No. 24-1068

In the Supreme Court of the United States

MONSANTO COMPANY, PETITIONER

v.

JOHN L. DURNELL, RESPONDENT

ON WRIT OF CERTIORARI TO THE MISSOURI COURT OF APPEALS

BRIEF FOR THE RESPONDENT

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QUESTIONS PRESENTED

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prohibits the sale or distribution of a pesticide that is "not registered" with EPA. 7 U.S.C. § 136j(a)(1)(A). FIFRA delegates to EPA significant powers in the registration process. EPA is required to make various determinations, including whether a pesticide's label complies with FIFRA. 7 U.S.C. § 136a(c)(5)(B). Those determinations control only whether EPA "shall register" the pesticide. They do not impose new statutory requirements for labeling.

FIFRA imposes an independent prohibition on the sale or distribution of any "misbranded" pesticide. 7 U.S.C. § 136j(a)(1)(E). A pesticide can be misbranded because its label is inadequate. 7 U.S.C. § 136(q)(1)(A), (G). Unlike the registration requirement, the misbranding prohibition does not vest EPA with *any* delegated authority to interpret or implement the statutory ban on selling or distributing misbranded products. And FIFRA explicitly states that compliance with FIFRA's *registration* requirements is no defense when a pesticide manufacturer is sued for selling or distributing a *misbranded* product. *See* 7 U.S.C. § 136a(f)(2) ("In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter.").

Respondent John Durnell contracted cancer after using Roundup and sued Monsanto for failing to warn him of the risks. Monsanto claims that Durnell's failure-to-warn claim is preempted under 7 U.S.C. § 136v(b), which displaces state-law labeling requirements that are "in addition to or different from" those required by FIFRA. Durnell claims that Missouri failure-to-warn law imposes

the same requirements as FIFRA's textual prohibition on selling a misbranded pesticide. Monsanto relies not on FIFRA's text, but EPA's registration decision to argue a difference between Missouri and federal law. So Monsanto must believe that section 136a(c)(5) vests EPA with *Chevron*-like powers to interpret the ultimate meaning of the statutory "misbranding" prohibition in a manner that binds the judiciary. The questions presented are:

1. Is Durnell's failure-to-warn claim expressly preempted on the ground that Missouri law imposes labeling requirements that add to or differ from the misbranding provisions in FIFRA?

2. Is Durnell's failure-to-warn claim impossibility preempted on the ground that federal law requires Monsanto to use the Roundup labeling that Missouri law deems misleading or inadequate?

PARTIES TO THE PROCEEDING

Petitioner Monsanto Company was the appellant in the Missouri Court of Appeals. Respondent John L. Durnell was the appellee.

Monsanto's stock-ticker symbol was MON, which traded on the New York Stock Exchange (NYSE) until June 7, 2018. On that date, Monsanto was acquired by Bayer and subsequently delisted, and its operations were integrated into Bayer's Crop Science division. Bayer AG's primary stock-ticker symbol in the United States is BAYRY, which represents its American Depositary Receipt (ADR) traded on the OTCQX market in USD. In its home market (Germany), the stock trades on the XETRA exchange under the ticker BAYN.

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BRIEF FOR THE RESPONDENT

In a typical civil case, judges announce the law and juries determine the facts. If Congress wants to adjust that paradigm and empower a federal bureaucrat to act as judge, jury, and executor, it must say so expressly. FIFRA does not. To the contrary, it textually reinforces the traditional role of the judiciary. In this case, a properly empaneled jury made factual findings that Roundup caused Mr. Durnell's cancer and failed to warn him of that risk. On those facts, it further concluded that Roundup was unlawful to sell under Missouri common law that tracks FIFRA's misbranding standards. Those straightforward points resolve this appeal.

There is no affirmative right to sell pesticides. Instead, FIFRA makes it "*unlawful*" to "distribute or sell" "any pesticide" when one of five conditions is met. 7 U.S.C. § 136j(a)(1)(A)–(E) (emphasis added). Any one of those

conditions is sufficient to trigger a ban. The first prohibition forbids the distribution or sale of a pesticide that is not registered by EPA. *See* 7 U.S.C. § 136j(a)(1)(A). FIFRA delegates to the EPA Administrator significant powers over registration, including the authority to evaluate evidence and make factual determinations about safety. *See* 7 U.S.C. § 136a(c)(5)(A)–(D). Challenges to registration decisions are judicially reviewed deferentially and must be affirmed when based on substantial evidence. *See* 7 U.S.C. §§ 136a(c)(6), 136d, 136n(b).

Even if a pesticide *is* registered, however, a manufacturer *still* must not distribute or sell it for four independent reasons,[1] including that it is "misbranded." 7 U.S.C. § 136j(a)(1)(E); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 438 (2005) (a pesticide can be "registered but nevertheless misbranded"). A pesticide is "misbranded," in turn, if it falls afoul of any of a dozen independent safeguards. At least two are implicated here. First, a pesticide is misbranded if its label "bears any statement … which is false or misleading in any particular." 7 U.S.C. § 136(q)(1)(A). Second, a pesticide is misbranded if its label "does not contain a warning or caution statement which may be necessary and if complied with … is adequate to protect health and the environment." § 136(q)(1)(G).

This Court held over 20 years ago that state failure-to-warn law that imposes civil liability for selling a misbranded pesticide is not preempted. *Bates,* 544 U.S. at 447 ("[A] state-law labeling requirement is not pre-empted by [FIFRA's express preemption provision] if it is equivalent to, and fully consistent with, FIFRA's misbranding pro-

1. *See* 7 U.S.C. § 136j(a)(1)(B)–(E).

visions."). And *Bates* holds that state law is "fully consistent" with FIFRA if it targets a label's "false or misleading statements" or "inadequate instructions or warnings." 544 U.S. at 447 (cleaned up).

The reasoning is straightforward: Federal law forbids those things, too. And where both sovereigns forbid the same conduct, state law is not "in addition to or different from"[2] federal law, and there is no "logical contradiction" between the sovereign commands. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 319 (2019) (Thomas, J., concurring). Both laws must be obeyed.

That is the situation here. Missouri law has long imposed "a duty on the manufacturer not to introduce into commerce an unreasonably dangerous product" because of its "failure to warn of danger." *Racer v. Utterman,* 629 S.W.2d 387, 395 (Mo. Ct. App. 1981). So state and federal law lay down parallel rules. State law forbids the sale of a pesticide without a truthful and "adequate warning." *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. 2011). Federal law prohibits selling a pesticide with a misleading or "inadequate warning[]." *Bates*, 544 U.S. at 451. Barring an outright copy-and-paste, it would be hard to have less daylight escape between the legal standards established by state and federal law.

The facts relevant to applying *Bates* in this case have all been conclusively established by a jury. Durnell used Monsanto's flagship pesticide, Roundup, for decades. Though Monsanto protests that its product is safe, the jury found that Roundup increases the risk of cancer, caused Durnell to develop cancer, and never warned Durnell of this risk. Monsanto was therefore liable on Dur-

2. 7 U.S.C. § 136v(b).

nell's failure-to-warn claim. Monsanto does not contest that the jury's verdict rests on substantial evidence.

The jury's findings conclusively establish for purposes of this case that Roundup is misbranded under federal law. A label that lists carcinogens without identifying them as such is "misleading." 7 U.S.C. § 136(q)(1)(A). A cancer-causing pesticide that "does not contain" a cancer warning omits information "necessary" to protect "health and the environment." 7 U.S.C. § 136(q)(1)(G). The jury's verdict accordingly enforces a state-law duty not to sell a dangerous pesticide that "parallel[s]" the federal duty under FIFRA's misbranding provisions. *Bates*, 544 U.S. at 447.

So how, then, does Monsanto gin up the putative conflict of law necessary to implicate the Supremacy Clause? Monsanto rests its preemption defense on the EPA Administrator's factual finding (during the registration process) that Roundup is safe—and argues that this registration decision decisively controls whether a pesticide is "misbranded" under federal law. Pet. Br. 35.

Monsanto's maneuver does not withstand scrutiny. Whether Roundup is misbranded turns on both a question of fact: does Roundup cause cancer?; and a question of law: is a cancer-causing pesticide that fails to warn of this risk "inadequate" or misleading? *Bates*, 544 U.S. at 451. The question of fact is one over which reasonable people—such as the jurors and the EPA Administrator—can disagree. But absent an *express statutory delegation*, the Administrator's factual findings are not "laws of the United States" that Congress "made in pursuance" of the Constitution. U.S. Const. art. VI, cl. 2. The Supremacy Clause does not of its own force anoint Lee Zeldin the

supreme arbiter of scientific truth with a veto over a Missouri jury. The Administrator's factual findings during the registration process are good for registration only. They do not create non-mutual collateral estoppel in Durnell's civil action.

On the question of law, Monsanto and the Solicitor General cannot argue that *if* Roundup causes cancer, but lacks a cancer warning, it is anything other than the textbook example of a misbranded pesticide. EPA has never offered that interpretation of the relevant congressional definitions. And even if EPA had adopted that interpretation, it would not bind the Missouri jury because not one word of FIFRA's text delegates power to the Administrator to "give meaning to" these statutory provisions. *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 394 (2024). There is similarly no provision of FIFRA that requires judges or juries to defer to the Administrator's determination that a pesticide complies with (or violates) the misbranding prohibition.

Yet the *only* way that Monsanto can prevail is by showing that FIFRA delegates *Chevron*-like powers to EPA, allowing the Administrator—not judges and juries—to conclusively interpret the law and find the facts necessary to ascertain whether a pesticide is "misbranded." Monsanto has not even attempted to make this showing in its opening brief. It simply assumes that the Administrator has these sweeping powers, spending page after page begging the relevant question. And Monsanto cannot show that FIFRA delegates these powers to EPA because it faces two insuperable obstacles.

The first is *Loper Bright*. Courts no longer assume that agencies rather than courts hold delegated powers to

render binding interpretations of federal statutes. So Monsanto must point to *statutory text* that vests EPA with the authority to render universally binding interpretations of "misbranding," as well as the power to bind juries to its factual conclusion that Roundup is *not* misbranded. There is nothing in FIFRA that remotely suggests EPA can bind the judiciary on these points.

The second insurmountable obstacle is that FIFRA contains numerous provisions that expressly reconfirm the default rule. Most notably, 7 U.S.C. § 136a(f)(2) makes clear that EPA's decision to register a pesticide is *not* a "defense for the commission of any offense under this subchapter." This proves that EPA's decision to approve a label during the registration process does not definitively answer any factual or legal questions in a civil action that parallels the misbranding prohibition. A jury may consider the Administrator's determinations only as "prima facie evidence." 7 U.S.C. § 136a(f)(2). It is not obliged to treat them as pronouncements *ex cathedra*.

Monsanto's implied-preemption claim is equally unavailing. Monsanto claims that "federal law" compels it to continue using the labels that EPA approved during the registration process. But that is patently false. FIFRA imposes no such requirement, and EPA's own regulations—even assuming they are valid—authorized unilateral label changes without agency preapproval. Monsanto knows this well, as its own parent company unilaterally added a cancer warning to a pesticide label in 2012.

In any event, Monsanto's ability to unilaterally change the label is not determinative. Though EPA purports to arrogate lawmaking power to itself, exclaiming that "the

label is the law!"[3] does not make it so. The *actual* law is the written text of FIFRA, which flatly requires a manufacturer to stop selling a misbranded pesticide. That duty is the same one imposed by Missouri law. It is not impossible to simultaneously obey identical commands.

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions are included in the appendix.

STATEMENT

I. STATUTORY AND REGULATORY BACKGROUND

Neither Missouri nor federal law establishes "an affirmative permit scheme for the actual use of pesticides." *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 613 (1991). Instead, each of these independent sovereigns has established a series of independent and overlapping rules that forbid the sale or distribution of pesticides unless stringent safety conditions are satisfied.

A. Federal Law

FIFRA establishes a series of independent *prohibitions* on selling and distributing pesticides. A pesticide must successfully run the entire gauntlet before it can be sold consistent with federal law.

1. Registration

Federal law forbids the distribution or sale of any pesticide unless it has first been registered with EPA. *See* 7 U.S.C. § 136j(a)(1)(A) ("[I]t shall be unlawful for any person in any State to distribute or sell … any pesticide that

3. Pet. Br. 8 (quoting EPA, Pesticide Registration Manual: Introduction (May 21, 2025), https://perma.cc/RRQ4-S928).

is not registered under section 136a of this title"); 7 U.S.C. § 136a(a). To register a pesticide, an applicant must submit to EPA "the complete formula of the pesticide," along with "a statement of all claims to be made for it," "directions for use," and "a complete copy of the labeling." 7 U.S.C. § 136a(c)(1)(C), (D).

Upon receiving an application, the EPA Administrator must promptly "review the data" and either "register the pesticide" or else "notify the applicant" that the application "does not comply" with FIFRA's requirements. 7 U.S.C. § 136a(c)(3)(A). FIFRA requires EPA to make several determinations before deciding to register a pesticide, including that "its labeling and other material required to be submitted comply with the requirements of this subchapter." 7 U.S.C. § 136a(c)(5)(B). So the Administrator, under the registration process, assesses whether a pesticide "compl[ies] with the requirements of" FIFRA, including FIFRA's (separate) statutory prohibition on the sale or distribution of misbranded pesticides. *See* 7 U.S.C. § 136j(a)(1)(E).

But the EPA Administrator makes these determinations only for the purpose of deciding whether to register the pesticide under section 136a. FIFRA does *not* vest him with the power to issue authoritative and final pronouncements on whether a pesticide is misbranded. Section 136a(f)(2) proves as much, stating in no uncertain terms that:

> In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter.

Selling an unregistered pesticide is one offense, while selling a misbranded pesticide is a distinct one.

To be sure, EPA *is* entitled to deference when it determines whether a pesticide should or should not be registered. 7 U.S.C. § 136a(c)(6). And EPA's decision to register a pesticide is conclusive for *one* statutory requirement—the prohibition on the sale or distribution of unregistered pesticides. 7 U.S.C. § 136j(a)(1)(A).[4] But FIFRA does *not* give conclusive effect to the subsidiary assessments of fact that the Administrator makes when deciding whether to register a pesticide under section 136a. *See* 7 U.S.C. § 136a(f)(2). Outside the registration context, Congress has not delegated to EPA the authority to interpret or apply FIFRA's separate misbranding provisions. Nor has Congress empowered EPA to resolve disputed legal or factual questions in a manner that binds judges and jurors. Any factual or legal determinations that EPA makes during the registration process are relevant *only* to whether EPA must register the pesticide under section 136a.

2. Misbranding

FIFRA categorically forbids the distribution or sale of a "misbranded" pesticide. *See* 7 U.S.C. § 136j(a)(1)(E). A pesticide can be "misbranded" under FIFRA for any number of reasons. *See* 7 U.S.C. § 136(q)(1)–(2) (defining "misbranded" pesticides). Two definitions are relevant

4. If Mr. Durnell had sued Monsanto on a negligence *per se* theory by claiming that EPA never should have registered Roundup—and thus that Monsanto violated section 136j(a)(1)(A) by selling an unregistered pesticide—EPA's decision to register Roundup would *definitively foreclose* this theory of liability. The only thing that matters under section 136j(a)(1)(A) is whether EPA has in fact registered the pesticide under section 136a, and no state or federal jury is allowed to second-guess or collaterally attack EPA's registration decision.

here. First, a pesticide is misbranded if its label "does not contain a warning or caution statement which may be necessary … to protect health and the environment." 7 U.S.C. § 136(q)(1)(G). Second, a pesticide is misbranded if "its labeling bears any statement … which is false or misleading in any particular." 7 U.S.C. § 136(q)(1)(A). When EPA makes its misbranding assessment at registration, it considers even "[a] true statement" misleading if "used in such a way as to give a false or misleading impression to the purchaser." 40 C.F.R. § 156.10(a)(5)(vii).[5]

The text makes clear what this Court has confirmed: the "unlawful act" of selling a misbranded pesticide is separate and distinct from the unlawful act of selling an unregistered pesticide. *See Bates*, 544 U.S. at 438 ("Because it is unlawful under the statute to sell a pesticide that is *registered but nevertheless misbranded*, manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements." (emphasis added)). So even if EPA determines during the registration process that a pesticide is not misbranded—as it must as a condition for registration[6]—that determination is not conclusive on whether the pesticide is *actually* misbranded. *See* 7 U.S.C. § 136a(f)(2) ("In no event shall registration of an article be construed as a defense for the commission of *any* offense under this subchapter." (emphasis added)); *Bates*, 544

5. No provision of the statute delegates to EPA the authority to give meaning to the words "false or misleading," so this regulatory gloss receives only *Skidmore* deference. *See Loper Bright*, 603 U.S. at 412–13; *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001). But EPA is correct that a technically true statement can nevertheless be "misleading" if it omits key information.

6. *See* 7 U.S.C. § 136a(c)(5)(B).

U.S. at 438 ("[R]egistration does not provide a defense to the violation of the statute").

That is because FIFRA delegates to the judiciary, not to EPA, the ultimate power to determine whether a pesticide is misbranded within the meaning of the statute. *See Loper Bright*, 603 U.S. at 412–13. EPA's decision to register a pesticide, and EPA's tentative assessments that a pesticide and its label comply with the requirements of FIFRA, serve only as "prima facie evidence" that the pesticide is not misbranded. 7 U.S.C. § 136a(f)(2).

3. Post-Registration Changes To Labels

After EPA registers a pesticide, a manufacturer may change its label so long as the updated label complies with FIFRA's requirements. Monsanto claims that 7 U.S.C. § 136j(a)(1)(B) prohibits changes to an EPA-approved label,[7] but that is demonstrably false. Section 136j(a)(1)(B) prohibits the distribution or sale of a registered pesticide only if the "claims made for it" substantially differ from the "claims made for it" in the registration statement. The "statement of all claims to be made for" a pesticide is distinct from its "labeling." *See* 7 U.S.C. § 136a(c)(1)(C) (distinguishing "the labeling of the pesticide" from the "statement of all claims to be made for it"); *see also* pp. 37–39, *infra*.[8]

4. Express Preemption

Section 136v provides:

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7. Pet. Br. 8–9, 21, 25, 30, 45.

8. The Solicitor General refuses to endorse Monsanto's characterization of section 136j(a)(1)(B). SG Br. 5, 20.

> (a) 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) 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.

This means that "States may ban or restrict the uses of pesticides that EPA has approved." *Bates*, 544 U.S. at 450. The only limitation is that a state may not enforce any "requirements for labeling or packaging" that are "in addition to or different from those required under this subchapter." 7 U.S.C. § 136v(b).

B. Missouri Law

Missouri bars the sale of an unreasonably dangerous pesticide that lacks an "adequate warning." *Moore*, 332 S.W.3d at 756. And it defines inadequacy to include any "warning that has been given [that] is informationally deficient." *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 382 (Mo. 1986). A label with truthful information that nonetheless creates a "misleading effect" supports a jury verdict for failure to warn. *Haberly v. Reardon Co.*, 319 S.W.2d 859, 867 (Mo. 1958); *La Plant v. E.I. DuPont De Nemours & Co.*, 346 S.W.2d 231, 245 (Mo. Ct. App. 1961) (similar).

Missouri law does *not* impose a duty to *change* a pesticide label. It establishes only a duty "*not to introduce into commerce*" a product whose label "fail[s] to warn of danger." *Racer*, 629 S.W.2d at 395 (emphasis added); *see*

also id. ("The breach of that duty occurs by the act of introducing such product into commerce."); *Nesselrode*, 707 S.W.2d at 382 (similar).[9] So Missouri law tracks 7 U.S.C. § 136(q)(1)(A) and (G) by forbidding the sale of pesticides that lack "adequate" warnings, and leaves it to the judiciary—judges and juries—to determine whether a particular warning is "adequate." The only differences between Missouri law and the requirements of 7 U.S.C. § 136(q)(1)(A) and (G) are the remedies. Missouri requires compensation to tort victims, while federal law authorizes condemnation proceedings, civil penalties, and jail time.

Whether a manufacturer has violated its duty, *i.e.*, sold an "unreasonably dangerous" pesticide for lack of an adequate warning, is "an ultimate issue" for the jury, *i.e.*, a classic fact question. *Moore*, 332 S.W.3d at 756 ("The concept of unreasonable danger … is presented to the jury as an ultimate issue without further definition." (cleaned up)). The jurors "give[] th[e] concept [of unreasonable danger] content by applying their collective intelligence and experience to the broad evidentiary spectrum of facts and circumstances presented by the parties." *Nesselrode*, 707 S.W.2d at 378. A product can be unreasonably dangerous both because of a true "absence of a warning" or because "the warning that has been given is informationally deficient." *Id.* at 382. In arguing about whether the pesticide was in fact unreasonably dangerous, the defendant is permitted "to argue that the utility of a design outweighs its risks." *Rodriguez v. Suzuki Motor Corp.*, 996 S.W.2d 47, 65 (Mo. 1999) (cleaned up). So a defendant is free to

9. These duties imposed by Missouri law still qualify as "requirements for labeling" under 7 U.S.C. § 136v(b)(2).

argue that the *benefits* of the product as sold outweigh any *costs*.[10]

II. PROCEDURAL HISTORY

A. History Of Roundup Litigation

Roundup is a weedkiller developed by Monsanto. Its active ingredient is glyphosate, which kills plants at their roots. In 1985, EPA reviewed a rodent-model study showing that "glyphosate was oncogenic" and caused "rare tumor[s]."[11] Based on that review, EPA classified glyphosate as a possible human carcinogen.[12] It later reclassified glyphosate as a chemical for which there exists "evidence of non-carcinogenicity for humans."[13] Over the next decade, studies showed that glyphosate was possibly genotoxic, *i.e.*, capable of causing mutations in genes that lead to cancer. Court of Appeals Respondent's Appendix 41, 73.

In 2015, the International Agency for Research on Cancer (IARC) concluded that glyphosate is probably carcinogenic to humans.[14] Two years later, California cate-

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10. Monsanto repeatedly made those arguments to the jury here. *See, e.g.*, JA 135–136 (describing how Roundup is "a big deal to farmers" because it kills weeds, which "actually make it impossible for [farmers] to grow food because it blocks the sun"); JA 136 (describing Roundup as "an advance" from other pesticides that were "toxic" and created "environmental issues like sticking around for a long time in the soil and groundwater").
11. EPA, *Memorandum re: Glyphosate Mouse Oncogenicity Study* (Apr. 3, 1985), https://perma.cc/T6FJ-VAL9.
12. *See* EPA, *Consensus Review of Glyphosate* (Mar. 4, 1985), https://perma.cc/Z4ZZ-PE8Z.
13. EPA, *Memorandum re Second Peer Review of Glyphosate* (Oct. 30, 1991), https://perma.cc/5GEG-RFH3.
14. IARC Monographs Volume 112 (Mar. 20, 2015), https://perma.cc/L79E-6LEF.

gorized glyphosate as a carcinogen under Proposition 65.[15] In 2020, EPA issued an "interim decision" stating EPA's own view that "glyphosate is not likely to be carcinogenic to humans." *NRDC v. EPA*, 38 F.4th 34, 43 (9th Cir. 2022). The Ninth Circuit then vacated EPA's factual findings after holding them unsupported by substantial evidence and inconsistent with the views of EPA's own epidemiologists. *Id.* at 51. EPA never sought review in this Court, so the vacatur is final.[16]

In 2021, Monsanto's parent company, Bayer, announced that it would discontinue its glyphosate-based products sold in the residential market. Although farmers continue to use glyphosate-containing Roundup, Monsanto says that it has been using other ingredients in Roundup for the lawn-and-garden market since 2023.[17]

B. History Of This Suit

John L. Durnell began using Roundup in 1996. For more than 20 years, he sprayed Roundup without wearing protective equipment. Based on Monsanto's label and marketing, Durnell believed that Roundup was safe. In 2018, Durnell was diagnosed with mantle cell lymphoma, a rare and aggressive form of non-Hodgkin lymphoma.

Durnell sued Monsanto in Missouri state court, bringing design-defect and failure-to-warn claims. He present-

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15. Cal. Office of Env't Health Hazard Assessment, *Initial Statement of Reasons: Glyphosate* (Mar. 28, 2017), https://perma.cc/N4DK-FWEG.

16. Monsanto's unbalanced and tendentious presentation of the scientific evidence does not reflect reality. *See* Brief of *Amici Curiae* Roundup and Paraquat MDL Leadership.

17. Bayer, *Managing the Roundup Litigation*, https://perma.cc/UGV5-Y8MV.

ed expert testimony that Roundup caused his cancer and that Monsanto had failed to warn about it. Monsanto never requested a *Bates* instruction to ensure that the jury would interpret and apply Missouri law in a manner consistent with FIFRA's misbranding requirements.[18] The jury awarded Durnell $1.25 million on his failure-to-warn claim. To reach this verdict, the jury necessarily had to find that Roundup lacked an adequate warning and caused Durnell's cancer. The jury found for Monsanto on the remaining claims.

Monsanto appealed to the Missouri Court of Appeals. Monsanto did not contest that the jury's verdict rests on substantial evidence, but argued only that Durnell's failure-to-warn claim was preempted. The Missouri Court of Appeals affirmed, holding that Missouri law does not impose any requirement "in addition to or different from" those imposed by FIFRA. Pet. App. 7. The Missouri Supreme Court declined further review, and this Court granted certiorari.

SUMMARY OF ARGUMENT

The Court should reject Monsanto's preemption arguments and affirm.

Monsanto and the Solicitor General are making two separate arguments for express preemption. Their first

18. *Bates* holds that juries considering failure-to-warn claims must be instructed to apply state law in a manner that tracks the misbranding requirements of FIFRA, but it places the onus on the defendant to request such a jury instruction if it believes that state law could extend beyond federal labeling requirements. *See Bates*, 544 U.S. at 454 ("If a defendant so requests, a court should instruct the jury on the relevant FIFRA misbranding standards."); *see also* pp. 34–35, *infra*.

argument is that EPA has authoritatively pronounced that Roundup's labeling does not violate FIFRA's misbranding provisions. On this view, EPA's approval of the label represents a binding agency determination that the label comports with federal law, so *any* state-law failure-to-warn claim over an EPA-approved label will add to the federal labeling requirements under section 136v(b).

This argument fails because EPA has no delegated authority to interpret or apply FIFRA's misbranding provisions in a manner that binds the judiciary. Under *Loper Bright*, it is for courts to determine the meaning of FIFRA's provisions absent an express delegation of interpretive authority to the agency. Monsanto does not even *attempt* to identify any language in FIFRA that departs from *Loper Bright*'s default rule. Instead, Monsanto begs the question by assuming that EPA's beliefs on the legality of Roundup's labeling must somehow bind the courts, and that EPA's factual assertions that glyphosate is non-carcinogenic must somehow bind juries under a doctrine akin to nonmutual collateral estoppel. But there is *no* statutory language in FIFRA that purports to give EPA these powers, and there are numerous provisions throughout FIFRA that explicitly refute the notion that EPA's registration decision has binding effect in subsequent court proceedings. Foremost among them is 7 U.S.C. § 136a(f)(2), which explicitly prohibits EPA's registration decisions from being invoked as a "defense" to a misbranding charge.

Monsanto and the Solicitor General's second argument for express preemption is equally unavailing. They contend that Missouri's failure-to-warn law differs from the requirements of FIFRA because federal law *compels*

courts to consider both costs and benefits when deciding whether a pesticide warning is "adequate" under 7 U.S.C. § 136(q)(1)(G), while Missouri merely *allows* the fact-finder to conduct a cost-benefit analysis. Pet. Br. 43; SG Br. 24–25. But FIFRA requires consideration of both costs and benefits when the *only* basis for declaring a pesticide "misbranded" is failure to include an "adequate" warning under 7 U.S.C. § 136(q)(1)(G). FIFRA does not require (or even allow) consideration of costs and benefits when a pesticide is misbranded because its label is "misleading" under 7 U.S.C. § 136(q)(1)(A), and a label that lists carcinogens as ingredients without mentioning the risk of cancer is "misleading" (and thus misbranded) under FIFRA. Monsanto also forfeited this argument by failing to request a *Bates* instruction that would have told the jury to apply Missouri law in a manner that tracks FIFRA's misbranding requirements. *See Bates*, 544 U.S. at 454. And any forfeited error in the jury instructions would be harmless, as it is inconceivable that a jury instructed to apply cost-benefit analysis would conclude that (1) Roundup in fact caused Durnell's cancer but (2) the supposed financial benefits of the weedkiller somehow outweigh the minimal costs of including a life-saving cancer warning.

Finally, the Court should reject Monsanto's implied-preemption argument. If Missouri and federal law impose the *same* duty—as required to avoid express preemption—it is logically *impossible* for Monsanto to show impossibility. Monsanto claims that "federal law" prohibits it from adding a cancer warning to its Roundup labels, but nothing in FIFRA or EPA's regulations says that. Monsanto repeatedly cites 7 U.S.C. § 136j(a)(1)(B), but that

provision does not mention labels, and prohibits manufacturers from altering only the "claims made for" the pesticide in the registration statement. *See* 7 U.S.C. § 136a(c)(1)(C). Monsanto also asserts that adding a cancer warning on its Roundup labels would render those labels "false" under 7 U.S.C. § 136(q)(1)(A), but Monsanto could add tomorrow an indisputably truthful and appropriately hedged warning such as: "The International Agency for Research on Cancer considers glyphosate probably carcinogenic to humans." Monsanto also mischaracterizes EPA's regulations, which allow these sorts of label changes without EPA's preapproval.

Even if FIFRA or EPA's regulations somehow barred Monsanto from adding a cancer warning, that *still* would not establish impossibility. That is because FIFRA *requires* Monsanto to comply with the statutory misbranding provisions, regardless of whether EPA regulations allow Monsanto to alter a label. 7 U.S.C. § 136j(a)(1)(E). If Roundup's labels are misleading or inadequate, then Monsanto must either stop selling Roundup, as it has in the residential market, or pay the damages that result from its decision to distribute or sell a pesticide that Durnell's jury found was misbranded. When both state and federal law require cessation, stopping is both possible and required. *See Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 487 n.4 (2013).

ARGUMENT

I. DURNELL'S FAILURE-TO-WARN CLAIM IS NOT EXPRESSLY PREEMPTED

FIFRA preempts state laws only when they impose labeling requirements "in addition to or different from

those required under" FIFRA. 7 U.S.C. § 136v(b). Monsanto cannot establish a preemption defense under this section for two reasons.

First, Missouri tort law does not impose any labeling requirements that add to or differ from FIFRA's requirements. That is because: (1) Missouri law tracks the language of 7 U.S.C. § 136(q)(1)(A), (G) by requiring "adequate" warnings on pesticide labels that are not "false or misleading"; and (2) Both Missouri law and FIFRA delegate to the judiciary the power to fill the interstices of their adequate-warning requirement. So both state and federal law establish identical legal standards, and each of them empowers the same actors—judges and jurors—to decide *whether* a particular pesticide label *actually* contains lawful warnings. Monsanto's argument to the contrary presumes that FIFRA has delegated to EPA the power to interpret the misbranding prohibition in a manner that binds state and federal judiciaries. But Monsanto never even attempts to explain how FIFRA delegates these powers to EPA given the holding of *Loper Bright*.

Second, even if Monsanto could show some difference between Missouri law and FIFRA, it *still* cannot prevail on its express-preemption defense. As an initial matter, Monsanto forfeited its affirmative defense by failing to ask for a *Bates* instruction at trial. Regardless, any error was harmless, as no jury that necessarily found that Roundup causes cancer would conclude that the benefits of ignorance outweigh the costs of the truth.

A. Missouri Tort Law Does Not Add To Or Differ From FIFRA's Adequate-Warning Requirement

Monsanto's and the Solicitor General's more ambitious express-preemption argument depicts EPA's deci-

sion to register a pesticide as the final and authoritative pronouncement that the pesticide complies with the misbranding prohibition. On this theory, *any* failure-to-warn claim against an EPA-approved label is automatically preempted by 7 U.S.C. § 136v(b). Pet. Br. at 23–26. Because registration is simply EPA's *application* of the FIFRA requirements, not a binding determination that changes their legal content, the argument fails.

1. FIFRA Delegates To The Judiciary And Not EPA The Power To Determine Whether Roundup Is Misbranded

If FIFRA authorizes the judiciary to decide whether Roundup is misbranded under 7 U.S.C. § 136j(a)(1)(E), then the jury verdict and the Missouri Court of Appeals' ruling do not "add" anything to FIFRA's labeling requirements. They represent nothing more than a judicial interpretation and application of the adequate-and-non-misleading-warning standard, which is established in FIFRA and mirrored in Missouri law. A court does not "add" to or "differ" from existing law by applying an established legal standard to a particular set of facts. And a state does not "add" to the labeling requirements of FIFRA by authorizing judges and jurors to enforce parallel state law.

EPA's determinations that a label complies with FIFRA's misbranding provisions are nothing more than EPA's opinion on the matter, and they do not bind the courts unless Congress has delegated interpretative authority to the Administrator. *See Loper Bright*, 603 U.S. at 413 ("[W]hen a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that the agency acts within it.").

Monsanto's brief *assumes* that FIFRA vests EPA with powers to bind the judiciary to its interpretations and applications of the statutory misbranding provisions. But Monsanto never attempts to explain *how* the statutory text could be read to provide such a delegation given *Loper Bright*, which holds that the default regime empowers courts to interpret and apply the law. *Id.* at 394–96, 412–13. That default applies because FIFRA's registration provision delegates only narrow and carefully defined powers to EPA. Consider the text of 7 U.S.C. § 136a(c)(5):

> 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.

All of the Administrator's factfinding authority is textually linked to his power to "register a pesticide." That includes determining whether a pesticide's proposed la-

beling "compl[ies] with the requirements"[19] of FIFRA. The statute requires EPA to register a pesticide if it concludes that its labeling complies with FIFRA and that the remaining requirements of section 136a(c)(5) have been met.

But this provision does *not* vest EPA with authority to conclusively and definitively resolve whether a pesticide's label complies with FIFRA in an adversarial judicial proceeding. It merely instructs EPA to make a one-time, limited-purpose determination whether the label (in EPA's opinion) comports with FIFRA's registration requirements. The powers conferred by section 136a(c)(5) cannot be construed to give EPA authority to render binding pronouncements on whether a pesticide actually violates FIFRA's misbranding provisions. This is so for at least three reasons.

First, EPA's findings during the registration process are based on the limited information submitted at that time, and subsequent discoveries could show that an EPA-registered pesticide is in fact misbranded. It is untenable to think that section 136a(c)(5) would make EPA's approval of a label during the registration process the authoritative and conclusive determination of whether a label actually and always complies with FIFRA's misbranding provisions.

Second, the statute provides that the *only* legal consequence of EPA's decision to approve a label during the registration process is that EPA "shall register" the pesticide, so long as the remaining criteria listed in section 136a(c)(5) are also met. Neither section 136a nor any other provision of FIFRA purports to attach additional legal

19. 7 U.S.C. § 136a(c)(5)(B).

significance to EPA's determination that a proposed label complies with the statutory misbranding provisions.

Third, there is no language in section 136a(c)(5) or elsewhere in FIFRA that purports to delegate such sweeping interpretive powers to EPA.[20] After *Loper Bright*, Monsanto must point to text that *expressly* vests EPA with authority to render conclusive pronouncements on the meaning of FIFRA's misbranding provisions and their application to particular pesticides. Monsanto has not even attempted to carry its burden,[21] content to assume that FIFRA departs from *Loper Bright*'s rule without presenting an argument to that effect.

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20. Does Monsanto truly believe that section 136v's reference to requirements "under" FIFRA — as opposed to "by" FIFRA — shows that Congress delegated to EPA the authority to definitively pronounce that a pesticide's label is not misbranded? Pet. Br. 26–27. That "is too extravagant to be maintained." *Marbury v. Madison*, 1 Cranch 137, 179 (1803). Congress's choice of preposition comes nowhere close to a legislative decision to "expressly delegate" binding interpretative authority to EPA or to empower the Administrator to "fill up the details" of the misbranding prohibition. *Loper Bright*, 603 U.S. at 394–95 (cleaned up). Whether requirements are created "under," "by", or "in" FIFRA, Monsanto must show *on the face of the statute* that Congress intended to give controlling legal effect to EPA pronouncements "that do not appear on the face of the statute." Pet. Br. 26. Apart from EPA's decision to register a pesticide, Monsanto has not and will not make that showing.

21. Neither has the Solicitor General, who baldly asserts that EPA's determinations under section 136a(c)(5) have binding legal force without ever bothering to address the delegation issue. *See* SG Br. 27 ("[W]hen EPA carries out its duties under FIFRA by making a statutorily required determination — here, whether a pesticide contains all warnings necessary and adequate to protect human health — that determination preempts different state-law requirements on the topic.").

To the extent one can cobble together a delegation argument from Monsanto's brief, it rests on nothing more than snippets of legislative history[22] and handwringing over the policy implications of a non-preemption holding.[23] As Monsanto would have it, EPA *must* be vested with delegated authority to construe FIFRA's misbranding provisions and render binding factual determinations on whether glyphosate causes cancer—even though Monsanto cannot identify any statutory language empowering EPA to displace the judiciary's law-interpretation and factfinding functions—because congressional committee reports discuss the need for "balance" and "uniformity,"[24] and because agency diktats are needed to prevent a "crazy-quilt"[25] of conflicting state regulations. That won't cut it under the *Loper Bright* regime. Agencies must identify textual delegations of authority before their pronouncements can bind the judiciary, and delegations to agencies cannot be effectuated through congressional committee reports. *See Epic Systems Corp. v. Lewis*, 584 U.S. 497, 523 (2018) ("[L]egislative history is not the law."); John F. Manning, *Textualism as a Nondelegation Doctrine*, 97 Colum. L. Rev. 673 (1997).

Monsanto's policy concerns are likewise irrelevant to the delegation issue. A desire to promote "uniformity" is no reason to construe federal statutes as vesting agencies with the power to bind courts to their interpretations and applications of the law. *See Loper Bright*, 603 U.S. at 403. If Monsanto wants to wage a rearguard action against this

22. Pet. Br. 5–6.

23. Pet. Br. 36–37, 50–53.

24. Pet. Br. 6 (quoting H.R. Rep. No. 104-669(II), at 29-30 (1996)).

25. Pet. Br. 2, 6.

holding, it should say so candidly. A mere two years after *Loper Bright*, the Court should not begin creating one-off exceptions of the sort that eventually doomed *Chevron*'s presumed-delegation regime. *See id.* at 404–06.

Monsanto's concerns about balkanized and conflicting state regulatory regimes are also overblown. Section 136v(b) prohibits state legislatures from enacting labeling requirements that cannot be found in FIFRA. So there is *no* possibility of conflicting state legislation over whether pesticide warnings must appear in red or yellow letters or whether ignitable pesticides will be described as "flammable" or "inflammable." Pet. Br. 5. There is also no judge or jury that will find a pesticide insufficiently labeled under state common law over issues of coloring or nomenclature, and any manufacturer sued on such a theory would be entitled to a directed verdict. And EPA's labeling regulations are still entitled to *Skidmore* deference from the judiciary, even though EPA lacks delegated interpretive authority over FIFRA's misbranding provisions. *See Mead*, 533 U.S. at 227–28.

Courts and juries may well diverge in applying the standards in FIFRA, but that is *always* the consequence of allowing citizen fact-finders — not government technocrats — to safeguard the people's cherished rights. Where Monsanto and the Solicitor General see a "patchwork"[26] or hear a "cacophony,"[27] Madison and Blackstone saw "the glory of the English law." 3 W. Blackstone, *Commentaries on the Laws of England* 379 (Robert Bell ed., 1771–72). Monsanto cannot deny the power of the jury to determine

26. Pet. Br. 5, 50–51; SG Br. 13.

27. Pet. Br. 5; SG Br. 4.

the ultimate facts when applying the standards from state tort law that parallel FIFRA's requirements.

Monsanto also worries that preemption is needed to protect American "agriculture and innovation." Pet. Br. 50. That cannot serve as a reason to construe FIFRA as giving EPA powers to bind the judiciary. Courts do not have the capacity to assess the policy consequences of their rulings, and judges are bound by oath to administer justice without regard to persons or pesticides. *See* 28 U.S.C. § 453. Whatever preemptive force FIFRA might have over state law is entirely unaffected by the importance of the pesticide or the effects that liability might have on the overall economy. If a non-preemption holding would produce the dire results Monsanto fears, then it must ask Congress and not the courts to change the law. Monsanto and its parent company Bayer have more than enough clout with state and federal officials,[28] and they are about as far as one can get from the "discrete and insular minorities"[29] that can rely only on courts to protect their interests.

Indeed, after a decade of litigation and billions of dollars of settlement payments, Monsanto has been vigorously lobbying Congress and state legislatures to secure the immunity from suit that the company is telling this Court has been hidden in a law of the United States since 1974. In 2023 and 2024, Monsanto tried to insert a provision into FIFRA that bars state-law liability "for failing

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28. *See, e.g.,* Hiroko Tabuchi, *A Trump Order Protected a Weedkiller. And Also a Weapon of War*, New York Times, March 6, 2026, http://bit.ly/40wpdac (visited March 25, 2026)

29. *United States v. Carolene Products Co.*, 304 U.S. 144, 152 n.4 (1938).

to comply with requirements with respect to labeling or packaging that is in addition to or different from the labeling or packaging approved by the Administrator."[30]

The difference between the law Monsanto *wishes* Congress would enact and the one that has already navigated the bicameralism and presentment process is obvious. Perhaps the political branches will be swayed by Monsanto's policy arguments and enact the express preemption clause the company so desperately seeks. The executive branch, at least, seems receptive to Monsanto's entreaties. *See* Executive Order No. 14387, *Promoting the National Defense by Ensuring an Adequate Supply of Elemental Phosphorus and Glyphosate-Based Herbicides*, 91 Fed. Reg. 8703 (Feb. 18, 2026). But this Court is confined to reviewing the enacted law, not the rewrite a massive corporation might one day shepherd through the halls of Congress.

2. FIFRA's Provisions Show That EPA's Decision To Register A Pesticide Does Not Preclude Courts From Finding That Pesticide Misbranded

FIFRA *explicitly negates* the idea that EPA's approval of a label during the registration process somehow insulates that label from subsequent judicial attack.

Start with 7 U.S.C. § 136a(f)(2), which says:

> 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

30. H.R. Rep. No. 188-4288, at 2 (2023). Monsanto has also persuaded lawmakers in Georgia and North Dakota to enact immunity legislation under state tort law. Ga. Code Ann. § 2-7-171; N.D. Cent. Code § 28-01.3-11.

> 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.

This means that there *will be* EPA-approved labels that courts may find "inadequate" or "misleading" under 7 U.S.C. § 136(q). That cannot be squared with Monsanto's claim that the use of an EPA-approved label prevents courts from finding that label "inadequate" or "misleading" under FIFRA or a state law that tracks the federal misbranding standards.

The statute also says that EPA's decision to register a pesticide—and the concomitant determinations that EPA makes during the registration process—serve as nothing more than "prima facie evidence" that the label complies with FIFRA's registration provisions. Monsanto, by contrast, is insisting that EPA's determinations have res judicata effect. *Cf. B&B Hardware, Inc. v. Hargis Industries, Inc.*, 575 U.S. 138, 148 (2015) (allowing agency findings to bind a court only when the agency was "acting in a judicial capacity" and all the issue-preclusion factors are met, including an issue actually litigated between the same parties (cleaned up)).

Monsanto and the Solicitor General try to get around section 136a(f)(2) by suggesting it applies only when someone sells a pesticide without the EPA-approved label or in violation of its terms of registration. Pet. Br. 38–39; SG Br. 26. But *according to Monsanto,* that conduct is prohibited by 7 U.S.C. § 136j(a)(1)(B), *not* the misbranding provision of (a)(1)(E). Pet. Br. 8–9, 21, 25, 30. The separate prohibition on selling a misbranded pesticide—

which surely counts as "any offense" under FIFRA—does not do any work on Monsanto's view. Superfluity is not Monsanto's only problem. The text of section 136j(a)(1)(B) forbids selling a "registered pesticide" with claims that differ from "the statement required in connection with its registration." The very next section uses identical language, forbidding the sale of a "registered pesticide" if the composition differs from the registration statement. 7 U.S.C. § 136j(a)(1)(C). If the misbranding prohibition were *only* meant to cover a registered pesticide that departed from the label contained in the registration statement, surely Congress would have used a parallel formulation.

One needs only to read section 136a(f)(2) to see that it applies without regard to the type of FIFRA violation that a plaintiff or prosecutor alleges. *See* 7 U.S.C. § 136a(f)(2) ("*In no event shall* registration of an article be construed as a defense for the commission of *any* offense under this subchapter." (emphases added)). And Monsanto does not engage with the *second* sentence of 7 U.S.C. § 136a(f)(2), which makes EPA's label-approval decisions "prima facie evidence" of statutory compliance. Prima facie evidence, by its very nature, is evidence *that can be rebutted* in court. *See* Black's Law Dictionary (12th ed. 2024). Indeed, the reason this Court long ago construed an almost identical provision in the Interstate Commerce Act *not* to violate the Seventh Amendment is because making an agency finding "prima facie evidence" "takes *no* question of fact from either court or jury." *Meeker v. Lehigh Valley R. Co.*, 236 U.S. 412, 430 (1915) (emphasis added); *see also Theatre Enterprises, Inc. v. Paramount Film Distributing Corp.*, 346 U.S. 537, 541 (1954) (Prima facie evidence

was not enough, even in conjunction with other evidence, to form the basis for a directed verdict). Without even grappling with the text, Monsanto wants to convert "prima facie evidence" into an irrebuttable presumption.[31]

If EPA's determinations about misbranding were conclusive, they would apply with as much force whenever the Administrator believes that a pesticide *is* misbranded as when he thinks, as here, that one is *not* misbranded. After all, a textual delegation to definitively announce misbranding *vel non* does not turn on the answer the Administrator gives for a particular pesticide. But FIFRA unambiguously rejects that approach. Section 136k, for example, allows the United States to bring condemnation actions against misbranded pesticides, but it guarantees the right to a jury trial in those proceedings. *See* 7 U.S.C. § 136k(c) ("[E]ither party may demand trial by jury of any issue of fact joined in any case"). FIFRA also empowers the Administrator to seek civil penalties against those who distribute or sell misbranded pesticides,[32] where the accused would be constitutionally entitled to a jury trial under the Seventh Amendment. *See SEC v. Jarkesy*, 603 U.S. 109 (2024). And FIFRA authorizes criminal prosecutions of those who knowingly violate the statute's misbranding provision,[33] where the defendant likewise enjoys a constitutional right to a jury trial. *See* U.S. Const. amend. VI; *Bates*, 544 U.S. at 452 ("In criminal prosecu-

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31. It is astounding that Monsanto would deny that juries may "second-guess" the findings and determinations that EPA makes during the registration process when section 136a(f)(2) not only allows but explicitly invites courts and juries to second-guess those findings and determinations. Pet. Br. 2, 22, 50.

32. 7 U.S.C. § 136*l*(a)(1).

33. *See* 7 U.S.C. § 136*l*(b).

tions for violation of FIFRA's provisions … juries necessarily pass on allegations of misbranding.").

In all of these judicial proceedings, there would be nothing for a jury to do if jurors must simply accept the Administrator's factual determinations and legal conclusions as binding "laws of the United States." Yet Congress expressly contemplated that a jury will decide for itself whether a pesticide is misbranded under FIFRA, performing its traditional role of resolving any disputed questions of fact relevant to the inquiry. The jury can consider EPA's views as "prima facie evidence," 7 U.S.C. § 136a(f)(2), which is the opposite of a legal conclusion that cannot be second guessed absent jury nullification.

Congress's decision to reaffirm the right to trial by jury hammers home that FIFRA does not delegate to EPA the prerogative to decree as a matter of law whether a pesticide is misbranded as a matter of fact. No different result can obtain when a litigant such as Durnell is contesting EPA's belief that a pesticide is *not* misbranded. FIFRA delegates these decisions to judges and juries regardless of whether EPA takes the side of the injured tort victim or the manufacturer.

Monsanto's next move, echoed by the Solicitor General, is to claim that the Court can ignore section 136a(f)(2) because it "is not a preemption provision at all," Pet. Br. 38–39; SG Br. 25–27. So what? By negating registration as a defense to *any* federal offense, section 136a(f)(2) confirms beyond doubt that the separate prohibition on selling a misbranded pesticide remains a federal "requirement." Missouri failure-to-warn law is thus free to operate so long as it parallels that federal obligation. 7 U.S.C. § 136v(b). Indeed, the key federal require-

ments *themselves* are not contained in "a preemption provision," *see* 7 U.S.C. § 136j, but that hardly makes them irrelevant to an express-preemption clause that turns entirely on whether state law dictates what federal law also compels.

3. Missouri's Warning Requirements Do Not Add To Or Differ From FIFRA's Misbranding Provisions

Monsanto and the Solicitor General have a more modest express-preemption theory. They try to concoct a "difference" between Missouri and federal warning regimes by claiming that FIFRA *requires* consideration of costs and benefits when assessing the "adequacy" of a warning, while Missouri merely *allows* that analysis. Pet. Br. 40–43; SG Br. 24–25. But this argument pretends that the statutory definition of "misbranding" encompasses only the adequate-warning requirement in 7 U.S.C. § 136(q)(1)(G). Monsanto and the Solicitor General *completely ignore* the definition that forbids the sale of pesticides with a "false or misleading" label. *See* 7 U.S.C. § 136(q)(1)(A); *cf. Bates,* 544 U.S. at 438 (citing that provision). That definition of "misbranding" does *not* require or even *allow* cost-benefit analysis.

Missouri law similarly allows a jury to determine whether Roundup's label is "informationally deficient" by listing glyphosate without disclosing its risks.[34] This does not reach beyond the requirements of FIFRA, which categorically prohibits "misleading" labeling without regard to costs or benefits, and it vests the judiciary with auth-

34. *See Nesselrode*, 707 S.W.2d at 382; *La Plant*, 346 S.W.2d at 245; *Haberly*, 319 S.W.2d at 867 (similar holding regarding a label with "misleading effect").

ority to determine whether a particular pesticide label is "misleading" (and therefore misbranded). So Missouri's failure-to-warn law does not add to or differ from FIFRA's misbranding requirements, regardless of the extent to which Missouri law merely allows or requires consideration of cost-benefit analysis.

B. Even If Monsanto Could Show That Missouri Tort Law Adds To Or Differs From FIFRA, Monsanto Forfeited This Argument By Failing To Ask For A *Bates* Instruction At Trial

Even if Monsanto could show some difference between Missouri law and FIFRA, it *still* cannot prevail because Monsanto forfeited this affirmative defense by failing to ask for a *Bates* instruction at trial. To ensure that Monsanto was found liable only for a "*genuinely* equivalent" Missouri labeling requirement, the burden was on the company to "request[]" an instruction "on the relevant FIFRA misbranding standards." *Bates*, 544 U.S. at 454. Monsanto, however, *agreed with* the jury instructions in the trial court and never challenged them on appeal.

Bates was right to require defendants to seek corrective jury instructions where state common law could extend beyond the requirements of FIFRA. Federal preemption operates *as applied*, displacing *only* the applications of state law that conflict with federal law. *English v. General Electric Co.*, 496 U.S. 72, 79 (1990) ("[S]tate law is pre-empted to the extent that it actually conflicts with federal law"); *Bates*, 544 U.S. at 453 (If state law imposed a "broader obligation" than FIFRA, plaintiff's claim would be preempted only "to the extent of that difference."). If Missouri law permitted Durnell to recover on one theory of liability that entirely tracks FIFRA, *i.e.*, one

where a necessary cost-benefit analysis cuts in plaintiff's favor, and another theory that is slightly easier for plaintiff to satisfy, *i.e.*, one where a cost-benefit analysis is merely a consideration, the burden was on Monsanto to seek the appropriate limiting instruction so the jury could only return a plaintiff's verdict on the parallel theory. Monsanto cannot convert section 136v(b) into a categorical immunity from suit by lying behind the log and refusing to request a jury instruction that would have obviated its grievances with the scope of Missouri law.

Even if this Court were to assume that Monsanto had preserved its objections to the jury instructions, any failure to make the jury conduct a cost-benefit analysis was harmless. There is no conceivable scenario in which a jury would conclude: "Roundup causes cancer, but it was acceptable not to warn Durnell of this deadly risk because the benefits of ignorance induced him and others to keep using the product, leaving gardens beautiful and farm yields abundant. You cannot have manicured lawns and cheap groceries without some people getting cancer, so omitting the warnings was worth it." That kind of callous disregard for human agency and informed consent would be dead on arrival even at a University of Chicago law-and-economics seminar. There is no chance it would have persuaded Durnell's jury—which even Monsanto agrees was *permitted* to consider costs and benefits—to reach a different verdict.[35]

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35. If the Court holds that Missouri's state-law labeling requirements reach beyond the commands of FIFRA and further rejects Durnell's forfeiture and harmless-error defenses, it should remand for a new trial with proper jury instructions under *Bates*.

II. DURNELL'S FAILURE-TO-WARN CLAIM IS NOT IMPLIEDLY PREEMPTED

Durnell's claim is not expressly preempted because it is not "in addition to or different from" federal law. 7 U.S.C. § 136v(b). That means Missouri law imposes *the same* requirements that appear in the federal misbranding provisions: do not sell a pesticide the label of which is misleading or inadequate.

That dooms Monsanto's impossibility-preemption argument as a matter of basic logic. Two equivalent commands cannot logically contradict each other, so no court would view federal law as displacing state law under the traditional doctrine of implied repeals. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 622 (2011) (plurality op.) ("[F]ederal law should be understood to impliedly repeal conflicting state law.") (citing Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225 (2000)). Nor is it "impossible" to do what both state *and* federal law require. *Albrecht*, 587 U.S. at 313.

Refusing to accept state and federal duties on their own terms, Monsanto repackages its obligation under Missouri law as a duty to change the label. Even with this framing, Monsanto has come nowhere close to establishing the "demanding defense" of impossibility. *Id.* Nothing in FIFRA prevents unilateral label changes to cure a misbranded label. *See* pp. 38–39, *infra*. EPA's regulations, even if they carried the force of law, permitted such changes. *See* pp. 39–42, *infra*. And there is no EPA rule akin to the pharmaceutical Changes Being Effected regulation that would allow the Administrator to order Monsanto to walk back a unilateral change. 21 C.F.R. § 314.70(c)(6)–(7).

Though Monsanto could have (and should have) changed Roundup's label, it was duty bound not to sell a misbranded pesticide under state and federal law. And although this Court has rejected a "stop-selling" response when only state law imposes a labeling requirement,[36] the analysis is entirely different when *federal law* also compels an actor to stop selling the product that is mislabeled under state law. *Bartlett*, 570 U.S. at 487 n.4. If state and federal law both require an actor to stop selling, it is not impossible to obey both commands.

In short, there is no impossibility because: (1) Nothing in FIFRA or EPA's regulations prevented Monsanto from adding a cancer warning; and (2) Even if federal law prevented Monsanto from changing Roundup's labeling, it was obligated by FIFRA's misbranding requirements to either stop selling Roundup or willingly pay the damages and penalties that attach to selling a pesticide that Durnell's jury determined to be misbranded.

A. Neither FIFRA Nor Its Implementing Regulations Prevent Monsanto From Adding A Cancer Warning To Roundup's Labeling

Monsanto's impossibility-preemption argument hinges on its assertion that "federal law" requires it to use labels identical to those EPA approved during the registration process.[37] Pet. Br. 35. But nothing in FIFRA or

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36. *Bartlett*, 570 U.S. at 488.

37. Pet. Br. 2 ("Monsanto could not provide the warnings Missouri law requires without rendering Roundup misbranded under federal law."); *id.* at 30 ("FIFRA makes it illegal to distribute a pesticide with health warnings other than those approved by EPA."); *see also id.* at 8–9, 21–22, 25–26, 33, 35, 44–45.

EPA regulations prevents Monsanto from unilaterally adding cancer warnings to Roundup's labeling.

1. 7 U.S.C. § 136j(a)(1)(B) Prevents Manufacturers From Altering The Statement Of Claims Made For A Pesticide, Not Its Labeling

Monsanto falsely asserts that 7 U.S.C. § 136j(a)(1)(B) prohibits post-registration label changes. Pet. Br. 25 ("FIFRA makes it illegal to distribute a pesticide with labeling substantially different from the EPA-approved label. 7 U.S.C. § 136j(a)(1)(B)."). What the provision actually prohibits is the distribution or sale of:

> 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;

7 U.S.C. § 136j(a)(1)(B) (emphases added). The "claims made" in the registration statement are *distinct* from the label:

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

7 U.S.C. § 136a(c)(1)(C) (emphases added). So the "labeling," the "statement of all claims to be made for" the pesticide, and the "directions for its use" are different pieces of information that an applicant submits during the regis-

tration process. Yet section 136j(a)(1)(B) locks into place *only* the statement of claims made for the pesticide, leaving manufacturers free to change the "labeling" and the "directions for its use." Equating the statement of claims with the label is nothing short of misdirection.

Monsanto also claims that including a cancer warning on Roundup labels would violate FIFRA's misbranding provisions by making those labels "false or misleading" under 7 U.S.C. § 136(q)(1)(A). Pet. Br. 2. That defense was available to Monsanto, but the jury disagreed. It is for jurors and judges, not Monsanto, to resolve the factual question of whether a cancer warning would violate FIFRA's misbranding provisions. And in all events, Monsanto can easily provide an adequate cancer warning that is irrefutably truthful and not misleading, such as: "The International Agency for Research on Cancer considers glyphosate probably carcinogenic to humans." Nothing in FIFRA prohibits such a warning, and nothing in state law required a particularly worded warning so long as it was adequate. *See Wyeth v. Levine,* 555 U.S. 555, 565 (2009).

2. EPA's Regulations Do Not And Cannot Prevent Monsanto From Adding A Cancer Warning To Roundup's Labeling

Monsanto also cites EPA regulations that purport to prohibit unilateral modifications to the label of a registered pesticide. *See* 40 C.F.R. §§ 152.44, 152.46. But regulations cannot prohibit what the statute allows under *Loper Bright*, and EPA cannot concoct a prohibition on label modifications when 7 U.S.C. § 136j(a)(1)(B) bars manufacturers from altering only the *claims* made for the pesticide. Nothing else in FIFRA prevents a manufacturer from unilaterally changing the registered label. In

fact, complying with the misbranding provision will often *require* that the manufacturer either amend the label or cease selling the pesticide altogether. EPA lacks statutory authority to impose a preclearance requirement for label modifications, especially when a manufacturer is seeking to add warnings or caution statements that are "necessary … to protect health and the environment" or to avoid rendering the label "false or misleading." 7 U.S.C. § 136(q)(1)(G), (A).

Even assuming the regulations are valid, these EPA rules are no help to Monsanto because they *allow* Monsanto to unilaterally add cancer warnings so long as it avoids placing the warning in certain sections of the label. And the versions of these rules in effect when Durnell first started using Roundup were even clearer in permitting unilateral changes.

Under 40 C.F.R. § 152.46(a)(1), EPA may permit "minor" label modifications to proceed through notification without the need for EPA approval. EPA lists the permissible unilateral changes in its "Pesticide Registration Notices" or "PRNs." In 1995, EPA issued PRN 95-02, which provides that "advisory statements," including "those related to precautions," "may be added or revised via notification."[38] In 1998, EPA issued PRN 98-10, which reaffirmed that PRN 95-02's rule on "advisory statements … related to precautions" remains the PRN that manufacturers should "continue to follow."[39] This PRN also made clear that "other revisions" to the label were permissible

38. EPA, *Pesticide Registration Notice* 95-02, 3 (May 31, 1995), https://perma.cc/C8XM-7NAZ.

39. EPA, *Pesticide Registration Notice* 98-10, 3 (Oct. 22, 1998), https://perma.cc/ZK8Z-2NNM.

if they are "consistent with 40 CFR Part 156" and "involve no change" to certain *sections* of the label, *e.g.*, the "ingredients statement," "First Aid statement," or "precautionary statements."[40]

It was not until 2000—four years *after* Durnell began using Roundup—that EPA issued PRN 2000-5, which states that "registrants may no longer add or change advisory labeling statements to existing products by notification as previously permitted by PR Notices 95-2 and 98-10."[41] But PRN 2000-5 made no adjustment to a manufacturer's ability to change *other sections* of the Roundup label unilaterally. *Id.*

Durnell used Roundup for more than 20 years. For the first four years of that use—1996 to 2000—Monsanto could have unilaterally added a cancer warning in the "advisory statements" section of the Roundup label. And for the remaining years of use, unilateral warnings could still be added so long as the manufacturer placed them in the proper section of the label.

Monsanto knows full well that this sort of label change was permissible. Its parent company Bayer notified EPA in 2012 that it had unilaterally added a cancer warning to the very end of one of its pesticide labels.[42] And EPA *con-*

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40. *Id.* at 8.

41. EPA, *Pesticides; Guidance for Pesticide Registrants on Mandatory and Advisory Labeling Statements*, 65 Fed. Reg. 31,313, 31,314 (May 17, 2000).

42. *See* Letter from Larry R. Hodges, Bayer CropScience, to EPA, Office of Pesticide Programs 4 (Nov. 29, 2012), https://perma.cc/X64N-WX5F ("As allowed by PR Notice 98-10, we are notifying the Agency of a minor labeling amendment for LARVIN Technical (EPA Reg. No. 264-343). As required by California Proposition 65, the following statement was added to label, 'This pro-

(continued…)

firmed that Bayer was allowed to make this unilateral change.[43] It cannot be impossible to do what has already been done.

Monsanto's fallback argument is to assert that EPA would have vetoed the change, and it claims to have produced "clear evidence" that this would have happened. Pet. Br. 48 (citing *Albrecht*, 587 U.S. at 314). But this "clear evidence" defense comes from cases interpreting the Food Drug and Cosmetic Act (FDCA), which requires manufacturers to submit unilateral label changes to FDA and gives the agency authority to reject them even after the manufacturer has made the changes. 21 C.F.R. § 314.70(c)(1), (c)(7). With the agency empowered to veto a label change, this Court held that a manufacturer can establish preemption if it proves by "clear evidence" that FDA would have walked back a stronger warning. *Albrecht,* 587 U.S. at 315; *but see id.* at 321 (Thomas, J., concurring) ("[N]either agency musings nor hypothetical future rejections constitute pre-emptive 'Laws' under the Supremacy Clause.").

That rationale does not apply here. FIFRA freely allows manufacturers to make unilateral changes to their labels. *See* pp. 38–39, *supra*. So do EPA's regulations. And neither FIFRA nor EPA's regulations establish any mechanism for EPA to force a manufacturer to undo a uni-

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duct contains a chemical known to the state of California to cause cancer.'")

43. *See* Letter from Jennifer Gaines, EPA, Office of Pesticide Programs, to Larry Hodges, Bayer CropScience 2 (Dec. 17, 2012), https://perma.cc/X64N-WX5F ("The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10.").

lateral change. That Monsanto thinks it has adduced "clear evidence" that EPA *dislikes* a hypothetical cancer warning that the company *never added* to its label says nothing about whether it was *impossible* to provide this warning to Durnell.

And even if this Court were to import the clear-evidence regime into FIFRA, Monsanto has not satisfied it. Monsanto never once asked EPA to approve a Roundup label that warns about the risk of cancer. But to establish clear evidence, Monsanto must "show that it fully informed the [agency] of the justifications for the warning required by state law and that the [agency], in turn, informed the … manufacturer that the [agency] would not approve changing the [product's] label to include that warning." *Albrecht*, 587 U.S. at 314. Monsanto claims that EPA sent letters *to other manufacturers* suggesting that it no longer agreed with their cancer warnings,[44] but none of that matters under *Albrecht*. Perhaps Monsanto could have made a more persuasive case. It cannot throw up its hands and declare "impossibility" when it did not deign to try. *Albrecht*, 587 U.S. at 314.

B. Durnell's Claim Is Not Preempted Even If Monsanto Could Not Change The Label

Even accepting the (false) premise that Monsanto was forbidden to change the EPA-approved label, that *still* does not establish an implied-preemption defense. Monsanto is arguing *impossibility*, and the only way that Missouri law can be "impossible" for Monsanto to comply with is by characterizing the relevant state-law duty as a duty to *change* the label.

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44. Pet. Br. 48.

But that is simply not the relevant duty under state or federal law. The duty under federal law is to *not sell* a misbranded pesticide. *See* 7 U.S.C. § 136j(a)(1)(E). The duty under state law is to *not sell* a pesticide that has an inadequate or misleading label. *Racer*, 629 S.W.2d at 395. There cannot be an "impossibility" conflict between those two duties.

It is true enough that this Court has held that a party cannot be required to cease activity altogether as *an alternative* to complying with a state duty that contradicts federal law. If federal law commands "drive on the right" and Missouri law proclaims "drive on the left," a plaintiff cannot avoid preemption by asserting that the defendant should have ceased driving altogether. *See* Transcript of Oral Argument at 46–47, *Bartlett*, 570 U.S. 472. Neither sovereign was attempting to force drivers off the road. Each simply selected incompatible modes of driving. While not driving at all is both possible and a way to avoid liability, "physical impossibility" is not always the test for preemption. *See Bartlett*, 570 U.S. at 488.

None of that applies when federal and state law both *require* a party to cease acting. In that circumstance, cessation is not some pettifogger's excuse to leave in place conflicting legal commands. It is instead the *only way* to ensure that both commands are obeyed. That is why *Bartlett* made clear that it was not addressing claims "that parallel the federal misbranding statute" under the FDCA, which, like FIFRA, compels drugmakers to stop selling misbranded pharmaceuticals. *Id.* at 487 n.4 (citing *Bates*, 544 U.S. at 447). The Court cited *Bates* because that case already applied the same logic under FIFRA. *Bates* affirmed that states have the complete prerogative to re-

quire a manufacturer to stop selling a pesticide *for any reason*, to say nothing of reasons that parallel federal law. *Bates*, 544 U.S. at 450 ("States may ban or restrict the uses of pesticides that EPA has approved.").

Settled or not, the question is straightforward. FIFRA unambiguously requires Monsanto to stop selling a misbranded pesticide. Missouri law requires the exact same thing. Where complying with "the supreme law of the land" requires cessation, Monsanto must comply with both state and federal law by either withdrawing Roundup from the market or willingly accepting the risk that it must pay individual tort victims the damages that juries award them.[45]

Monsanto, of course, remains free to argue in future cases by future plaintiffs that Roundup is not misbranded and can continue to be sold. By its nature, the judicial power binds only the parties to the case, so the jury verdict and judicial decisions below (and here) bind Monsanto only vis-à-vis Durnell. They do not have universal effect. *Cf. Trump v. CASA, Inc.*, 606 U.S. 831 (2025). State and federal legal duties—stop selling if the pesticide is inadequately or misleadingly labeled—will remain completely parallel in those future actions. But future juries may accept Monsanto's presentation of the facts and conclude that selling Roundup did not breach any state and federal obligations.

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45. Monsanto never deals with this fact because its entire argument is premised on the idea that Roundup cannot possibly be "misbranded" under FIFRA because EPA approved its label during the registration process. *See* pp. 21–33, *supra*.

III. MONSANTO'S PREEMPTION ARGUMENTS FIND NO SUPPORT IN THIS COURT'S CASE LAW

Monsanto's preemption arguments are incompatible with this Court's precedents.

A. Monsanto's Preemption Arguments Are Incompatible With *Bates*

Monsanto's preemption arguments would have required a finding of preemption in *Bates*. The Strongarm label, which failed to warn Texas peanut farmers that it would destroy their crops, had been approved by EPA during the registration process. *Bates*, 544 U.S. at 434–35. So if "the label is the law!," as Monsanto insists throughout its brief,[46] then *any* failure-to-warn claim predicated on an EPA-approved label is preempted. The Court obviously did not take that view in *Bates*; it allowed the failure-to-warn claim to proceed.

Monsanto and the Solicitor General attempt to circumvent *Bates* by observing that EPA never actually weighed in on the efficacy of Strongarm or the accuracy of the labeling statements that recommended its use for peanut crops. Pet. Br. 32, SG Br. 27. But the outcome in *Bates* did not in any way depend on that fact. 544 U.S. at 438 ("Because it is unlawful under the statute to sell a pesticide that is registered but nevertheless misbranded, manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements."). That is because nothing in FIFRA's text turns on whether the Administrator ignored

46. Pet. Br. 8, 26, 45.

or thoughtfully weighed a scientific question.[47] *Id.* at 448 ("[A]lthough FIFRA does not provide a federal remedy to farmers and others who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements, *nothing* in § 136v(b) precludes States from providing such a remedy." (emphasis added)).

Monsanto's effort to distinguish *Bates* is also incompatible with its sweeping statements on the supposed sanctity of the EPA-approved label that appear throughout its brief. Instead of proclaiming that "the label is the law!", Monsanto should appropriately hedge this slogan given its desire to accommodate *Bates*. Perhaps it could try: "The label is the law, but only if EPA actually considered and affirmatively agrees with the particular statements that appear on the label!" But then Monsanto would have to explain what would happen if a future Administrator determines that glyphosate does indeed cause cancer. Could Durnell then reopen his case under the state-law equivalent of Rule 60(b)? And would EPA's new factual determination entitle Durnell (and similarly situated plaintiffs) to a directed verdict? *Cf. National Cable & Telecommunications Association v. Brand X Internet Services,* 545 U.S. 967 (2005). Modified once again, Monsanto's mantra must really be: "The label is the law, so long as EPA has actually considered and blessed its contents, but only for so long as EPA has not changed its

47. The argument fails on its own terms. EPA has never considered whether all of the ingredients in Roundup — including surfactants, ethylene oxide, and 1, 4-Dioxane — combined with glyphosate can cause cancer. And it has never considered Durnell's experts' interpretations and analysis of the scientific evidence.

mind!" That catchphrase has little to recommend it. And it is inconsistent with *Bates,* to say nothing of FIFRA.

Bates also shuts down Monsanto's fears that civil-jury enforcement of FIFRA's labeling standards will produce a "crazy quilt"[48] of conflicting obligations. *Bates* considered and rejected this idea both as an empirical matter and as a reason to find preemption. *Bates*, 544 U.S. at 451–52 ("Dow and the United States exaggerate the disruptive effects of using common-law suits to enforce the prohibition on misbranding.") And although *Bates* acknowledges that "properly instructed juries might on occasion reach contrary conclusions on a similar issue of misbranding," it specifically holds that the prospect of divergent verdicts is no reason to prevent state juries from enforcing "state rules that are fully consistent with federal requirements." *Id.* at 452. Yesterday's "crazy quilts" are today's "patchworks" and "cacophonies,"[49] but changing the nomenclature does not change *Bates*'s holding. Whatever discordant noises Monsanto fears will emanate from jury boxes, *Bates* does not permit the company to take the interpretation and application of the misbranding standard from the judiciary.

Bates poses an even bigger problem for Monsanto's implied-preemption argument. If Monsanto is right to claim that "federal law" prohibits manufacturers from changing EPA-approved labels without permission, then Dow would have been forbidden to change its Strongarm labels absent prior EPA approval. So Dow would have been in the same position that Monsanto claims to be in. And although Dow eventually obtained EPA approval to

48. *Bates*, 544 U.S. at 448, 451.

49. Pet. Br. at 5, 50, 51.

include the desired warning,[50] Monsanto insists that is irrelevant. Pet Br. 44 ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." (cleaned up)). *Bates* would have to come out the other way if this Court accepts Monsanto's impossibility-preemption argument.

B. The Court's Decision In *Riegel v. Medtronic, Inc.* Is Inapposite

Monsanto and the Solicitor General try to analogize this case to *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which held that a similarly worded express-preemption provision blocked a state-law failure-to-warn claim over a medical device that had received premarket approval from FDA. But *Riegel* is inapposite for two reasons. First, the Court in *Riegel* held that the Medical Device Amendments banned manufacturers from altering an FDA-approved device or its labeling absent FDA permission. *See id.* at 319 (citing 21 U.S.C. § 360e(d)(5)(A)(i)). Nothing in FIFRA or its implementing regulations prohibits Monsanto from adding a cancer warning to its Roundup labels; indeed, the EPA regulations explicitly *allow* Monsanto to add this warning without seeking EPA approval. *See* pp. 39–42, *supra*.

Second, no one in *Riegel* even attempted to argue that the FDA-approved medical device violated the separate statutory misbranding prohibitions in the FDCA. *See* 21 U.S.C. § 331 ("The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any … device … that is adulterated or misbranded."). The plaintiff in *Riegel*

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50. *Bates*, 544 U.S. at 435.

hinged her entire case on the contentions that: (1) FDA's premarket approval of a medical device failed to impose "requirements" within the meaning of the statute's express-preemption provision, 21 U.S.C. § 360k(a)(1); and (2) state common-law duties fail to qualify as "requirements." *See Riegel*, 552 U.S. at 322–25.

Durnell *concedes*[51] that Missouri's failure-to-warn law imposes some "requirements for labeling" within the meaning of 7 U.S.C. § 136v(b). And Durnell—unlike Riegel—is arguing that Missouri may impose failure-to-warn liability on Monsanto because the jury could reasonably conclude that Roundup's labeling violates FIFRA's prohibition on selling misbranded pesticides. *Riegel* is no help at all to Monsanto because it expressly refused to address a situation in which a plaintiff claims that a state-law failure to warn *also* violates the misbranding prohibitions enshrined in federal law.

* * *

Monsanto's brief is a 53-page non sequitur. EPA's belief that Roundup's labels comply with FIFRA's misbranding provisions means nothing when *Loper Bright* gives courts rather than agencies the authority to interpret and apply those provisions. EPA's repeated pronouncements that glyphosate is noncarcinogenic are likewise irrelevant unless this Court is prepared to extend the doctrine of nonmutual collateral estoppel to an agency's factual assertions. And Monsanto's policy arguments for why EPA *should* be given delegated power belong in its lobbying materials for congressmen and senators, not in a Supreme Court brief. Monsanto has forfeited any claim

51. *See Bates*, 544 U.S. at 443, 446; *Riegel*, 552 U.S. at 323–25.

that Missouri tort law adds to or differs from FIFRA's requirements by failing to request a *Bates* instruction at trial, and there is no reason to believe that a cost-benefit analysis instruction would have affected the jury's verdict in any way.

Monsanto's claims that FIFRA and EPA's regulations prohibit it from adding a cancer warning to Roundup's labels are untrue. And even if federal law prevented Monsanto from adding a cancer warning to Roundup's EPA-approved labels, FIFRA would *still* prohibit Monsanto from distributing or selling Roundup if the judiciary finds its labels misleading or inadequate under 7 U.S.C. § 136(q) or state tort law. Monsanto cannot escape the fact that *Loper Bright* empowers the judiciary and not EPA to interpret and apply FIFRA's misbranding prohibitions, and it cannot establish express or implied preemption by ignoring the statutory delegation issue and begging the question throughout its brief.

CONCLUSION

The judgment of the Missouri Court of Appeals should be affirmed.

Respectfully submitted.

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APPENDIX

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TITLE 7—AGRICULTURE

SUBCHAPTER II—ENVIRONMENTAL PESTICIDE CONTROL

§ 136. Definitions

For purposes of this subchapter— . . .

(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".

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or dis-

played under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter—

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

. . .

(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.

§ 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.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if—

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(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:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years

for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing

registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, ex-

cept for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this sub-

paragraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after August 3, 1996, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after August 3, 1996, by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Ad-

ministrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(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.

(B) Additional data

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise

the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of

intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that

served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 136a–1 of this title for the other uses of the pesticide established as of August 3, 1996, if—

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 136a-1 of this title; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance

with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under section 136a–1 of this title for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not

meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified procedures

Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption

No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor use waiver

In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining—

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(3) Application

(A) In general

The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance

with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

(B) Identical or substantially similar

(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(i) In expediting the review of an application for an action described in clause (i), the Administrator shall—

(I) review the application in accordance with section 136w-8(f)(4)(B) of this title and, if the application is found to be incomplete, reject the application;

(II) not later than the applicable decision review time established pursuant to section 136w–8(f)(4)(B) of this title, or, if no review time is established, not later than 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(C) Minor use registration

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application—

(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)—

(I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and

(II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 136p of this title for that minor use.

(D) Adequate time for submission of minor use data

If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) Application

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(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.

(6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of

the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

(7) Denial of registration

Notwithstanding the provisions of paragraph (5)—

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that

(i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly in crease the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may

amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) Interim administrative review

Notwithstanding any other provision of this subchapter, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this subchapter, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasona-

ble adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

(9) Labeling

(A) Additional statements

Subject to subparagraphs (B) and (C), it shall not be a violation of this subchapter for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) Requirements

Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) Notification and disapproval

(i) Notification

A registration may be modified under subparagraph (A) if—

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of the modification under clause (ii).

(ii) Disapproval

Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) Restriction on sale

A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) Objection

A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) Final action

A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) Use dilution

The label or labeling required under this subchapter for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that—

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) Expedited registration of pesticides

(A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(11) Interagency working group

(A) Interagency working group

In this paragraph, the term "covered agency" means any of the following:

(i) The Department of Agriculture.

(ii) The Department of Commerce.

(iii) The Department of the Interior.

(iv) The Council on Environmental Quality.

(v) The Environmental Protection Agency.

(B) Establishment

The Administrator shall establish an interagency working group, to be comprised of representatives from each covered agency, to provide recommendations regarding, and to implement a strategy for improving, the consultation process required under section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1536) for pesticide registration and registration review.

(C) Duties

The interagency working group established under subparagraph (B) shall—

(i) analyze relevant Federal law (including regulations) and case law for purposes of providing an outline of the legal and regulatory framework for the consultation process referred to in that subparagraph, including—

(I) requirements under this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.);

(II) Federal case law regarding the intersection of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.); and

(III) Federal regulations relating to the pesticide consultation process;

(ii) provide advice regarding methods of—

(I) defining the scope of actions of the covered agencies that are subject to the consultation requirement referred to in subparagraph (B); and

(II) properly identifying and classifying effects of actions of the covered agencies with respect to that consultation requirement;

(iii) identify the obligations and limitations under Federal law of each covered agency for purposes of providing a legal and regulatory framework for developing the recommendations referred to in subparagraph (B);

(iv) review practices for the consultation referred to in subparagraph (B) to identify problem areas, areas for improvement, and best practices for conducting that consultation among the covered agencies;

(v) develop scientific and policy approaches to increase the accuracy and timeliness of the process for that consultation, in accordance with requirements of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including—

(I) processes to efficiently share data and coordinate analyses among the Department of Agriculture, the Department of Commerce, the Department of the Interior, and the Environmental Protection Agency;

(II) a streamlined process for identifying which actions require no consultation, informal consultation, or formal consultation;

(III) an approach that will provide clarity with respect to what constitutes the best scientific and commercial data available in the fields of pesticide use and ecological risk assessment, pursuant to section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1536(a)(2)); and

(IV) approaches that enable the Environmental Protection Agency to better assist the Department of the Interior and the Department of Commerce in carrying out obligations under that section in a timely and efficient manner; and

(vi) propose and implement a strategy to implement approaches to consultations under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) and document that strategy in a memorandum of understanding, revised regulations, or another appropriate format to promote durable cooperation among the covered agencies.

(D) Reports

(i) Progress reports

(I) In general

Not later than 18 months after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing the progress of the working group

in developing the recommendations under subparagraph (B).

(II) Requirements

The report under this clause shall—

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of new consensus and continuing topics of disagreement and debate.

(ii) Results

(I) In general

Not later than 1 year after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(aa) the recommendations developed under subparagraph (B); and

(bb) plans for implementation of those recommendations.

(II) Requirements

The report under this clause shall—

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of consensus and continuing topics of disagreement and debate, if any.

(iii) Implementation

Not later than 1 year after the date of submission of the report under clause (i), the Administrator, in coordination with the head of each other covered

agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(iv) Other reports

Not later than the date that is 180 days after the date of submission of the report under clause (iii), and not less frequently than once every 180 days thereafter during the 5-year period beginning on that date, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing—

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(E) Consultation with private sector

In carrying out the duties under this paragraph, the working group shall, as appropriate—

(i) consult with, representatives of interested industry stakeholders and nongovernmental organizations; and

(ii) take into consideration factors, such as actual and potential differences in interest between, and the views of, those stakeholders and organizations.

(F) Chapter 10 of title 5

Chapter 10 of title 5 shall not apply to the working group established under this paragraph.

(G) Savings clause

Nothing in this paragraph supersedes any provision of—

(i) this subchapter; or

(ii) the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including the requirements under section 7 of that Act (16 U.S.C. 1536).

(d) Classification of pesticides

(1) Classification for general use, restricted use, or both

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If

some of the uses of the pesticide are classified for general use, and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to

the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) Change in classification

If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 136d(b) of this title.

(3) Change in classification from restricted use to general use

The registrant of any pesticide with one or more uses classified for restricted use may petition the Adminis-

trator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 136n of this title.

(e) Products with same formulation and claims

Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(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.

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§ 136j. Unlawful acts

(a) In general

(1) Except as provided by subsection (b), 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.

(2) It shall be unlawful for any person—

(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this subchapter;

(B) to refuse to—

(i) prepare, maintain, or submit any records required by or under section 136c, 136e, 136f, 136i, or 136q of this title;

(ii) submit any reports required by or under section 136c, 136d, 136e, 136f, 136i, or 136q of this title; or

(iii) allow any entry, inspection, copying of records, or sampling authorized by this subchapter;

(C) to give a guaranty or undertaking provided for in subsection (b) which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) may give a guaranty to the same effect, which guaranty shall contain, in addition to the person's own name and address, the name and address of the person residing in the United States from whom the person received the guaranty or undertaking;

(D) to use for the person's own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this subchapter which is confidential under this subchapter;

(E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a product registered under this subchapter for restricted use without giving the classification of the product assigned to it under section 136a of this title;

(F) to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 136a(d) of this title and any regulations thereunder, except that it shall not be unlawful

to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator;

(G) to use any registered pesticide in a manner inconsistent with its labeling;

(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

(I) to violate any order issued under section 136k of this title;

(J) to violate any suspension order issued under section 136a(c)(2)(B), 136a–1, or 136d of this title;

(K) to violate any cancellation order issued under this subchapter or to fail to submit a notice in accordance with section 136d(g) of this title;

(L) who is a producer to violate any of the provisions of section 136e of this title;

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 136e of this title, any records required to be maintained pursuant to this subchapter, any report filed under this subchapter, or any information marked as confidential and submitted to the Administrator under any provision of this subchapter;

(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this subchapter;

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this subchapter;

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the na-

ture and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test;

(Q) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this subchapter;

(R) to submit to the Administrator data known to be false in support of a registration; or

(S) to violate any regulation issued under section 136a(a) or 136q of this title.

. . .

§ 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.

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§ 136w. Authority of Administrator

(a) In general

(1) Regulations

The Administrator is authorized, in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this subchapter. Such regulations shall take into account the difference in concept and usage between various classes of pesticides, including public health pesticides, and differences in environmental risk and the appropriate data for evaluating such risk between agricultural, nonagricultural, and public health pesticides.

(2) Procedure

(A) Proposed regulations

At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding the foregoing 60-day time requirement.

(B) Final regulations

At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such effect.

(C) Time requirements

The time requirements imposed by subparagraphs (A) and (B) may be waived or modified to the extent agreed upon by the Administrator and the Secretary.

(D) Publication in the Federal Register

The Administrator shall, simultaneously with any notification to the Secretary of Agriculture under this paragraph prior to the issuance of any proposed or fi-

nal regulation, publish such notification in the Federal Register.

(3) Congressional committees

At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, the Administrator shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(4) Congressional review of regulations

Simultaneously with the promulgation of any rule of regulation under this subchapter, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule of regulation shall not become effective until the passage of 60 calendar days after the rule of regulation is so transmitted.

(b) In general

The Administrator may exempt from the requirements of this subchapter by regulation any pesticide which the Administrator determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter.

(c) Other Authority

The Administrator, after notice and opportunity for hearing, is authorized—

(1) to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and

other micro-organisms on or in living man or other living animals) which is injurious to health or the environment;

(2) to determine any pesticide which contains any substance or substances in quantities highly toxic to man;

(3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91–601) [15 U.S.C. 1471 et seq.]) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this subchapter as well as to accomplish the other purposes of this subchapter;

(4) to specify those classes of devices which shall be subject to any provision of section 136(q)(1) or section 136e of this title upon the Administrator's determination that application of such provision is necessary to effectuate the purposes of this subchapter;

(5) to prescribe regulations requiring any pesticide to be colored or discolored if the Administrator determines that such requirement is feasible and is necessary for the protection of health and the environment; and

(6) to determine and establish suitable names to be used in the ingredient statement.

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TITLE 40 —PROTECTION OF ENVIRONMENT

SUBCHAPTER E —PESTICIDE PROGRAM

§ 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 re-

quired supporting materials (for example, labeling) for each affected product.

§ 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.

PESTICIDE (PR) NOTICE 95-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION:	Persons Responsible for Federal Registration and Reregistration of Pesticide Products
SUBJECT:	Notifications, Non-Notifications and Minor Formulation Amendments

This Notice describes new policies and procedures effective immediately which will help streamline and accelerate many registration amendments. Highlights of this notice include:

- expanding the types of labeling and product chemistry amendments which may be accomplished by notification,
- accelerating the review of minor formulation amendments, and
- a new certification statement which affirms compliance with this PR Notice and applicable regulations, and which describes the consequences of noncompliance.

This PR Notice supersedes PR Notice 88-6 (August 12, 1988) and the second edition of General Information On Applying For Registration of Pesticides In The United States (The Blue Book, Chapter 4. C. and D). This PR Notice also modifies parts of PR Notices 83-3 and 84-1 (Storage and Disposal Statements), and PR Notice 91-1 (Use Deletions). Table A lists the registration amendments which may be accomplished by notification, non-

notification or accelerated minor formulation changes as described in this notice.

I. BACKGROUND

On August 12, 1988, the Agency issued PR Notice 88-6 to implement 40 CFR 152.46, Modifications To Registration Not Requiring Amended Applications. §152.46(a) allows certain registration amendments to be accomplished by notifying the Agency of those changes before the product is distributed or sold. §152.46(b) allows other minor changes in labeling or packaging to be made without notification to the Agency. PR Notice 88-6 described the Agency's policies and procedures at that time for notifications and non-notifications under § 152.46.

§152.44(b), Application for Amended Registration, requires any modification in the composition, labeling or packaging of a registered product to be submitted with an application for amended registration, with the exception of notifications and non-notifications under §152.46. §152.44(b) provides that the Agency may waive the requirement for an amendment or permit a registrant to certify compliance with an Agency requirement instead of submitting an amendment.

EPA is issuing this notice to allow minor, low risk registration amendments to be accomplished through notification, non-notification or as accelerated amendments. EPA believes these streamlining changes will speed up the process, reduce the waiting time for registrants and maintain protection to the public health and the environment.

II. NOTIFICATIONS

The following registration amendments may be accomplished by notification.

A. Labeling

1. Adding Alternate Brand Names

A registrant may sell a product under one or more **alternate brand names** provided he/she notifies the Agency of those names. Each name must differ from the name of any other of the registrant's products so as to permit clear identification. Brand names may not be false or misleading. The addition of alternate brand names for use by the registrant is not the same as supplemental distribution by a different company or individual under agreement . with the registrant (see 40 CFR 152.132). Changing the **primary brand name** of a product must be done by submitting an application for amendment.

2. Adding or Deleting Pests

A pest that does not pose a threat to public health, except termites, may be added to the label provided that:

(a) the registrant maintains efficacy data for each pest added;

(b) the pest occurs on one or more sites on the approved label;

(c) the pest matches the type of product registered (e.g., a fungus may not be added to an insecticidal product); and

(d) the dosage, frequency, concentration or method of application do not change.

To add public health pests or termites to a label, the registrant must submit an Application for Amended Registration (EPA Form 8570-1). Public health pests include, but are not limited to, mosquitoes, rodents, viruses and bacteria (other than odor-causing). Microbial pests and claims which are related to public health are de-

scribed in OPP's Antimicrobial Program Branch DSS/TSS Sheet #16. Questions on whether other pests are considered public health related may be referred to the appropriate branch or PM team. Questions on termiticide products may be referred to the Insecticide-Rodenticide Branch.

A pest may be deleted from the label by notification at any time.

3. Adding Indoor, Nonfood Sites for Antimicrobial Products

Indoor, nonfood sites, subsites or substrates may be added to antimicrobial products provided that:

(a) no additional data (such as efficacy data for public health pests or termites, groundwater data, ecological effects data, etc.) are required for the added nonfood sites;

(b) these sites are within an already registered use pattern category for the product (as specified in 40 CFR Part 158);

(c) exposure is not increased (examples of increased exposure include adding use in paints to a product registered for caulking, or adding broadcast treatment to a product registered for spot treatment);

(d) an agency decision or directive does not explicitly prohibit addition of nonfood sites to particular products;

(e) the labeling of the technical product from which the end use product is formulated does not prohibit the proposed site; and

(f) the dosage, concentration, frequency or method of application do not change.

4. Adding, Revising or Deleting Advisory Statements

Advisory statements (such as those related to use precautions, efficacy, crop damage and product incompatibility) may be added or revised provided that the statements:

(a) are not mandatory phrases such as: "do not," "must not" and "shall not;"

(b) do not negate or detract from the required precautionary statements or other label statements;

(c) do not trigger efficacy, human health or environmental concerns;

(d) do not change the dosage, frequency, concentration or method of application;

(e) are not false or misleading; and

(f) do not negate or conflict with statements made on any other product label which refers to use of the subject product or chemical.

Examples of advisory statements include: "This product is not recommended for use on natural marble surfaces" and "This product should not be used with products containing X due to risk of explosive reaction."

Advisory statements may be deleted by notification at any time.

5. Changes in Packaging and Related Labeling Statements

Changes in the shape, color or composition of packaging and in related labeling statements may be done by notification only if all of the following criteria are met:

(a) the dosage, concentration, frequency or method of application do not change;

(b) exposure is not likely increased (examples that might increase exposure include: adding non-water soluble packaging to a product which is only registered for water-soluble packaging; protective clothing or equipment required because of the proposed package change; and new data requirements triggered for increased exposure);

(c) the product is not subject to child resistant packaging (CRP), either before or after the proposed change;

(d) the product is not a rodenticide;

(e) no Worker Protection Standard labeling statements are changed;

(f) the package size is not reduced to the point that the net contents of the package is smaller than the dosage required by directions for use;

(g) the package size or other ·characteristics is not changed in a way which violates EPA-mandated restrictions imposed on a product (e.g., size limitations may be imposed on a product to limit its use to homeowners only); and

(h) no changes are made to "bait stations," "control stations," "attractant stations" or other packaging that houses the pesticide during its use.

6. Use Deletions Related to Data Call-In's

Section 6(f) of FIFRA requires EPA to publish a notice of receipt of a voluntary cancellation of a product or one or more of its uses in the Federal Register for public comment. If a registrant of the source(s) of an active ingredient (manufacturing use product-MP) decides to voluntarily cancel one or more uses in response to a data call-in, EPA will publish a Federal Register notice an-

nouncing the proposed voluntary cancellation of those uses on the MP and indicate that such uses will be deleted from all products containing the active ingredient unless someone responds within the comment period that they wish to support the continued registration of those uses. After the comment period closes and no one has requested to support the use(s) proposed for deletion, end use registrants will be given three options: support the deleted use(s), request deletion of the use(s) by notification or voluntarily cancel the product. **If deletion of the use(s) is chosen as a response to a data call-in, the end use registrant should submit a notification for each product rather than an amendment as described in PR Notice 91-1.** Use deletions for MP products, or for end use not responding to a data call-in, may only be submitted as amendments as described in PR Notice 91-1.

7. Storage and Disposal Statements

PR Notices 83-3 and 84-1 permitted registrants to adopt storage and disposal labeling statements as specified in those notices without amendment. Registrants may continue to adopt labeling statements verbatim from those notices by notification. However, a request for variation in the wording of those statements should be submitted as an amendment.

8. Bilingual Labeling

The Agency may require bilingual labeling to protect public health and the environment [40 CFR 156.10(a)(3)]. When bilingual labeling is not required by the Agency, registrants may submit by notification a copy of the foreign language labeling. The foreign text must be a true and accurate translation of the English text. Note: Both

language versions of the labeling should appear on a container in their entirety.

9. Use of Symbols and Graphics

Symbols and graphics may be used in conjunction with and in close proximity to explanatory label text, provided that they do not substitute for or conflict with label text, and are not false or misleading (as described in 40 CFR 156.10(a)(5)). Examples include:

- arrow diagrams demonstrating how to open product containers.
- graphics displaying application patterns such as aerial application.
- pictograms displaying various exposure routes.
- pictures of where the product can be used.
- pictures of persons wearing appropriate protective clothing.

10. Redundant Labeling Statements

Statements may be combined to remove redundancy anywhere on the label, provided that statements required by the Agency are not removed or changed. The revised statements must be consistent with 40 CFR 156.10 and Agency policy.

11. Changes in Warranty Statement

Warranty statements may be revised provided they do not disclaim the performance or safety of the product when used in accordance with label directions, and are otherwise consistent with 40 CFR Part 156.

12. Other Revisions

Minor label changes not described in Section II.A.1.-11. and Section III. which are related to FIFRA may be made by notification, provided they:

(a) are consistent with 40 CFR Part 156; and

(b) involve no change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use; and/or

(c) are permitted or required by a PR Notice.

B. Product Chemistry

1. Active Ingredients

A registrant may change the source of an active ingredient by notification, provided that the alternate source:

(a) is registered for at least the same uses for which the formulated product is registered; and

(b) is similar to the current source, i.e., meets the criteria given in 40 CFR 152.43(b)(l) and (2).

A registrant should submit a Formulator's Exemption (EPA Form 8570-27) along with the notification of source change if the new source is registered for the same uses as the existing source [40 CFR 152.85(c)].

A registrant may **not** make the following active ingredient related changes by notification, but must submit an application for amendment:

- A change in the source of an active ingredient which would result in a change in the amount of any inert ingredient such that it would fall outside its certified limits. This would be considered an alternate formulation. Such a change may result in significant changes in the toxicological or chemical properties of the product.

- A change to an unregistered source of an active ingredient.
- Addition, deletion, or substitution of an active ingredient or increase or decrease in the amounts of existing active ingredient would constitute a new formulation, which requires a separate registration.
- A change in the stated nominal concentration of any active ingredient or change of certified limits that are not shown on the previously submitted Confidential Statement of Formula (CSF), EPA Form 8570-4.
- If the new source is not registered for the same uses as the existing source, an amendment for registration must be submitted to delete unsupported uses from the formulated product, or to support the additional uses with data.

2. Inert Ingredients

a. Change in Source

If the Agency has required that a registrant identify the source of an individual inert ingredient, the identity of which is known to the registrant, the registrant may change the source of that inert ingredient by notification. However, if the Agency has not required identification of the source of an inert ingredient, the registrant may change a source without notification to the Agency.

b. Change in Nominal Concentration

A registrant may change the stated nominal concentration of any inert ingredient by notification, provided that:

(1) the nominal concentration falls within the certified limits for that ingredient as listed on the accepted CSF; and

(2) the composition of the ingredient is known to the registrant.

c. Change in Certified Limits

A registrant may change the certified limits of any inert ingredient(s) in a formulation by notification, provided that they fall within the standard certified limits in 40 CFR 158.175(b)(2). Certified limits may not be changed via notification for products for which:

(1) the Agency has previously determined that alternative certified limits will apply; or

(2) the registrant has already changed the nominal concentration per Section 11.B.2.b. above.

d. Inert Changes **Not** Permitted by Notification

- Changes in proprietary ingredients such as specific solvents or common commodity diluents, which generally are composed of a mixture of ingredients and whose composition is not disclosed to the registrant, require the Agency to determine their acceptability based upon information on their composition supplied by the producer.
- Changes of inerts for: (1) antifoulant paints (because such changes may affect the release rate of these products) or (2) products used for the control of vertebrate animals (because odor, taste and dye are usually crucial to product effectiveness).
- Minor formulation changes covered in Section IV. below.

3. Starting Materials for Integrated Systems Products

A registrant who produces a product by an integrated system [40 CFR 158.153(g)] which uses an unregis-

tered source of active ingredient is required to supply the Agency with the sources of the starting materials for each ingredient (40 CFR 158.153). A registrant may change the source of his starting materials to other sources if the change will not result in:

(a) an increase in the upper certified limit of any existing impurity;

(b) the formation of any new impurity at a level greater than 0.1 percent by weight of the technical grade active ingredient; or

(c) the formation of other impurities of toxicological concern (e.g., dioxins, furans, nitrosamines, arsenicals) above levels previously permitted by the Agency.

4. Change in Formulation Process

A registrant may modify a formulation process of a product made by a non-integrated system (a blending or dilution of product components involving no chemical reaction--distinguished from a reaction process), provided:

(a) the certified limits of the active and inert ingredients do not change as a result; and

(b) the physical/chemical/biological characteristics and/or the effectiveness (efficacy) of the product will not change.

III. NON-NOTIFICATIONS

In accordance with 40 CFR 152.46(b), a registrant may accomplish the following types of actions without notification to the Agency:

A. Correcting typographical and printing errors in labeling as well as changes in grammar and/or phrasing that do not change how the product will be used (e.g., adding and/or changing prepositions) provided that the

use directions, signal words or requirement for child-resistant packaging does not change and that the format is consistent with Agency labeling requirements. Any corrections which result in changes in use directions, use precautions or the ingredient statement must be submitted as a notification or an amendment as described in this PR Notice.

B. Changes in package size and the net contents, except for:

(1) products subject to child-resistant packaging requirements under 40 CFR Part 157 (either before or after the package size change);

(2) product subject to other special Agency-mandated size-related requirements; and

(3) rodenticidal products.

C. Revision, addition or deletion of non-FIFRA related label elements, such as the following:

- Symbols and graphics required by other government agencies such as the Department of Transportation.
- State-required analysis of a fertilizer product.
- Lot or batch codes, barcodes or other production identifiers.
- Date of manufacture or label approval.
- Use of metric units in addition to standard U.S. units for net contents, dosages and other numeric expressions.

D. Changes in the name or address of the registrant on the label, except for a change resulting from transfer of ownership, which requires Agency approval in accordance with 40 CFR 152.135. 40 CFR Section 152.122 re-

quires, however, that a registrant notify EPA of a change in its company name, address or designated agent.

E. Redesign of label format that does not modify approved label text and is consistent with the format requirements of 40 CFR 156.10 and Agency policy. These may include, among other things, changes in color, type size or style, use of space, configuration or placement of label elements.

IV. ACCELERATED REVIEW OF MINOR FORMULATION CHANGES

Although a formulation change may only be accomplished through submission of an application for amended registration, the Agency has developed an accelerated review for certain minor formulation amendments. The criteria are listed below, followed by a description of the review process.

A. Minor Formulation Amendments

Amendments involving the following types of formulation changes will be considered eligible for accelerated review subject to these limitations:

1. Addition, deletion or substitution of one or more colorants in a formulation:
   (a) the total percentage of changed colorant does not exceed 1% by weight of the formulation;
   (b) the component(s) of the colorant are listed on EPA's Pesticide Inert Ingredient Lists 3 or 4;
   (c) if the product is registered for food use, the colorant has the appropriate exemption from the requirement of a tolerance under 40 CFR 180.1001; and

(d) the product is not intended for use on seed.

2. Addition, deletion or substitution of one or more fragrances in a formulation:

(a) the total percentage of changed, added or deleted fragrance does not exceed 1% by weight of the formulation;

(b) information on the composition of the fragrance has been provided to the Agency by the fragrance manufacturer or registrant;

(c) the fragrance has been determined to be acceptable for such use by the Agency at the proposed concentration or the component(s) of the fragrance are listed on EPA's Pesticide Inert Ingredient Lists 3 or 4; and

(d) if the product is registered for food use, the fragrance components are exempt from the requirement of a tolerance under 40 CFR 180.1001.

(e) the product is not intended for use in baits or repellents.

3. Addition, deletion or substitution of one or more inert ingredients (other than fragrances or dyes) in a formulation:

(a) the nominal concentration of active ingredient does not change;

(b) the change does not invalidate any product-specific data submitted in support of the initial registration which causes additional data to be required;

(c) the identity of any proposed substitute inert ingredient is known by the registrant and is listed on EPA's Pesticide Inert Ingredient Lists 3 or 4;

(d) if the product is registered for food use, the inert ingredient is considered to be exempt from the requirement of a tolerance under 40 CFR 180.1001;

(e) any change is for inert ingredients used for the same purpose in the formulation (e. g. , carrier, emulsifier, surfactant); and

(f) the product is not intended for use in public health antimicrobial products, baits or repellents.

Applications for accelerated review of the above kinds of amendments should not be submitted if the proposed reformulation will:

(1) change the product's acute toxicity category or physical/chemical characteristics necessitating label modifications; or

(2) affect the product's efficacy so that supporting data are required (such as for vertebrate control products, tin-based antifoulant paints, food-contact sanitizing solutions subject to regulation under 21 CFR 178.1010, and liquid or aerosol insecticides intended for household use).

B. Review Process

If a registrant believes that an amendment meets the criteria above, he/she should identify it as such on the application-for amended registration with a statement such as **"Minor Formulation Amendment per PR No-**

tice 95-2 .” The submission should be addressed to the Product Manager and contain:

1. an application (EPA Form 8570-1),
2. one (1) copy of the CSF for the existing formulation,
3. two (2) copies of the CSF of the proposed formulation, and
4. any supporting information such as MSDS sheets on the added inert ingredient(s).

The PM will make every effort to prepare an appropriate response to the registrant either accepting or rejecting the amendment within **45 days** of receipt of application.

V. PROCEDURES FOR NOTIFICATIONS

A. Notifications

1. Notification Submission.

For **each product** a notification should be submitted with a completed Application for Registration (EPA Form 8570-1). A **photocopy** of the EPA application form is acceptable; an original form is not needed. The application should bear the following statements:

- **“Notification of (insert type of change, such as ‘Alternate Brand Name’) per PR Notice (insert number).”**
- **“This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand**

that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

2. Labeling

For each notification involving labeling changes, one (1) copy of the labeling must be submitted **with the changes clearly marked so that they can be photocopied.**

3. Confidential Statement of Formula (CSF)

Two (2) original and signed CSFs must be submitted for either a notification or an amendment involving a CSF change. In addition, a Formulator' s Exemption form (EPA Form 8570-27) should be submitted for any change in the identity or source of active ingredients.

4. Signature

Each notification should be signed by the registrant or authorized agent and include that person's current address and telephone number.

5. EPA Mailing Address

All correspondence concerning notification actions should be addressed and mailed to:

Document Processing Desk (NOTIF) or
(AMEND) (as applicable)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460-0001

6. EPA Delivery Address

The official delivery address used for notification actions hand-carried or courier delivered Monday through Friday, 8:00 AM to 4:30 PM, excluding Federal holidays is:

Document Processing Desk (NOTIF) or
(AMEND) (as applicable)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection
Agency Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

7. EPA Processing of Notifications

EPA will screen all notifications to determine whether they meet the criteria in this PR Notice or other notices. If a notification is determined not to qualify for notification, EPA will inform the registrant via letter that the submission does not qualify and is being sent to the RD PM team for processing as an application for amended registration. EPA will attempt to screen each notification within 30 days of receipt.

B. Pending Applications

If a registrant has an application for amended registration pending with the Agency which qualifies for notification pursuant to this Notice, the registrant should: (1) send a letter to the PM requesting that the application for amended registration be withdrawn and (2) submit a notification to one of the addresses above. The Agency will then process the notification in lieu of the application for amended registration.

C. Distribution and Sale

When amendment of a registration is permissible by notification, the notification must be received by the

Agency before the registrant may distribute or sell the product. Final printed labeling must be also be submitted to the Agency before a product, as modified, may be sold or distributed [PR Notice 82-2 and 40 CFR 156.10(a)(6)]. For notifications, one (1) copy of the final printed labeling is required per product, either with or separate from the notification. For all other amendments, two (2) copies of the final printed labeling are required. A product distributed or sold before a notification and final printed labeling are received is in violation of FIFRA.

VII. COMPLIANCE

Notifications and non-notifications should comply with Agency regulations and policy. Notifications and non-notifications which are not in compliance may be subject to enforcement action under FIFRA sections 12 and 14. The Agency will audit notifications to assure that the process is working properly and that such submissions are in compliance.

VIII. ADDITIONAL INFORMATION

If you have questions about this notice, call Ms. Sherada Hobgood (703-308-8352)

Stephen L. Johnson, Director
Registration Division

PESTICIDE (PR) NOTICE 98-10

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration and Reregistration of Pesticide Products

SUBJECT: Notifications, Non-Notifications and Minor Formulation Amendments

This notice expands the changes to registration which may be made by notification and non-notification, maintains the expedited review of minor formulation changes, and modifies the procedures for notifications of antimicrobial products. This notice is effective immediately and supersedes PR Notice 95-2 (May 31, 1995), except with regard to advisory statements (see section II.D. below).

I. BACKGROUND

On August 3, 1996, the Food Quality Protection Act (FQPA) was passed with a provision that added section 3(c)(9) to FIFRA concerning notifications for labeling of antimicrobial products. This section allows a registrant to add relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to pesticide claims or activity. In addition, the FQPA describes the process which a registrant and the agency must follow with respect to notifications for antimicrobial products.

EPA is issuing this notice to meet the new requirements of the FQPA and to allow additional minor, low risk registration amendments to be accomplished through notification, non-notification or as accelerated amendments. EPA believes these changes will save reg-

istrants and the Agency time and resources, while maintaining full protection of public health and the environment. Table A lists all registration amendments which may be accomplished by notification, non-notification or accelerated minor formulation changes.

II. LABELING NOTIFICATIONS

40 CFR 152.46 was revised on August 26, 1996 to allow EPA to issue procedures describing modifications to registration that are permitted by notification. This section applies only to labeling notifications. The following registration amendments may be accomplished by notification:

A. Brand Names

A registrant may change the **primary brand name** and add or change one or more alternate brand names by notification. Each name must differ from the name of any other of the registrant's products so as to permit clear identification. Brand names may not be false or misleading [40 CFR 156.10(a)(5)]. The change or addition of alternate brand names for use by the registrant is not the same as supplemental distribution by a different company or individual under agreement with the registrant (see 40 CFR 152.132 for information on supplemental distribution). The registrant **must indicate** whether the name being submitted by notification is the **primary brand name** or an **alternate brand name**.

B. Adding or Deleting Pests

A claim against a pest that does not pose a threat to public health, except termites, may be added to the label provided that:

1. the registrant maintains efficacy data for each pest added;

2. the pest occurs on a specific site on the approved label;
3. the pest matches the type of product registered (e.g., a fungus may not be added to an insecticidal product);
4. the dosage, frequency, concentration or method of application do not change;
5. addition of the pest does not increase exposure of the pesticide to humans or the environment; and
6. the pests are not subject to quarantine by the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

To add label claims against a public health pest, termites or pests subject to quarantine to a label, the registrant may not use notification, but must submit an Application for Amended Registration (EPA Form 8570-1). Public health pests include, but are not limited to, mosquitoes, cockroaches, fleas, ticks, biting flies, rodents, viruses and bacteria (other than odor-causing). Antimicrobial pests and claims which are related to public health are described in OPP's Antimicrobial Division DSS/TSS Sheet #16. Questions about public health pests, termiticides and products used for plant quarantine may be referred to the appropriate Registration or Antimicrobial Division branch which manages those products.

A pest may be deleted from the label by notification at any time.

C. Adding an Indoor, Nonfood Site for an Antimicrobial Product

An indoor, nonfood site or substrate may be added to an antimicrobial product provided that:

1. no additional data (such as efficacy data for public health pests, groundwater data, ecological effects data) are required for the added nonfood site;
2. this site is within an already registered use pattern category for the product (as specified in 40 CFR Part 158);
3. exposure is not increased (examples of increased exposure include adding use in paints to a product registered for caulking, or adding broadcast treatment to a product registered for spot treatment);
4. an agency decision or directive does not explicitly prohibit addition of nonfood sites to particular products;
5. the labeling of the technical product from which the end use product is formulated does not prohibit the proposed site; and
6. the dosage, concentration, frequency or method of application are not changed.

D. Adding, Revising or Deleting Advisory Statements

EPA is currently examining the issue of mandatory and advisory statements and plans to propose a PR Notice regarding such statements in the near future. The proposal will be issued for public comment and then finalized upon consideration of comments received. Until that final PR Notice is issued, registrants should continue to follow the guidance in PR Notice 95-2 concerning notifications for advisory statements. Registrants should also note that advisory statements **required** by EPA may **not** be deleted by notification.

E. Changes in Packaging and Related Labeling Statements

Changes in the shape, color or composition of packaging and in labeling statements that change directly because of changes in the package size and type may be done by notification only if **all** of the following criteria are met:

1. the dosage, concentration, frequency or method of application do not change;
2. exposure is not increased (examples that increase exposure include: adding non-water soluble packaging to a product which is only registered for water-soluble packaging; protective clothing or equipment required because of the proposed package change; and new data requirements triggered for increased exposure);
3. either before or after the proposed change, the product is neither subject to child resistant packaging (CRP), nor has the registrant voluntarily used CRP;
4. the product is not a rodenticide;
5. no Worker Protection Standard labeling statements are changed;
6. the package size is not reduced to the point that the net contents of the package is smaller than the dosage required by directions for use or that a reduced package size will require CRP;
7. the package size or other characteristics is not changed in a way which violates EPA-mandated restrictions imposed on a product (e.g., size limitations may be imposed on a product to limit its use to homeowners only); and

8. no changes are made to "bait stations," "control stations," "attractant stations" or other packaging that houses the pesticide during its use.

When the size of a package is changed via non-notification per Section IV.B., associated labeling statements may be changed by notification if the above criteria are met.

F. Use Deletions Related to Data Call-In's

Section 6(f) of FIFRA requires EPA to publish in the Federal Register for public comment a notice of receipt of a voluntary cancellation of a product or deletion of one or more of its uses. If a registrant of the source(s) of an active ingredient (manufacturing use product--MP) decides to delete one or more uses in response to a data call-in, EPA will publish a Federal Register notice announcing the proposed deletion of those uses from the MP label and indicate that such uses must be deleted from the labels of all products containing the active ingredient unless someone responds within the comment period that they wish to support the continued registration of those uses. After the comment period closes and no one has requested to support the use(s) proposed for deletion, end use product registrants will be given three options: support the deleted use(s), delete use(s) by notification, or voluntarily cancel the product. **If deletion of the use(s) is chosen as a response to a data call-in, the end use product registrant should respond to the DCI and submit a notification for each changed product label rather than an amendment as described in PR Notice 91-1.** Use deletions for MP products, or for end use products not subject to a data call-in, may only be submitted as amendments as described in PR Notice 91-1.

G. Storage and Disposal Statements (PR Notices 83-3 and 84-1). These notices permit registrants to adopt storage and disposal labeling statements as specified in those notices without submitting an amendment for approval. Registrants may continue to adopt labeling statements verbatim from those notices by notification. However, a request for variation in the wording of those statements must be submitted as an amendment.

H. Use of Symbols and Graphics

Symbols and graphics may be used in conjunction with and in close proximity to explanatory label text, provided that they do not substitute for or conflict with label text, and are not false or misleading (as described in 40 CFR 156.10(a)(5)). Examples include:

- --diagrams demonstrating how to open product containers.
- --graphics displaying application patterns such as aerial application.
- --pictograms displaying various exposure routes.
- --pictures of where the product can be used.
- --pictures of persons wearing appropriate protective clothing.

I. Redundant Labeling Statements

Statements may be combined to remove redundancy anywhere on the label, provided that statements required by the Agency are not removed, changed or moved. The revised statements must be consistent with 40 CFR 156.10 and Agency policy.

J. Changes in Warranty Statement

Warranty statements may be revised provided they do not disclaim the performance or safety of the product

when used in accordance with label directions, and are otherwise consistent with 40 CFR Part 156.

K. Product Composition

1. Pesticide Category. A statement identifying one of the following pesticide categories to which the product belongs may be added by notification: "fungicide," "insecticide," "rodenticide," "herbicide," "defoliant," "repellant," "desiccant," "microbiocide," "antimicrobial," "disinfectant," "sanitizer," "biochemical," "microbial," "plant regulator," "nematicide" and "plant-pesticide." Use of terms other than these is not acceptable by notification.

2. Source of ingredient(s). If a product is derived from plant extracts and is classified for acute toxicity categories III or IV, then a statement such as the following may be added to the ingredients statement: "rotenone, a botanical insecticide." Botanical claims may also be added by notification for inert ingredients if **all** inert ingredients are listed in the ingredients statement and is classified for acute toxicity categories III or IV. Broad, non-specific terms such as "natural" or "organic" are not acceptable.

3. Odor. If a product has been amended to add or change a fragrance, terms such as "fresh scent," "floral scent" and "lemon scent" which describe that odor may be added by notification. The terms "fragrance free" or "unscented" may be added by notification only if the product is odorless or nearly odorless and contains no odor-masking ingredient such as a

perfume. The term "descented" may be added by notification if the product contains an odor-masking ingredient. These terms may also be added to the product name; the registrant should specify whether it is an additional brand name or a change to the primary brand name.

4. Water-based. The term "water based" may be added by notification if the product contains at least 50% water by weight, is classified in acute toxicity category III or IV, and presents no physical/chemical hazard that requires a warning statement. All ingredients must be in an aqueous solution (not a dispersion or emulsion and only be diluted with water.

5. Changed formulation. Truthful statements about alternate formulations or minor formulation changes (such as "new" or "new formula") which have been approved by EPA may be added by notification for a period of six months after EPA's approval of a revised or alternate formula and beginning when the product with this claim is first sold or distributed. The term "improved" is allowed by notification only if it is qualified as to how the product has been improved such as "improved wettability" or "improved pouring spout." Safety related claims or other false or misleading claims are not permitted (e.g., "less toxic," "worker safe").

L. Risk Reduction

1. Non-flammability. The claim "non-flammable" may be added by notification if a product

meets the following criteria according to data entered on the confidential statement of formula:

a. If the product contains or becomes a gas, the product must not ignite when exposed to a lighted match; or

b. If the product is a liquid, the product has a flash point greater than 350° F; and

c. No test of any kind demonstrates that the product is flammable. A claim of nonflammability may not be made if any test other than in (1) or (2) above demonstrates that the product is flammable.

2. Closed system. If a product has already been approved for use in a closed system for transfer during mixing and loading, or during application, a label statement such as "Closed system for (insert 'mixing,' 'loading,' 'transfer' or 'application' as applicable)" may be added by notification. A closed system is designed to eliminate worker exposure during pesticide handling.

3. Water Soluble Packaging. A phrase such as "water soluble packaging" may be added by notification for this form of packaging.

M. Directions for Use

1. Changes in mixing directions which do not affect the dilution ratio or the minimum or maximum use dilutions. Examples:

a. When a package size is changed, the use directions may be changed to accommodate the larger size, provided the dilution

ratio remains constant (e.g., a one gallon package to be mixed with 2 gallons of water could be changed to a five gallon package to be mixed with ten gallons of water.

b. Instructions relating to cleaning or precleaning of surfaces prior to use of the product may be added for antimicrobial products, as long as such instructions do not change the dilution or application rate with respect to the approved pesticidal claim.

2. Addition of tables, charts or other graphics which present the same use directions already approved by EPA in narrative form. Providing graphic or tabular presentation of use directions which have already been approved is encouraged as long as the substance of the use directions remains the same. Parts of the narrative use directions may be removed if those directions are presented in the graphics or tables, and if no use limitations were omitted.

3. Addition of similar application methods. An additional method of application permitted under Sec. 2(ee)(3) of FIFRA which meets the following criteria may be added to the label by notification: (1) the application method results in exposure no greater than exposure from the currently registered method(s); (2) the new application method results in no change in dosage, concentration, timing or frequency of application of the product; and (3) the product is not registered for public health related uses or termiticides. For example, a trigger foamer

sprayer may be added to a trigger sprayer product if the likely exposure is no greater, if the dosage, concentration or frequency of application falls within the range of currently approved use directions, and if the label makes no public health related claims. The registrant must have data in its files to show that the product meets the above criteria.

4. Mixing with a fertilizer. The use directions may be modified by notification to include mixing with a fertilizer, provided that the dosage, concentration and frequency of the pesticide application do not change.

N. Other Revisions

Minor label changes not described in Section II.A.-M. and Section III. which are related to FIFRA may be made by notification, provided they:

1. are consistent with or specified by a PR Notice; or
2. are consistent with 40 CFR Part 156; and
3. involve no change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use.

III. PRODUCT CHEMISTRY NOTIFICATIONS

A. Source of Active Ingredients

A registrant may change the source of an active ingredient by notification, provided that the alternate source:

1. is registered for at least the same uses for which the formulated product is registered; and

2. is similar to the current source, i.e., meets the criteria given in 40 CFR 152.43(b)(1) and (2).

A registrant must submit a Formulator's Exemption (EPA Form 8570-27) along with the notification of source change if the new source is registered for the same uses as the existing source [40 CFR 152.85(c)].

A registrant may NOT make the following active ingredient related changes by notification, but must submit an application for amendment:

--A change in the source of an active ingredient which would result in a nominal inert ingredient total, or result in a changed toxicological category or chemical property of a product. This changed formula would be considered an alternate formulation.

--A change to an unregistered source of an active ingredient.

--Addition, deletion, or substitution of an active ingredient or increase or decrease in the amounts of existing active ingredient would constitute a new formulation, which may require a separate registration.

--A change in the stated nominal concentration of any active ingredient or change of certified limits from that shown on the previously submitted Confidential Statement of Formula (CSF), EPA Form 8570-4.

--If the new source is not registered for at least the same uses as the existing source, an amendment for registration must be submitted to delete unsupported uses from the formulated product, or to support the additional uses with data.

A. <u>Inert Ingredients</u>

1. <u>Change in Source</u>

If the Agency has required that a registrant identify the source of an individual inert ingredient, the identity of which is known to the registrant, the registrant may change the source of that inert ingredient by notification. However, if the Agency has not required identification of the source of an inert ingredient, the registrant may change a source without notification to the Agency.

2. Change in Nominal Concentration

A registrant may change the stated nominal concentration of any inert ingredient by notification, provided that:

a. the nominal concentration falls within the certified limits for that ingredient as listed on the accepted CSF; and

b. the composition of the ingredient is known to the registrant.

3. Change in Certified Limits

A registrant may change the certified limits of any inert ingredient(s) in a formulation by notification, provided that they fall within the standard certified limits in 40 CFR 158.175(b)(2). Certified limits may not be changed via notification for products for which:

a. the Agency has previously determined that alternative certified limits will apply; or

b. the registrant has already changed the nominal concentration per Section III.B.2. above.

4. Inert Changes Not Permitted by Notification

-- Changes in proprietary ingredients such as specific solvents or common commodity diluents, which generally are composed of a mixture of ingredients and whose composition is not disclosed to the registrant,

require the Agency to determine their acceptability based upon information on their composition supplied by the producer.

-- Changes of inerts for: (1) antifoulant paints (because such changes may affect the release rate of these products); (2) products used for the control of vertebrate animals (because odor, taste and dye are usually crucial to product effectiveness); and (3) baits used to control insects and other vertebrates.

-- Minor formulation changes covered in Section V. below.

C. Sources for Starting Materials for Integrated Systems Products

A registrant who produces a product by an integrated system [40 CFR 158.153(g)] which uses an unregistered source of active ingredient is required to supply the Agency with the sources of the starting materials for each ingredient (40 CFR 158.153). A registrant may change the source of the starting materials to other sources by notification if the integrated systems product is (1) not a microbial pesticide, a botanical pesticide, or any other pesticide produced via any methods other than man-made chemical synthesis and (2) the change will not result in:

1. an increase in the upper certified limit of any existing impurity;
2. the formation of any new impurity at a level greater than 0.1 percent by weight of the technical grade active ingredient; or
3. the formation of other impurities of toxicological significance (e.g., dioxins, furans, nitrosamines, arsenicals) that have not previously been reported

to the agency or that occur above levels previously permitted by or reported to the Agency.

D. Change in Formulation Process

A registrant may modify a formulation process of a product made by a non-integrated system (a blending or dilution of product components involving no chemical reaction--distinguished from a reaction process), provided:

1. the certified limits of the active and inert ingredients do not change as a result; and
2. the physical/chemical/biological characteristics and/or the effectiveness (efficacy) of the product will not change.

IV. NON-NOTIFICATIONS

In accordance with 40 CFR 152.46(b), a registrant may accomplish the following types of actions without notification to the Agency:

A. Typographical and Printing Errors. Correcting typographical and printing errors in labeling as well as changes in grammar and/or phrasing that do not change how the product will be used (e.g., adding and/or changing prepositions) are permitted by non-notification, provided that the use directions, signal words or requirement for child-resistant packaging do not change and that the format is consistent with Agency labeling requirements. Any corrections which result in changes in use directions, use precautions or the ingredient statement must be submitted as a notification or an amendment as described in this PR Notice.

B. Changes in Package Size and Net Contents. These changes are permitted by non-notification, except for:

1. products subject to or which voluntarily adopt child-resistant packaging requirements under 40 CFR Part 157 (either before or after the package size change);
2. products subject to other special Agency-mandated size-related requirements; and
3. rodenticide products; or
4. changes which would change the toxicity category or chemical properties of the product.

C. Revision, Addition or Deletion of Non-FIFRA Related Label Elements. Changes such as the following are permitted by non-notification:

--Symbols and graphics required by other Federal agencies such as the Department of Transportation.

--State-required analysis of the fertilizer component of a pesticide product.

--Lot or batch codes, barcodes or other production identifiers.

--Date of manufacture or label approval.

--Use of metric units in addition to standard U.S. units for net contents, dosages and other numeric expressions.

D. Changes in the Name or Address of the Registrant on the Label.

1. In accordance with 40 CFR 152.135, the transfer of ownership must be approved by the Agency. Once a product's ownership has been approved by EPA, the registrant need not

submit labeling reflecting the new registrant's company name and address.

2. In accordance with 40 CFR 152.122, registrants are required to notify EPA of a change in the company name, address or designated agent. Subsequent product labels must bear the new name and/or address of the registrant. However, the registrant need not submit copies of the amended labeling reflecting the registrant's new company name and/or address to the Agency.

E. Redesign of Label Format. A label format change that does not modify approved label text and is consistent with the format requirements of 40 CFR 156.10 and Agency policy. These may include, among other things, changes in color, type size or style, use of space, configuration or placement of label elements.

F. Non-Pesticidal Characteristics

1. Non-pesticidal effectiveness. A non-pesticidal claim, provided it is not false or misleading, does not conflict with the pesticide labeling and is consistent with other applicable statutes or regulations that may apply to such claims. Examples of such claims include "Cleans," "Whitens and brightens laundry," "Removes soap scum," and "eliminates odors." In addition, brief directions which pertain only to these non-pesticidal uses may be added by non-notification. For example, "Use at full strength (2 cups per gallon) to remove tough stains."

2. Cleanup. A statement with respect to the ease of cleanup or removal after use, such as "leaves no film or deposit" and "cleans easily with water" as long as such statement does not conflict with the use directions or adversely affect the efficacy or safety of the product.
3. Effects on treated objects or sites. Beneficial product attributes not related to pesticidal effect, such as "non-staining" and "non-corrosive to metals."
4. Price. Claims regarding price or price-related marketing information such as "low price," "25 cents off" and "rebate available."
5. Where product is made. Factual statements about where the product was made ("Made in U.S.A."), provided these comply with other regulatory requirements.
6. Approval by other federal agencies. Factual statements about uses approved by government agencies other than EPA provided such statements do not imply endorsement by those agencies. An example of an acceptable statement would be "Approved for use in USDA-inspected meat and poultry plants." An unacceptable statement would be "Contains materials that meet all FDA standards and regulations."
7. Consumer Access Numbers. Per PR Notice 97-4, telephone numbers and internet addresses may be added to the label without notification.

8. Use of "Other Ingredients" in the Ingredients Statement. Per PR Notice 97-6, the term "Other Ingredients" may be substituted for "Inert Ingredients" in the label ingredients statement without notification.

G. Statement of Practical Treatment. The heading "First Aid" may be substituted for "Statement of Practical Treatment."

H. Product Packaging

1. Recycled content. A statement about the recycled content of pesticide packaging itself may be made in accordance with guidance from the Federal Trade Commission.

2. Refillable. After obtaining approval from EPA for a refillable container (including instructions), a registrant may add a claim that a pesticide package is refillable if:

   a. if a system exists for the collection and return of the package to a dealer for refill with the same pesticide, and instructions on how to do so are provided, or

   b. if the pesticide container may be refilled from a larger container of the same product, and instructions for refilling are provided.

I. Bilingual Labeling. A registrant may provide bilingual labeling on any product without notification. The foreign text must be a true and accurate translation of the English text. Note: Both language versions of the labeling must appear on a container. Foreign text may be used on all or part of the labeling.

J. Recycling of Containers. The following statements may be added:

a. Aerosol Containers. As described in PR Notice 94-2, the following statement may be added to pesticide aerosol containers:

"This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label (DO NOT PUNCTURE!). If recycling is not available, wrap the container and discard in the trash."

b. Residential Use Containers Other Than Aerosols. For either refillable or non-refillable containers (other than aerosol containers), the following statement may be added:

"Use product until container is empty. Offer for recycling if possible. If recycling is not available or if the container is not empty, wrap the container in several layers of paper and discard in the trash."

As permitted by Section II.D. of this notice, the registrant may add relevant advisory language pertaining to recycling by notification, such as "It is recommended that you contact your local waste management facility about recycling."

V. ACCELERATED REVIEW OF MINOR FORMULATION CHANGES

Although a formulation change may only be accomplished through submission of an application for amended registration, the Agency has developed an accelerated review for certain minor formulation amendments. The

criteria are listed below, followed by a description of the review process. Note that confirmatory efficacy data are not required for minor formulation amendments, except for aerosols.

A. Minor Formulation Amendments

Amendments involving the following types of formulation changes will be considered eligible for accelerated review subject to the following limitations:

1. Addition, deletion or substitution of one or more colorants in a formulation:
   a. the total percentage of changed colorant does not exceed 1% by weight of the formulation;
   b. the component(s) of the colorant are listed on EPA's Pesticide Inert Ingredient Lists 3 or 4;
   c. if the product is registered for food use, the colorant has the appropriate exemption from the requirement of a tolerance under 40 CFR 180.1001(c), (d) or (e); and
   d. the product is not intended for use as a seed treatment or rodenticide.
2. Addition, deletion or substitution of one or more fragrances in a formulation:
   a. the total percentage of changed, added or deleted fragrance does not exceed 1% by weight of the formulation;
   b. information on the composition of the fragrance has been provided to the Agency by the fragrance manufacturer or registrant;

c. the fragrance has been determined to be acceptable for such use by the Agency at the proposed concentration or the component(s) of the fragrance are listed on EPA's Pesticide Inert Ingredient Lists 3 or 4; and

d. if the product is registered for food use, the fragrance components are exempt from the requirement of a tolerance under 40 CFR 180.1001(c), (d) or (e).

e. the product is not intended for use in baits or repellents.

3. Addition, deletion or substitution of one or more inert ingredients (other than fragrances or dyes) in a formulation:

a. the nominal concentration of active ingredient does not change;

b. the change does not invalidate any product-specific data submitted in support of the initial registration which causes additional data to be required;

c. the identity of any proposed substitute inert ingredient is known by the registrant and is listed on EPA's Pesticide Inert Ingredient Lists 3 or 4;

d. if the product is registered for food use, the inert ingredient is considered to be exempt from the requirement of a tolerance under 40 CFR 180.1001(c), (d) or (e);

e. any change is for inert ingredients used for the same purpose in the formulation (e.g., carrier, emulsifier, surfactant); and

f. the product is not a bait or repellent and is not intended to be used to control pests of significance to public health.

Applications for the above kinds of amendments will not be considered for accelerated review if they will:

- change the product's acute toxicity category or physical/chemical characteristics necessitating label modifications; or
- affect the product's efficacy so that supporting data are required (such as for vertebrate control products, tin-based antifoulant paints, food-contact surface sanitizers, and liquid or aerosol insecticides intended for household use).

B. Review Process

If a registrant believes that an amendment meets the criteria above, he/she should identify it as such on the application for amended registration with a statement such as **"Minor Formulation Amendment per PR Notice 98-10."** The submission should be addressed to the Minor Formulation Review Coordinator (MFRC), Registration Support Branch and contain:

1. an application (EPA Form 8570-1),
2. one (1) copy of the CSF for the existing formulation,
3. two (2) copies of the CSF of the proposed formulation, and
4. any supporting information such as MSDS sheets on the added inert ingredient(s).
5. confirmatory efficacy data only if the product is an aerosol or bears a public health claim.

EPA will make every effort to prepare an appropriate response to the registrant either accepting or rejecting the amendment within **45 days** of receipt of application except when confirmatory data are submitted; additional time is required for review of such data. The MFRC will refer applications to the appropriate offices for review.

VI. PROCEDURES FOR NOTIFICATIONS

A. Notifications

1. Notification Submission. For **each product** a notification should be submitted with a completed Application for Registration (EPA Form 8570-1). A **photocopy** of the EPA application form is acceptable; an original form is not needed. In order for the application to be processed, include the following statements on the application:

- **"Notification of (insert type of change, such as 'Alternate Brand Name') per PR Notice 98-10."**
- **"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."**

2. Procedures for notification for **antimicrobial products**. All notifications for antimicrobial products must be submitted in accordance with the procedures of this paragraph and any supplemental notice to registrants.

   a. **Submission**. A registrant must submit the notification to the Agency at least 60 days before distribution or sale of a product as modified.

   b. **Substantiation**. A registrant must retain in his files, and make available for inspection or copying, substantiating information or data supporting the proposed modification. These data need not be submitted with the notification, but may be required by the Agency if the notification is disapproved.

   c. **Agency decision**. Within 30 days after receipt of a notification, the Agency will notify the registrant in writing if the notification is disapproved and state the reasons why it is unacceptable.

   d. **Objection**. A registrant may file an objection in writing to a disapproval not later than 30 days after receipt of the Agency's disapproval. If the basis for the disapproval is that substantiating information is needed, the registrant must submit such information as part of the objection. A decision by EPA after receipt and consideration of an objection is a final agency action.

e. **Distribution or sale**. A registrant may not distribute or sell an antimicrobial product for which a modification by notification is proposed until he receives EPA notice of approval, or until 60 days after submission, whichever comes first. A registrant may not sell or distribute a product bearing a disapproved modification.

3. Procedures for notification for products **other than antimicrobials**. Notifications for non-antimicrobial products must be submitted in accordance with the procedures of this paragraph and any supplemental notice to registrants.

a. **Submission**. A registrant must submit a notification to the Agency before distributing or selling a product amended in accordance with this notice or any other notice authorizing specific amendments by notification. A registrant wishing to be informed of an acceptable notification may submit a stamped, self-addressed postcard identifying the notification and EPA Registration number of the product.

b. **Agency objection**. Normally within 30 days of receipt of a notification, the Agency will notify the registrant if the application does not qualify as a notification and state the reasons why. The application will then be processed as an amendment.

c. **Distribution or sale**. A registrant may distribute or sell a non-antimicrobial

product modified by notification once EPA receives that notification. However, a registrant may not sell or distribute a product bearing a disapproved modification.

4. Labeling

For each notification involving labeling changes, one (1) copy of the labeling must be submitted **with the changes clearly marked so that they can be photocopied**.

5. Confidential Statement of Formula (CSF)

Two (2) original and signed CSFs must be submitted for either a notification or an amendment involving a CSF change. In addition, a Formulator's Exemption form (EPA Form 8570-27) must be submitted for any change in the identity or source of active ingredients.

6. Signature

Each notification must be signed by the registrant or authorized agent and include that person's current address and telephone number.

7. EPA Mailing Address

All mail concerning notification actions should be addressed to:

Document Processing Desk (NOTIF) or
(AMEND) (as applicable)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460-0001

8. EPA Delivery Address

The official delivery address used for notification actions hand-carried or courier delivered Monday through

Friday, 8:00 AM to 4:30 PM, excluding Federal holidays is:

Document Processing Desk (NOTIF) or
(AMEND) (as applicable)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

B. Pending Applications

If a registrant has an application for amended registration pending with the Agency which qualifies for notification, and wishes to have it processed as a notification, then he/she should: (1) send a letter to the relevant PM or Branch requesting that the application for amended registration be withdrawn and (2) submit a notification to one of the addresses above.

C. Final Printed Labeling

Two (2) copies of final printed labeling must be also be submitted to the Agency before a product, as modified, may be sold or distributed [PR Notice 82-2 and 40 CFR 156.10(a)(6)].

VII. COMPLIANCE

Notifications and non-notifications must comply with Agency regulations. As provided in 40 CFR 152.46(c), if the Agency determines that a product has been modified through notification or without notification in a manner inconsistent with this notice or applicable law or regulations, EPA may initiate regulatory or enforcement action without first providing the registrant with an opportunity to submit an application for amended registration. The Agency will audit notifications to assure that the

process is working properly and that such submissions are in compliance.

VIII. ADDITIONAL INFORMATION

If you have questions about this notice, call Linda Arrington, Registration Division (703-305-5446), Robert Torla, Biopesticides and Pollution Prevention Division (703-308-8098) or Walter Francis, Antimicrobial Division (703-308-6419).

/signed by Marcia E. Mulkey/

Marcia E. Mulkey, Director
Office of Pesticide Programs

PRN 2000-5: Guidance for Mandatory and Advisory Labeling Statements

May 10, 2000

Notice To: Manufacturers, Producers, Formulators, and Registrants of Pesticide Products

Attention: Persons Responsible for Registration and Reregistration of Pesticide Products

Subject: Guidance for Mandatory and Advisory Labeling Statements

This notice provides guidance to the registrant for improving the clarity of labeling statements in order to avoid confusing directions and precautions, and to prevent the misuse of pesticides. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 2(ee) defines the term "to use any registered pesticide in a manner inconsistent with its labeling" (i.e., misuse) as use of "...any registered pesticide in a manner not permitted by the labeling...." For purposes of this notice, the term "use" includes storage, transportation, handling, pre-application activities, mixing and loading, worker notification and worker protection, application, post-application activities and disposal. Registrants are not required to submit applications in response to this notice, however, EPA will review applications in light of the guidance presented here and seek to clarify labeling statements that are unclear or ambiguous. Finally, registrants may no longer add or change advisory labeling statements to existing products by notification as previously permitted by PR Notices 95-2 and 98-10. This PR Notice supersedes those PR Notices concerning the use of notification for adding or modifying advisory statements.

* * *

I. Guidance On Mandatory And Advisory Labeling Statements

Statements on the pesticide labeling may be interpreted by users differently from what the registrant or EPA intended when the labeling was accepted. If EPA believes that misuse has occurred, an administrative law judge or a court may have to decide whether a product's labeling statements are clear enough for the user to understand how to lawfully use the product. **Pesticide labeling needs to clearly identify what is required of the user to handle and apply a pesticide safely.** The Agency is engaged in numerous efforts to improve pesticide product labels in general (e.g., the Consumer Labeling Initiative), as well as in specific areas of the labeling (e.g., bee precautionary labeling and pesticide drift labeling).

Mandatory statements, which commonly use imperative verbs such as "must" or "shall," either require action or prohibit the user from taking certain action. **Advisory statements** generally provide information, either in support of the mandatory statements or about the product in general. **To ensure that the intent of each labeling statement is clear, mandatory statements need to be clearly distinguishable from advisory statements.**

Currently, labeling provisions are enforced by taking into consideration all of the information presented on the label and by reading advisory statements in the context of the entire label. Problems can arise when advisory statements are either vague or ambiguous in meaning, or are inconsistent with mandatory labeling statements. In

the past, advisory statements have commonly used suggestive verbs such as "should," "may" or "recommend" to encourage the user to achieve the directed behavior, but often these statements can be unclear as to whether they are mandatory or advisory. In a recent misuse enforcement action, for example, the person charged with the violation argued that advisory statements misled him into taking action which was inconsistent with the mandatory statements.

Advisory language using terms such as "should," "may" and "recommend" can create ambiguities as to the intent of the direction or precaution. Too often, common everyday speech using the word "should" creeps into mandatory label statements where the imperative tense is needed to communicate that certain action is required. Another problem is contradictory headings and statements. A set of mandatory directions preceded by an advisory heading such as "Use Recommendations" potentially conflicts as to the nature of the intended action. Lastly, the use of words such as "should" in advisory language can mistakenly imply that an unaccepted use is permissible. For example, the direction "you should remove all food articles prior to use" on a product that is not registered for any food uses could be mistakenly read to suggest that it is not mandatory to remove all food from the area to be treated. Consequently, such a statement would not be acceptable.

The Agency seeks to improve mandatory and advisory labeling statements by providing guidance (see Appendix) on how they can best be written. **Mandatory statements** are generally written in ***imperative or directive terms*** (such as "shall," "must," "do this," "do not") so that a typical user will understand that these

statements direct the user to take or avoid certain actions, and that failure to follow these instructions is a misuse of the product. **Advisory statements** are generally best written in ***descriptive or nondirective terms*** to support the mandatory statements or provide information. Suggestive terms such as "should," "may" or "recommend" may be confusing or ambiguous, or potentially conflict with mandatory labeling statements; thus, they are to be avoided. EPA realizes that the use of descriptive terms for advisory statements is not appropriate for every situation and that there are times where it may be necessary to use "should," "may," "recommend" or similar words. However, in most cases it is best to craft advisory labeling statements in straightforward, descriptive language.

II. How To Change Labels

Registrants should follow the guidance above and in the Appendix whenever submitting new or revised labeling to EPA for registration or reregistration. Registrants of new or existing products should draft their product labels to be consistent with the guidance, and submit them for acceptance as follows:

- Registrants may modify or add mandatory or advisory labeling statements for currently registered products **only by submitting an application for amended registration**. This application must include the following items: a completed EPA application form 8570-1, five copies of the draft label, and a description of the intended modification.
- Registrants may **no longer** add or change advisory labeling statements to existing products by **notification** as previously permitted by PR Notices 95-2 and

98-10. **This PR Notice supersedes those PR Notices concerning the use of notification for adding or modifying advisory statements.**

- Applicants for registration of new products should follow the guidance in this notice when drafting labeling to be submitted with an application.

Because of the importance of maintaining a clear distinction between mandatory and advisory statements, and of making these statements as clear as possible to pesticide users, EPA will review all new or changed mandatory and advisory labeling statements through the amendment process, except for those statements specifically permitted by other PR Notices (other than PR Notice 98-10) to be submitted by notification.

Registrants must submit applications for new products and amendment according to the Pesticide Registration Manual.

III. Non-Binding Statement

This PR Notice provides guidance to EPA and to pesticide registrants. This notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance provided in individual circumstances. Likewise, pesticide registrants may assert that the guidance is not appropriate for a specific pesticide or situation.

IV. For Further Information

If you have questions, contact the appropriate Product Manager (Registration Division and Antimicrobial Division) or Regulatory Action Leader (Biopesticides and Pollution Prevention Division) for your product.

Appendix To PR Notice 2000-5: Guidance For Writing Clear Labeling

A. Mandatory Statements

Mandatory statements generally relate to the actions that are necessary to ensure the proper use of the pesticide and to prevent the occurrence of unreasonable adverse effects, which means any unreasonable risk to man or the environment (including all living organisms and non-living things such as water, soil, air, property, etc.). Mandatory statements include directions for use and precautions that direct the user to take or avoid specific actions. The directions and precautions specify where, when and how a pesticide is to be applied. Mandatory statements are generally written in imperative or directive sentences (e.g., "Wash application equipment…," "Do not use …," "Users must…," "Apply to corn at a maximum rate of one to two pounds per acre 30 days prior to harvest."). Either EPA or the registrant may develop mandatory labeling statements. When writing mandatory statements, both EPA and the registrant need to ensure that such statements meet the criterion above that the statement is necessary to ensure proper use of a pesticide and to prevent unreasonable adverse effects.

The following directions and precautions are examples of mandatory statements:

- "Keep Out of Reach of Children."
- "Wear chemical resistant gloves."
- "If swallowed, call a doctor."
- "Do not induce vomiting."
- "Do not apply directly to water."
- "Do not apply within 66 feet of wells."

- "Keep away from heat, sparks and open flame."
- "Do not enter into treated areas for 12 hours."
- "Apply immediately after mixing."
- "Do not apply when wind speed exceeds 15 mph."

B. Advisory Statements

Advisory statements provide information to the product user on such topics as product characteristics and how to maximize safety and efficacy while using the product. Such statements are acceptable as long as they do not conflict with mandatory statements, and are not false or misleading.

Advisory statements are best written in **descriptive or nondirective terms**. Phrasing advisory statements in straightforward, factual terms minimizes the possibility that they will conflict with mandatory statements. The use of certain words such as "should," "may" or "recommend" in advisory statements has the potential to lead the product user to erroneously believe that he/she must comply with such statements, when in fact such statements do not have to be followed. These words may also give the user the erroneous impression that a use that is not recommended is still somehow permitted (that is, someone could believe that a particular use is permitted because a statement recommending against such use does not have to be followed). To avoid these potential problems, the best way to express advisory statements is to use descriptive or nondirective language. Nevertheless, EPA will allow the use of "should," "may," "recommend" or similar terms as long as they do not appear to cause these kinds of problems.

Following are hypothetical advisory statements followed by examples of how they can be rewritten using

descriptive terms, which is EPA's preference. These examples are arranged as follows:

a. A typical label advisory statement as it may have been written prior to this PR Notice.

b. The same advisory statement written in descriptive terms.

Precautionary Statements

a. Latex gloves are recommended.

b. Latex gloves provide the best protection.

Physical And Chemical Hazards

a. It is preferable to open containers of aluminum phosphide products in open air as under certain conditions they may flash upon opening. Containers may also be opened near a fan or other appropriate ventilation which will rapidly exhaust contaminated air.

b. Opening aluminum phosphide containers outdoors or indoors near an exhaust fan or other ventilation assures that the gas will be rapidly dispersed if the product flashes.

Directions For Use

Mixing

a. Tank mixtures should be applied immediately after preparation. If for any reason this is not possible, ensure that sufficient agitation has been provided to re-mix all products and check for complete resuspension prior to application.

b. Applying the product immediately after preparation assures that it is in suspension. If application is delayed, agitation to re-mix the

products and checking for resuspension ensures proper blending.

Application

1. a. Factors such as depth to the drain system, soil type, and degree of compaction should be taken into account in determining the depth of treatment.

b. The depth of treatment depends on the depth of the drain system, soil type, and degree of soil compaction.

2. a. It may be necessary to treat along one side of interior partition walls if there are cracks in the slab, plumbing entry points, existing termite infestations, or other conditions which would make treatment appropriate.

b. Treatment along one side of interior partition walls where there are cracks in the slab, plumbing entry points, existing termite infestations, or evidence of other means of access prevents further infestation.

3. a. Rotary hoeing is recommended for preemergence applications which do not receive adequate rainfall or sprinkler irrigation to wet the top 2 inches of soil or to the depth of germinating weeds within about 10 days after application.

b. If rainfall or sprinkler irrigation does not wet the top 2 inches of soil or depth of germinating weeds within 10 days of a preemergence application, rotary hoeing will ensure soil incorporation.

4. a. The spray mixture should be directed to the soil around base of the cotton plants. Care should be taken to prevent the spray from striking the cotton leaves as injury will occur. The use of leaf lifters or shields on application equipment is recommended to avoid spraying the cotton foliage.

b. Directing the spray mixture around the base of the cotton plants and using leaf lifters and shields on application equipment will help minimize foliage contact and plant injury.

Cleaning

1. a. It is recommended that the sprayer be thoroughly cleaned by flushing with a detergent solution at the end of each work day when any emulsifiable oil, oil concentrate, or other emulsifiable formulation has been used either alone or in tank mix combinations with other pesticide formulations, even if no obvious problems have been encountered. This precaution will ensure a clean sprayer and continued trouble-free operation.

b. If an emulsifiable oil, oil concentrate, or other emulsifiable formulation has been used, flushing the sprayer with a detergent solution at the end of the workday will ensure a clean sprayer and trouble-free operation.

Bayer CropScience
2 T.W. Alexander Drive
P. 0. Box 12014
Research Triangle Park, NC
27709 Tel: 919 549-2000

November 29, 2012

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Re: LARVIN Technical (EPA Reg. No. 264-343): Amendment by Notification (per PR Notice 98-10) to Add the Required California Proposition 65 Statement to the Label.

To Whom It May Concern:

As allowed by PR Notice 98-10, we are notifying the Agency of a minor labeling amendment for LARVIN Technical (EPA Reg. No. 264-343). As required by California Proposition 65, the following statement has been added to the label, "This product contains a chemical known to the state of California to cause cancer."

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to

willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

In support of this action, you will find the following:

- EPA Form 8570-1. Application for Pesticide Amendment, dated November 29, 2012.
- The amended label, dated November 29, 2012.
- The amended label, dated November 29, 2012, with the change highlighted in yellow.

Please email me at larry.hodgesl@bayer.com or phone me at (919) 549-2686 if you have any questions regarding this submission.

Sincerely,

Larry R. Hodges, Ph.D.
Registration Manager

United States Environmental Protection Agency
Washington, D.C. 20460

December 17, 2012
Dr. Larry Hodges
Bayer CropScience
2 T.W. Alexander Dr.
P.O. Box 12014
Research Triangle Park, NC 27709

Subject: Notification to add CA Proposition 65 statement to the label
LARVIN Technical
EPA Reg. No. 264-343

Dear Dr. Hodges:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated November 29, 2012 for the product LARVIN Technical. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-5967 or e-mail me at gaines.jennifer@epa.gov.

Sincerely,

Jennifer Games
Wildlife Biologist

Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs