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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

NATIONAL ASSOCIATION OF WHEAT
GROWERS; NATIONAL CORN
GROWERS ASSOCIATION; UNITED
STATES DURUM GROWERS
ASSOCIATION; WESTERN PLANT
HEALTH ASSOCIATION; MISSOURI
FARM BUREAU; IOWA SOYBEAN
ASSOCIATION; SOUTH DAKOTA AGRI-
BUSINESS ASSOCIATION; NORTH
DAKOTA GRAIN GROWERS
ASSOCIATION; MISSOURI CHAMBER
OF COMMERCE AND INDUSTRY;
MONSANTO COMPANY; ASSOCIATED
INDUSTRIES OF MISSOURI;
AGRIBUSINESS ASSOCIATION OF
IOWA; CROPLIFE AMERICA; AND
AGRICULTURAL RETAILERS
ASSOCIATION,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 2:17-cv-02401-WBS-
EFB

**AMENDED 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, Agribusiness Association of Iowa,
11 CropLife America, and Agricultural Retailers Association bring this suit to prevent Defendants
12 from mandating false, misleading, and highly controversial cancer warnings concerning the
13 herbicide glyphosate on a wide variety of food, agricultural, industrial, and lawn and garden
14 products.

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

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

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

with federal label instructions does not present any unreasonable adverse effects on human health or the environment, and specifically that glyphosate *is not a carcinogen*. See *infra* ¶¶ 37, 38, 46. Likewise, California itself has *twice* examined glyphosate in its own reviews—in 1997 and in 2007—and on both occasions concluded that glyphosate is “unlikely to pose a cancer hazard to humans.” *Infra* ¶ 43. The same is true for every other regulatory body worldwide that has evaluated glyphosate, including regulatory agencies in Europe, Canada, New Zealand, Australia, Japan, and South Korea, and the International Programme on Chemical Safety (the recognized authoritative body on these issues in the World Health Organization), as well as the Joint Food and Agricultural Organization and World Health Organization Meeting on Pesticide Residues (JMPR). See *infra* ¶¶ 36-43, 47-50 (listing more than a dozen regulatory and scientific agencies that have reviewed glyphosate and found that it is not likely to be a carcinogen).

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

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

1 Not only does the scientific community firmly disagree with IARC’s substantive conclusion,
2 IARC’s internal process for reviewing glyphosate has also been roundly criticized. *See infra*
3 ¶¶ 51-54 (identifying multiple published reports that IARC purposely declined to share critical
4 data with its glyphosate review panel).

5 6. California has no administrative or regulatory mechanism for reviewing the validity
6 of an IARC conclusion before a Proposition 65 listing is made. Once IARC designates a substance
7 as carcinogenic, OEHHA takes the position that Proposition 65 listing is then a “ministerial” task.
8 That listing then triggers Proposition 65’s compelled speech requirements in the form of consumer
9 “warnings.” And any relevant product without an appropriate warning—including consumer
10 products, foods, and crops—will be subject to Proposition 65’s enforcement mechanisms,
11 including private strike suits filed by so-called bounty hunters, who are entitled to retain one-fourth
12 of the \$2,500 per violation per day in civil penalties that are potentially available under California
13 Health & Safety Code section 25249.12(d). Such suits are already threatened regarding numerous
14 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 nation’s
22 food production and processing supply chains. As set forth herein, the listing threatens to change
23 the way of life for many farmers who currently rely on glyphosate herbicides as a mainstay of their
24 farming practices. It is no surprise, then, that Plaintiffs—a national coalition of farming interests,
25 food producers, glyphosate manufacturers, and others—have coalesced to bring this suit. Had
26 California conducted any sort of reasonable scientific review before taking the action challenged
27 here, it would have determined—as more than a dozen other global regulatory and scientific
28 agencies already have—that the cancer listing at issue is false and inappropriate. This suit,

1 accordingly, should be unnecessary. In addition to being enjoined, Defendants should be assessed
2 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 Wheat
6 Growers is to mobilize wheat farmers to advocate for beneficial policies, cultivate productive
7 relationships with partners and the public, and champion opportunities through research,
8 innovation, education, and stewardship. Members of the National Association of Wheat
9 Growers—many of whom sell their wheat into California or sell their wheat to milling facilities
10 that in turn sell into California—depend on glyphosate as a critical tool in their farming practices.

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

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

24 12. Plaintiff Western Plant Health Association is a California based association that
25 represents the interests of fertilizer and crop protection manufacturers, distributors, and
26 agricultural retailers (including those that sell and use glyphosate) in California, Arizona, and
27 Hawaii. The Western Plant Health Association's mission is to promote agronomically sound and
28 environmentally safe use and handling of plant health products and services for the production of

1 safe and high quality food. The association's members comprise more than 90% of all companies
2 marketing plant nutrients, soil amendments, agricultural minerals, and crop protection products in
3 California, Arizona, and Hawaii, including glyphosate products.²

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

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

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

22 16. Plaintiff North Dakota Grain Growers Association is the premier voice for North
23 Dakota's wheat and barley producers. The association's mission is to educate its members and
24 represent them to increase profitability. Many of the association's members use glyphosate on
25 their wheat products (including right before harvest), a portion of which makes its way into
26 California.

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

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

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

19 19. Plaintiff Associated Industries of Missouri is the oldest general business trade
20 association in Missouri. Its mission is to promote a favorable climate for business, manufacturing,
21 and industry by empowering its members through communications, education, and advocacy.
22 More than half of this association's members are manufacturers, many of whom are in the direct
23 business of manufacturing products that contain glyphosate. The Associated Industries of
24 Missouri also has many food producer members who produce products with trace amounts of
25 glyphosate residues, a portion of which are sold in California.

26 20. Plaintiff Agribusiness Association of Iowa is an Iowa-based organization with over
27 1,100 members. Among other things, this organization protects the reputation of its members and
28 advances their business interests. More than half of this organization's members are agricultural

1 retailers, such as cooperatives and independent retailers who sell agronomy products or who have
2 grain storage facilities or are in the business of manufacturing. Glyphosate is very important to
3 this organization's members, many of whom sell the herbicide or use it as their primary weed
4 control product.

5 21. Plaintiff CropLife America is a national, not-for-profit trade association that
6 represents developers, manufacturers, formulators, and distributors of crop protection products and
7 plant science solutions for agriculture and pest management in the United States. CropLife
8 America's many registrant member companies produce pesticides registered with EPA for use in
9 the United States under FIFRA, including glyphosate. CropLife America's members sell
10 glyphosate products, as well as other pesticide products, in California.

11 22. Plaintiff Agricultural Retailers Association is a nationwide, not-for-profit
12 association representing agricultural retailers and distributors of agronomic crop inputs with
13 members in 48 states, representing over 70% of all crop input materials sold to America's farmers.
14 The Association's mission is to advocate, influence, educate, and provide services to support its
15 members, including helping its members adapt to a changing world and preserving their freedom
16 to operate. The Association's retail members provide their farmer customers with essential crop
17 inputs like fertilizer, seed, pesticide, and equipment; application services; and crop consulting
18 services, including conservation methodology.

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

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

26 **JURISDICTION AND VENUE**

27 25. This Court has jurisdiction over this action under 28 U.S.C. § 1331, which confers
28 original jurisdiction on federal district courts over actions arising under the Constitution or laws

1 of the United States.

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

5 **FEDERAL REGULATORY FRAMEWORK**

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

9 **A. FIFRA**

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

21 **B. The FDCA**

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

26 30. The FDCA also regulates the presence of herbicides on foods. The FDCA deems
27 "unsafe foods" to be "adulterated," 21 U.S.C. § 342(a), and renders their distribution in interstate
28 commerce unlawful, *id.* § 331(b). The statute specifically provides, however, that a food will not

1 be deemed “unsafe” due to the presence of herbicide residue in a quantity within the limits of an
 2 EPA-established “tolerance for such pesticide chemical residue in or on such food.”
 3 *Id.* § 346a(a)(1)(A). In evaluating appropriate tolerances, EPA specifically evaluates the human
 4 health impact of the presence of an herbicide residue, including potential carcinogenicity.
 5 *Id.* § 346a(b)(2)(A)(ii). EPA has set comprehensive tolerances for glyphosate, covering relevant
 6 U.S. crops and food inputs. 40 C.F.R. § 180.364.

7 31. While the FDCA comprehensively regulates permissible herbicide residues in food
 8 for safety, it also explicitly provides that disclosure of such safe residue amounts to consumers
 9 purchasing food products is *not* required. 21 U.S.C. § 343(l), (k). States are barred under the
 10 FDCA from “prohibit[ing] or penaliz[ing] the production, processing, shipping, or other handling
 11 of a food because it contains a pesticide residue.” *Id.* § 346a(n)(4). And States may not “enforce
 12 any regulatory limit on the *level* of a pesticide chemical residue that may appear in or on any food
 13 if, at the time of the application of the pesticide that resulted in such residue, the sale of such food
 14 with such residue level was lawful” under the FDCA. *Id.* § 346a(n)(7) (emphasis added).

15 **FACTUAL BACKGROUND**

16 **A. Overview Of Glyphosate**

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

27 33. Glyphosate is approved for use in more than 250 agricultural crop applications in
 28 California and elsewhere. It is used on the vast majority of corn, soybean, and canola crops across

the United States. It is also widely used on Canadian crops—including oats—and in conjunction with the cultivation of wheat, beans, peas, and other crops in many locations. It is also used in conjunction with cultivation of almond, citrus, cotton, and other crops in California. Glyphosate-based herbicides are particularly desirable in the agricultural setting because of their broad-spectrum effectiveness, which allows farmers to control weeds with minimal tilling of soil (a practice known as conservation tilling), thereby conserving valuable topsoil, reducing soil movement into streams and other surface water, and retaining soil moisture. The scientific literature has expressly recognized these environmental benefits of using glyphosate, and has explained why these practices are preferable to traditional means of cultivation, which involve multiple other potentially significant impacts. *See, e.g.,* Stephen O. Duke & Stephen B. Powles, *Mini-Review Glyphosate: A Once-in-a-Century Herbicide*, 64 Pest Mgmt. Sci. 319, 322 (2008).

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

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

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

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

1 37. Glyphosate was first registered in the United States as an herbicide in 1974. In
2 1991, EPA conducted a peer review of glyphosate under FIFRA and, in 1993, approved the
3 renewal of its registration. At the time EPA concluded that:

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

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

9 38. EPA has reaffirmed this conclusion more recently. In relevant part:

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

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

15 39. This view of glyphosate's safety is widely shared by the international community.
16 In 2002, for instance, the Health and Consumer Protection Directorate-General of the European
17 Commission conducted a review of glyphosate for its re-registration for use in Europe and likewise
18 concluded there was "[n]o evidence of carcinogenicity." Health & Consumer Prot. Directorate –
19 Gen., European Comm'n, *Report for the Active Substance Glyphosate*, Directive 6511/VI/99, at
20 12 (Jan. 21, 2002). The same agency reaffirmed that conclusion on July 11, 2016.

21 40. Germany's Federal Institute for Risk Assessment—BfR—also recently reviewed
22 glyphosate. In December 2013 it submitted a glyphosate Renewal Assessment Report to the
23 European Food Safety Authority recommending re-approval of glyphosate for use in Europe. The
24 Report was revised in 2014 and again in 2015 in response to comments, and in it BfR concluded
25 that glyphosate was "unlikely to pose a carcinogenic risk in humans." *See BfR, Renewal*
26 *Assessment Report and Proposed Decision – Volume 1*, at 35 (Mar. 31, 2015). More emphatically,
27 BfR found that:
28

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

3 *Id.* at 36.

4 41. The European Food Safety Authority (EFSA) concurred with BfR's assessment. It
 5 evaluated BfR's findings and "concluded that glyphosate is unlikely to pose a carcinogenic hazard
 6 to humans and the evidence does not support classification with regard to its carcinogenic
 7 potential." EFSA, Abstract, *Conclusion on the Peer Review of the Pesticide Risk Assessment of*
 8 *the Active Substance Glyphosate*, at 1 (Nov. 12, 2015),
 9 <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4302/epdf>.

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

26 43. Indeed, even *California itself, through OEHHA*, has concluded that glyphosate is
 27 non-carcinogenic. In 1997 and 2007, OEHHA conducted risk assessments for glyphosate in
 28

1 drinking water in order to set public health goals, including evaluation of glyphosate’s potential
 2 carcinogenicity. OEHHA reviewed several studies in which glyphosate was administered to rats
 3 and mice, including the *same* studies (or reviews of those studies) IARC later used to reach its own
 4 conclusion. Based on its review of those studies and other data, OEHHA concluded that there was
 5 no evidence demonstrating that glyphosate causes cancer. *See, e.g.,* OEHHA, *Public Health Goal*
 6 *for Chemicals in Drinking Water: Glyphosate*, at 1 (June 2007) (“Based on the weight of the
 7 evidence, glyphosate is judged unlikely to pose a cancer hazard to humans.”). In short, it is
 8 definitively untrue that glyphosate “is known to the State of California to cause cancer.”

9 C. IARC

10 44. IARC is an international organization based in Lyon, France. It is not a regulator.
 11 Instead, IARC prepares so-called informational “Monographs” regarding the possibility that
 12 everyday products and substances may be carcinogenic. IARC is perhaps most famous (or
 13 infamous) for its conclusions that substances like coffee, aloe vera, pickled vegetables, and food
 14 exposed to “high temperatures”—such as French fries—are probably or possibly carcinogenic.
 15 *See, e.g.,* Akshat Rathi & Gideon Lichfield, *Why it Sometimes Seems Like Everything Causes*
 16 *Cancer*, Quartz (June 23, 2016) (“[O]f all the things the IARC has looked at, there is just *one* it is
 17 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/)
 18 [seems-like-everything-causes-cancer/](https://qz.com/708925/why-it-sometimes-seems-like-everything-causes-cancer/).

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

24 46. For example, following IARC’s determination, EPA Deputy Director for Pesticide
 25 Programs, William Jordan, testified before the U.S. Senate Committee on Agriculture, Nutrition
 26 and Forestry and reaffirmed EPA’s longstanding non-carcinogenic conclusion for glyphosate. In
 27 that same Committee hearing, the Chief Physician at MassGeneral Hospital for Children observed
 28 that IARC’s recent contrary conclusion was “not supported by the data,” and “flies in the face of

comprehensive assessments from multiple agencies globally.” More recently, EPA “reviewed and analyzed the results of 15 rodent bioassays and concluded that the results as a whole do not indicate carcinogenicity of glyphosate.” FIFRA Sci. Advisory Panel, EPA, *Meeting Minutes and Final Report* No. 2017-01, at 17 (Mar. 16, 2017), https://www.epa.gov/sites/production/files/2017-03/documents/december_13-16_2016_final_report_03162017.pdf.

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

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

49. Indeed, although IARC is part of the World Health Organization (WHO), the WHO itself has separately, and repeatedly, concluded that “glyphosate is *unlikely* to pose a carcinogenic risk to humans,” including in a 2016 review and conclusion after the IARC classification. *See supra* at ¶ 42; *see also* FAO/WHO, *Pesticide Residues in Food – 2004, Part II: Toxicological*, at 158 (2004) (emphasis added), http://apps.who.int/iris/bitstream/10665/43624/1/9241665203_eng.pdf; WHO, *Glyphosate and AMPA in Drinking Water: Background Document for Development of WHO Guidelines for Drinking-Water Quality*, at 5 (June 2005) (“[n]o effect on survival” in glyphosate “carcinogenicity study”); WHO/Int’l Programme on Chem. Safety, *Environmental Health Criteria 159: Glyphosate*, at 15 (1994) (“The available studies do not indicate that technical glyphosate is

1 mutagenic, carcinogenic or teratogenic.”). In other words, of the four subgroups within WHO that
2 have looked at the carcinogenicity of glyphosate, three of them have determined glyphosate is *not*
3 *carcinogenic*; IARC stands alone in its opinion otherwise.

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

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

23 52. For example, according to recent articles in Reuters and many other publications,
24 court documents reflect that Aaron Blair—the chair of the IARC “working group” that produced
25 the glyphosate finding—knew about unpublished research (notably, a 2013 draft report of the AHS
26 study) finding no evidence of a link between glyphosate and cancer, but concealed this evidence
27 from his colleagues. According to these reports, Blair also admitted that the research, if presented,
28 would have undercut IARC’s cancer classification. Kate Kelland, *Cancer Agency Left in the Dark*

over *Glyphosate Evidence*, Reuters (June 14, 2017), <https://www.reuters.com/investigates/special-report/glyphosate-cancer-data/>. And another scientist who was advising IARC when it published its dubious finding, Christopher Portier, reportedly concealed that he was paid \$160,000 from law firms bringing claims by cancer victims against glyphosate manufacturers. See Ben Webster, *Weedkiller Scientists Was Paid £120,000 by Cancer Lawyers*, The Times (Oct. 18, 2017), <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 might present “a conflict of interest” and that even *he* “would have concern” stating that glyphosate “100 percent” causes cancer. And others have reported that IARC conspicuously and inexplicably removed “multiple scientists’ conclusions that their studies had found no link between glyphosate and cancer” between a draft version of IARC’s report and the final version. See Kate Kelland, *In Glyphosate Review, WHO Cancer Agency Edited out “Non-Carcinogenic” Findings*, Reuters (Oct. 19, 2017), <https://www.reuters.com/investigates/special-report/who-iarc-glyphosate/>.

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

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

D. Proposition 65 & IARC

55. In 1986, the California voters, by initiative, enacted the Safe Drinking Water and

1 Toxic Enforcement Act of 1986—commonly known as Proposition 65. In general, Proposition 65
 2 prohibits businesses from both exposing California residents to chemicals known to the State to
 3 cause cancer without providing required warnings, and from knowingly discharging a chemical
 4 known to the state to cause cancer into the environment where the chemical passes or will probably
 5 pass into a source of drinking water. Cal. Health & Safety Code §§ 25249.5, 25249.6.

6 56. Mechanically, the Proposition 65 process works as follows:

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

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

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

1 how clearly erroneous.

2 60. Once a chemical is listed and after a 12-month grace period, the statute requires
3 that any “person in the course of doing business” provide a “clear and reasonable warning” before
4 “expos[ing] any individual to” the listed chemical. Cal. Health & Safety Code § 25249.10(b). As
5 a practical matter, this means that affected entities must take action far earlier than the warning’s
6 effective date. *See infra* ¶¶ 73-91 (discussing impacts of listing).

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

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

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

1 history of enforcing Proposition 65's warning requirement.

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

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

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

28 67. The California courts have recognized how onerous strike suits can be for industry.

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

9 68. A long history of these strike suits demonstrates what typically happens in practice:
 10 in the face of this litigation threat, businesses are forced to simply acquiesce and post a warning,
 11 regardless of the fact that those businesses know the warning is affirmatively false and misleading.
 12 See All. for Nat. Health, *Proposition 65: Evaluating Effectiveness and a Call for Reform*, at 7,
 13 <https://www.anh-usa.org/wp-content/uploads/2015/09/Prop-65.pdf> (last accessed Nov. 9, 2017);
 14 see also, LATIMES, *Warning: Too Many Warning Signs are Bad for Your Health* (Sept. 30, 2017),
 15 (noting “Starbucks, Whole Foods and about 80 other places in California that sell coffee” are
 16 exposed under Proposition 65 even though “research increasingly” indicates coffee does *not* cause
 17 cancer), [http://beta.latimes.com/opinion/editorials/la-ed-proposition-65-warning-coffee-](http://beta.latimes.com/opinion/editorials/la-ed-proposition-65-warning-coffee-20170930-story.html)
 18 [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, California Classifies*
 19 *Soft Drinks as a Cancer Risk*, *Forbes* (Feb. 20, 2014) (compelling warnings for soda drinks on the
 20 basis that if consumers drink “over 1,000 sodas a day” they would have increased cancer risk);
 21 Greg Ryan, *Rice Sellers Threatened with Prop 65 Suits over Lead, Arsenic*, *Law360* (Feb. 20,
 22 2014).

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

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

27 70. Despite the overwhelming contrary views of the U.S. government, the international
 28 community, and even OEHHA that glyphosate is not carcinogenic, on July 7, 2017, California

1 finalized its listing of glyphosate under Proposition 65 as a chemical “known to the state to cause
 2 cancer.” As the basis for the listing, California relied exclusively on IARC’s flawed determination,
 3 discussed *supra* at ¶¶ 44-54, that glyphosate is a “*probabl[e]* carcinogen[.]” OEHHA explained
 4 that glyphosate met the requirements for listing simply because (1) IARC classified glyphosate as
 5 a “*probabl[e]* carcinogen[.]” and (2) IARC concluded that there was “sufficient evidence” of
 6 carcinogenicity in experimental animals. IARC Monograph Vol. 112 at 398; *see also* 27 Cal. Code
 7 Regs § 25904(b). That is, California—through Proposition 65—is now requiring industry to state
 8 that glyphosate is “**known**” to cause cancer even though (a) *no one* has ever reached that
 9 conclusion and (b) even IARC concluded only that it is “**probably**” carcinogenic, a conclusion
 10 which IARC itself admits has “no quantitative significance” and should not be viewed (and hence
 11 used) as a recommendation for legislation or regulation. *See* IARC, *IARC Monographs on the*
 12 *Evaluation of Carcinogenic Risk to Humans: Preamble*, at 22 (2006),
 13 <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>.

14 71. 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/crn/notice-intent-list-](https://oehha.ca.gov/proposition-65/crn/notice-intent-list-tetrachlorvinphos-parathion-malathion-glyphosate)
 19 [tetrachlorvinphos-parathion-malathion-glyphosate](https://oehha.ca.gov/proposition-65/crn/notice-intent-list-tetrachlorvinphos-parathion-malathion-glyphosate).

20 72. 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 Health
 23 Program Manager of ‘As you Sow,’ to Denise Morrison, CEO, Campbell Soup Company (Oct. 5,
 24 2016).

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

26 73. 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.

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

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

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

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

5 77. 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 78. The listing of glyphosate under Proposition 65 will also impact sellers,
10 manufacturers, and retailers of glyphosate. Major municipal applicators, for example, have
11 already expressed that they will cease using glyphosate-based products. *See City of Burbank, 2017*
12 *City Council Meeting – Joint, MP4 video at 3:01:05 (July 11, 2017), available at*
13 <http://www.burbankca.gov/what-s-new/meeting-agendas-minutes>.

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

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

1 through distributors and business partners. All of these sales channels will be impacted by
2 glyphosate's listing and the false warning requirement.

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

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

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

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

27 85. Plaintiff CropLife America likewise has members that manufacture glyphosate-
28 based products and sell those products in California.

86. Because of California's listing of glyphosate, Monsanto and other CropLife America members must either take action to provide false and highly controversial health warnings to California consumers about glyphosate in their products, and work with their distributors and customers to do so, or face potential enforcement actions seeking civil money penalties for failing to do so. Even if OEHHA ultimately establishes an NSRL, Monsanto and other CropLife America members will still be injured because they will be forced to choose between applying, and working with their distributors and customers to apply, a false and highly controversial warning on their products, or undertaking costly exposure assessments for their glyphosate-based products to demonstrate that any glyphosate exposures will invariably fall below the NSRL. Monsanto, for example, would need to engage in this expensive exposure assessment process for each anticipated use of glyphosate and glyphosate products. And regardless of whether Monsanto's exposure assessment indicates that a product or use will invariably fall below the NSRL, unless Monsanto complies with Proposition 65's false warning requirements, Monsanto would need to prepare to defend against likely enforcement actions, including private strike suits brought by rent-seeking litigants.

87. Due to the unreasonable litigation risk created by Proposition 65, multiple major retailers of glyphosate products in California have determined that they will not sell glyphosate-based products unless those products contain a Proposition 65 warning on the products' labels. Indeed, major retailers have determined that any glyphosate-based products that do not contain a Proposition 65 warning will be removed from their California stores' shelves and their inventory weeks or months in advance of the applicable date of the warning requirement, to ensure that no unlabeled product remains on the shelves at the time the warning requirement goes into effect.

88. Moreover, California's Proposition 65 listing of glyphosate and the false warning requirement broadly disparage Monsanto's glyphosate products and glyphosate tolerant seed products, causing harm to the company, its reputation, and the company's hundreds of millions of dollar investments in these products. CropLife America's other members who manufacture and sell glyphosate will be similarly injured.

89. Both the glyphosate Proposition 65 listing itself, and the required warning, are

1 affirmatively and destructively misleading. They create a misimpression among consumers that
 2 glyphosate is dangerous when all relevant regulators have found that it indisputably is *not*. The
 3 disparagement of all products that contain glyphosate and all food products that may legally
 4 contain trace glyphosate residues—and the legal jeopardy hanging over retailers who carry them—
 5 has already adversely affected and unless enjoined will continue to adversely affect both the supply
 6 and demand for glyphosate and glyphosate-exposed products at all levels of the national
 7 distribution chain.

8 90. All of Plaintiffs and Plaintiffs' members who sell products that contain glyphosate
 9 that ultimately end up in California desire that those products continue to be sold in California.
 10 None of those entities, however, wants to be forced to engage in false speech about products that
 11 contain glyphosate, or to have false warnings provided about products that contain glyphosate.

12 91. An order enjoining and declaring invalid California's listing of glyphosate under
 13 Proposition 65 and its attendant false warning requirement would redress the harms described
 14 above.

15 **CLAIMS FOR RELIEF**

16 **CLAIM I: VIOLATION OF THE FIRST AMENDMENT TO THE UNITED STATES** 17 **CONSTITUTION**

18 92. The foregoing Paragraphs are incorporated by reference as if set forth in full herein.

19 93. The Free Speech Clause of the First Amendment of the United States Constitution
 20 provides that "Congress shall make no law . . . abridging the freedom of speech." U.S. Const.
 21 amend. I. The Fourteenth Amendment of the United States Constitution made this proscription
 22 applicable to the States and their political subdivisions. *See id.* amend. XIV, § 1.

23 94. In addition to providing protections against restrictions on speech, the First
 24 Amendment provides protection against the government *compelling* individuals or entities to
 25 engage in speech.

26 95. Under the First Amendment, laws compelling speech ordinarily receive strict
 27 scrutiny. *See Wooley v. Maynard*, 430 U.S. 705, 715-16 (1977). Laws regulating commercial
 28 speech generally receive at least intermediate scrutiny, *i.e.*, they are prohibited if they do not

1 directly and materially advance the government’s interest, or are more extensive than necessary.
 2 *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980). And even laws
 3 that require disclosure of information in connection with commercial transactions are permissible
 4 only if the compelled disclosure is of information that is purely factual, uncontroversially accurate,
 5 reasonably related to a substantial government purpose, and not unduly burdensome or chilling.
 6 *See Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985); *Am. Beverage Ass’n v.*
 7 *City & Cty. of S.F.*, 871 F.3d 884, 892-93 (9th Cir. 2017); *CTIA – Wireless Ass’n v. City & Cty. of*
 8 *S.F.*, 494 F. App’x 752, 753 (9th Cir. 2012).

9 96. Contrary to the warning mandated by Proposition 65, glyphosate does not cause
 10 cancer.

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

15 98. Every major and credible scientific body to consider the issue disagrees with
 16 IARC’s determination.

17 99. Moreover, even IARC itself has not said that it “knows” that exposure to glyphosate
 18 causes cancer in humans. The most it has said is that glyphosate is “*probably carcinogenic*.”

19 100. The Proposition 65 glyphosate warning mandate thus compels speech that is false
 20 and misleading.

21 101. At the very least, the Proposition 65 glyphosate warning mandate compels speech
 22 that is factually controversial.

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

27 103. Proposition 65’s glyphosate warning mandate constitutes impermissible compelled
 28 speech under the First Amendment to the U.S. Constitution.

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

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

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

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

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

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

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

110. The FDCA prohibits misbranding a food product, including where “its labeling is

1 false or misleading in any particular.” 21 U.S.C. § 343(a).

2 111. Selling a food product with Proposition 65’s false mandated glyphosate warning
3 would render that product misbranded under federal law. As a result, a food product producer
4 and/or seller cannot reasonably comply with both federal law and Proposition 65, giving rise to
5 conflict preemption.

6 112. Plaintiffs consist of members who must comply with Proposition 65’s compelled
7 glyphosate warning requirement for products that contain glyphosate to avoid the prospect of
8 costly enforcement actions and other burdens, and must also comply with the FDCA’s labeling
9 requirements.

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

14 114. The FDCA also provides that pesticide residues on food may not exceed EPA-
15 established limits but that labeling shall *not* be required for such foods. *See id.* §§ 346a(a)(1)(A),
16 343(k), (l).

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

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

28 117. Even if Proposition 65’s mandated glyphosate warning is not expressly preempted

by the FDCA's tolerance regime, it is impliedly preempted as an obstacle to the accomplishment of the purposes and objectives of federal law. The legislative history underlying the pesticide residue tolerance regime reflects that Congress affirmatively rejected labeling on foods that contained a permissible pesticide residue quantity. And EPA, the regulatory agency tasked with administering the pesticide residue tolerance regime, has found in its most recent analyses that glyphosate is non-carcinogenic and that its presence on food up to the tolerance level poses no public health risks. Thus, Proposition 65's listing of glyphosate and its attendant glyphosate warning mandate directly undermine this federal tolerance regime.

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

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

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

120. California does not *know* that glyphosate *causes* cancer.

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

122. Even IARC's Monograph does not support the warning that Proposition 65 will require, because IARC did not conclude that glyphosate *causes* cancer in humans. Instead, it concluded that "there is limited evidence in humans for the carcinogenicity of glyphosate" and that glyphosate is "probably carcinogenic in humans."

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

1 State of California to cause cancer as a result of that listing.

2 124. Listing glyphosate falsely as a known carcinogen and requiring a warning that
3 misleadingly states that California knows glyphosate is a carcinogen are not actions rationally
4 related to any legitimate state interest.

5 125. California's listing of glyphosate and the attendant warning requirement are
6 therefore invalid under the Fourteenth Amendment's Due Process Clause.

7 **PRAYER FOR RELIEF**

8 WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

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

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

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

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

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

24 (6) Such other and further relief as this Court deems just and proper.
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28

1 Dated: December 5, 2017

2
3 Respectfully submitted,

4
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CERTIFICATE OF SERVICE

I, Philip J. Perry, declare under penalty of perjury that on December 5, 2017, I caused the foregoing document to be electronically filed with the Court's CM/ECF Filing System which will send a Notice of Electronic Filing to all parties of record who are registered with CM/ECF. I further certify that on the same date, I caused the attached document to be placed in the U.S. Mail, postage paid and properly addressed to the parties below:

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