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CALIFORNIA PROPOSITION 65 LISTINGS AND CONSTITUTIONAL NON-DELEGATION: GLYPHOSATE AS A CASE STUDY

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California Proposition 65 Listings AND CONSTITUTIONAL NON-DELEGATION: **GLYPHOSATE AS A CASE STUDY**

INTRODUCTION

Glyphosate is an herbicide that has been in use since the 1970s¹. The chemical was recently listed as "known to the State of California to cause cancer" under the California Safe Drinking Water and Toxic Enforcement Act, also known as "Proposition 65." This listing was, and remains, controversial. Glyphosate's major producer and user, Monsanto Company, filed a court challenge when regulators initially proposed the listing in 2015. Following an adverse trial court ruling, the company appealed, seeking a judicial stay of the listing decision. The Court of Appeal refused the stay, and California finalized the listing earlier this year.

Monsanto's challenge and subsequent appeal, which is still pending, raises a number of issues. Perhaps the most significant claim—one that could dramatically alter the Proposition 65 listing process for all regulated entities—is that the so-called Labor Code listing mechanism used to list glyphosate violates the California Constitution's non-delegation doctrine. That listing mechanism effectively allows the International Agency of Research on Cancer (IARC) to make the final listing decision for a carcinogen under California law.

¹ https://www.epa.gov/ingredients-used-pesticide-products/glyphosate.

The question the Court of Appeal is asked to decide is essentially this: If the State of California has allowed an ad hoc, non-governmental, foreign entity like IARC to decide whether a chemical should be listed as a carcinogen under California law, is that chemical really "known to the State of California" to cause cancer, as the law requires?

The question is not rhetorical, and its answer has significant consequences. Proposition 65 requires businesses to provide "clear and reasonable" warnings before exposing individuals to chemicals that are "known to the State of California to cause cancer or reproductive harm." Failure to comply can result in up to \$2,500 in civil penalties per day of violation; a court also may impose injunctive relief.³ Proposition 65 is enforced exclusively by civil lawsuits, which may be filed by certain public enforcers as well as private persons "in the public interest." In fact, the vast majority of enforcement actions are filed by such private persons. Defending a Proposition 65 enforcement action is an expensive endeavor, and most cases settle with significant payments made to plaintiffs.

In addition, the subject chemical may be stigmatized by being identified on the Proposition 65 list, causing severe supply-chain and other economic disruptions. Products may be similarly stigmatized by bearing warnings, which may not even be

² Cal. Health & Safety Code, §25249.6.

³ Cal. Health & Safety Code, §25249.7.

⁴ Ibid.

strictly necessary but that companies nevertheless provide simply to avoid expensive enforcement actions.

These consequences can only make sense if there is scientific consensus that a chemical is "known" to cause the relevant harm. That is exactly what the statute requires, and exactly what the California citizens voted for, when they approved Proposition 65 in 1986. Ballot pamphlet statements emphasized that the law would be enforced only as to chemicals that are "known" to cause cancer or reproductive harm. For this reason, Monsanto's legal challenge raises a significant concern that the basis of the glyphosate listing does not support a finding that the substance is "known" to cause cancer—and that, therefore, the listing has thwarted the intent of the voters.

OEHHA, IARC, AND THE LABOR CODE LISTING MECHANISM I.

Proposition 65 requires the California Office of Environmental Health Hazard Assessment (OEHHA or the Agency) to publish "a list of those chemicals known to the state to cause cancer or reproductive toxicity." The statute provides several mechanisms by which OEHHA may place a substance on the Proposition 65 list, including "at a minimum those substances identified by reference in Labor Code

⁵ Proposition 65 1986 Ballot Initiative at 54 (found at https://oehha.ca.gov/media/downloads/proposition-65/general-info/prop65ballot1986.pdf) (emphasis added).

⁶ CAL. HEALTH & SAFETY CODE, § 25249.8(a).

§ 6382(b)(1)." In turn, § 6382(b)(1) of the Labor Code identifies by reference "[s]ubstances listed as human or animal carcinogens by the International Agency for Research on Cancer."

OEHHA regulations implementing the Labor Code reference state: "A chemical or substance shall be included on the list if it is classified by [IARC] in its IARC Monographs series on the Evaluation of Carcinogenic Risks to Humans, or in its list of Agents Classified by the IARC Monographs, as: (1) Carcinogenic to humans (Group 1), or (2) Probably carcinogenic to humans (Group 2A) with sufficient evidence of carcinogenicity in experimental animals, or (3) Possibly carcinogenic to humans (Group 2B) with sufficient evidence of carcinogenicity in experimental animals."8 OEHAA's implementation of the Labor Code reference is widely referred to as the "Labor Code listing mechanism."

According to OEHHA, if IARC classifies a substance as a carcinogen in one of the manners set forth above, the Agency is required to include—and has no discretion to exclude—the substance from the Proposition 65 list. For example, OEHHA's regulations state that OEHHA "shall not consider comments related to the underlying scientific basis for classification of a chemical by IARC as causing cancer."9

⁷ Ibid.

⁸ CAL. CODE REGS., Title 27, § 25904(b).

⁹ *Id.* at § 25904(c).

Consequently, OEHHA has described listings under the Labor Code listing mechanism as a "ministerial" and essentially automatic process. 10

On September 4, 2015, OEHHA issued a Notice of Intent to List glyphosate under Proposition 65 as a chemical "known to the state to cause cancer," under the Labor Code listing mechanism and pursuant to IARC's carcinogenic classification of glyphosate. This decision has caused widespread dissent, as glyphosate is the most widely used herbicide in the world, 11 and most regulatory bodies to previously review the chemical determined it does not present a carcinogenic risk to humans. 12 Following glyphosate's proposed addition to the list, Monsanto filed suit against OEHHA. The First Amended Petition and Complaint (the Complaint) claims, among other things, that IARC's determination was unreliable and OEHHA's reliance on that determination is unconstitutional. As to its unconstitutionality, Monsanto alleges as follows:

> [B]y delegating law-making authority to an unelected, undemocratic, unaccountable, and foreign body without providing intelligible principles or procedural safeguards to define the boundaries of that authority or prevent its arbitrary exercise, the Labor Code listing

¹⁰ OEHHA, Notice of Intent to List Glyphosate (Sept. 4, 2015).

¹¹ See Stephen B. Powles, Evolved Glyphosate-Resistant Weeds around the World: Lessons to be Learnt, 64 PEST MANAGEMENT SCIENCE 360, 360-65 (Apr. 2008).

¹² See Monsanto Company's First Amended Verified Petition for Writ of Mandate and Complaint for Preliminary and Permanent Injunctive and Declaratory Relief (hereinafter Complaint), Case No. 16CECG00183, ¶¶ 4-5.

mechanism ... violates the non-delegation doctrine ... in violation of the California Constitution. 13

The trial court found in OEHHA's favor, and Monsanto has appealed.

IARC and its Chemical Review Process Α.

IARC is a specialized cancer agency of the World Health Organization (WHO) based in Lyon, France. IARC is funded by the governments of 25 countries, as well as by grants from various governmental and non-governmental agencies around the world. One of IARC's activities is the *Monograph* program. As part of this program, IARC convenes groups of scientists that are selected by IARC staff in a non-public process, to review and summarize scientific research on the carcinogenicity of a wide range of chemicals, complex mixtures, occupational exposures, physical agents, biological agents, and behavioral practices. 14

IARC explains that its focus is on cancer "hazards," as distinct from cancer "risks." According to IARC, the "distinction between hazard and risk is important, and the Monographs identify cancer hazards even when risks are very low at current exposure levels." ¹⁵ According to the IARC Preamble, IARC staff select agents for review based on two main criteria: "(a) there is evidence of human exposure and (b)

¹³ *Id.* at ¶ 10(a).

¹⁴ See Preamble to the IARC Monographs, § A(2).

¹⁵ Ibid.

there is some evidence or suspicion of carcinogenicity."¹⁶ IARC exercises sole discretion in its selection of agents for review, as well as the individual scientists who form the group (Working Group) for evaluating a particular agent.¹⁷

The Preamble dictates that "[t]he procedures through which a Working Group implements these principles are not specified in detail" and "remain, predominantly, the prerogative of each individual Working Group." Although the Working Group does not perform any studies and does not generate new data, it is permitted to reevaluate preexisting studies and reach different conclusions than the authors of those studies. The Working Group is only allowed to consider "reports that have been published or accepted for publication in the openly available scientific literature," "[d]ata from government agency reports that are publicly available," and, in exceptional circumstances, "doctoral theses and other material that are in their final form and publicly available."

Each Working Group convenes for a multi-day meeting in person. Before the meeting, IARC staff collects the "relevant biological and epidemiological data ... from recognized sources of information on carcinogenesis, including data storage and

¹⁷ *Id.* at § A(5).

¹⁶ Ibid.

¹⁸ Preamble to the IARC Monographs, § A(1).

¹⁹ *Id.* at § A(4).

²⁰ Ibid.

retrieval systems such as PubMed."²¹ Six months before the meeting, the relevant literature is sent to meeting participants to prepare preliminary working papers. The Working Group members are expected to review the relevant scientific literature and preliminary working papers in advance of the meeting. The "objectives of the meeting are peer review and consensus."²² According to IARC, "[c]onsensus reflects broad agreement among Working Group Members, but not necessarily unanimity." 23

IARC's Review and Designation of Glyphosate as a Probable В. Carcinogen

In 2014, IARC convened a Working Group of 17 scientists to assess the carcinogenicity of glyphosate and four insecticides. In March of 2015, an IARC Working Group met in Lyon, France and ultimately classified glyphosate as "probably carcinogenic to humans" (Group 2A).

IARC concluded that there was "sufficient evidence" of carcinogenicity in experimental animals based on four long-term carcinogenicity studies in rodents. Specifically, IARC made the following findings:

(i) "[t]here was a positive trend in the incidence of renal tubule carcinoma and of renal tubule adenoma or carcinoma (combined) in males in one feeding study in CD-1 mice";

²¹ *Id.* at § A(6).

²² Ibid.

²³ Ibid.

- "[t]here was a significant positive trend in the incidence of (ii) hemangiosarcoma in male CD-1 mice" in a second feeding study of mice; and
- two studies in rats "showed a significant increase in the incidence of (iii) pancreatic islet cell adenoma in males," and "one of these two studies also showed a significant positive trend in the incidences of hepatocellular adenoma in males and of thyroid C-cell adenoma in females."24

Largely based on these findings, glyphosate was judged as "probably carcinogenic to humans." The Working Group's conclusions were published in Volume 112 of IARC's *Monographs* series.

1. Allegations of a Biased, Flawed, and/or Incomplete Study of the Evidence

Omitted Data a.

According to recently revealed deposition testimony in other litigation pending against Monsanto Company, the Chair of the IARC Working Group that considered glyphosate, Dr. Aaron Blair, failed to disclose unpublished epidemiological data that showed no evidence of a link between glyphosate and cancer. 25 The research at issue came from the Agricultural Health Study (AHS), led by scientists at the U.S. National Cancer Institute. Monsanto's vice president of strategy described the study as "the largest and most comprehensive study on farmer exposure to pesticides and

²⁴ IARC *Monograph*, Vol. 112.

²⁵ See Reuters Investigates, Glyphosate Battle, Cancer Agency Left in the Dark Over Glyphosate Evidence, by Kate Kelland (June 14, 2017).

cancer."26 He also pointed out that the study was particularly important because it examined real-life human exposure to glyphosate, whereas much of the research IARC analyzed involved rodent testing.²⁷ According to a Reuters expose, only a handful of the published studies IARC did consider in its glyphosate article were cohort studies in humans, the variety that are most transferable to real-life situations.²⁸

The IARC Working Group never reviewed the unpublished data, although it was available two years before IARC's glyphosate assessment, because the agency's rules only allow it to consider *published* research. Since 2003, AHS researchers published at least ten papers using different sets of updated data to explore the potential correlation between pesticides and certain diseases, yet this new data did not surface.²⁹ In sworn testimony, Blair admitted that he was aware of the data at the time of IARC's review, was a senior researcher on the study producing the data, and was partially responsible for the decision not to publish the data prior to the IARC review.³⁰

Blair provided curious explanations that the glyphosate data was removed from publications "to make the paper a more manageable size." He reportedly told Reuters

²⁶ Ihid.

²⁷ Ibid.

²⁸ Ibid.

²⁹ Ibid.

³⁰ Ibid.

the data was not published in time because there was not enough room, and "you couldn't put it all in one paper." Nevertheless, Blair admitted that, had it been published and available, it would have made an impact on IARC's carcinogenicity analysis.³¹ In fact, he acknowledged that if the IARC Working Group had been given the opportunity to review the additional data, it would have made it less likely that glyphosate would meet the agency's criteria for being classed as "probably carcinogenic."32

The European Food Safety Authority (EFSA) has also addressed IARC's anomalous opinion on glyphosate and outlined additional omissions on IARC's part. EFSA, which deemed glyphosate as unlikely to pose a carcinogenic hazard to humans, noted that "three of the five mice studies used by the EU peer review and three of the nine studies in rats were not assessed by the IARC."³³ These collective omissions have raised eyebrows as to the legitimacy of IARC's findings and the motivation behind them.

b. **Potential Bias and Flaws**

Monsanto's Complaint and appeal brief also note that the decisions of IARC staff are final, and there is no process for challenging the selection of any individual or

³¹ *Id.* (emphasis added).

³² Ibid.

³³ European Food Safety Authority, Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate (Nov. 2015).

for proposing that any other individual be named to the Working Group.³⁴ Furthermore, the conflict-of-interest policy is limited to commercial entities and does not apply to activist organizations, not-for-profit organizations, or academic institutions, despite those entities also having agendas that go beyond scientific interests. 35 One group of scientists has claimed that IARC's working groups are "clearly not disinterested evaluators of the research evidence being considered, as much of it represents their own work."36

IARC's process for choosing a Working Group has also been called into question. A Working Group may include scientists with a "vested professional interest" in a particular finding, while definitively excluding scientists affiliated with an industry who may, in fact, have useful knowledge about the agent.³⁷ In other words, IARC—whether intentionally or not—may invite biased scientists while eliminating individuals with highly relevant contributions. Admittedly, much of these claims remain conjecture due to IARC's opaque selection process. Yet the overall lack of transparency supports the overarching argument that IARC is making numerous, nuanced decisions that may lead to inappropriate lawmaking responsibilities.

³⁴ Complaint, ¶ 62.

³⁵ *Id.* at ¶ 63.

³⁶ Id. at ¶ 72; and see Joseph K. McLaughlin et al., Problems with IARC's 'Expert' Working Groups, 40 INT'L J. OF EPID. 1728 (Nov. 2011).

³⁷ Complaint, ¶¶ 64-72.

2. Prior Studies Determined Glyphosate Did Not Pose a Health Risk

All of the unusual circumstances set forth above, in combination with IARC's contrarian view of glyphosate, have called IARC'S findings into question. To wit, in 1997 and again in 2007, OEHHA conducted risk assessments of glyphosate for purposes of setting a public-health goal (PHG) for glyphosate in drinking water. ³⁸ OEHHA develops PHGs "for chemical contaminants based on the best available toxicological data in the scientific literature." Based on its review of the scientific data, OEHHA, in both 1997 and 2007, concluded that there was no evidence that glyphosate causes cancer. The Pesticide and Environmental Toxicology Branch of OEHHA prepared the OEHHA Assessments, and several OEHHA staff members and scientists contributed to the evaluation of glyphosate and the corresponding technical-support documents.⁴⁰

In preparing its 2007 Assessment, OEHHA evaluated the very same four longterm carcinogenicity studies in rodents that IARC relied on in reaching its contrary conclusion that there is "sufficient evidence" of carcinogenicity in experimental animals. After reviewing the data, OEHHA concluded: "Based on the weight of the

³⁸ See OEHHA, Public Health Goal for Chemicals in Drinking Water: Glyphosate (Dec. 1997 and June 2007) (OEHHA Assessments).

³⁹ OEHHA Assessments, 2007.

⁴⁰ OEHHA Assessments, 1997 and 2007.

evidence, glyphosate is judged unlikely to pose a cancer hazard to humans."41 OEHHA also previously cited WHO's finding as to that study that "[glyphosate] has no genotoxic potential ... or carcinogenicity in rats or mice." 42

On 17 different occasions, other regulatory and scientific bodies have evaluated one or more of these same long-term carcinogenicity studies in rodents. Each of these reviews reached conclusions contrary to IARC's. Each determined that tumor growths were unrelated to glyphosate. 43 The regulatory and scientific bodies which reviewed the same four animal studies that the IARC working group reviewed reached the opposite conclusion: Glyphosate is not carcinogenic. That includes the U.S. Environmental Protection Agency in September 2016, which found that none of the tumors in fifteen different animal studies are related to the administration of glyphosate and concluded that glyphosate should be classified as "not likely to be carcinogenic to humans."44

II. THE NON-DELEGABLE DUTY OF LEGISLATIVE POWER

This factual backdrop sets up the legal argument against glyphosate's Proposition 65 listing. In its legal challenge, Monsanto alleges that OEHHA's use of the Labor Code listing mechanism to list glyphosate violates the non-delegation doctrine

⁴¹ OEHHA Assessments, 2007 at 20.

⁴² Ibid.

⁴³ Monsanto Amended Complaint, ¶ 96.

⁴⁴ Glyphosate Issue Paper: Evaluation of Carcinogenic Potential, EPA's Office of Pesticide Programs (Sept. 12, 2016).

as set forth in the California Constitution, by granting IARC law-making responsibility without providing proper safeguards.

The Principle of Non-Delegable Duty Α.

The legislative power of the state is vested in the Legislature. 45 "An unconstitutional delegation of legislative authority occurs if a statute authorizes another person or group to make a fundamental policy decision or fails to provide adequate direction for the implementation of a fundamental policy determined by the Legislature."46 The doctrine of non-delegable duty rests upon the premise that the legislative body must itself resolve the truly fundamental issues and cannot escape responsibility by explicitly passing off that function to others, or by failing to establish an effective mechanism to assure the proper implementation of its policy decisions.

OEHHA's use of the Labor Code's listing mechanism, which compels the agency to adopt an unelected, unaccountable, foreign entity's determinations and offers no limiting safeguards, treads on that non-delegation doctrine.⁴⁷ The listing of a chemical has serious policy implications and results in regulation of that chemical under California law. 48 Moreover, neither Proposition 65 nor OEHHA regulations

⁴⁵ See CAL. CONST., art. IV, § 1.

⁴⁶ Plastic Pipe and Fittings Ass'n v. California Building Standards Commission, 124 Cal. App. 4th 1390, 1410 (2004) (citing Carson Mobilehome Park Owners' Assn. v. City of Carson, 35 Cal.3d 184, 190 (1983) and Kugler v. Yocum, 69 Cal.2d 371, 376-377 (1968)).

⁴⁷ See Monsanto Amended Complaint, at ¶ 10(a).

⁴⁸ Cal. Health & Saf. Code, §§ 25249.5, 25249.6.

implementing Proposition 65 provide any direction to IARC about how to make classification determinations. This leaves IARC with unchecked discretion. No mechanisms or procedural safeguards are in place to ensure that IARC performs its function consistent with the policy goals of Proposition 65.

Moreover, OEHHA relied exclusively on an IARC determination that glyphosate is a "probable carcinogen," despite its own previous findings that failed to find "sufficient evidence" of carcinogenicity in experimental animals. OEHHA has stated that in implementing the Labor Code listing mechanism, OEHHA's duty is "ministerial" and it cannot examine the underlying basis of IARC's conclusion. In other words, OEHHA effectively elevated the determination of an ad hoc committee of an unelected, foreign body, which answers to no United States or California official, over the prior conclusions of its own scientific experts.⁴⁹

В. **Relevant Case Law**

1. Adopting Future IARC Classifications is Tantamount to **Delegating Lawmaking Authority to a Private Entity**

The statutory provision at § 25249.8(a) of the California Health & Safety Code leaves ambiguity as to whether the Legislature intended it to refer only to those substances classified by IARC as of the enactment of Proposition 65, or instead also to those substances that IARC may classify in the future. The second interpretation

⁴⁹ See Monsanto Amended Complaint, at ¶ 8.

would delegate to IARC the ongoing power to list chemicals under Proposition 65, whereas the former interpretation would merely have incorporated a known set of substances. OEHHA has adopted and codified the second approach. 50 In 2011, the First District Court of Appeal upheld OEHHA's interpretation and allowed it to list chemicals classified by IARC on an ongoing basis. 51 Notably, however, that court did not consider the constitutional concerns related to non-delegable duties. Two court decisions, though, have addressed such constitutional concerns, albeit in different contexts.

International Association of Plumbing and Mechanical Officials a.

First, in International Assn. of Plumbing and Mechanical Officials (IAPMO), et al. v. California Building Standards Commission, the Court of Appeal held that the Legislature, in setting state building standards, could adopt by reference model building codes published by IAPMO, a private trade association composed of state and local regulators.⁵² However, the court ruled that the Legislature "could adopt only an existing version of the model code and could not take into account future revisions without improperly delegating lawmaking authority to the private entity that produced the code." 53 The court reasoned that "while the Legislature can provide for

⁵⁰ CAL. CODE REGS., title 27, § 25904.

⁵¹ See California Chamber of Commerce v. Brown, 196 Cal. App. 4th 233 (2011).

⁵² 55 Cal. App. 4th 245 (1997).

⁵³ *Id. at* 254 (emphasis added).

and encourage the participation of private associations in the regulatory process, it must stop short of giving such groups the power to initiate or enact rules that acquire the force of law."54

Thus, under IAPMO, a state statute cannot constitutionally incorporate by reference future determinations of an outside entity unless the Legislature or a state regulatory agency exercises ultimate discretion to decide whether the determination becomes state law.⁵⁵ Under the Labor Code listing mechanism, IARC is the sole decision maker, leaving OEHHA with no discretion to question or veto IARC's judgments. Through the lens of IAPMO, this allocation of rulemaking responsibility is tantamount to granting lawmaking responsibility to IARC, and thereby would constitute a violation of the non-delegation doctrine.

b. Plastic Pipe and Fittings Association

More recently, in *Plastic Pipe and Fittings Association (PPFA) v. California* Building Standards Commission, the Court of Appeal held that a state statute may not incorporate by reference the future determinations of an outside entity unless the Legislature or a state regulatory agency has the final say over whether the determination becomes law.⁵⁶

⁵⁴ *Id*.

⁵⁵ *Id.* at 255.

⁵⁶ 124 Cal. App. 4th 1390, 1410 (2004)

In *Plastic Pipe*, the Commission, a state agency responsible for approving or adopting building standards, proposed adopting a model code published by a private organization, including provisions that allowed for the use of PEX pipes and fittings.⁵⁷ During the public comment period, the Commission and adopting agencies received responses that were both critical and supportive of allowing the use of PEX.⁵⁸ Ultimately, the Commission adopted the model code but modified its building standards to exclude the use of PEX. 59 PPFA filed suit, arguing that the PEX exclusion was arbitrary, contrary to the evidence, and influenced by political agendas. 60 The trial court sided with PPFA and ordered the Commission to adopt and approve the code provisions allowing the use of PEX. 61 The Court of Appeal reversed the trial court's decision and held that the Commission's decision not to allow the use of PEX was proper, because it was based on their reasonable conclusion that the use of PEX could potentially present an unacceptable danger to public health. 62

Relevant to the non-delegation issue at hand, both the Superior Court and the Court of Appeal rejected PPFA's argument that the model code could become

⁵⁷ *Id.* at 1398-99. "PEX" is shorthand for cross-linked polyethylene.

⁵⁸ *Id.* at 1398-1400.

⁵⁹ *Id.* at 1401.

⁶⁰ *Id.* at 1402.

⁶¹ *Id.* at 1403.

⁶² *Id.* at 1407.

California law without any review by either the adopting agency or the Commission. 63 In so finding, the court held that "[f]or the Legislature to grant a private association ... the power to make law with no direction from the Legislature and no review by a state agency would be unconstitutional."64

In other words, the incorporation by reference of *future* decisions of an outside entity delegates to that entity the power to make California law, regardless of whether that entity acts directly in response to the delegation or not. Under the Labor Code listing mechanism, no California governmental entity exercises "final say" over whether IARC classification decisions become California law. Indeed, OEHHA exercises no independent judgment at all. To the contrary, OEHHA interprets that it must include a chemical on the Proposition 65 list if IARC so classifies it. 65 Furthermore, OEHHA refuses to take public comment on the "weight or quality of the evidence considered by IARC."66

Thus, the Labor Code listing mechanism improperly transforms the decisions of IARC Working Groups into California law. The listing determinations have serious legal ramifications and result in regulation of the listed chemical under California law. They

⁶³ *Id.* at 1409.

⁶⁴ *Id.* (*citing IAPMO*, 55 Cal. App. 4th at 253).

⁶⁵ See 27 Cal. Code Regs. § 25904(b).

⁶⁶ OEHHA, Notice of Intent to List Glyphosate (Sept. 4, 2015).

also subject businesses who sell products containing glyphosate in California to the enforcement provisions of Proposition 65, which may include penalties.

2. The Monsanto Trial Court's Tenuous Reliance on Kugler v. Yocum

Constitutional Initiative—Fact-Finding, Not Law Making a.

In dismissing Monsanto's case against OEHHA, the trial court relied heavily on Kugler v. Yocum when reasoning that IARC's role in Proposition 65 listings does not violate the non-delegation doctrine.⁶⁷ Kugler addresses the constitutionality of a proposed initiative that established a floor for the City of Alhambra's compensation of its firefighters that was based on the prevailing wages in Los Angeles. The California Supreme Court found that the proposed initiative was constitutional based on several factors.

First, the court determined that the ordinance itself established "the fundamental decision: the policy of parity with Los Angeles" based on a vote of Alhambra voters, and calculating the actual floor amount would be "filling in of the facts"⁶⁸ and "no more than the automatic execution of that policy."⁶⁹ Additionally, the city council was still entrusted with setting salaries subject to that floor, and,

⁶⁷ 69 Cal.2d 371 (1968).

⁶⁸ *Id.* at 377.

⁶⁹ Ibid.

therefore, the proposed ordinance would "not delegate[] legislative power." Finally, the arrangement included "built-in and automatic protections" deriving from Los Angeles's self-interest in avoiding "an excessive wage scale" and "the interplay of competitive economic forces and bargaining power [that] will tend to settle the wages at a realistic level."⁷¹ The court determined that the voters "could properly expect" that "the Los Angeles governing bodies ... would reasonably investigate, negotiate, and finally determine such salaries," and that proper safeguards were in place. 72

b. Proposition 65 Listing—Law-Making, Not Fact-Finding and No Safeguards

None of these factors exist in the challenge to listing glyphosate. First, contrary to the trial court's reasoning, the Labor Code listing mechanism does not use an outside entity's expertise to fill in factual findings necessary to implement the underlying legislative policy. Rather, the decision to list a substance pursuant to Proposition 65 is a "quasi-legislative action," or rulemaking, and not just filling in factual findings.⁷³ The city manager's administrative task in *Kugler* was to determine the prevailing wage for firefighters that two other government entities paid, which is an objectively verifiable factual determination. On the other hand, the Labor Code

⁷⁰ *Id.* at 377, n.3.

⁷¹ *Id*. at 381.

⁷² *Id.* at 382-83.

⁷³ See Exxon Mobil Corp. v. Office of Environmental Health Hazard Assessment, 169 Cal. App. 4th 1264, 1276 n.10.

mechanism delegated to IARC is a layered policy judgment, including nuanced decisions such as which scientists to use, which studies to consider, what weight to afford each study, how to evaluate historical control data, how to aggregate statistical analyses across studies, and what criteria to apply.

Put another way, the classification of glyphosate as a carcinogen is arguably itself the established rule that triggers legal obligations under Proposition 65, and not just a fact upon which application of the law depends. When IARC classifies a chemical as a carcinogen, it is not just filling in a fact. Instead, it is drawing a scientific conclusion that subjects the chemical under review to regulation under California law. Monsanto argues that this constitutes law-making, not fact-finding.

Furthermore, unlike the city council's continuing role in setting salaries in Kugler, no such California entity exercises any substantive role in the proposed listing of glyphosate. In Kugler, the court emphasized that the Alhambra city council retained ultimate discretion to set wages, explaining that the city manager's findings merely served as a lowest floor for the council's decision. In this case, no discretion is left to OEHHA in terms of deciding what chemical triggers Proposition 65 enforcement. Finally, unlike the wage determination in Kugler, 74 the Labor Code listing mechanism is not subject to any safeguard whatsoever, since whatever IARC says, goes.

⁷⁴ *Kugler*, 69 Cal.2d at 382.

CONCLUSION

In light of these cases and the facts at hand, the appellate court may well conclude that OEHHA's reliance on IARC in listing glyphosate violates the nondelegable duties prohibition of the California Constitution. While the Legislature may encourage the participation of private associations in the regulatory process, it must stop short of giving such groups the power to enact rules that acquire the force of law, and related punitive consequences. Adopting future (and potentially unreliable) IARC carcinogenic classifications without any state or legislative direction, "final say" or safeguards is tantamount to granting IARC lawmaking power. Through this lens, and beyond this defined constitutional issue, one must necessarily question whether, indeed, glyphosate is "known to the State" to cause cancer, as Proposition 65 requires—and as California voters intended.