No. 21-10994

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

JOHN D. CARSON,
Plaintiff-Appellant,

v.

MONSANTO COMPANY,
Defendant-Appellee.

On Appeal From The United States District Court For The Southern District of Georgia
No. 4:17-cv-00237-RSB-CLR (Baker, J.)

EN BANC BRIEF OF DEFENDANT-APPELLEE MONSANTO COMPANY

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CERTIFICATE OF INTERESTED PARTIES

Pursuant to Federal Rule of Appellate Procedure 26.1, Eleventh Circuit Rule 26.1-1(a)(1), and Eleventh Circuit Rule 26.1-2(d), Appellee Monsanto Company, through undersigned counsel, hereby submits this Certificate of Interested Parties and Corporate Disclosure Statement.

Below is a complete list of all trial judges, attorneys, persons, associations of person, firms, partnerships, or corporations that have an interest in the outcome of the particular case or appeal, including subsidiaries, conglomerates, affiliates, part corporations, any publicly-held corporations that own 10% or more of the parties' stock, and other identifiable legal entities related to a party. Pursuant to Eleventh Circuit Rule 26.1-2(d), this list also incorporates all persons and entities listed on all CIPs previously filed in this appeal.

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64. Carson, John D., Jr., P.C.
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81. Public Citizen, Inc.

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83. Public Justice, P.C.

84. Southeast Law, LLC

85. Steptoe & Johnson LLP

86. United Farm Workers

87. UFW Foundation

88. U.S. Chamber Litigation Center

89. Washington Legal Foundation

STATEMENT REGARDING ORAL ARGUMENT

The en banc Court has ordered that oral argument will be held the week of June 12, 2023, and that each side will be allotted 20 minutes for oral argument.

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Supp.App.	Appellee's Supplemental Appendix, comprising four volumes: Vol. 1 (Supp.App. 1-165) Vol. 2 (Supp.App. 166-383) Vol. 3 (Supp.App. 384-436) Vol. 4 (Supp.App. 437-629)
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
1978 EPA Glyphosate Tolerances	EPA, Glyphosate Tolerances (Aug. 22, 1978)
1986 Registration Standard	EPA, Guidance for the Reregistration of Pesticide Products Containing Glyphosate as the Active Ingredient (June 1986)
1993 Reregistration Eligibility Decision	EPA, Reregistration Eligibility Decision (RED) – Glyphosate (Sept. 1993)
1998 Registration Notice	EPA, Pesticide Registration Notice (PR) 98-10 (Oct. 22, 1998)
2009 Surfactant Approval	EPA, Alkyl Amine Polyalkoxylates, Human Health Risk Assessment (Apr. 3, 2009)
Glyphosate Issue Paper	EPA, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017)
2019 EPA Letter	EPA, Office of Pesticide Programs, Letter to Glyphosate Registrants Regarding Labeling Requirements (Aug. 7, 2019)
2020 Interim Decision	EPA, Glyphosate: Interim Registration Review Decision Case No. 0178 (Jan. 2020)

2022 EPA Letter	Letter from Michal Freedhoff, Assistant Administrator, EPA, to Lauren Zeise, Director, Office of Environmental Health Hazard Assessment, California EPA (Apr. 8, 2022)
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NRDC U.S. 9th Cir. Br.	Brief of the United States as Respondent, *Natural Resources Defense Council, et al. v. EPA*, No. 20-70787 (9th Cir.)

INTRODUCTION

According to the Environmental Protection Agency, glyphosate—the world's most widely-used herbicide—does not cause cancer. That is the formal conclusion of an expert agency exercising congressionally-delegated authority. Acting pursuant to its responsibilities under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), EPA has studied the extensive body of science on glyphosate and repeatedly found that it is not likely to be carcinogenic. Consistent with this determination, EPA has approved scores of labels bearing no cancer warning for Monsanto's Roundup®-branded glyphosate products. By law, EPA could only approve these Roundup® labels after determining that they included all necessary health warnings.

Plaintiff nonetheless maintains that a jury applying state law can hold Monsanto liable for failing to provide a cancer warning that EPA determined is not required—indeed is prohibited—under FIFRA. Congress enacted a preemption provision that bars this claim. Titled "Uniformity," FIFRA's express-preemption provision provides that a "State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter," *i.e.*, under FIFRA. 7 U.S.C. §136v(b). The Supreme Court has interpreted that provision to mean that no state labeling requirement may be enforced unless it is "*genuinely* equivalent" to federal labeling requirements. *Bates*

v. Dow Agrosciences LLC, 544 U.S. 431, 454 (2005). And the Court has interpreted a similarly-worded preemption provision to mean that when an agency conducts a product-specific safety review and approves that product's labeling, that regulatory action "imposes 'requirements' under" the statute. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322-23 (2008).

The fundamental issue in this appeal, reflected in the questions this Court posed, is whether EPA's determination of what is required under FIFRA matters for preemption. Plaintiff says EPA's pesticide-specific determinations are irrelevant. In his view, so long as FIFRA and state law both require, at a high level of generality, "necessary" health warnings, 50 States can take 50 different approaches to what specific health warnings are necessary for specific pesticides—never mind what the expert federal regulator, exercising congressionally-delegated authority, determines is required under FIFRA. To reach this result, Plaintiff imports a force-of-law analysis the Supreme Court has never applied to express preemption, and then misapplies it, ignoring textbook agency actions carrying the force of law. Plaintiff admits this is not how similarly-worded preemption statutes work. But he insists that FIFRA preemption operates differently because of a separate provision under the statutory heading "Miscellaneous," which does not mention preemption, and merely confirms that the bare fact of a pesticide registration is not a defense to the

commission of "offenses"—that is, violations enforced by the federal government—under FIFRA.

This Court should reject Plaintiff's reading and interpret FIFRA's preemption provision consistent with its plain text, its surrounding statutory framework, and Supreme Court precedent interpreting that provision and similar statutory language. When EPA performs its statutory responsibility to determine what safety warnings are required under FIFRA, that controls whether a state-law labeling requirement is "in addition to or different from those required under [FIFRA]." And there is no doubt that EPA has determined that no cancer warning for Roundup® was required under FIFRA—a reality Plaintiff cannot escape by ignoring most of the relevant agency record, and responding to the rest with distortions and distractions.

The district court's decision dismissing Plaintiff's claim as preempted should be affirmed.

JURISDICTION

Monsanto adopts Plaintiff's jurisdictional statement and adds that the parties' high-low settlement does not deprive this Court of appellate jurisdiction, because such jurisdiction continues where a settlement leaves "both [parties] with a considerable financial stake in the resolution of the question presented." *Nixon v. Fitzgerald*, 457 U.S. 731, 744 (1982).

ISSUES PRESENTED

1. Whether Plaintiff's state-law failure-to-warn claim is expressly preempted because it is "in addition to or different from" requirements under FIFRA, where EPA has repeatedly determined that the warning Plaintiff seeks is not required under FIFRA.

2. Whether impossibility preemption bars Plaintiff's claim.

STATEMENT

Monsanto has manufactured Roundup®-branded herbicides, a line of products for which glyphosate is the active ingredient. EPA extensively regulates herbicides like Roundup® and for decades has exercised its authority under FIFRA to approve the labeling of hundreds of glyphosate-based products, including Roundup®—without cancer warnings.[3]

A. EPA's Statutory Authority Over Pesticides And Their Labeling.

FIFRA is a "comprehensive regulatory statute," regulating "the use, … sale[,] and labeling[] of pesticides." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991-92 (1984). Congress enacted a detailed scheme through which EPA has authority to register pesticides, and it is unlawful to sell unregistered pesticides within the United States. 7 U.S.C. §136j(a)(1)(A).

[3] FIFRA defines "pesticide" to include herbicides, which eliminate unwanted vegetation. 7 U.S.C. §136(u).

Before EPA registers a pesticide, it must "determine that the pesticide will not cause 'unreasonable adverse effects on the environment.'" *Ruckelshaus*, 467 U.S. at 992 (quoting 7 U.S.C. §136a(c)(5)(C)). That assessment includes determining that a pesticide will not pose "any unreasonable risk to man." 7 U.S.C. §136(bb). Accordingly, "EPA reviews pesticides for potential carcinogenicity," and its resulting "classification will determine how the Agency regulates [a] pesticide." EPA, *Evaluating Pesticides for Carcinogenic Potential*, https://perma.cc/3SZ4-NQ6F. For example, if the agency determines that a pesticide is carcinogenic, it will consider limiting permissible applications through a restricted use classification, 40 C.F.R. §152.170(b)(vi), and impose "labeling requirements intended to protect human health," *Nat. Res. Def. Council v. EPA* ("*NRDC*"), 38 F.4th 34, 45 (9th Cir. 2022). EPA makes these expert determinations only after analyzing exhaustive scientific data. *See* 7 U.S.C. §§136a(c)(1)(F), (2)(A); 40 C.F.R. §158.500.

EPA's initial registration of a pesticide does not complete its work. For certain pesticides (including glyphosate), Congress requires "reregistration," a one-time, formal regulatory proceeding in which EPA determines whether a pesticide continues to meet FIFRA's registration requirements. *See* 7 U.S.C. §136a-1. Reregistration is defined by statute to comprise five "phases"—including the gathering and analysis of significant data and EPA's independent verification of that data's adequacy—culminating in "regulatory action." *Id.* §136a-1(b).

Separately, and since 2007, FIFRA requires EPA to complete a "registration review" every 15 years, during which the agency again determines whether a pesticide meets FIFRA's registration requirements. *Id.* §136a(g)(1)(A).[4]

EPA must also review and approve the labeling of pesticide products. 7 U.S.C. §136j(a)(1)(E). Based on its safety assessment, EPA may require a pesticide's labeling to feature: (i) specific health and safety statements, such as "human hazard" or "precautionary statements," to convey warnings about potential health risks and mitigation, 40 C.F.R. §§156.60-156.70; (ii) personal protective equipment requirements, *id.* §156.212; (iii) application directions, *id.* §156.10(i)(1)-(2); and/or (iv) designations restricting use to "certified applicators," 7 U.S.C. §136a(d); 40 C.F.R. §156.10(j). If EPA classifies a pesticide for restricted use upon finding it carcinogenic, regulations prescribe specific labeling. *See* 40 C.F.R. §§156.10(j)(2), 152.166(a).

FIFRA prohibits EPA from registering a pesticide unless the agency determines that the pesticide's "labeling … compl[ies] with the requirements of" FIFRA. 7 U.S.C. §136a(c)(5)(B). By regulation, EPA confirmed that these requirements include that the pesticide not be "misbranded as that term is defined in

[4] Plaintiff conflates these two distinct procedures: "reregistration," 7 U.S.C. §136a-1(b), which occurs once, and "registration review," *id.* §136a(g)(1)(A), which occurs every 15 years. *See, e.g.*, Pl.'s Br. 19, 37 (referring to registration review proceedings as "re-registration," "re-registration review," and "re-registration proceeding").

FIFRA." 40 C.F.R. §152.112(f). A pesticide is "misbranded" if its label lacks any "warning or caution statement which may be necessary … to protect health and the environment," or is "false or misleading in any particular." 7 U.S.C. §§136(q)(1)(A), (F)-(G), 136a(c)(5)(B); 40 C.F.R. §156.10(a)(5)(ii). It is unlawful to distribute or sell a pesticide "if any claims made for it as a part of its distribution or sale substantially differ" from its approved labeling. 7 U.S.C. §136j(a)(1)(B); *see also id.* (prohibiting claims that differ from "the statement required in connection with [the pesticide's] registration"); *id.* §136a(c)(1)(C) (statement must include "complete copy of the labeling").

Many pesticide products share the same active ingredient, and EPA may conduct registration and reregistration proceedings for an active ingredient. *See, e.g.*, Supp.App.127 (1993 Reregistration Eligibility Decision) (reregistration of "the active ingredient glyphosate"). For individual products, EPA must also determine that "[t]he entire formulation, including the inert ingredients," satisfies statutory requirements. EPA, *Pesticide Registration Manual: Chapter 8 – Inert Ingredients*, https://perma.cc/82R8-7VEW. EPA further determines that each individual "product" it registers "is not misbranded." 40 C.F.R. §152.112(f).

Anyone who violates FIFRA's requirements risks civil and criminal penalties, stop-sale orders, and product seizures. 7 U.S.C. §§136k, 136*l*. And any proposed change to a pesticide's approved labeling, save for certain "minor modifications,"

requires a new application that EPA must approve. 40 C.F.R. §§152.44, 152.46. Accordingly, registrants are prohibited from adding a new "health hazard" to the "precautionary statement" portion of the label without prior EPA approval. *See* Supp.App.488 (1998 Registration Notice) (change to "precautionary statements" does not qualify as "[m]inor label change"). Even where EPA permits a label change without prior approval, it may "initiate regulatory or enforcement action" if it "determines" that the change was inconsistent with "applicable law or regulations." Supp.App.499 (1998 Registration Notice).

FIFRA includes an express-preemption provision, providing that States may "not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter," *i.e.*, under FIFRA. 7 U.S.C. §136v(b).

B. EPA Consistently Determines That Glyphosate Does Not Cause Cancer And Glyphosate-Based Pesticides Do Not Require A Cancer Warning.

1. EPA Registers And Reregisters Glyphosate, Determining It Is Not Likely To Be Carcinogenic.

EPA first registered glyphosate for use as a pesticide in 1974. In the half century since, EPA has repeatedly evaluated the scientific evidence on glyphosate and approved its use as a pesticide, concluding that glyphosate is not likely to be carcinogenic to humans and approving product labeling with no cancer warning.

In 1978, following the discovery of a third-party laboratory's industry-wide fraudulent conduct, EPA reviewed validated studies of glyphosate and concluded that glyphosate had "relatively low oncogenic [*i.e.*, carcinogenic] potential." Supp.App.440 (1978 Glyphosate Tolerances). In 1986, EPA convened an expert scientific panel to review the agency's preliminary evaluation of new studies addressing glyphosate's potential carcinogenicity. The panel found that the evidence was "equivocal" and did not support a conclusion that glyphosate causes cancer, and recommended that EPA call for additional studies. Supp.App.179-180 (Glyphosate Issue Paper). EPA adopted this recommendation, decided that "the Agency will issue registrations" for glyphosate products while these studies were ongoing, and prescribed "Required Labeling" with no cancer warning. Supp.App.456, 462-469 (1986 Registration Standard). In 1991, after EPA received and analyzed additional studies on glyphosate, its Cancer Peer Review Committee classified glyphosate "as a Group E chemical: 'Evidence of Non-Carcinogenicity for Humans.'" Supp.App.180 (Glyphosate Issue Paper).

In 1993, EPA completed its statutory reregistration of glyphosate. Although Plaintiff's brief ignores EPA's reregistration decision, the agency concluded that it had "sufficient information on the health effects of glyphosate," and determined that the "toxicological data base on glyphosate," including with respect to carcinogenicity, was "adequate and … support[ed] reregistration." Supp.App.80,

127 (1993 Reregistration Eligibility Decision). Relying on its conclusion that glyphosate showed "evidence of non-carcinogenicity for humans," EPA "determined that glyphosate products, labeled and used as specified [by EPA], will not pose unreasonable risks or adverse effects to humans." Supp.App.69, 127. EPA described this as a "Regulatory Conclusion." Supp.App.478. Since then, "the carcinogenic potential of glyphosate has been evaluated by EPA several times," with the agency consistently finding no such potential. Supp.App.179 (Glyphosate Issue Paper). For example, EPA determined in 2008, based on an "extensive database," that glyphosate is "not a carcinogen." Final Rule: Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008).

2. An International Working Group Releases A Hazard Assessment For Glyphosate.

In 2015, a working group of the International Agency for Research on Cancer ("IARC"), an agency of the World Health Organization, classified glyphosate as a "Group 2A" agent—meaning it is, in IARC's view, "probably carcinogenic to humans" based on "limited" evidence of cancer in humans and "sufficient" evidence in animals. IARC, Monograph on Glyphosate at 78, https://perma.cc/GV8J-LJYB. IARC's classification reflected a "hazard assessment"—*i.e.*, IARC considered whether glyphosate was capable of causing cancer under any circumstances, without assessing the risk it actually poses in real-world conditions. IARC, Preamble at 10-11, https://perma.cc/39YF-FMAU.

3. EPA Reiterates Its Determination That Glyphosate Does Not Cause Cancer And Expressly Rejects A Cancer Warning.

In conducting its continuing scientific review, EPA developed an extensive database on glyphosate's carcinogenic potential, reviewing 736 studies as part of an open-literature review as well as "numerous studies … submitted to the agency." Supp.App.188-189 (Glyphosate Issue Paper). The agency examined the studies "included in the evaluation by IARC," and convened a scientific advisory panel to contribute to EPA's analysis. Supp.App.190. After considering IARC's classification, EPA again determined that "[t]he strongest support" is for classifying glyphosate as "'not likely to be carcinogenic to humans.'" Supp.App.310.

In 2019, after considering public comments, EPA issued a proposed registration review decision in which the agency reiterated its long-held conclusion that glyphosate is not likely carcinogenic to humans—noting that its evaluation was "more robust" and "more transparent" than IARC's and "consistent with" those of "other regulatory authorities and international organizations." Supp.App.56-57.

In an August 2019 letter to registrants of glyphosate products, EPA again reaffirmed its determination that glyphosate is "not likely to be carcinogenic to humans." Supp.App.11. "Given EPA's determination," the agency confirmed that a label warning that glyphosate causes cancer would render a pesticide "misbranded pursuant to section 2(q)(1)(A) of FIFRA [7 U.S.C. §136(q)(1)(A)]," and ordered any such warnings removed "from all product labels." Supp.App.11-12. EPA more

recently stated that it "could approve" labels noting both that IARC has "classified glyphosate as probably carcinogenic to humans" and that EPA and other regulatory authorities have "determined that glyphosate is not likely to be carcinogenic to humans." App.119-120 (2022 EPA Letter). It simultaneously reiterated its earlier determination that glyphosate is not likely carcinogenic. *See id.*

Separately, after considering public comments for a second time, EPA in 2020 finalized its interim registration review determination that glyphosate does not cause cancer. Supp.App.395.[5] In response to petitions filed in the Ninth Circuit and a change in administration, EPA again reviewed its decision in early 2021. The agency reaffirmed the view espoused without interruption over the last six administrations: "glyphosate is not likely to be a human carcinogen and … it poses no human-health risks of concern." Supp.App.613 (*NRDC* U.S. 9th Cir. Br.). In June 2022, the Ninth Circuit vacated EPA's 2020 Interim Registration Review Decision for lack of adequate explanation, emphasizing that vacatur would not be "disruptive" and no individual pesticide was "deregist[ered]." *NRDC*, 38 F.4th at 52 & n.13. The following September, EPA announced it will "revisit and better explain its evaluation of the carcinogenic potential of glyphosate," while

[5] Throughout this process, EPA considered the allegations raised in the Roundup® litigation. One commenter, for example, shared with EPA his "expert report in the Hardeman case." Comment by Charles Benbrook, http://bit.ly/3TciRZ1 (visited March 15, 2023).

emphasizing that "EPA's underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic to humans, remain the same." Supp.App.624 (2022 Interim Decision Withdrawal).

Throughout the entire period relevant to this litigation, and continuing through the present, EPA has approved the labeling of numerous glyphosate-based pesticide products without cancer warnings.

C. Procedural History.

In December 2017, Plaintiff John Carson, Sr. sued Monsanto, alleging that he applied Roundup® to his lawn from 1986 to 2016, and thereafter was diagnosed with cancer. App.27. Plaintiff asserted several claims, including a failure-to-warn claim under Georgia law. App.27-43.

Monsanto moved for judgment on the pleadings, which the district court granted in relevant part, concluding that FIFRA expressly preempts Plaintiff's failure-to-warn claim. App.98. The parties then reached a "high-low" settlement under which Plaintiff dropped his remaining claims, the district court entered final judgment, and the amount of Plaintiff's recovery depends on whether this Court affirms or reverses the dismissal of his failure-to-warn claim.

A panel of this Court reversed, and Monsanto petitioned for rehearing en banc. The panel issued a revised opinion, and Monsanto renewed its petition, which this Court granted.

SUMMARY OF ARGUMENT

1. FIFRA expressly preempts "any" state-law "requirements for labeling or packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. §136v(b).

a. Under Supreme Court precedent, state labeling requirements are preempted unless they are genuinely equivalent to federal ones. Plaintiff's approach—which compares federal and state requirements at the highest level of abstraction, without regard to the product-specific requirements determined by EPA—does not ensure genuine equivalence.

b. FIFRA requires pesticide manufacturers to include any warning necessary to protect health, and prohibits any false or misleading statement. Congress delegated to EPA the responsibility to determine, on a pesticide-by-pesticide basis, whether these requirements are met. When EPA makes a statutory determination that a particular safety warning is not required for a specific pesticide, it establishes what is required under FIFRA for that pesticide. As the Supreme Court held interpreting a preemption provision similar to FIFRA's, a federal agency's product-specific approval establishes product-specific requirements under the relevant statute.

c. FIFRA's preemption provision itself has the force of law, and because EPA determinations define the scope of preemption as a matter of statutory construction,

no force-of-law analysis is required. In any event, EPA's formal determinations with respect to glyphosate, made pursuant to congressional delegation, are classic agency actions with the force of law. That conclusion is not undermined by a "Miscellaneous" provision of FIFRA, which has nothing to do with preemption but instead provides that pesticide registration is not a defense to "offenses" enforced by the federal government. Moreover, Monsanto does not argue that the bare fact of registration preempts state law, but relies on EPA's regulatory determinations that glyphosate does not cause cancer and that a cancer warning for glyphosate products is not required under FIFRA. Plaintiff admits that such agency action supports preemption under similar preemption provisions.

d. Throughout Plaintiff's alleged use of Roundup® from 1986 to 2016, EPA repeatedly discharged its statutory responsibilities to determine that glyphosate is not likely to cause cancer and that no cancer warning is required on Roundup® products. Plaintiff ignores these actions. He instead focuses on a 2022 Ninth Circuit vacatur on administrative-law grounds of a 2020 EPA registration review decision—even though the Ninth Circuit stressed that the vacatur changed nothing about existing glyphosate product registrations. To this day, EPA continues to approve glyphosate product labels without a cancer warning, and has expressly informed registrants that a cancer warning would make their products misbranded in violation of FIFRA.

e. Applying the plain text of FIFRA's preemption provision to the long record of EPA determinations concerning glyphosate and the labeling of glyphosate-based pesticides, Plaintiff's claim is preempted. A state-law requirement to warn that glyphosate causes cancer is in addition to what is required under FIFRA, because EPA has determined that a cancer warning is not required under FIFRA. It is also different from what is required under FIFRA, because EPA has determined that a cancer warning would violate FIFRA.

2. Plaintiff's state-law failure-to-warn claim is independently barred by impossibility preemption.

a. Under FIFRA, Monsanto cannot add a warning to the Roundup® label that EPA would reject, and state law may not compel Monsanto to do what federal law forbids. Neither the existence of an express-preemption provision, nor the Supreme Court's decision in *Bates*, alters the application of ordinary impossibility-preemption principles.

b. Impossibility preemption applies because EPA has been fully informed of the supposed basis for a cancer warning, and repeatedly concluded that glyphosate does not cause cancer, making clear the agency would not approve a warning that it does. These agency determinations were made through agency action carrying the force of law.

STANDARD OF REVIEW

This Court reviews *de novo* an order granting judgment on the pleadings. *Cunningham v. Dist. Atty's Office for Escambia Cnty.*, 592 F.3d 1237, 1255 (11th Cir. 2010). "Judgment on the pleadings is proper when … the moving party is entitled to judgment as a matter of law based on the substance of the pleadings and any judicially noticed facts." *Id.* EPA materials are judicially noticeable. *See Dimanche v. Brown*, 783 F.3d 1204, 1213 n.1 (11th Cir. 2015).

ARGUMENT

I. FIFRA Expressly Preempts Plaintiff's State-Law Failure-to-Warn Claim.

The Constitution's Supremacy Clause—providing that "the Laws of the United States" are "the supreme Law of the Land," U.S. Const. art. VI—"enshrines the basic principle that federal law supersedes state law whenever they conflict," *Kordash v. United States*, 51 F.4th 1289, 1293 (11th Cir. 2022). Congress thus has "the power to pre-empt state law" through "express language in a congressional enactment." *Graham v. R.J. Reynolds Tobacco Co.*, 857 F.3d 1169, 1186 (11th Cir. 2017) (en banc) (quotation omitted). When Congress exercises that authority, the scope of preemption is a question of statutory interpretation, turning on "the language of the pre-emption statute and the 'statutory framework' surrounding it." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996).

FIFRA contains an express-preemption provision. When Congress in 1972 transformed FIFRA into a "comprehensive regulatory statute," *Ruckelshaus*, 467 U.S. at 991, it prohibited States from imposing "any requirements for labeling or packaging in addition to or different from those required under this subchapter," *i.e.*, under FIFRA, 7 U.S.C. §136v(b). Congress later added a heading to §136v(b)—"Uniformity"—underscoring the provision's role in the statutory scheme. FIFRA Amendments of 1988, Pub. L. No. 100-532, 102 Stat. 2654 (1988). As the Supreme Court observed when describing the "important" role this provision plays, "imagine 50 different labeling regimes prescribing the … wording of warnings." *Bates*, 544 U.S. at 452. Section 136v(b) avoids that unworkable scenario, preempting state labeling rules that are not "fully consistent with federal requirements." *Id.*

The central question here is whether it matters what EPA determines is required under FIFRA for a particular pesticide. If EPA's decisions control, there is no serious question that the district court correctly entered judgment in Monsanto's favor. EPA has long determined that FIFRA does not require glyphosate products to bear a cancer warning, so a state requirement to add a warning is, at minimum, "in addition to" "those required under" FIFRA. Nor is there any doubt that under similarly-worded preemption provisions, a federal agency's product-specific approval establishes "'requirements' under" the statute, preempting state requirements to issue warnings beyond what the agency determined was required for

that product. *Riegel*, 552 U.S. at 322-23. FIFRA's preemption provision mirrors the one the Supreme Court interpreted in *Riegel*, and likewise forbids States from requiring safety warnings beyond what EPA determines is required under FIFRA.

A. Like Similar Provisions, FIFRA's Preemption Provision Ensures "Uniformity" By Limiting States To Labeling Requirements That Are "Genuinely Equivalent" To Federal Requirements.

A central premise of Plaintiff's brief is that FIFRA's express-preemption provision is *sui generis*. Plaintiff describes FIFRA's regulatory scheme as "relatively decentralized," and its preemption provision as "narrow," because the statute permits States to regulate the "'sale or use of any federally registered pesticide.'" Pl.'s Br. 26, 29 (quoting 7 U.S.C. §136v(a)). That is true as far as it goes—Section 136v(b) does not apply to all requirements relating to pesticide sale or use. It does, however, apply to requirements *for labeling and packaging*. Within that core federal domain, the statutory scheme is decidedly centralized, preempting state requirements that are "in addition to or different from" federal requirements. The statutory text prescribing the scope of preemption with respect to labeling and packaging requirements is just like the text of the preemption provisions Plaintiff tries to distinguish. *Compare* 7 U.S.C. §136v(b), *with* 21 U.S.C. §360k(a) (preempting state-law requirements "different from, or in addition to, any requirement applicable under [the Medical Device Amendments] to the device"),

and 21 U.S.C. §678 (preempting state-law requirements "in addition to, or different than those made under" the Federal Meat Inspection Act).

Each of these provisions—including FIFRA's—permits States to enforce only those requirements that truly "parallel" federal requirements. *Bates*, 544 U.S. at 447; *accord Riegel*, 552 U.S. at 330; *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 459 (2012) (even "non-conflicting" requirements may be "additional or different"). In other words, a State can only supply "remedies that enforce federal misbranding requirements." *Bates*, 544 U.S. at 451. That means state requirements must be "*genuinely* equivalent," not just "nominally equivalent," to federal requirements, and a "manufacturer should not be held liable under a state labeling requirement subject to §136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA." *Id.* at 454; *see also id.* at 455 (Thomas, J., concurring in part and dissenting in part) (agreeing with majority that States may not "alter or augment the substantive rules governing liability for labeling").[6]

Plaintiff's interpretation of FIFRA creates a regime of, at best, nominal equivalence. In his view, it is enough to say that Georgia law required Monsanto to "inform him of Roundup's dangerous condition," and FIFRA "requires a warning

[6] Plaintiff (at 5, 26, 29, 52) repeatedly characterizes FIFRA preemption as "narrow" by quoting *Bates* out of context. The Court rejected an argument that *all* "failure-to-warn claims were pre-empted under FIFRA," and described preemption under the "parallel requirements" rule as "narrow, but still important." *Bates*, 544 U.S. at 446, 452. Plaintiff omits the word "important."

'necessary' and 'adequate to protect health,'" so the state requirement "tracks" the federal one. Pl.'s Br. 31-32 (cleaned up). Framed at this high level of generality, 50 States can require 50 different warnings for the same pesticide, even if an expert federal agency, exercising congressionally-delegated authority, has determined that those warnings are not required under FIFRA. That is not genuine equivalence, *Bates*, 544 U.S. at 454, nor a regime securing any semblance of labeling "Uniformity," 7 U.S.C. §136v(b). As explained below, the only way to give meaning to FIFRA's preemption provision is to interpret it the same way the Supreme Court interprets the same language in similar provisions. That means taking seriously EPA's statutorily-assigned role in implementing FIFRA.

B. EPA's Pesticide-Specific Labeling Determinations Establish Federal Requirements Under FIFRA.

This Court directed the parties to address how "a reviewing court [should] identify the federal 'requirements … under this subchapter' to which §136v(b) refers." Courts should do so based on the "language of the pre-emption statute and the 'statutory framework' surrounding it," *Lohr*, 518 U.S. at 486, and in line with how the Supreme Court interprets similar language. Where EPA makes a statutorily-mandated, pesticide-specific determination of what FIFRA requires, that establishes what is required under FIFRA for that pesticide.[7]

[7] Monsanto addresses the Court's force-of-law questions in the next section, after addressing how requirements under FIFRA are determined.

1. FIFRA prescribes numerous requirements, including that pesticides not be "misbranded." 7 U.S.C. §136j(a)(1)(E). Misbranding includes labels that do not "contain a warning or caution statement which may be necessary and if complied with … is adequate to protect health and the environment." *Id.* §136(q)(1)(G). A pesticide is also misbranded if its "labeling bears any statement … which is false or misleading in any particular." *Id.* §136(q)(1)(A).

FIFRA further requires registrants to adhere to EPA-approved labeling. It is unlawful to sell "any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration," *id.* §136j(a)(1)(B), which includes "a complete copy of the labeling," *id.* §136a(c)(1)(C). As the agency puts it, "the label is the law." EPA, *Label Review Manual* 1-2 (Dec. 2016), https://perma.cc/RKT8-GFKR.

Congress charged EPA with implementing FIFRA's requirements. Critically, it created statutory procedures by which EPA must assess safety on a pesticide-by-pesticide basis, remain apprised of relevant scientific developments, and decide the contents of each pesticide product's labeling. Under FIFRA, no pesticide may be sold unless EPA has "registered" it—that is, approved it for sale after an extensive scientific review and a determination that the pesticide will not pose an unreasonable risk to human health. *See* 7 U.S.C. §§136(bb), 136a(a),

(c)(1)(F), (c)(2)(A); 40 C.F.R. §§152.20, 158.200. Before registering a pesticide, EPA reviews a "complete copy" of the proposed "labeling of the pesticide," 7 U.S.C. §136a(c)(1)(C), and may not register the pesticide unless EPA "determines" that the labeling "compl[ies] with" FIFRA's "requirements," *id.* §§136a(c)(5)(B), 136a(c)(6). Thus, "EPA will approve an application" for registration "only if," *inter alia*, "[t]he Agency has determined that the product is not misbranded as that term is defined in FIFRA." 40 C.F.R. §152.112(f). And since a pesticide lacking a warning that is "necessary" to "protect health" is misbranded, 7 U.S.C. §136(q)(1)(G), EPA may register a pesticide only if it "determines" that any necessary health warning is provided.

EPA has long recognized that "it is impossible to prescribe … exact statements for all combinations of ingredients, formulation types, and uses" by rulemaking, so it instead makes pesticide-specific labeling determinations through registration. Labeling Requirements for Pesticides and Devices, 49 Fed. Reg. 37,960, 37,965 (Sept. 26, 1984). Against the backdrop of that agency practice, Congress adopted the formalized, pesticide-specific "Reregistration" process, which incorporates determinations about the label's compliance with FIFRA, and results in "regulatory action by the Administrator" for that pesticide. 7 U.S.C. §136a-1(b)(5); *see also* Pub. L. No. 100-532, 102 Stat. 2654, 2656 (1988). In light of this statutory text and longstanding agency practice, Plaintiff cannot be correct

that EPA only determines what is required under FIFRA when it acts "through notice-and-comment rulemaking." Pl.'s Br. 27.

In sum, the relevant "'statutory framework,'" *Lohr*, 518 U.S. at 486, demonstrates that FIFRA requires necessary health warnings on a pesticide's label, charges EPA with determining what health warnings FIFRA requires, and prohibits registrants from deviating from an EPA-approved label. Together, FIFRA's text and structure establish that Congress delegated to EPA the critical role of making scientific determinations regarding pesticide safety, and corresponding labeling determinations regarding the need for, and content of, safety warnings. EPA's pesticide-specific actions discharging these responsibilities establish the pesticide-specific "requirements under FIFRA" against which state labeling requirements must be measured.

2. Supreme Court precedent compels the same conclusion. As the Court explained in *Bates*, EPA "give[s] content to FIFRA's misbranding standards" in a way that matters for preemption. 544 U.S. at 453. The Court illustrated that point with an example: if EPA determines that the toxicity level of a pesticide warrants a label that states "CAUTION," a "failure-to-warn claim alleging that a given pesticide's label should have stated 'DANGER' instead of the more subdued 'CAUTION' would be pre-empted." *Id.* at 453.

In dismissing that example, Plaintiff makes a revealing mistake. He emphasizes (at 51) that EPA acted "by regulation" to establish toxicity categories and to "mandate[] toxicity warnings for qualifying pesticides." But he does not mention how pesticides "qualify" for these categories and warnings. As *Bates* explained, an EPA regulation "assigns these warnings to particular *classes* of pesticides based on their toxicity." 544 U.S. at 453 (emphasis added); *see* 40 C.F.R. §§156.62, 156.64. EPA does not, however, assign toxicity levels or warning language to particular pesticides by rulemaking; rather, EPA makes that pesticide-specific determination through the registration process. *See, e.g.*, Supp.App.80-90 (1993 Reregistration Eligibility Decision) (determining toxicity categories for glyphosate). In Plaintiff's view, a State *can* require a "DANGER" warning when EPA requires a "CAUTION" warning, simply by disagreeing with the toxicity determination EPA makes during registration. In other words, Plaintiff's reading would allow States to do exactly what *Bates* says they cannot.

Riegel v. Medtronic removes any doubt that EPA's pesticide-specific determinations matter for preemption. 552 U.S. 312 (2008). At issue there were the Medical Device Amendments of 1976 ("MDA"), which *Bates* described as having a "similarly worded pre-emption provision" to FIFRA. 544 U.S. at 447. *Riegel* held that "premarket approval" of a device by the Food and Drug Administration

("FDA") "imposes 'requirements' under the MDA" that preempt non-parallel state requirements. 552 U.S. at 322-23.

That is so, *Riegel* explained, because "FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness." *Id.* at 323. Thus, "FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.*; *see also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340-41 (10th Cir. 2015) (Gorsuch, J.) ("device-specific federal requirements apply" because "the device endured the premarket approval process," and state-law warning claims are preempted because "once the FDA approves a device's label as part of the premarket approval process …, the manufacturer usually may not alter the label's warnings without prior agency approval"). The same is true here: FIFRA prescribes a premarket approval process through which EPA must determine the safety of a specific product and the adequacy of its labeling, and then generally prohibits unilateral changes by the manufacturer.

Other circuits interpret similar preemption provisions the same way. The Federal Meat Inspection Act ("FMIA") contains an express-preemption provision similar to FIFRA's. *See* 21 U.S.C. §678. Like FIFRA, the FMIA requires a federal agency to conduct premarket review of a product's label, and approve it only if "'not

false or misleading.'" *Thornton v. Tyson Foods, Inc.*, 28 F.4th 1016, 1021 (10th Cir. 2022) (quoting 21 U.S.C. §607(d)). In *Thornton*, the Tenth Circuit held that a state-law claim that agency-approved labels were deceptive and misleading was preempted: since the agency "ha[d] already determined that defendants' labels are not deceptive or misleading under federal law," "the state law plaintiffs seek to rely on cannot be coextensive with federal law." *Id*. at 1025.

The same is true under the Poultry Products Inspection Act ("PPIA"). "[W]hen the agency reviews and approves a label, the agency is deciding that it is *not* false or misleading under the PPIA, and thus the agency 'imposes' a federal requirement within the meaning" of the preemption provision. *Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1288 (9th Cir. 2021) (citing *Riegel*). Preemption applies because "[i]f a plaintiff claims that such a label is false or misleading notwithstanding review and approval by [the agency], he is essentially claiming that the agency's decision to approve the label was wrong." *Id*. That is precisely what Plaintiff claims here.

3. The foregoing does not mean that any claim involving EPA-approved labeling is preempted. "[M]ere inconsistency between the duty imposed by state law and the content of a manufacturer's labeling approved by the EPA at registration d[oes] not *necessarily* mean that the state law duty [i]s preempted." *Indian Brand Farms, Inc. v. Novartis Crop. Prot. Inc.*, 617 F.3d 207, 222 (3d Cir. 2010) (emphasis

added). That was true in *Bates*, where the plaintiff alleged a failure to warn that the pesticide Strongarm was inappropriate for certain soil types, and Congress authorized EPA to waive review of pesticide efficacy in order to focus the agency's efforts on safety and environmental effects. 544 U.S. at 435, 440; *see* 7 U.S.C. §136a(c)(5)(D). Accordingly, EPA "never passed on the accuracy of the statement in Strongarm's original label" that the plaintiff challenged, and its approval did "not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage." *Bates*, 544 U.S. at 440 (cleaned up).

Reading *Bates* in harmony with *Riegel*, the rule is straightforward: when EPA makes no determination of compliance with FIFRA, registration alone does not establish what the federal requirements are. But where EPA *does* make a statutory determination of compliance with FIFRA, that determination establishes federal requirements, and state law may not impose additional requirements. The Supreme Court drew precisely this distinction under the MDA. As noted, *Riegel* held that since FDA's premarket approval involved safety and efficacy review, it established device-specific "requirements" under the MDA. By contrast, *Lohr* involved approval based on "substantial equivalence" with previously approved devices. 518 U.S. at 492-94. Critically, in that "substantial equivalence" process, FDA does not "formally review[]" devices "for safety or efficacy," so it does not produce device-

specific "requirements" for preemption purposes. *Riegel*, 552 U.S. at 323; *accord Cohen*, 16 F.4th at 1287 (under the PPIA, no preemption for "generically approved labels" that "are deemed approved without being submitted for evaluation"). *Bates* is like *Lohr*, where agency approval did not entail review of the relevant labeling issue, made no determination of statutory compliance, and thus established no requirements under the statute. This case is like *Riegel*, where the agency was statutorily-required to make a determination on the safety issue and repeatedly did so, establishing product-specific federal requirements.

This distinction is reinforced by other aspects of *Bates*. The Court observed that tort suits can "'aid in the exposure of new dangers associated with pesticides.'" 544 U.S. at 451 (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)). That point was apt in *Bates*, where the agency never had occasion to consider the alleged new danger to crops. But tort suits play no role in exposing alleged dangers that EPA has not only identified, but concluded (after analyzing all the relevant science) are not actual dangers.[8]

[8] The Court need not decide whether every non-efficacy failure-to-warn claim is preempted. *See* Pl.'s Br. 53. After *Riegel*, subsequent device cases presented questions about newly-arising safety risks, and similar issues might arise in future pesticide cases. *Compare In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205-06 (8th Cir. 2010) (claim that device manufacturer "failed to provide the FDA with sufficient information" was preempted), *with Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1232-34 (9th Cir. 2013) (en banc) (claim that manufacturer failed to file adverse event reports was not preempted). Plaintiff hints at such a claim in a footnote (at 10 n.5), but did not plead it in his complaint or

C. No Threshold Force-of-Law Inquiry Applies, But In Any Event Would Be Satisfied.

This Court asked whether "an express-preemption provision like §136v(b) gives preemptive effect to a federal agency action that otherwise lacks the 'force of law,'" and "what role, if any, does a 'force of law' analysis play" in determining "the federal 'requirements … under'" FIFRA. In an express-preemption case, the statute—which by definition has the force of law—preempts. Congress can make the scope of preemption turn on agency determinations, contracts, or something else, without a freestanding force-of-law analysis. In any event, EPA's determinations that glyphosate does not cause cancer, and glyphosate-based products do not require a cancer warning, are classic agency actions with the force of law.

Plaintiff says little about any of this. In passing, he cites *implied*-preemption authority to justify a force-of-law analysis, but cannot explain why that is relevant to express preemption, where the scope of preemption is simply a question of statutory interpretation. Nor does he contest that EPA's actions would ordinarily satisfy any force-of-law test. Instead, Plaintiff's force-of-law argument centers on the notion that a "Miscellaneous" provision upends how FIFRA's preemption provision would otherwise operate, rendering EPA's labeling determinations irrelevant. That surprising conclusion is simply not supported by the plain text of

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otherwise preserve it. Understandably so, as there is no serious possibility that EPA lacked some critical piece of available information that would have changed its view of glyphosate.

the statute.

1. No Force-of-Law Analysis Is Necessary To Determine The Scope Of An Express-Preemption Provision.

There is no question what "law" does the preempting here: the statute. In enacting an express-preemption provision, Congress may point to non-legislative acts to define the scope of preemption. For instance, many "federal statutes preempt state law" by "leaving the context-specific scope of preemption to contractual terms." *Coventry Health Care of Mo. Inc. v. Nevils*, 581 U.S. 87, 98 (2017). But it remains "the statute, not a contract, [that] strips state law of its force." *Id.*

Here, the context-specific scope of FIFRA's express-preemption provision turns on "the language of the pre-emption statute and the 'statutory framework' surrounding it." *Lohr*, 518 U.S. at 486. As explained above, FIFRA's text and structure make clear that Congress charged EPA with making product-specific labeling determinations of what is required under FIFRA. *Supra* pp. 21-24. Those agency determinations shape the context-specific scope of preemption, but it remains "the statute"—FIFRA's express-preemption provision— that "strips state law of its force." *Coventry*, 581 U.S. at 98.

Unsurprisingly, then, the Supreme Court has never conducted a force-of-law inquiry to determine the relevance of agency actions under express-preemption provisions. It did not mention the concept in *Bates*. Likewise in *Riegel*, the Court concluded that agency "[p]remarket approval … imposes 'requirements under the

MDA,'" without asking whether premarket approval carries the force of law. 552 U.S. at 322.

Tellingly, in *Hardeman v. Monsanto Company*, the decision Plaintiff asks this Court to adopt, the Ninth Circuit relied on *implied*-preemption authority to justify a force-of-law analysis for FIFRA preemption. *See* 997 F.3d 941, 957 (9th Cir. 2021) (citing *Wyeth*, 555 U.S. 555, 576 (2009)).[9] Plaintiff (at 35) does the same. But the reason agency action with the force of law is important for implied preemption is that no *statute* with the force of law preempts state law. Where a statute does so, no further force-of-law inquiry is necessary.

2. EPA's Actions Determining What Safety Warnings Are Required Have The Force Of Law.

Setting aside the poor fit between a force-of-law analysis and FIFRA's express-preemption provision, EPA's labeling determinations nonetheless carry the force of law. As the Supreme Court recently explained in the implied-preemption context, the touchstone of the force-of-law question is whether the agency's actions "lie within the scope of the authority Congress has lawfully delegated." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668, 1679 (2019). Citing no authority, Plaintiff maintains that the question is more specific: whether Congress "delegate[d]

[9] When Plaintiff (at 1) says "every appellate court to consider" Monsanto's preemption argument has rejected it, he means the vacated panel opinion here, *Hardeman*, and an intermediate California court that followed *Hardeman*, *Pilliod v. Monsanto Co.*, 282 Cal. Rptr. 3d 679 (Cal. Ct. App. 2021).

to EPA the authority *to preempt*." Pl.'s Br. 42 (emphasis added). That is not what the Supreme Court said in *Merck*, and it conflicts with *Riegel*, where a materially identical preemption provision did not expressly say it "delegate[d] to [FDA] the authority to preempt."

Plaintiff further suggests (at 34) that anything short of notice-and-comment rulemaking lacks the force of law. Yet *Merck* confirms (in the implied-preemption context, where "force of law" is actually relevant) that a range of agency action—not just notice-and-comment rulemaking—has the force of law for preemption purposes. The Court explained that "[f]ederal law permits the FDA to communicate its disapproval of a warning" through a letter to the applicant "formally rejecting a warning label," as well as "other agency action" under a procedure where the agency must consider new information pursuant to 21 U.S.C. §355(o)(4)(A). *Merck*, 139 S.Ct. at 1679. Under the former, the agency issues a product-specific "complete response letter" to the manufacturer, which is neither subject to notice and comment nor published in the Federal Register. *See* 21 C.F.R. §314.110(a). The other statutory provision the Court cited "impose[s] on the FDA a duty to initiate a label change" if FDA becomes aware of new safety information warranting a change. *Merck*, 139 S.Ct. at 1684 (Alito, J., concurring). As elaborated by Justice Alito in a three-Justice concurrence, this statutory obligation is "highly relevant to the pre-emption analysis," because "if the FDA declines to require a label change

despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified." *Id.* at 1684-85.[10]

Applying this framework, EPA's statutory determinations of what safety warnings are required have the force of law. Congress delegated to EPA authority to conduct registration and reregistration, expressly specifying that reregistration results in "regulatory action." 7 U.S.C. §136a(a), §136a-1(b)(5). Congress prescribed detailed procedures that EPA must follow. *See, e.g.*, *id*. §136(bb), §§136a(c)(1)(F), (2)(A), (5)(C), §136a(g)(1)(A), §136a-1. And EPA seeks extensive public comment as it discharges these statutory responsibilities. *See, e.g.*, *id*. §§136a-1(c)(2), (f)(1)(B); 40 C.F.R. §155.25. Every time EPA approves a pesticide product and its labeling, Congress authorized—indeed required—the agency to determine whether the pesticide causes unreasonable adverse health effects, and whether the labeling includes all necessary health warnings. 7 U.S.C. §§136(bb), 136a(c)(5)(C). And when EPA follows these statutory procedures, its action creates binding obligations. *See Reckitt Benckiser, Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010) ("A FIFRA registration is a product-specific license describing the terms

[10] *Merck*'s examples were informed by its impossibility-preemption context, where the defendant had to establish that FDA would "reject[] a warning label" that state law required. 139 S.Ct. at 1679. Here, FIFRA preempts requirements "in addition to" what is required under FIFRA, so all that is necessary is agency action establishing the *lack* of a federal requirement to warn.

and conditions under which the product can be legally distributed, sold, and used."). If these are not agency actions with the force of law, it is hard to imagine what beyond notice-and-comment rulemaking could be. *See United States v. Mead Corp.*, 533 U.S. 218, 230-31 (2001) ("It is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force.").

A recent First Circuit decision confirms that agency product approvals have the force of law. The court held that where "FDA approved [an] updated [drug] label," and that label was "fundamentally incompatible with plaintiffs' position," the agency acted with the "force of law" supporting preemption. *In re Zofran (Ondansetron) Prod. Liab. Litig.*, 57 F.4th 327, 342 (1st Cir. 2023). Here, EPA has repeatedly approved glyphosate labeling without a cancer warning, making a statutory determination that no such warning is required. That is agency action with the force of law that is fundamentally incompatible with Plaintiff's position that a warning is required under FIFRA.

Riegel again confirms this conclusion. If "force of law" is relevant to express preemption, *Riegel* means that an agency's product-specific approval carries the force of law—otherwise, "approval" could not "impose[] device-specific 'requirements.'" 552 U.S. at 322. Just as agency label approvals can establish

device-specific requirements under the MDA, they can establish pesticide-specific requirements under FIFRA.

3. A "Miscellaneous" Provision Does Not Make EPA's Labeling Determinations Irrelevant To Preemption.

Plaintiff's main argument that EPA's actions lack the force of law (and are otherwise irrelevant to preemption) is that a "Miscellaneous" provision of FIFRA deprives them of that status. Pl.'s Br. 43-46, 49. That is, Plaintiff appears to concede that the normal hallmarks of agency action with the force of law are present, but says §136a(f)(2) *deprives* EPA's actions of the preemptive effect they would otherwise have. Similarly, Plaintiff apparently recognizes that if this Court interprets FIFRA's preemption clause the same way the Supreme Court interpreted the MDA's preemption clause, his appeal fails. Here too, §136a(f)(2) supposedly makes the difference. In other words, Plaintiff says that this clause, which is not part of FIFRA's preemption provision, requires that provision to be interpreted radically differently from other preemption provisions that are written the same way. That "Miscellaneous" clause cannot bear this substantial weight.

By its plain terms, §136a(f)(2) has nothing to do with preemption, instead addressing the defenses available in a federal enforcement action. It provides that "[i]n no event shall registration of an article be construed as a defense for the commission of *any offense under this subchapter*." (emphasis added); *see also id.* (continuing that "[a]s long as no cancellation proceedings are in effect registration

of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of this subchapter"). As the Fifth Circuit explained, "[a] claim grounded in state common law is not an offense under FIFRA," so "§136a(f)(2) does not apply," and "has no bearing" on preemption. *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 n.4 (5th Cir. 1994). While Plaintiff (at 45) argues that *Bates* superseded this aspect of *MacDonald*, *Bates* actually confirms the irrelevance of §136a(f)(2). Unlike Plaintiff, who makes §136a(f)(2) the centerpiece of his preemption analysis, *Bates* referenced it exactly once, in a "see also" citation, in the background section of the opinion. *See* 544 U.S. at 438. That passing reference hardly supports Plaintiff's notion that §136a(f)(2) upends the way FIFRA's preemption provision would otherwise operate.

Further, even if §136a(f)(2) were relevant to preemption, it says only that "registration" may not "be construed as a defense." 7 U.S.C. §136a(f)(2). In *Bates*, the defendant arguably relied on registration as a defense, but in light of EPA's waiver of efficacy review, registration did "not reflect any determination on the part of EPA" as to the labeling issues raised by the plaintiff. 544 U.S. at 440. Monsanto, by contrast, does not invoke the bare fact of registration as a defense. It invokes EPA's determinations that a cancer warning for glyphosate is not required under FIFRA, and EPA's countless approvals of glyphosate product labels without such a warning. As explained, States cannot impose requirements in addition to what is

required under FIFRA, and Congress directed EPA to "determine," *through the registration process*, whether a pesticide label has the necessary safety warnings required under FIFRA. 7 U.S.C. §136a(c)(5)(B). Nothing in §136a(f)(2) suggests that EPA's statutory labeling determination cannot establish what is required under FIFRA for preemption purposes. Indeed, EPA also makes toxicity determinations during registration; if §136a(f)(2) deprived those determinations of effect, then the Supreme Court's "CAUTION" versus "DANGER" example in *Bates* was wrong. *See supra* pp. 24-25.

Nor does §136a(f)(2) meaningfully distinguish *Riegel*. *See* Pl.'s Br. 46-47. The provision may confirm that registration "is not conclusive of FIFRA compliance," *Hardeman*, 997 F.3d at 956, but premarket approval of devices is likewise not conclusive of MDA compliance. A manufacturer may be liable for violating the terms of the product-specific premarket approval, and the mere fact such approval was granted does not prove otherwise. *See, e.g.*, *Sprint Fidelis Leads*, 623 F.3d at 1205 (claim that a device-maker "modified or failed to include FDA-approved warnings" was not preempted); *accord Reckitt Benckiser, Inc. v. Jackson*, 762 F.Supp.2d 34, 45 (D.D.C. 2011) ("Section [136a(f)(2)] stands for the unremarkable proposition that a registration is not a defense against an allegation that a product violates the terms of that registration, just as a valid driver's license is not a defense against a speeding ticket.").

Statutory context confirms that §136a(f)(2) does not have the sweeping reach Plaintiff ascribes to it. Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Yet on Plaintiff's view, §136a(f)(2) fundamentally alters the normal operation of an express-preemption provision written in familiar terms, without even mentioning preemption. That inference is all the more untenable given Congress's decision to locate §136a(f)(2) separate from FIFRA's preemption provision, under the statutory heading "Miscellaneous." Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973, 973-75; *see Fla. Dep't of Rev. v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 47 (2008) ("statutory titles and section headings are tools available for the resolution of a doubt about the meaning of a statute" (cleaned up)). And under that "Miscellaneous" heading, §136a(f)(2) sits between similarly modest provisions, which merely confirm what might otherwise have been assumed: one provides that "[i]f the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change," and the other provides that EPA "may consult with any other Federal agency" during the registration process. 7 U.S.C. §§136a(f)(1), (3). To put it mildly, that is not where one would expect to find buried the potent provision that Plaintiff describes.

The irrelevance of §136a(f)(2) to preemption is further confirmed by FIFRA's "statutory history," *i.e.*, "the enacted lineage of [the] statute"—not to be confused with "legislative history," "the proceedings leading to the enactment of a statute." *Chhetri v. United States*, 823 F.3d 577, 587 n.13 (11th Cir. 2016) (quoting Scalia & Garner, READING LAW 432, 440 (2012)). Congress enacted a predecessor of §136a(f)(2) in 1947—25 years before FIFRA even had a preemption provision. *See* Pub. L. No. 80-104, §4(c), 61 Stat. 163, 168 (1947). At that time, the Secretary of Agriculture (who originally administered FIFRA) lacked authority to refuse registration even if the pesticide did not comply with FIFRA. *Id*. That background explains the original importance of a "Miscellaneous" provision clarifying that registration shall not be construed as a defense, even if today it plays a more modest role.[11]

Finally, overreading §136a(f)(2) would nullify FIFRA's preemption provision. For decades, EPA has made pesticide-specific labeling determinations through individual registration proceedings—not rules—because "it is impossible to prescribe" by rulemaking "exact statements for all combinations of ingredients,

[11] Legislative history, to the extent the Court considers it, is in accord. When drafters added language that registration is "prima facie evidence" of FIFRA compliance, it was introduced to memorialize "an unstated premise" already "in the present Act." *Federal Environmental Pesticide Control Act: Hearings before the Subcomm. on Agric. Research and Gen. Legislation of the S. Comm. on Agric. and Forestry on H.R. 10729, Part II*, 92nd Cong. 263 (1972) (statement of E. Hertel, NACA Chairman). No one suggested that §136a(f)(2) bore any connection to preemption.

formulation types, and uses." Labeling Requirements for Pesticides and Devices, 49 Fed. Reg. 37,960, 37,965 (Sept. 26, 1984). If these agency determinations are rendered irrelevant to preemption, States would be free to impose labeling requirements in addition to or different from what EPA—acting through statutorily-mandated procedures—has concluded pesticide labels must say, so long as each jurisdiction purported to require "necessary" warnings. That would defeat Congress's goal of achieving "Uniformity," allowing "50 different labeling regimes prescribing the … wording of warnings." *Bates*, 544 U.S. at 452. Plaintiff (at 54) dismisses uniformity as a "policy point," but the policy choice was made by Congress, which specifically enacted the word "Uniformity" as the preemption provision's title. *See* Pub. L. No. 100-532, 102 Stat. 2654 (1988).

In sum, this Court should "interpret the statute as a symmetrical and coherent regulatory scheme, and fit, if possible, all parts into an harmonious whole." *F.D.A. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citations and quotation marks omitted). Section 136a(f)(2) ensures that registration is not a defense to federal enforcement when a registrant deviates from the approved label or violates one of FIFRA's many other requirements. Section 136v(b), meanwhile, ensures nationwide labeling uniformity, such that when EPA determines what safety warnings are required under FIFRA, those determinations cannot be overridden by

50 different States. That harmonious interpretation of FIFRA is the most natural one.

D. EPA Has Repeatedly Determined That A Cancer Warning For Glyphosate Is Not Required Under FIFRA, And Would Be False.

Once this Court's questions are answered, and it is recognized that EPA's labeling determinations establish the relevant requirements under FIFRA, preemption follows naturally, since EPA's position on glyphosate and the safety warnings it requires is not reasonably in dispute. As the Ninth Circuit acknowledged in the decision Plaintiff asks this Court to follow, "EPA has repeatedly approved the use of glyphosate as a pesticide, each time concluding that it is not likely to be carcinogenic to humans." *Hardeman*, 997 F.3d at 951. Unsurprisingly, EPA has also "never required a labeling warning of a cancer risk posed by Roundup." Supp.App.32 (*Hardeman* U.S. 9th Cir. Br.).

Seeking to evade this conclusion, Plaintiff raises extraneous factual arguments and asserts that every EPA action on which Monsanto relies has "been either vacated or retracted." Pl.'s Br. 2. That dramatically misstates the agency record, most of which Plaintiff simply ignores.

1. Throughout Plaintiff's Alleged Use Of Roundup®, EPA Determined That Glyphosate Does Not Cause Cancer And That Registrants Do Not Need To Warn That It Does.

Plaintiff alleges that he used Roundup® from 1986 to 2016. During this period, EPA followed the statutory procedures described above, repeatedly

examined the scientific evidence on glyphosate, concluded that it is not likely to be carcinogenic to humans, and approved myriad Roundup® labels without a cancer warning.

In 1986, for example, EPA issued a "Registration Standard" for glyphosate products. Supp.App.444-469; *see also* 40 C.F.R. §155.25 (requiring "the pesticides … for which Registration Standards are currently being developed" to be listed in the Federal Register for public comment); 51 Fed. Reg. 5,246 (Feb. 12, 1986) (listing glyphosate). As the agency explained, its "Registration Standards program involve[d] a thorough review of the scientific data base underlying a pesticide's registration," allowing it to "determine whether the pesticide meets the 'no unreasonable adverse effects' criteria of FIFRA," and identify any "[l]abeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment." Supp.App.447. In the 1986 Registration Standard for glyphosate, EPA considered cancer risks, adopted the "regulatory position" that it "will issue registrations for" glyphosate products, and prescribed labeling that did not include a cancer warning. Supp.App.448, 456.

In 1993, EPA completed its one-time statutory reregistration of glyphosate pursuant to 7 U.S.C. §136a-1. The agency's Reregistration Eligibility Decision determined that the "toxicological data base on glyphosate"—including with respect to carcinogenicity—was "adequate and … support[ed] reregistration eligibility."

Supp.App.80. Through these proceedings, EPA reached the "Regulatory Conclusion" "that glyphosate products, labeled and used as specified [by EPA], will not pose unreasonable risks or adverse effects to humans." Supp.App.127, 478. EPA directed that "[a]ll end-use glyphosate products must comply with EPA's current pesticide product labeling requirements," and imposed certain required labeling changes—again without requiring a cancer warning. Supp.App.476-477.

Throughout the 2000s, the agency reviewed updated scientific data on glyphosate and reaffirmed, in notice-and-comment rulemaking, its finding of no cancer risk in setting pesticide tolerances. *See, e.g.*, Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,935-43 (Sept. 27, 2002); Final Rule: Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008).

Consistent with this uninterrupted chain of agency determinations, EPA repeatedly approved the labeling of glyphosate-based products without a cancer warning throughout the entire period of Plaintiff's alleged use. As EPA informed the Ninth Circuit in 2019, for example, "forty-four versions of the label for the original formulation of Roundup have been accepted by EPA since 1991." Supp.App.45 (*Hardeman* U.S. 9th Cir. Br.). EPA could not lawfully have approved any of these labels unless the agency "determine[d]" that they "compl[ied] with" FIFRA's "requirement" to include any warning "necessary" to "protect health." 7 U.S.C. §§136a(c)(5)(B), 136a(c)(6), 136(q)(1)(G).

2. EPA Continues To Make The Same Determinations, Which Are Undisturbed By The Ninth Circuit's Vacatur Of An Interim Registration Review Decision.

The agency actions described above establish that throughout the period Plaintiff allegedly used Roundup®, a warning that glyphosate causes cancer was not "required under" FIFRA. Yet Plaintiff addresses none of these agency actions. Instead, Plaintiff focuses on a 2020 agency action affirming that glyphosate is not likely carcinogenic as part of the pesticide's "registration review," and the Ninth Circuit's vacatur of that decision on administrative-law grounds for lack of adequate explanation. Plaintiff does not explain how a 2022 vacatur of a 2020 decision can alter what was required under FIFRA from 1986 to 2016.

Plaintiff also misstates the legal consequences of the Ninth Circuit's decision. It is simply not correct that "whatever preemptive effect *registration* might have had has been nullified" by the vacatur. Pl.'s Br. 38 (emphasis added). As a statutory matter, "registration review" (the process that produced the decision the Ninth Circuit vacated) is distinct from "registration" and "reregistration." Indeed, "[n]o registration shall be canceled as a result of the registration review process," unless EPA follows FIFRA's separate cancellation procedures. 7 U.S.C. §136a(g)(1)(A)(v); *see also* Supp.App.616 (*NRDC* U.S. 9th Cir. Br.) ("Nothing in FIFRA makes the status of individual registrations contingent on the outcome of registration review."). The Ninth Circuit itself explained that "no disruptive

consequences will result from vacating the human-health portion of the Interim Decision because that portion simply maintained the status quo," adding that "[e]ven assuming that we could order deregistration outright, we would not do so here." *NRDC*, 38 F.4th at 52 & n.13.

Plaintiff's insistence that several decades of EPA label approvals were "nullified" by the Ninth Circuit contradicts that court's assurance that its decision disrupted nothing. And any suggestion that EPA would now require a cancer warning is refuted by EPA's reaffirmation, in September 2022, that its "underlying scientific findings regarding glyphosate, including its finding that glyphosate is not likely to be carcinogenic to humans, remain the same." Supp. App.624 (2022 Interim Decision Withdrawal).

Indeed, individual glyphosate products continue to come before EPA, and EPA continues to approve their labels. Since September 2022, EPA has registered at least four glyphosate products and approved over a dozen glyphosate product labels—all without cancer warnings. *See* EPA, *Chemical Name: Glyphosate*, https://perma.cc/39Y2-P24M. Again, EPA could not lawfully approve these labels without determining that they include all safety warnings required under FIFRA.

3. EPA Confirmed To Registrants That A Cancer Warning Would Make Their Products Misbranded, And Has Never "Retracted" That Confirmation.

In 2019, EPA issued a letter to all registrants of glyphosate products, stating that "[g]iven EPA's determination that glyphosate is 'not likely to be carcinogenic to humans,'" a warning that it causes cancer would be a "false and misleading statement" and make the product "misbranded" in violation of FIFRA. Supp.App.11. An EPA determination that a cancer warning *violates* FIFRA is not necessary to establish preemption, because it suffices that a cancer warning is not *required* under FIFRA. Nonetheless, the obligation not to make a false or misleading statement on a pesticide's labeling is itself a FIFRA requirement and a separate basis for preemption. EPA's long record of determinations that glyphosate does not cause cancer establishes that a cancer warning is false and violates FIFRA, and EPA's 2019 letter confirms what has long been apparent from the agency record. To the extent it matters whether a letter to all registrants of glyphosate products mandating the contents of their labels has the force of law, it is an exercise of EPA's authority to determine whether pesticide labels comply with FIFRA, and is comparable to the FDA's "complete response letters" that *Merck* held have the force of law. 139 S.Ct. at 1679.[12]

[12] Plaintiff errs in suggesting (at 50-51) that the 2019 letter somehow relied on the subsequently-vacated 2020 Interim Registration Review Decision. As EPA conducted its review of glyphosate as an active ingredient, it continuously had to

EPA did not, as Plaintiff asserts (at 2, 25, 49, 50, 61), "retract" its 2019 letter. To the contrary, in the 2022 letter Plaintiff invokes, EPA explained that it "continues to stand behind its robust scientific evaluation of the carcinogenic potential of glyphosate." App.119. EPA described its 2019 letter as follows: "The Agency concluded that the standard warning language for products containing glyphosate was false or misleading and therefore, any glyphosate products bearing the statement would be considered misbranded." *Id*. Nowhere does the 2022 letter suggest a change in what "the Agency concluded" about "standard warning language for products containing glyphosate." EPA's characterization of the 2019 letter as an "agency conclusion" also refutes Plaintiff's quibble (at 49-50) that it was signed by "a subordinate agency official."

Rather than retract anything, EPA's 2022 letter stated that it "could approve" language stating that IARC has "classified glyphosate as probably carcinogenic to humans" *and* that "US EPA has determined that glyphosate is not likely to be carcinogenic to humans." App.119. Plaintiff demands a cancer *warning*, not this informational statement, so it is irrelevant to his claim. *See* App.20-25. And nowhere has EPA suggested that the language it "could approve" is *required* under FIFRA, which is the critical question for express preemption.

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make labeling determinations for individual glyphosate-based pesticide products. In writing to registrants "concerning label and labeling requirements for products that contain glyphosate," EPA discharged those statutory responsibilities. Supp.App.11.

4. Plaintiff's Assertions About Roundup®'s Formulation And Testing Are Irrelevant To Preemption.

Plaintiff's remaining arguments are distractions. *First*, the Court should disregard Plaintiff's argument (at 44) that "EPA's registration of glyphosate did not assess the health risks of glyphosate-based formulations like Roundup." It is irrelevant to this case, because Plaintiff's complaint alleges that the danger of Roundup® concerns "specifically, the active ingredient glyphosate," not its formulation. App.31-32. The argument is also waived, because Plaintiff's briefs before the panel drew no distinction between glyphosate and formulated Roundup®. *See United States v. Campbell*, 26 F.4th 860, 871 (11th Cir. 2022) (en banc) ("[t]ypically, issues not raised in the initial brief on appeal are deemed abandoned" for purposes of en banc proceedings, absent "extraordinary circumstances").

In any event, Plaintiff is wrong. EPA has a statutory obligation to determine whether a "pesticide," not just its active ingredient, causes unreasonable adverse health effects. 7 U.S.C. §136a(a); *see id.* §136(u) ("'pesticide' means (1) any substance *or mixture of substances* intended for preventing, destroying, repelling, or mitigating any pest" (emphasis added)). It adheres to that obligation: "[t]he registration … of pesticide products under FIFRA include[s] a determination that the pesticide product formulation meets the registration standard under FIFRA section 3 … The entire formulation, including the inert ingredients, must meet this standard." EPA, *Pesticide Registration Manual: Chapter 8 – Inert Ingredients*,

https://perma.cc/82R8-7VEW; *see also* Supp.App.448 (1986 Registration Standard) ("[T]he Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient."); Supp.App.504-597 (2009 Surfactant Approval) (approval of inert ingredients in Roundup®, addressing toxicity and lack of carcinogenicity). And EPA must specifically approve the labeling of each individual pesticide product formulation.

Second, Plaintiff's assertion (at 53-54) that "Monsanto never has tested Roundup properly" does not "counsel[] against preemption." EPA could have requested more testing—indeed it was required to do so if it deemed it necessary to determine FIFRA compliance. *See* 7 U.S.C. §§136a(c)(2)(B), (g)(2), 136a-1(b)(4); 40 C.F.R. §158.75. No party to this litigation is "the arbiter of which data and information is or is not 'material' …—the [agency], and only the [agency], can determine what information is 'material' to its own decision." *In re Avandia Mktg., Sales & Prod. Liab. Litig.*, 945 F.3d 749, 759 (3d Cir. 2019).[13]

E. A State-Law Requirement To Warn That Glyphosate Causes Cancer Is "In Addition To Or Different From" Requirements Under FIFRA.

Applying the legal principles established above to EPA's long record of agency action concerning glyphosate, Plaintiff's claim is preempted. He rightly does

[13] It is unclear what significance to preemption Plaintiff ascribes to his discussion of Dr. Parry (at 9-12, 55), but these allegations have also been presented to EPA. Supp.App.424-425, 429 (EPA, Jan. 2020 Response from the Pesticide Re-Evaluation Division to Comments on the Glyphosate Proposed Interim Decision).

not dispute that his failure-to-warn claim seeks to enforce a state-law labeling requirement. *See Bates*, 544 U.S. at 434, 446. That requirement is both "in addition to" and "different from" what is required under FIFRA.

"In addition to." EPA's pesticide-specific labeling determinations establish what is required under FIFRA, and EPA "has never required a labeling warning of a cancer risk posed by Roundup." Supp.App.32 (*Hardeman* U.S. 9th Cir. Br.). For this straightforward reason, a state-law requirement to warn that glyphosate causes cancer is "in addition to" what is required under FIFRA. When a manufacturer declines to give a warning that EPA, exercising its statutory authority, has determined is not required under FIFRA, it is not "liable for misbranding as defined by FIFRA," so it "should not be held liable under a state labeling requirement" to give that warning. *Bates*, 544 U.S. at 454. A state-law claim for failure to provide such a warning does far more than "enforce federal misbranding requirements," which is all state law may do. *Id.* at 451.

Plaintiff's reliance on the Solicitor General's brief in *Hardeman* is unpersuasive. According to the Solicitor General, "EPA's approval of pesticide labeling without a chronic-risk warning is not naturally characterized as a FIFRA 'requirement' *that no such warning appear*." Pl.'s Br. 43 (emphasis added). In fact, there is a requirement that no such warning appear, because EPA has determined it would be false and misleading. *See supra* pp. 11-12, 47-48. But more importantly,

under *Bates*'s "parallel requirements" interpretation of §136v(b), preemption does not depend on a federal requirement "that no warning appear." Even assuming EPA would *permit* a cancer warning, the key point—which the Solicitor General did not and could not dispute—is that EPA has long determined there is no federal requirement *to* warn. "Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005).

Indeed, the Solicitor General's argument is virtually identical to the one *Riegel* rejected. The *Riegel* plaintiffs noted that premarket approval "does not lock the manufacturer into a particular label," since it can "seek FDA permission to alter the labeling" in order to "strengthen[] warnings." Petrs' Br., *Riegel v. Medtronic, Inc.*, 2007 WL 2456946, at *30-31 (U.S. Aug. 27, 2007). For that reason, the plaintiffs maintained, premarket approval "did not impose device-specific labeling requirements." *Id.* at *31. That argument failed. Even if there was no federal requirement *not* to warn, premarket approval still established what *was required* under the MDA, and States were prohibited from imposing requirements "in addition" to what the agency determined was required. *See supra* 25-26, 28-29. For

the same reason the *Riegel* plaintiffs misread the MDA, the Solicitor General misreads FIFRA.[14]

"Different from." A state-law requirement to warn that glyphosate causes cancer is also "different from" requirements under FIFRA, because providing such a warning would *violate* the statute. FIFRA prohibits registrants from making statements on a pesticide's labeling that are "false or misleading," 7 U.S.C. §136(q)(1)(A), and from unilaterally deviating from the EPA-approved labeling, *id.* §136j(a)(1)(B). EPA has consistently determined that glyphosate does *not* cause cancer, so it would violate FIFRA's requirements for Monsanto to warn that glyphosate *does* cause cancer. *Supra* pp. 42-29. Indeed, in light of EPA's scientific determination, it had a duty to reject any labeling change that included the false statement that glyphosate causes cancer. *See* 40 C.F.R. §152.112(f). A state-law requirement to do the opposite of what FIFRA requires is "different from" requirements under FIFRA.

[14] The United States previously interpreted FIFRA's preemption provision correctly, *see* Supp.App.33-46 (*Hardeman* U.S. 9th Cir. Br.), but informed the Supreme Court it switched positions "[i]n light of … the change in Administration," App.133. These shifting interpretations are irrelevant to the interpretation of §136v(b), which is for this Court to decide. What is relevant, and has not changed, is EPA's determination, pursuant to statutory mandate, that no cancer warning is required under FIFRA.

II. Impossibility Preemption Independently Bars Plaintiff's Failure-to-Warn Claim.

A. Impossibility Preemption Applies.

State law is preempted "where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (citation omitted). This applies, for instance, in the context of brand-name drug manufacturers, who under limited circumstances can unilaterally add a new safety warning to a drug's labeling, subject to the FDA's "authority to reject labeling changes." *Wyeth*, 555 U.S. at 571. Where FDA would reject a change, it is impossible to comply with a state-law requirement to make it, so preemption applies. *Merck*, 139 S.Ct. at 1672, 1676. It is even more difficult to change a pesticide label; safety warnings cannot be added unilaterally, but only with EPA approval. *Supra* pp. 7-8; *see PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it.'"). At minimum, though, under *Wyeth* and *Merck*, a state-law requirement to make a pesticide labeling change is preempted where EPA would reject that change.

Plaintiff errs (at 61) in arguing that these principles are categorically inapplicable to pesticides because "FIFRA has an express preemption provision." An "express pre-emption provision" does not "bar the ordinary working of conflict preemption principles." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-72

(2000). Nor does it help Plaintiff that FIFRA recognizes "a state's authority 'to regulate the sale and use of pesticides' and 'to ban the sale of a pesticide that it finds unsafe.'" Pl.'s Br. 59-60 (quoting *Pilliod*, 282 Cal. Rptr. 3d at 701). That authority does not extend to labeling and packaging. *See* 7 U.S.C. §136v(b). Further, even when States regulate sale or use, they may do so only "to the extent the regulation does not permit any sale or use prohibited by this subchapter." 7 U.S.C. §136v(a). That is consistent with ordinary principles of impossibility preemption, under which state law may not compel private parties to violate federal law.

Plaintiff correctly observes (at 60) that "*Bates* did not conduct an implied-preemption analysis." But it does not follow that *Bates foreclosed* an implied-preemption analysis. The Court simply "decline[d] to address respondent's argument that petitioners' claims are subject to other types of pre-emption." 544 U.S. at 458 (Thomas, J., concurring in part and dissenting in part). "Questions which merely lurk in the record … are not to be considered as having been … decided[.]" *Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 170 (2004). In any event, the argument for impossibility preemption here is different, and stronger, than in *Bates*. In *Bates*, there could have been no clear evidence EPA would reject the efficacy warning sought, because EPA had waived efficacy review. *See* 544 U.S. at 440. That is very different from a situation where state law requires a cancer warning that EPA has determined would be false and misleading in violation of federal law.

B. Monsanto Cannot Provide Plaintiff's Desired Cancer Warning Without Violating Federal Law.

Federal law prohibits Monsanto from unilaterally adding a warning that glyphosate causes cancer, and EPA would not and could not approve such a warning. Accordingly, it is impossible for Monsanto to comply with a state-law requirement to provide that warning.

Under *Merck*, impossibility preemption applies where: (i) the agency was "fully informed" of "the justifications for the warning" the plaintiff demands; (ii) the agency has "informed the … manufacturer that [it] would not approve changing the … label to include that warning"; and (iii) the agency's action is "taken pursuant to … congressionally delegated authority" such that it "carr[ies] the force of law." 139 S.Ct. at 1678-79. Clear evidence in this context is "a matter of law for the judge to decide." *Id.* at 1679.

1. EPA was "fully informed" of "the justifications for the warning required by state law." *Id.* at 1678. As described above, the agency has repeatedly undertaken in-depth scientific reviews of the evidence on glyphosate's safety, concluding it is not likely carcinogenic. *See, e.g.*, Supp.App.80-127 (1993 Reregistration Eligibility Decision) (listing over 250 studies EPA relied upon in reregistering glyphosate). EPA has "considered a more extensive dataset than IARC," the organization whose cancer assessment is central to Plaintiff's claim. Supp.App.11 (2019 EPA Letter). Moreover, Plaintiff's assertion (at 62) that Monsanto "declined to test Roundup as

formulated" misses the point. One can always hypothesize more testing, but it is EPA that decides whether the data is sufficient to support its statutorily-required safety and labeling determinations. *See supra* pp. 50-51.

2. EPA has "informed" registrants of glyphosate-based products—including Monsanto—that it "would not approve changing … the label to include [a cancer] warning." *Merck*, 139 S.Ct. at 1678-79. It has long been clear that EPA would not approve a cancer warning. In 1993, for example, EPA concluded that glyphosate met the requirements for reregistration under FIFRA, relying on its 1991 decision "classif[ying] glyphosate in Group E (evidence of non-carcinogenicity for humans)." Supp.App.84. In determining that glyphosate is likely non-carcinogenic, EPA could not have approved a warning stating the opposite. A false warning makes a pesticide misbranded under FIFRA, *see* 7 U.S.C. §136(q)(1)(A), and EPA may not register a pesticide that violates FIFRA's misbranding prohibition, *see id.* §136a(c)(5)(b). *Accord Zofran*, 57 F.4th at 342 ("[W]hen the FDA formally approves a label stating one thing with full and obvious notice of the directly contrary position, one can read the approval as rejecting the contrary position."). That straightforward conclusion was confirmed by EPA's 2019 determination that a cancer warning for glyphosate would be a "false and misleading statement" in violation of FIFRA. Supp.App.11.

Plaintiff's reliance (at 61-62) on EPA's 2022 letter is misplaced. As explained, Plaintiff mischaracterizes that letter. *Supra* pp. 47-49. Further, whether

EPA would approve language that reports IARC's and EPA's respective positions is irrelevant to Plaintiff's claim. Plaintiff complains not that Roundup® lacked such informational language, but that he was not warned of "the carcinogenic characteristics of glyphosate." App.33. That is the type of "standard warning language" EPA has said, without retraction, is "false or misleading." App.119 (EPA 2022 Letter). Nor would it have made sense for Plaintiff to complain that he was not alerted to IARC's 2015 determination, which post-dates 29 out of 30 years of his alleged Roundup® use.

3. For the reasons explained above, EPA's determinations that glyphosate does not cause cancer, and that no cancer warning is either required or allowed under FIFRA, carry the force of law. *See supra* pp. 32-36. It is hard to imagine more formal agency procedures than those EPA has used to make those determinations. And even if §136a(f)(2) prevented EPA's labeling determinations from establishing a pesticide's compliance with FIFRA for purposes of express preemption, *but see supra* pp. 36-42, it would provide no reason to ignore EPA's actions as clear evidence that EPA would *reject* a cancer warning.

If Monsanto had unilaterally altered the Roundup® label to issue a cancer warning it knew EPA considered false, it would have risked severe civil and criminal penalties for committing federal misbranding offenses. Under the Supremacy Clause, a state-law duty to violate federal law is preempted.

CONCLUSION

This Court should affirm the district court's judgment.

Respectfully submitted,

Dated: March 15, 2023

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), it contains 12,983 words.

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point, Times New Roman font.

/s/ *David M. Zionts*

CERTIFICATE OF SERVICE

I hereby certify that on March 15, 2023, I caused the foregoing document to be electronically filed with the United States Court of Appeals for the Eleventh Circuit using the appellate CM/ECF System for filing and transmittal of a Notice of Electronic Filing to counsel of record.

/s/ *David M. Zionts*

ADDENDUM

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7 U.S.C. § 136 Definitions

For purposes of this subchapter—

* * *

(p) Label and labeling

(1) Label
The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling
The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

* * *

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

* * *

(bb) Unreasonable adverse effects on the environment

The term "unreasonable adverse effects on the environment" means (1) any

unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

7 U.S.C. § 136a Registration of pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

* * *

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

* * *

(c) Procedure for registration

(2) Data in support of registration

(A) In general

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

* * *

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines

that, when considered with any restrictions imposed under subsection (d)—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

* * *

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the

commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

(3) Authority to consult other Federal agencies

In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

* * *

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations
In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review
The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of—

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) Cancellation

No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

* * *

7 U.S.C. § 136a-1 Reregistration of registered pesticides

(b) Reregistration phases

Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator.

7 U.S.C. § 136j Unlawful acts

(a) In general

(1) Except as provided by subsection (b) of this section, it shall be unlawful for any person in any State to distribute or sell to any person—

(A) any pesticide that is not registered under section 136a of this title or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this subchapter;

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this title;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 136a of this title;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 136w(c)(5) of this title;

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

* * *

7 U.S.C. § 136v Authority of States

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

* * *

21 U.S.C. § 355 New drugs

(o) Postmarket studies and clinical trials; labeling

(4) Safety labeling changes requested by Secretary

(A) New safety or new effectiveness information

If the Secretary becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the Secretary determines should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under subsection (b) is not currently marketed, the holder of an approved application under subsection (j).

* * *

40 C.F.R. § 152.44 Application for amended registration.

(a) Except as provided by § 152.46, any modification in the composition, labeling, or packaging of a registered product must be submitted with an application for amended registration. The applicant must submit the information required by § 152.50, as applicable to the change requested. If an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold.

(b) In its discretion, the Agency may:

> (1) Waive the requirement for submission of an application for amended registration;
>
> (2) Require that the applicant certify to the Agency that he has complied with an Agency directive rather than submit an application for amended registration; or
>
> (3) Permit an applicant to modify a registration by notification or non-notification in accordance with § 152.46.

(c) A registrant may at any time submit identical minor labeling amendments affecting a number of products as a single application if no data are required for EPA to approve the amendment (for example, a change in the wording of a storage statement for designated residential use products). A consolidated application must clearly identify the labeling modification(s) to be made (which must be identical for all products included in the application), list the registration number of each product for which the modification is requested, and provide required supporting materials (for example, labeling) for each affected product.

40 C.F.R. § 152.46 Notification and non-notification changes to registrations.

(a) Changes permitted by notification.

(1) EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished by notification to the Agency, without requiring that the registrant obtain Agency approval. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of modifications permitted by notification and any conditions and procedures for submitting notifications.

(2) A registrant may modify a registration consistent with paragraph (a)(1) of this section and any procedures issued thereunder and distribute or sell the modified product as soon as the Agency has received the notification. Based upon the notification, the Agency may require that the registrant submit an application for amended registration. If it does so, the Agency will notify the registrant and state its reasons for requiring an application for amended registration. Thereafter, if the registrant fails to submit an application the Agency may determine that the product is not in compliance with the requirements of the Act. Notification under this paragraph is considered a report filed under the Act for the purposes of FIFRA section 12(a)(2)(M).

(b) Changes permitted without notification. EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished without notification to or approval by the Agency. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of amendments permitted without notification (also known as non-notification). A registrant may distribute or sell a product changed in a manner consistent with such procedures without notification to or approval by the Agency.

(c) Effect of non-compliance. Notwithstanding any other provision of this section, if the Agency determines that a product has been modified through notification or without notification in a manner inconsistent with paragraphs (a) or (b) of this section and any procedures issued thereunder, the Agency

may initiate regulatory and/or enforcement action without first providing the registrant with an opportunity to submit an application for amended registration.

40 C.F.R. § 152.112 Approval of registration under FIFRA sec. 3(c)(5).

EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:

* * *

(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;

* * *

40 C.F.R. § 155.25 Schedule.

EPA will issue annually in the Federal Register a notice listing the pesticides (or groups of pesticides) for which Registration Standards are currently being developed. The list will include pesticides for which a Registration Standard is scheduled for issuance within the next year, and the approximate sequence of issuance. The list may also include pesticides for which a Registration Standard will be under development during the upcoming year, but which are not scheduled for issuance until the succeeding year. The notice will invite comment and submission of information on the individual pesticides on the list.

40 C.F.R. § 155.58 Procedures for issuing a decision on a registration review case.

(a) The Agency will publish a notice in the Federal Register announcing the availability of a proposed registration review decision or a proposed interim registration review decision. At that time, the Agency will place in the pesticide's registration review docket the Agency's proposed decision and the bases for the decision. There will be a comment period of at least 60 calendar days on the proposed decision.

(b) In its proposed decision, the Agency will, among other things:

(1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.

(2) Identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements.

(3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or final interim decision on a registration review case.

(4) Specify proposed labeling changes; and

(5) Identify deadlines that it intends to set for completing any required actions.

(c) After considering any comments on the proposed decision, the Agency will issue a registration review decision or interim registration review decision. This decision will include an explanation of any changes to the proposed decision and the Agency's response to significant comments. The Agency will publish a notice in the Federal Register announcing the availability of a registration review decision or interim registration review decision. The registration review case docket will remain open until all actions required in the final decision on the registration review case have been completed.

(d) If the registrant fails to take the action required in a registration review decision or interim registration review decision, the Agency may take appropriate action under FIFRA.

40 C.F.R. § 156.10 Labeling requirements

(a) *General—*

(1) *Contents of the label.* Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

* * *

(a) *General—*

(2) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as “safe,” “nonpoisonous,” “noninjurious,” “harmless” or “nontoxic to humans and pets” with or without such a qualifying phrase as “when used as directed”; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

* * *

(i) *Directions for Use—*

(1) *General requirements—*

(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

* * *

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Worker protection statements meeting the requirements of subpart K of this part.

(ix) Specific directions concerning the storage, residue removal and disposal of the pesticide and its container, in accordance with subpart H of this part. These instructions must be grouped and appear under the heading, "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See table in §156.60(b))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) For total release foggers as defined in §156.78(d)(1), the following statements must be included in the "Directions for Use."

* * *

(j) *Statement of use classification.* Any pesticide product for which some uses

are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.*

(A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

40 C.F.R. § 156.60 General.

Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) *Location of statements—*

(1) Front panel statements. The signal word, child hazard warning, and, in certain cases, the first aid statement are required to appear on the front panel of the label, and also in any supplemental labeling intended to accompany the product in distribution or sale.

(2) Statements elsewhere on label. Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, a Note to Physician, and physical or chemical hazard statements.

(b) *Placement and prominence—*

(1) Front panel statements. All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

* * *

40 C.F.R. § 156.62 Toxicity Category.

This section establishes four Toxicity Categories for acute hazards of pesticide products, Category I being the highest toxicity category. Most human hazard, precautionary statements, and human personal protective equipment statements are based upon the Toxicity Category of the pesticide product as sold or distributed. In addition, toxicity categories may be used for regulatory purposes other than labeling, such as classification for restricted use and requirements for child-resistant packaging. In certain cases, statements based upon the Toxicity Category of the product as diluted for use are also permitted. A Toxicity Category is assigned for each of five types of acute exposure, as specified in the table in this paragraph.

Acute Toxicity Categories for Pesticide Products

Hazard Indicators	**I**	**II**	**III**	**IV**
Oral LD_{50}	Up to and including 50 mg/kg	>50 thru 500 mg/kg	>500 thru 5,000 mg/kg	>5,000 mg/kg
Dermal LD_{50}	Up to and including 200 mg/kg	>200 thru 2000 mg/kg	>2000 thru 20,000 mg/kg	>20,000 mg/kg
Inhalation LC_{50}	Up to and including 0.2 mg/liter	>0.2 thru 2 mg/liter	>2 thru 20 mg/liter	>20 mg/liter
Eye irritation	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin irritation	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

40 C.F.R. § 156.64 Signal word.

(a) Requirement. Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal word, reflecting the highest Toxicity Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in § 156.62. The signal word must also appear together with the heading for the human precautionary statement section of the labeling (see § 156.70).

(1) Toxicity Category I. Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word "DANGER." In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word "Poison" must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word "Poison."

(2) Toxicity Category II. Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word "WARNING."

(3) Toxicity Category III. Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word "CAUTION."

(4) Toxicity Category IV. A pesticide product meeting the criteria of Toxicity Category IV by all routes of exposure is not required to bear a signal word. If a signal word is used, it must be "CAUTION."

(b) Use of signal words. In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

40 C.F.R. § 156.70 Precautionary statements for human hazards

(a) *Requirement.* Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading "Precautionary Statements" and under appropriate subheadings similar to "Humans and Domestic Animals," "Environmental Hazards" (see subpart E of this part) and "Physical or Chemical Hazards." The phrase "and Domestic Animals" may be omitted from the heading if domestic animals will not be exposed to the product.

(b) *Content of statements.* When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph must be immediately preceded by the appropriate signal word.

(c) *Typical precautionary statements.* The table below presents typical hazard and precautionary statements. Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. With Agency approval, statements may be augmented to reflect the hazards and precautions associated with the product as diluted for use. Refer to §156.68(b) for requirements for use dilution statements.

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