1 **A. FIFRA**

2 26. Under FIFRA, all commercial herbicides must be “registered” with EPA.
3 7 U.S.C. § 136a(a). Before EPA grants a registration, it must determine that the herbicide will
4 not cause “unreasonable adverse effects on the environment” or “human dietary risk.”
5 *Id.* §§ 136(bb), 136a. EPA’s review extends not only to the herbicide itself, but to formulations
6 and particular uses of the herbicide. *See generally id.* § 136a; 40 C.F.R. pt. 152. EPA also
7 evaluates each specific use of the herbicide (*i.e.*, its use on each particular type of crop) and,
8 when necessary, prescribes use restrictions to protect human health and the environment. *See*
9 7 U.S.C. §§ 136(bb), 136a(a). EPA’s extensive scientific safety review includes an evaluation of
10 whether the herbicide is potentially carcinogenic. *See, e.g.*, EPA, *Guidelines for Carcinogen*
11 *Risk Assessment* (Mar. 2005), [https://www.epa.gov/sites/production/files/2013-](https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf)
12 [09/documents/cancer_guidelines_final_3-25-05.pdf](https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf).

13 **B. The FDCA**

14 27. The FDCA prohibits “misbranding” of food products. 21 U.S.C. § 331(a). A
15 food product is misbranded if, among other things, “its labeling is false or misleading in any
16 particular.” *Id.* § 343(a). “Many statements,” including those that are “incomplete” or even
17 “true” can “be misleading.” *United States v. Watkins*, 278 F.3d 961, 967 (9th Cir. 2002).

18 28. The FDCA also regulates the presence of herbicides on foods. The FDCA deems
19 “unsafe foods” to be “adulterated,” 21 U.S.C. § 342(a), and renders their distribution in interstate
20 commerce unlawful, *id.* § 331(b). The statute specifically provides, however, that a food will not
21 be deemed “unsafe” due to the presence of herbicide residue in a quantity within the limits of an
22 EPA-established “tolerance for such pesticide chemical residue in or on such food.”
23 *Id.* § 346a(a)(1)(A). In evaluating appropriate tolerances, EPA specifically evaluates the human
24 health impact of the presence of an herbicide residue, including potential carcinogenicity.
25 *Id.* § 346a(b)(2)(A)(ii). EPA has set comprehensive tolerances for glyphosate, covering relevant
26 U.S. crops and food inputs. 40 C.F.R. § 180.364.

27 29. While the FDCA comprehensively regulates permissible herbicide residues in
28 food for safety, it also explicitly provides that disclosure of such safe residue amounts to

1 consumers purchasing food products is *not* required. 21 U.S.C. § 343(l), (k). States are barred
2 under the FDCA from “prohibit[ing] or penaliz[ing] the production, processing, shipping, or
3 other handling of a food because it contains a pesticide residue.” *Id.* § 346a(n)(4). And States
4 may not “enforce any regulatory limit on the *level* of a pesticide chemical residue that may
5 appear in or on any food if, at the time of the application of the pesticide that resulted in such
6 residue, the sale of such food with such residue level was lawful” under the FDCA.
7 *Id.* § 346a(n)(7) (emphasis added).

8 FACTUAL BACKGROUND

9 **A. Overview Of Glyphosate**

10 30. Glyphosate is a broad-spectrum herbicide that is used to control weeds in a
11 variety of agricultural, residential, aquatic, and other settings. Since it was first introduced in
12 1974, glyphosate has become the world’s most widely used herbicide because it is efficacious,
13 economical, and environmentally benign. Glyphosate is marketed under a number of trade
14 names and is registered for use as an herbicide in more than 160 countries, including the United
15 States. The “environmentally benign” glyphosate has, over the past several decades,
16 substantially displaced other herbicides which were perceived to pose environmental, health, or
17 safety risks. *See* Jorge Fernandez-Cornejo et al., U.S. Dep’t of Agric., *Pesticide Use in U.S.*
18 *Agriculture: 21 Selected Crops, 1960-2008*, at 21 (May 2014),
19 https://www.ers.usda.gov/webdocs/publications/43854/46734_eib124.pdf.

20 31. Glyphosate is approved for use in more than 250 agricultural crop applications in
21 California and elsewhere. It is used on the vast majority of corn, soybean, and canola crops
22 across the United States. It is also widely used on Canadian crops—including oats—and in
23 conjunction with the cultivation of wheat, beans, peas, and other crops in many locations. It is
24 also used in conjunction with cultivation of almond, citrus, cotton, and other crops in California.
25 Glyphosate-based herbicides are particularly desirable in the agricultural setting because of their
26 broad-spectrum effectiveness, which allows farmers to control weeds with minimal tilling of soil
27 (a practice known as conservation tilling), thereby conserving valuable topsoil, reducing soil
28 movement into streams and other surface water, and retaining soil moisture. The scientific

1 literature has expressly recognized these environmental benefits of using glyphosate, and has
2 explained why these practices are preferable to traditional means of cultivation, which involve
3 multiple other potentially significant impacts. *See, e.g.,* Stephen O. Duke & Stephen B. Powles,
4 *Mini-Review Glyphosate: A Once-in-a-Century Herbicide*, 64 *Pest Mgmt. Sci.* 319, 322 (2008).

5 32. Glyphosate-based herbicides are also widely used—including by municipal,
6 county, and California government agencies—to control vegetation in utility right-of-ways,
7 along roadsides and railways, in aquatic environments, in residential home and garden settings,
8 and to reduce the risk associated with the rapid spread of wildfires. In addition, glyphosate-
9 based herbicides are used by wildlife organizations to protect and restore wildlife habitats
10 threatened by invasive, non-native vegetation. For example, a glyphosate-based herbicide is
11 used to control arundo donax (giant reed) in central California’s river valleys; arundo donax is a
12 highly invasive weed that threatens California’s riparian ecosystems by competing with native
13 species, such as willows, for water.

14 33. For many applications, glyphosate is the most effective and reliable weed control
15 option. Indeed, very few herbicides other than glyphosate are approved by EPA for use in
16 aquatic environments.

17 **B. Glyphosate Has Been Widely Recognized To Be Non-Carcinogenic**

18 34. Glyphosate has been recognized as a safe herbicide for over 40 years by EPA,
19 regulators across the globe, and even OEHHA. Because of its immense popularity, glyphosate is
20 one of the most extensively studied herbicides in the world and has been subject to hundreds of
21 safety studies by the world’s most prominent and authoritative sources.

22 35. Glyphosate was first registered in the United States as an herbicide in 1974. In
23 1991, EPA conducted a peer review of glyphosate under FIFRA and, in 1993, approved the
24 renewal of its registration. At the time EPA concluded that:

25 Several chronic toxicity/carcinogenicity studies . . . resulted in no effects
26 based on the parameters examined, or resulted in findings that glyphosate
27 was not carcinogenic in the study. In June 1991, EPA classified
28 glyphosate as a Group E oncogen—one that shows evidence of non-
carcinogenicity for humans—based on the lack of convincing evidence of
carcinogenicity in adequate studies.

1 EPA, Reregistration Eligibility Decision (RED): Glyphosate, EPA-738-F-93-011, at 2 (1993).

2 36. EPA has reaffirmed this conclusion more recently. In relevant part:

3 [In 2014], EPA reviewed over 55 epidemiological studies conducted on
4 the possible cancer and non-cancer effects of glyphosate. Our review
5 concluded that this body of research does not provide evidence to show
6 that glyphosate causes cancer and it does not warrant any change in EPA's
7 cancer classification for glyphosate.

7 Statement of Carissa Cyran, Chem. Review Mgr., EPA Office of Pesticide Programs (2015).

8 37. This view of glyphosate's safety is widely shared by the international community.

9 In 2002, for instance, the Health and Consumer Protection Directorate-General of the European
10 Commission conducted a review of glyphosate for its re-registration for use in Europe and
11 likewise concluded there was "[n]o evidence of carcinogenicity." Health & Consumer Prot.
12 Directorate – Gen., European Comm'n, *Report for the Active Substance Glyphosate*, Directive
13 6511/VI/99, at 12 (Jan. 21, 2002). The same agency reaffirmed that conclusion on July 11, 2016.

14 38. Germany's Federal Institute for Risk Assessment—BfR—also recently reviewed
15 glyphosate. In December 2013 it submitted a glyphosate Renewal Assessment Report to the
16 European Food Safety Authority recommending re-approval of glyphosate for use in Europe.
17 The Report was revised in 2014 and again in 2015 in response to comments, and in it BfR
18 concluded that glyphosate was "unlikely to pose a carcinogenic risk in humans." *See* BfR,
19 *Renewal Assessment Report and Proposed Decision – Volume 1*, at 35 (Mar. 31, 2015). More
20 emphatically, BfR found that:

21 In epidemiological studies in humans, there was no evidence of
22 carcinogenicity and there were no effects on fertility, reproduction and
23 development or of neurotoxicity that might be attributed to glyphosate.

24 *Id.* at 36.

25 39. The European Food Safety Authority (EFSA) concurred with BfR's assessment.
26 It evaluated BfR's findings and "concluded that glyphosate is unlikely to pose a carcinogenic
27 hazard to humans and the evidence does not support classification with regard to its carcinogenic
28 potential." EFSA, Abstract, *Conclusion on the Peer Review of the Pesticide Risk Assessment of*

1 *the Active Substance Glyphosate*, at 1 (Nov. 12, 2015),
2 <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4302/epdf>.

3 40. Other similar conclusions abound. Canada's Pest Management Regulatory
4 Agency concluded *in April 2017* that "Glyphosate is not genotoxic and is unlikely to pose a
5 human cancer risk." The European Chemical Agency Committee for Risk Assessment
6 concluded *in March 2017* that "the available scientific evidence did not meet the criteria to
7 classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction." Korea's Rural
8 Development Administration observed that "animal testing found no carcinogenic association
9 and health risk of glyphosate on farmers was low." Australia's Pesticides and Veterinary
10 Medicines Authority found that "Glyphosate does not pose a cancer risk to humans when used in
11 accordance with the label instructions." New Zealand's Environmental Protection Authority
12 concluded that "Glyphosate is unlikely to be genotoxic or carcinogenic." And when Japan's
13 Food Safety Commission studied the substance, "[n]o neurotoxicity, carcinogenicity,
14 reproductive effect, teratogenicity or genotoxicity was observed." Similarly, in May 2016, the
15 Joint FAO/WHO Meeting on Pesticide Residues (JMPR) found that "[g]lyphosate is unlikely to
16 pose a carcinogenic risk to humans from exposure through the diet." JMPR, *Summary Report*
17 (May 16, 2016), <http://www.who.int/foodsafety/jmprsummary2016.pdf>. *In sum, no regulatory*
18 *agency, domestic or international, has found over its decades of safe use that glyphosate causes*
19 *cancer.*

20 41. Indeed, *even California itself, through OEHHA*, has concluded that glyphosate is
21 non-carcinogenic. In 1997 and 2007, OEHHA conducted risk assessments for glyphosate in
22 drinking water in order to set public health goals, including evaluation of glyphosate's potential
23 carcinogenicity. OEHHA reviewed several studies in which glyphosate was administered to rats
24 and mice, including the *same* studies (or reviews of those studies) IARC later used to reach its
25 own conclusion. Based on its review of those studies and other data, OEHHA concluded that
26 there was no evidence demonstrating that glyphosate causes cancer. *See, e.g., OEHHA, Public*
27 *Health Goal for Chemicals in Drinking Water: Glyphosate*, at 1 (June 2007) ("Based on the
28 weight of the evidence, glyphosate is judged unlikely to pose a cancer hazard to humans."). In

1 short, it is definitively untrue that glyphosate “is known to the State of California to cause
2 cancer.”

3 **C. IARC**

4 42. IARC is an international organization based in Lyon, France. It is not a regulator.
5 Instead, IARC prepares so-called informational “Monographs” regarding the possibility that
6 everyday products and substances may be carcinogenic. IARC is perhaps most famous (or
7 infamous) for its conclusions that substances like coffee, aloe vera, pickled vegetables, and food
8 exposed to “high temperatures”—such as French fries—are probably or possibly carcinogenic.
9 *See, e.g., Akshat Rathi & Gideon Lichfield, Why it Sometimes Seems Like Everything Causes*
10 *Cancer*, Quartz (June 23, 2016) (“[O]f all the things the IARC has looked at, there is just *one* it is
11 pretty sure *doesn’t* cause cancer.” (emphases added)), [https://qz.com/708925/why-it-sometimes-](https://qz.com/708925/why-it-sometimes-seems-like-everything-causes-cancer/)
12 [seems-like-everything-causes-cancer/](https://qz.com/708925/why-it-sometimes-seems-like-everything-causes-cancer/).

13 43. IARC’s pronouncements have been factually controversial among the scientific
14 and public health communities. This is certainly the case for glyphosate, which IARC classified
15 as “probably carcinogenic to humans” in March 2015. Among toxicology and regulatory
16 experts, who take great care not to exaggerate or inflame public understanding of cancer risks,
17 there has been extensive public criticism of IARC’s recent glyphosate conclusions.

18 44. For example, following IARC’s determination, EPA Deputy Director for
19 Pesticide Programs, William Jordan, testified before the U.S. Senate Committee on Agriculture,
20 Nutrition and Forestry and reaffirmed EPA’s longstanding non-carcinogenic conclusion for
21 glyphosate. In that same Committee hearing, the Chief Physician at MassGeneral Hospital for
22 Children observed that IARC’s recent contrary conclusion was “not supported by the data,” and
23 “flies in the face of comprehensive assessments from multiple agencies globally.” More
24 recently, EPA “reviewed and analyzed the results of 15 rodent bioassays and concluded that the
25 results as a whole do not indicate carcinogenicity of glyphosate.” FIFRA Sci. Advisory Panel,
26 EPA, *Meeting Minutes and Final Report No. 2017-01*, at 17
27 (Mar. 16, 2017), [https://www.epa.gov/sites/production/files/2017-03/documents/december_13-](https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf)
28 [16_2016_final_report_03162017.pdf](https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf).

1 45. Germany's national regulator BfR also publicly stated that, despite IARC's
2 contrary designation, it continued to assess "glyphosate as non-carcinogenic." BfR, *Does*
3 *Glyphosate Cause Cancer?*, BfR Communication No. 007/2015, at 1 (Mar. 23, 2015). In
4 rebutting IARC's assessment, BfR noted that it "has compiled the most comprehensive
5 toxicological database, presumably worldwide, for glyphosate" and "BfR thinks that the entire
6 database must be taken into account for toxicological evaluation and risk assessment of a
7 substance and not merely a more or less arbitrary selection of studies," as was the case with
8 IARC. *Id.*

9 46. The European Union's regulatory agency, EFSA, likewise rebutted IARC's
10 contrary classification and set forth several reasons similar to BfR's for its disagreement. EFSA,
11 *Abstract, Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active*
12 *Substance Glyphosate*, at 11 (Nov. 12, 2015),
13 <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4302/epdf>.

14 47. Indeed, although IARC is part of the World Health Organization (WHO), the
15 WHO itself has separately, and repeatedly, concluded that "glyphosate is *unlikely* to pose a
16 carcinogenic risk to humans," including in a 2016 review and conclusion after the IARC
17 classification. *See supra* at ¶ 40; *see also* FAO/WHO, *Pesticide Residues in Food – 2004, Part*
18 *II: Toxicological*, at 158 (2004) (emphasis added),
19 http://apps.who.int/iris/bitstream/10665/43624/1/9241665203_eng.pdf; WHO, *Glyphosate and*
20 *AMPA in Drinking Water: Background Document for Development of WHO Guidelines for*
21 *Drinking-Water Quality*, at 5 (June 2005) ("[n]o effect on survival" in glyphosate
22 "carcinogenicity study"); WHO/Int'l Programme on Chem. Safety, *Environmental Health*
23 *Criteria 159: Glyphosate*, at 15 (1994) ("The available studies do not indicate that technical
24 glyphosate is mutagenic, carcinogenic or teratogenic."). In other words, of the four subgroups
25 within WHO that have looked at the carcinogenicity of glyphosate, three of them have
26 determined glyphosate is *not carcinogenic*; IARC stands alone in its opinion otherwise.

27 48. Most recently, a report was published just last week in the Journal of the National
28 Cancer Institute on the largest and longest study to *ever* analyze human glyphosate exposure and

1 cancer—the Agricultural Health Study (AHS), sponsored by the U.S. National Institutes of
2 Health, National Cancer Institute, and the National Institute of Environmental Health Science,
3 among others. See Gabriella Andreotti et al., *Glyphosate Use and Cancer Incidence in the*
4 *Agricultural Health Study*, JNCI: Journal of the National Cancer Institute (Nov. 9, 2017),
5 <https://academic.oup.com/jnci/article/doi/10.1093/jnci/djx233/4590280>. The AHS has analyzed
6 health effects—including multiple cancers—in over 54,000 pesticide applicators (one of if not
7 the most highly exposed human populations to glyphosate) over the course of three decades. As
8 first reported from that study in 2005 and confirmed again just now in 2017 with additional data
9 support, the study found “no evidence of any association between glyphosate use and risk of any
10 solid tumors or lymphoid malignancies, including NHL (non-Hodgkin lymphoma) and its
11 subtypes.” *Id.* (emphasis added).

12 49. Not only is there widespread disagreement with IARC’s controversial glyphosate
13 conclusions, there has also been significant and widespread criticism of IARC’s internal
14 processes and potential conflicts of interest. In addition to the regulatory agencies, discussed
15 *supra*, who have noted that IARC arbitrarily refused to review certain highly relevant studies
16 about glyphosate, there are recent reports that IARC’s own scientists purposely withheld key
17 data from the IARC team addressing glyphosate.

18 50. For example, according to recent articles in Reuters and many other publications,
19 court documents reflect that Aaron Blair—the chair of the IARC “working group” that produced
20 the glyphosate finding—knew about unpublished research (notably, a 2013 draft report of the
21 AHS study) finding no evidence of a link between glyphosate and cancer, but concealed this
22 evidence from his colleagues. According to these reports, Blair also admitted that the research, if
23 presented, would have undercut IARC’s cancer classification. Kate Kelland, *Cancer Agency Left*
24 *in the Dark over Glyphosate Evidence*, Reuters (June 14, 2017),
25 <https://www.reuters.com/investigates/special-report/glyphosate-cancer-data/>. And another
26 scientist who was advising IARC when it published its dubious finding, Christopher Portier,
27 reportedly concealed that he was paid \$160,000 from law firms bringing claims by cancer
28 victims against glyphosate manufacturers. See Ben Webster, *Weedkiller Scientists Was Paid*

1 £120,000 by *Cancer Lawyers*, The Times (Oct. 18, 2017),
 2 [https://www.thetimes.co.uk/article/weedkiller-scientist-was-paid-120-000-by-cancer-lawyers-](https://www.thetimes.co.uk/article/weedkiller-scientist-was-paid-120-000-by-cancer-lawyers-v0qggbrk6)
 3 [v0qggbrk6](https://www.thetimes.co.uk/article/weedkiller-scientist-was-paid-120-000-by-cancer-lawyers-v0qggbrk6). In deposition testimony for other litigation Portier reportedly conceded that this
 4 might present “a conflict of interest” and that even *he* “would have concern” stating that
 5 glyphosate “100 percent” causes cancer. And others have reported that IARC conspicuously and
 6 inexplicably removed “multiple scientists’ conclusions that their studies had found no link
 7 between glyphosate and cancer” between a draft version of IARC’s report and the final version.
 8 See Kate Kelland, *In Glyphosate Review, WHO Cancer Agency Edited out “Non-Carcinogenic”*
 9 *Findings*, Reuters (Oct. 19, 2017), [https://www.reuters.com/investigates/special-report/who-iarc-](https://www.reuters.com/investigates/special-report/who-iarc-glyphosate/)
 10 [glyphosate/](https://www.reuters.com/investigates/special-report/who-iarc-glyphosate/).

11 51. In light of these revelations, it is no wonder that even the progressive periodical,
 12 *Mother Jones*, which frequently champions strict regulation of materials posing environmental
 13 and health risks, has questioned the integrity of IARC’s practices. Kiera Butler, *A Scientist*
 14 *Didn’t Disclose Important Data – and Let Everyone Believe a Popular Weedkiller Causes*
 15 *Cancer*, *Mother Jones* (June 15, 2017), [http://www.motherjones.com/environment/](http://www.motherjones.com/environment/2017/06/monsanto-roundup-glyphosate-cancer-who/)
 16 [2017/06/monsanto-roundup-glyphosate-cancer-who/](http://www.motherjones.com/environment/2017/06/monsanto-roundup-glyphosate-cancer-who/).

17 52. Indeed, in the past, OEHHA personnel have themselves raised concerns about the
 18 IARC process: “IARC *Monographs* do not undergo public review and are designed to reflect the
 19 opinion of convened experts, there is no opportunity to correct errors in judgment.” Other
 20 independent scientists have made similar claims. See, e.g., Joseph K McLaughlin et al.,
 21 *Problems with IARC’s ‘Expert’ Working Groups*, 40 *Int’l J. Epidemiology* 1728, 1728 (Nov.
 22 2011) (“They are clearly not disinterested evaluators of the research evidence being considered,
 23 as much of it represents their own work.”).

24 **D. Proposition 65 & IARC**

25 53. In 1986, the California voters, by initiative, enacted the Safe Drinking Water and
 26 Toxic Enforcement Act of 1986—commonly known as Proposition 65. In general, Proposition
 27 65 prohibits businesses from both exposing California residents to chemicals known to the State
 28 to cause cancer without providing required warnings, and from knowingly discharging a

1 chemical known to the state to cause cancer into the environment where the chemical passes or
2 will probably pass into a source of drinking water. Cal. Health & Safety Code §§ 25249.5,
3 25249.6.

4 54. Mechanically, the Proposition 65 process works as follows:

5 55. OEHHA is required to maintain “a list of those chemicals known to the state to
6 cause cancer.” *Id.* § 25249.8(a).

7 56. Proposition 65 then provides a number of mechanisms by which OEHHA is
8 directed to perform this listing function and, as relevant here, provides that OEHHA’s “list shall
9 include at a minimum those substances identified by reference in Labor Code Section
10 6382(b)(1).” *Id.* Section 6382(b)(1) of the Labor Code in turn references—as it did when
11 Proposition 65 was enacted—“[s]ubstances listed as human *or animal* carcinogens by the
12 International Agency for Research on Cancer.” Cal. Labor Code § 6382(b)(1) (emphasis added).
13 It is not clear whether, when Proposition 65 was passed, this cross-reference was designed to
14 incorporate only those substances IARC had *already* listed, or to force continual updating to
15 incorporate all chemicals IARC might at some future time designate (if and until the organization
16 dissolves). By regulation, however, OEHHA has taken the latter approach. 27 Cal. Code Regs
17 § 25904. This approach has been approved as a matter of statutory interpretation but without
18 considering its constitutionality. *See Cal. Chamber of Commerce v. Brown*, 196 Cal. App. 4th
19 233 (2011).

20 57. OEHHA has described its process for listing a chemical found by IARC to be
21 potentially carcinogenic as “ministerial” and essentially automatic. OEHHA publishes a “Notice
22 of Intent to List” a chemical and provides a 30-day period for comment on whether or not the
23 chemical “has been identified by reference in Labor Code section 6382(b)(1),” 27 Cal. Code
24 Regs § 25904(c)—in other words, whether IARC has determined that the chemical is potentially
25 carcinogenic. The regulations make plain that the scope of comments is limited: OEHHA “shall
26 not consider comments related to the underlying scientific basis for classification of a chemical
27 by IARC as causing cancer.” *Id.* Thus, there is no opportunity to contest IARC’s findings, no
28 matter how clearly erroneous.

1 58. Once a chemical is listed and after a 12-month grace period, the statute requires
2 that any “person in the course of doing business” provide a “clear and reasonable warning”
3 before “expos[ing] any individual to” the listed chemical. Cal. Health & Safety Code
4 § 25249.10(b). As a practical matter, this means that affected entities must take action far earlier
5 than the warning’s effective date. *See infra* ¶¶ 71-87 (discussing impacts of listing).

6 59. Although Proposition 65 does not define precisely what content suffices to
7 convey a “clear and reasonable warning,” OEHHA’s regulations have for almost 30 years
8 provided what the cancer warning should convey: “WARNING: This product contains a
9 chemical known to the State of California to cause cancer.” 27 Cal. Code Regs § 25603.2.
10 Indeed, no matter what words are used, “[t]he message must clearly communicate that the
11 chemical in question is known to the state to cause cancer.” *Id.* § 25601.

12 60. Proposition 65 also provides an affirmative defense in an enforcement action to
13 enforce the warning requirement if “the person responsible can show that the exposure poses no
14 significant risk assuming lifetime exposure at the level in question for substances known to the
15 state to cause cancer.” Cal Health & Safety Code § 25249.10(c). For some listed substances,
16 OEHHA will make its own determination of a “No Significant Risk Level” (NSRL), commonly
17 referred to as a “safe harbor.” But the NSRL provides only an “affirmative defense” to liability
18 under Proposition 65, it does not immunize industry from enforcement actions in the first
19 instance. *See DiPirro v. Bondo Corp.*, 153 Cal. App. 4th 150, 185 (2007). No NSRL for
20 glyphosate is in place at this time.

21 61. Proposition 65 has a multi-faceted enforcement scheme. First, the Attorney
22 General, a district attorney, or a variety of local government attorneys may bring an enforcement
23 action under Cal. Health & Safety Code § 25249.7(c). The statute imposes penalties up to
24 \$2,500 *per day* for *each* violation, and provides for recovery of attorneys’ fees. In addition to
25 these penalties, the statute also provides that any person who “*threatens* to violate” the warning
26 requirement may be “enjoined in a court of competent jurisdiction.” *Id.* § 25249.7(a) (emphasis
27 added). The Attorney General of California and other California public officials have a long
28 history of enforcing Proposition 65’s warning requirement.

1 62. Second, any *person* (even with no injury in fact) may bring a private enforcement
2 action for an alleged failure to provide an adequate warning. *Id.* § 25249.7(d). The same civil
3 penalties and attorneys’ fees scheme applies in these suits, creating very strong incentives for
4 private enforcement.

5 63. Indeed, the private enforcement mechanism allows any person or law firm to act
6 as a “bounty hunter” and prosecute any alleged violations of Proposition 65. Wide-scale abuse
7 of the Proposition 65 regime through “strike suits” by bounty hunters is broadly recognized. *See,*
8 *e.g., Anthony T. Caso, Bounty Hunters and the Public Interest—A Study of California*
9 *Proposition 65*, 13 Engage 30, 31 (Mar. 2012) (describing case in which “law firm created an
10 ‘astroturf’ environmental group to be a plaintiff in Proposition 65 litigation,” which group
11 “consisted of partners from the law firm” and which “sent out hundreds of demand letters
12 charging businesses with failure to provide warnings” and “extort[ing] payments of attorney fees
13 or contributions to the front group”).

14 64. Significantly, even when OEHHA has set a “safe harbor” NSRL purporting to set
15 a State-based tolerance or limit for chemical residues and exposure, the risk of enforcement
16 persists. Even with such a safe harbor in place, the defendant still bears the burden of
17 establishing as an affirmative defense that the exposure fell within the safe harbor. Cal. Health
18 & Safety Code § 25249.10(c). A Proposition 65 plaintiff need only allege possible exposure to a
19 listed substance, he need *not* prove that an established NSRL is not satisfied. *Consumer Cause,*
20 *Inc. v. SmileCare*, 91 Cal. App. 4th 454, 474 (2001). And litigating this defense is a costly and
21 time-consuming endeavor. *See, e.g., Env’tl. Law Found. v. Beech-Nut Nutrition Corp.*, 235 Cal.
22 App. 4th 307, 314 (2015) (safe harbor defense litigated at trial); *Council for Educ. & Research*
23 *on Toxics v. Starbucks Corp.*, No. BC435759 (Cal. Super. Ct., June 2, 2017) (rejecting
24 Starbucks’s “no significant risk level” defense at summary judgment). In other words, a safe
25 harbor does not effectively deter a private party with significant financial incentives from
26 initiating suit in the hopes of collecting a settlement.

27 65. The California courts have recognized how onerous strike suits can be for
28 industry. “[L]awsuits under Proposition 65 can be filed and prosecuted by any person against

1 any business based on bare *allegations* of a violation unsupported by any evidence of an actual
2 violation—or even a good faith belief that a defendant is using an unsafe amount of a chemical
3 known by the state to cause cancer.” *SmileCare*, 91 Cal. App. 4th at 477 (Vogel, J., dissenting)
4 (emphasis in original). This burden-shifting regime results in “judicial extortion” where bounty-
5 hunting plaintiffs bring Proposition 65 claims, admitting they have no specific evidence of any
6 danger, and force the defendant to settle to avoid legal fees and the costs of performing an
7 expensive expert scientific assessment. *Id.* at 477-79.

8 66. A long history of these strike suits demonstrates what typically happens in
9 practice: in the face of this litigation threat, businesses are forced to simply acquiesce and post a
10 warning, regardless of the fact that those businesses know the warning is affirmatively false and
11 misleading. *See* All. for Nat. Health, *Proposition 65: Evaluating Effectiveness and a Call for*
12 *Reform*, at 7, <https://www.anh-usa.org/wp-content/uploads/2015/09/Prop-65.pdf> (last accessed
13 Nov. 9, 2017); *see also*, LATIMES, *Warning: Too Many Warning Signs are Bad for Your Health*
14 (Sept. 30, 2017), (noting “Starbucks, Whole Foods and about 80 other places in California that
15 sell coffee” are exposed under Proposition 65 even though “research increasingly” indicates
16 coffee does *not* cause cancer), [http://beta.latimes.com/opinion/editorials/la-ed-proposition-65-](http://beta.latimes.com/opinion/editorials/la-ed-proposition-65-warning-coffee-20170930-story.html)
17 [warning-coffee-20170930-story.html](http://beta.latimes.com/opinion/editorials/la-ed-proposition-65-warning-coffee-20170930-story.html); Richard Berman, *Thanks to a Poorly-Designed Law,*
18 *California Classifies Soft Drinks as a Cancer Risk*, *Forbes* (Feb. 20, 2014) (compelling warnings
19 for soda drinks on the basis that if consumers drink “over 1,000 sodas a day” they would have
20 increased cancer risk); Greg Ryan, *Rice Sellers Threatened with Prop 65 Suits over Lead,*
21 *Arsenic*, *Law360* (Feb. 20, 2014).

22 67. Many hundreds of Proposition 65 strike suits have been filed in the past. Such
23 suits are often filed against defendants regarding a given chemical immediately after the
24 Proposition 65 warning requirement for that chemical goes into effect.

25 **E. Proposition 65 Listing Of Glyphosate**

26 68. Despite the overwhelming contrary views of the U.S. government, the
27 international community, and even OEHHA that glyphosate is not carcinogenic, on July 7, 2017,
28 California finalized its listing of glyphosate under Proposition 65 as a chemical “known to the

1 state to cause cancer.” As the basis for the listing, California relied exclusively on IARC’s
 2 flawed determination, discussed *supra* at ¶¶ 42-52, that glyphosate is a “*probabl[e]*
 3 carcinogen[.]” OEHHA explained that glyphosate met the requirements for listing simply
 4 because (1) IARC classified glyphosate as a “*probabl[e] carcinogen[.]*,” and (2) IARC concluded
 5 that there was “sufficient evidence” of carcinogenicity in experimental animals. IARC
 6 Monograph Vol. 112 at 398; *see also* 27 Cal. Code Regs § 25904(b). That is, California—
 7 through Proposition 65—is now requiring industry to state that glyphosate is “**known**” to cause
 8 cancer even though (a) *no one* has ever reached that conclusion and (b) even IARC concluded
 9 only that it is “**probably**” carcinogenic, a conclusion which IARC itself admits has “no
 10 quantitative significance” and should not be viewed (and hence used) as a recommendation for
 11 legislation or regulation. *See* IARC, *IARC Monographs on the Evaluation of Carcinogenic Risk*
 12 *to Humans: Preamble*, at 22 (2006),
 13 <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>.

14 69. Despite 9,183 comments being filed—many of which informed OEHHA that the
 15 IARC determination was flawed and should not be relied upon—OEHHA disclaimed any ability
 16 to address the underlying scientific dispute or reassess “the weight or quality of the evidence
 17 considered by IARC.” *See* OEHHA, *Notice of Intent to List: Tetrachlorvinphos, Parathion,*
 18 *Malathion, Glyphosate* (Sept. 4, 2015), [https://oehha.ca.gov/proposition-65/cmr/notice-intent-](https://oehha.ca.gov/proposition-65/cmr/notice-intent-list-tetrachlorvinphos-parathion-malathion-glyphosate)
 19 [list-tetrachlorvinphos-parathion-malathion-glyphosate](https://oehha.ca.gov/proposition-65/cmr/notice-intent-list-tetrachlorvinphos-parathion-malathion-glyphosate).

20 70. Past Proposition 65 litigants are already threatening new Proposition 65 lawsuits
 21 regarding glyphosate, “urg[ing]” companies to “phas[e] out the use of glyphosate,” and
 22 highlighting the “risk of legal action.” *See, e.g.*, Letter from Austin Wilson, Environmental
 23 Health Program Manager of ‘As you Sow,’ to Denise Morrison, CEO, Campbell Soup Company
 24 (Oct. 5, 2016).

25 **THREATENED IMPACTS OF CALIFORNIA’S LISTING OF GLYPHOSATE**

26 71. Without relief, California’s listing of glyphosate and its attendant false warning
 27 requirement threaten widespread impacts in California and across the U.S. These impacts would
 28 be felt in multiple different contexts.

1 72. Under federal law, foods made with crops treated with glyphosate are permitted to
2 contain certain trace levels of glyphosate residues. For entities that sell into California finished
3 food products made with glyphosate-treated crops—like members of Plaintiffs Missouri
4 Chamber of Commerce and Industry and Associated Industries of Missouri—California’s listing
5 of glyphosate as a carcinogen will force them to take one of three courses of action: (1) include
6 the false and disparaging glyphosate warning for their products, which likely will diminish
7 demand for those products; (2) engage in costly testing to demonstrate that exposure from any
8 glyphosate residues in their products invariably falls below any established NSRL safe harbor (or
9 impose those testing requirements on their suppliers) and even so still face the likely prospect of
10 expensive enforcement actions; or (3) stop using glyphosate-treated crops as inputs for their food
11 products sold to California. Food producers need to begin making these decisions and
12 communicating them through the supply chain imminently.

13 73. Entities that farm and process crops for integration into finished food products
14 that are sold into California face similar burdens from California’s listing of glyphosate. With
15 the threat of enforcement under Proposition 65, a number of grain handlers and finished food
16 producers will require that farmers providing inputs for food products destined for California
17 either not use glyphosate on their crops or certify that their crops do not contain glyphosate
18 residues beyond particular levels, which will in turn require expensive testing, segregation of
19 glyphosate-treated crops from non-glyphosate-treated crops, or a halt on using glyphosate at
20 all—each an undesirable option and one that comes at considerable expense. This will
21 dramatically affect the practices of farmers across the country, including members of Plaintiffs
22 National Association of Wheat Growers, National Corn Growers Association, United States
23 Durum Growers Association, Missouri Farm Bureau, Iowa Soybean Association, North Dakota
24 Grain Growers Association, and Missouri Chamber of Commerce and Industry. These entities
25 and their members need to begin planning for the impacts of Proposition 65 immediately.

26 74. The issues facing food producers and farmers are not merely hypothetical, but in
27 fact are already being borne out in the supply chain. For example, Plaintiff National Association
28 of Wheat Growers’ members sell their crops to common elevators or milling facilities, which

1 then turn the wheat into flour that is incorporated into products sold in California. The
2 association's members have already been told by millers that because millers do not want to test
3 for glyphosate residues themselves, this requirement will be imposed on the farmers. Testing for
4 glyphosate residues is very expensive.

5 75. The listing of glyphosate under Proposition 65 and the compelled glyphosate
6 warning requirement also broadly disparage Plaintiffs, Plaintiffs' members, and Plaintiffs'
7 members' food products and food inputs, by creating the false impression among consumers that
8 those products are unsafe.

9 76. The listing of glyphosate under Proposition 65 will also impact sellers and
10 manufacturers of glyphosate. Major municipal applicators, for example, have already expressed
11 that they will cease using glyphosate-based products. *See* City of Burbank, 2017 City Council
12 Meeting – Joint, at 3:01:05 (July 11, 2017), *available at* [http://burbank.granicus.com/—](http://burbank.granicus.com/—MediaPlayer.php?view_id=6&clip_id=7943&meta_id=325562)
13 [MediaPlayer.php?view_id=6&clip_id=7943&meta_id=325562](http://burbank.granicus.com/—MediaPlayer.php?view_id=6&clip_id=7943&meta_id=325562).

14 77. Plaintiff Western Plant Health Association has members that sell glyphosate-
15 based products in California and that have already experienced reduced demand in California for
16 glyphosate-based products on account of the Proposition 65 listing, even though the false
17 warning requirement is not yet in effect. And once that requirement goes into effect, such
18 members must either take action to communicate a false and highly controversial health warning
19 to consumers about the glyphosate products they sell, or face potential enforcement actions
20 seeking civil monetary penalties for failing to do so. And even if OEHHA ultimately establishes
21 an NSRL, they would need to ensure that any exposures to glyphosate from their products fall
22 below that level, and even then would need to also prepare to defend against costly suits.

23 78. Plaintiff Monsanto has already suffered—and will continue to suffer—significant
24 harm from the listing of glyphosate under Proposition 65. Monsanto supplies glyphosate to
25 public and private entities in California, as well as California consumers, through multiple sales
26 channels. Monsanto divides these sales channels into three market segments: (i) Agricultural,
27 (ii) Industrial, Turf and Ornamental, and (iii) Lawn and Garden. Monsanto sells glyphosate both
28 directly and through distributors and business partners. All of these sales channels will be

1 impacted by glyphosate's listing and the false warning requirement.

2 79. In the Agricultural segment, Monsanto sells glyphosate to agricultural wholesalers
3 which either re-sell glyphosate directly to farmers (to the extent they maintain retail locations) or
4 re-sell glyphosate to retailers who in turn sell the product to farmers.

5 80. In the Industrial, Turf, and Ornamental (IT&O) segment, Monsanto sells
6 glyphosate through a joint venture to wholesale distributors, which in turn re-sell glyphosate to
7 California end users. These distributors include both major, national distributors, including
8 "landscape supply" companies with storefronts across California, as well as small, independent
9 distributors. Glyphosate is sold through this segment for use by professionals that perform weed
10 control activities in office parks, golf courses, residential areas, and other landscaped or grass-
11 covered areas. Monsanto also sells glyphosate to professionals responsible for controlling weeds
12 on railroad rights of way, highways, roadside medians, and other rights of way and public
13 spaces. Monsanto also sells glyphosate for aquatic applications in the control of weeds at the
14 edge of California water bodies. Monsanto also sells glyphosate for use at California tree farms
15 and plant growth nurseries.

16 81. In the Lawn and Garden segment, Monsanto sells glyphosate (through its agent)
17 to retailers in California, including hardware stores, home and garden stores, and independent
18 nurseries, as well as to distributors that re-sell glyphosate to retailers. California retailers sell
19 Monsanto-produced glyphosate through storefronts directly to consumers, principally as
20 Roundup® branded products. These retail storefronts stock glyphosate on shelves alongside
21 other consumer products, such as fertilizers and mulch.

22 82. Also in the Lawn and Garden segment, Monsanto (through its agent) sells
23 glyphosate directly to California consumers over the Internet. California consumers place orders
24 online, and have glyphosate, including Roundup® branded products, shipped directly to their
25 doors for home lawn and garden use.

26 83. Because of California's listing of glyphosate, Monsanto must either take action to
27 provide false and highly controversial health warnings to California consumers about glyphosate
28 in its products, and work with its distributors and customers to do so, or face potential

1 enforcement actions seeking civil money penalties for failing to do so. Even if OEHHA
2 ultimately establishes an NSRL, Monsanto will still be injured because it will be forced to
3 choose between applying, and working with its distributors and customers to apply, a false and
4 highly controversial warning on its products, or undertaking costly risk assessments for all of its
5 many glyphosate products to demonstrate that glyphosate exposures will invariably fall below
6 the NSRL. Monsanto would need to engage in this expensive risk assessment process for each
7 anticipated use of glyphosate and glyphosate products. And regardless of whether Monsanto's
8 risk assessment indicates that a product or use will invariably fall below the NSRL, unless
9 Monsanto complies with Proposition 65's false warning requirements, Monsanto would need to
10 prepare to defend against likely enforcement actions, including private strike suits brought by
11 rent-seeking litigants.

12 84. Moreover, California's Proposition 65 listing of glyphosate and the false warning
13 requirement broadly disparage Monsanto's glyphosate products and glyphosate tolerant seed
14 products, causing harm to the company, its reputation, and the company's hundreds of millions
15 of dollar investments in these products.

16 85. Both the glyphosate Proposition 65 listing itself, and the required warning, are
17 affirmatively and destructively misleading. They create a misimpression among consumers that
18 glyphosate is dangerous when all relevant regulators have found that it indisputably is *not*. The
19 disparagement of all products that contain glyphosate and all food products that may legally
20 contain trace glyphosate residues—and the legal jeopardy hanging over retailers who carry
21 them—has already adversely affected and unless enjoined will continue to adversely affect both
22 the supply and demand for glyphosate and glyphosate-exposed products at all levels of the
23 national distribution chain.

24 86. All of Plaintiffs and Plaintiffs' members who sell products that contain glyphosate
25 that ultimately end up in California desire that those products continue to be sold in California.
26 None of those entities, however, wants to be forced to engage in false speech about products that
27 contain glyphosate, or to have false warnings provided about products that contain glyphosate.

28 87. An order enjoining and declaring invalid California's listing of glyphosate under

1 Proposition 65 and its attendant false warning requirement would redress the harms described
2 above.

3 **CLAIMS FOR RELIEF**

4 **CLAIM I: VIOLATION OF THE FIRST AMENDMENT TO THE UNITED STATES**
5 **CONSTITUTION**

6 88. The foregoing Paragraphs are incorporated by reference as if set forth in full
7 herein.

8 89. The Free Speech Clause of the First Amendment of the United States Constitution
9 provides that “Congress shall make no law . . . abridging the freedom of speech.” U.S. Const.
10 amend. I. The Fourteenth Amendment of the United States Constitution made this proscription
11 applicable to the States and their political subdivisions. *See id.* amend. XIV, § 1.

12 90. In addition to providing protections against restrictions on speech, the First
13 Amendment provides protection against the government *compelling* individuals or entities to
14 engage in speech.

15 91. Under the First Amendment, laws compelling speech ordinarily receive strict
16 scrutiny. *See Wooley v. Maynard*, 430 U.S. 705, 715-16 (1977). Laws regulating commercial
17 speech generally receive at least intermediate scrutiny, *i.e.*, they are prohibited if they do not
18 directly and materially advance the government’s interest, or are more extensive than necessary.
19 *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980). And even
20 laws that require disclosure of information in connection with commercial transactions are
21 permissible only if the compelled disclosure is of information that is purely factual,
22 uncontroversially accurate, reasonably related to a substantial government purpose, and not
23 unduly burdensome or chilling. *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626,
24 651 (1985); *Am. Beverage Ass’n v. City & Cty. of S.F.*, 871 F.3d 884, 892-93 (9th Cir. 2017);
25 *CTIA – Wireless Ass’n v. City & Cty. of S.F.*, 494 F. App’x 752, 753 (9th Cir. 2012).

26 92. Contrary to the warning mandated by Proposition 65, glyphosate does not cause
27 cancer.

28 93. Nor does California “know” that glyphosate causes cancer. To the contrary, the

1 pertinent California agency—OEHHA—has twice determined that it does not, and California
2 conducted no independent analysis to verify IARC’s outlier contrary conclusion. In fact,
3 California, through OEHHA, affirmatively disclaimed the ability to conduct any such analysis.

4 94. Every major and credible scientific body to consider the issue disagrees with
5 IARC’s determination.

6 95. Moreover, even IARC itself has not said that it “knows” that exposure to
7 glyphosate causes cancer in humans. The most it has said is that glyphosate is “*probably*
8 *carcinogenic*.”

9 96. The Proposition 65 glyphosate warning mandate thus compels speech that is false
10 and misleading.

11 97. At the very least, the Proposition 65 glyphosate warning mandate compels speech
12 that is factually controversial.

13 98. Because Proposition 65’s compelled glyphosate warning is false, misleading, or
14 factually controversial, it cannot survive any level of constitutional scrutiny. *See Video Software*
15 *Dealers Ass’n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009) (“[T]he State has no
16 legitimate reason to force retailers to affix false information on their products.”).

17 99. Proposition 65’s glyphosate warning mandate constitutes impermissible
18 compelled speech under the First Amendment to the U.S. Constitution.

19 100. Plaintiffs consist of entities and members who have already been harmed by
20 California’s false, misleading, and highly controversial listing of glyphosate as a known
21 carcinogen, and will be injured further if forced to either comply with Proposition 65’s
22 compelled false warning requirement, or incur other costly burdens and face the threat of bounty
23 hunter suits or other enforcement actions.

24 **CLAIM II: VIOLATION OF THE SUPREMACY CLAUSE OF THE UNITED STATES**
25 **CONSTITUTION**

26 101. The foregoing Paragraphs are incorporated by reference as if set forth in full
27 herein.

28 102. Article VI, Clause 2 of the United States Constitution provides that “the laws of

1 the United States . . . shall be the supreme law of the land.” Under the Supremacy Clause, state
2 laws that conflict with federal law are preempted and are thus without effect. Preemption can be
3 express, as when a federal law declares that it preempts state laws, or implied. State laws are
4 impliedly preempted whenever they conflict in their operation with federal law. Conflict
5 preemption can arise when a state law “stands as an obstacle to the accomplishment and
6 execution of the full purposes and objectives of Congress.” *Hines v. Davidowitz*, 312 U.S. 52, 67
7 (1941). In addition, state law is conflict preempted “where compliance with both federal and
8 state regulation is a physical impossibility.” *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373
9 U.S. 132, 142-43 (1963).

10 103. Proposition 65’s mandated glyphosate warning is false, because glyphosate does
11 not cause cancer.

12 104. Nor does California “know” that glyphosate causes cancer. To the contrary, the
13 pertinent California agency—OEHHA—has twice determined that it does not, and California
14 conducted no independent analysis to verify IARC’s outlier contrary conclusion. In fact,
15 California, through OEHHA, affirmatively disclaimed the ability to conduct any such analysis.

16 105. At the very least, Proposition 65’s mandated glyphosate warning is misleading,
17 insofar as it states definitively that glyphosate causes cancer when every other pertinent expert
18 regulatory agency worldwide has concluded otherwise.

19 106. The FDCA prohibits misbranding a food product, including where “its labeling is
20 false or misleading in any particular.” 21 U.S.C. § 343(a).

21 107. Selling a food product with Proposition 65’s false mandated glyphosate warning
22 would render that product misbranded under federal law. As a result, a food product producer
23 and/or seller cannot reasonably comply with both federal law and Proposition 65, giving rise to
24 conflict preemption.

25 108. Plaintiffs consist of members who must comply with Proposition 65’s compelled
26 glyphosate warning requirement for products that contain glyphosate to avoid the prospect of
27 costly enforcement actions and other burdens, and must also comply with the FDCA’s labeling
28 requirements.

1 109. It would be impossible to comply with the FDCA ban on mislabeling a product
2 (the product label cannot be false or misleading in any particular) and simultaneously comply
3 with California’s requirement to put a false, misleading, and highly controversial Proposition 65
4 warning on relevant products.

5 110. The FDCA also provides that pesticide residues on food may not exceed EPA-
6 established limits but that labeling shall *not* be required for such foods. *See id.* §§ 346a(a)(1)(A),
7 343(k), (l).

8 111. States are generally prohibited from “establish[ing] or enforc[ing] any regulatory
9 limit on a qualifying pesticide chemical residue,” including any “prohibit[ion] or penal[ty]” on
10 the “production, processing, shipping, or other handling of a food because it contains a pesticide
11 residue.” *Id.* § 346a(n)(4), (5), (6).

12 112. Proposition 65’s glyphosate listing and any related safe harbor effectively
13 establish or enforce a regulatory limit on a pesticide chemical residue. And Proposition 65’s
14 mandated glyphosate warning on food products is a “penalty” on the production, processing,
15 shipping, or handling of food because it contains a pesticide residue. California has neither
16 sought nor received an exemption from EPA to impose that penalty or prohibition. Thus,
17 Proposition 65’s glyphosate listing and mandated glyphosate warning are expressly preempted
18 by the FDCA’s tolerance regime.

19 113. Even if Proposition 65’s mandated glyphosate warning is not expressly preempted
20 by the FDCA’s tolerance regime, it is impliedly preempted as an obstacle to the accomplishment
21 of the purposes and objectives of federal law. The legislative history underlying the pesticide
22 residue tolerance regime reflects that Congress affirmatively rejected labeling on foods that
23 contained a permissible pesticide residue quantity. And EPA, the regulatory agency tasked with
24 administering the pesticide residue tolerance regime, has found in its most recent analyses that
25 glyphosate is non-carcinogenic and that its presence on food up to the tolerance level poses no
26 public health risks. Thus, Proposition 65’s listing of glyphosate and its attendant glyphosate
27 warning mandate directly undermine this federal tolerance regime.

28

1 **CLAIM III: VIOLATION OF THE DUE PROCESS CLAUSE OF THE FOURTEENTH**
2 **AMENDMENT TO THE UNITED STATES CONSTITUTION**

3 114. The foregoing Paragraphs are incorporated by reference as if set forth in full
4 herein.

5 115. The Due Process Clause of the Fourteenth Amendment provides that “[n]o state
6 shall . . . deprive any person of life, liberty, or property, without due process of law.” U.S.
7 Const. amend. XIV, § 1. At a minimum, the Clause requires that every state law “be rationally
8 related to legitimate government interests.” *Washington v. Glucksberg*, 521 U.S. 702, 728
9 (1997).

10 116. California does not *know* that glyphosate *causes* cancer.

11 117. California’s sole basis for listing glyphosate under Proposition 65 as a chemical
12 known to the state to cause cancer is IARC’s March 2015 Monograph. California made no effort
13 to examine any of the mass of studies that contradict IARC’s controversial finding, including
14 California’s own prior analyses, it conducted no new assessment itself, and it made no attempt
15 whatsoever to reconcile IARC’s findings with the contrary views of every government regulatory
16 body that has examined the question and concluded that glyphosate is unlikely to cause cancer.

17 118. Even IARC’s Monograph does not support the warning that Proposition 65 will
18 require, because IARC did not conclude that glyphosate *causes* cancer in humans. Instead, it
19 concluded that “there is limited evidence in humans for the carcinogenicity of glyphosate” and
20 that glyphosate is “probably carcinogenic in humans.”

21 119. California has no rational basis for listing glyphosate as a chemical known to the
22 State of California to cause cancer, or for compelling a warning that glyphosate is known to the
23 State of California to cause cancer as a result of that listing.

24 120. Listing glyphosate falsely as a known carcinogen and requiring a warning that
25 misleadingly states that California knows glyphosate is a carcinogen are not actions rationally
26 related to any legitimate state interest.

27 121. California’s listing of glyphosate and the attendant warning requirement are
28 therefore invalid under the Fourteenth Amendment’s Due Process Clause.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

(1) A declaration, pursuant to 28 U.S.C. § 2201, that the listing of glyphosate under Proposition 65 and its attendant glyphosate warning mandate violate the First Amendment of the United States Constitution.

(2) A declaration, pursuant to 28 U.S.C. § 2201, that the listing of glyphosate under Proposition 65 and its attendant glyphosate warning mandate violate the Supremacy Clause of the United States Constitution.

(3) A declaration, pursuant to 28 U.S.C. § 2201, that the listing of glyphosate under Proposition 65 and its attendant glyphosate warning mandate violate the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

(4) Preliminary and permanent injunctions prohibiting Defendants or any of their officers, employees, or agents, and all those in privity with those entities or individuals, from enforcing or threatening to enforce Proposition 65 or any of its implementing regulations with regard to glyphosate.

(5) All costs, attorneys' fees, and expenses that Plaintiffs reasonably incur, *see* 42 U.S.C. § 1988; and

(6) Such other and further relief as this Court deems just and proper.

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2 Dated: November 15, 2017

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4 Respectfully submitted,

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