

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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	:
TZUMI INNOVATIONS LLC,	:
	:
Plaintiff,	:
	:
-against-	:
	:
MICHAEL S. REGAN, ¹ et al.,	:
	:
Defendants.	:
-----X	:

21 Civ. 122 (LGS)

OPINION AND ORDER

LORNA G. SCHOFIELD, United States District Judge:

Plaintiff Tzumi Innovations LLC brings this action against the U.S. Environmental Protection Agency (“EPA”) and Michael S. Regan, in his official capacity as EPA Administrator (collectively “Defendants”). Plaintiff seeks injunctive and declaratory relief challenging certain actions taken by EPA regarding Plaintiff’s sanitizing wipes product Wipe Out! (“Product”). The First Amended Complaint (“Complaint”) alleges violations of (1) the Administrative Procedure Act (“APA”), 5 U.S.C. § 500 *et seq.*, (2) the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. § 136 *et seq.*, (3) Executive Order No. 13892 (“Executive Order”) and (4) the Due Process Clause of the Fifth Amendment to the Constitution.

Two motions are pending. First, Plaintiff seeks a preliminary injunction to enjoin Defendants from bringing certain enforcement actions related to the Product while this case proceeds. Second, Defendants move to dismiss the Complaint. For the reasons stated below, Defendants’ motion to dismiss is granted in part and denied in part, and Plaintiff’s motion for preliminary injunction is denied.

¹ Michael S. Regan, who became the 16th Administrator of EPA on March 11, 2021, is automatically substituted for former Administrator Andrew R. Wheeler as a Defendant in this action per Federal Rule of Civil Procedure 25(d).

I. BACKGROUND

The following facts are taken from the Complaint and are assumed to be true for purposes of this motion. *See R.M. Bacon, LLC v. Saint-Gobain Performance Plastics Corp.*, 959 F.3d 509, 512 (2d Cir. 2020).

In early 2020, Plaintiff Tzumi Innovations LLC sought to bring the Product to market in response to large demand for hand sanitizing products during the COVID-19 pandemic. The Product is a fabric wipe with .13% benzalkonium chloride, a substance that prevents disease by killing micro-organisms. The Product's physical label lists the bacteria the product kills and contains the following phrases: "Cleans and Sanitizes," "Use it Anytime, Anywhere" and "Safe on Hands." The Product's physical label does not mention surfaces or any use other than on hands.

A Tzumi employee drafted a description of the Product stating that the Product is effective on surfaces. That description appeared on a retailer's website ("Website"). The description stated: "These all-purpose disposable wipes remove common allergens, germs and messes on surfaces like kitchen counters, bathroom surfaces and more."

On or around September 1, 2020, EPA e-mailed Plaintiff and the retailer a letter dated August 29, 2020 ("Letter"), accusing Plaintiff of: (1) selling and distributing unregistered pesticides; (2) claiming that the Product is effective against viruses and bacteria; (3) implying that the Product could be used on inanimate surfaces through use of the phrase "Use it Anytime, Anywhere." The Letter is captioned "Advisory Letter," and states that it is based on information discovered on the Website.

The Letter requested that Plaintiff provide EPA a response "outlining what steps [it has] taken or will take to achieve compliance with FIFRA," including "the date on which the unregistered pesticides and misbranded devices were removed from commerce and how

[Plaintiff] intend[s] to lawfully dispose of any inventory of such products in [its] possession or control.” EPA stated that it “reserves the right to bring an action against [Plaintiff] assessing or seeking penalties and/or other relief for any FIFRA violations.”

Under EPA’s interpretation of FIFRA, EPA has a range of enforcement options in response to FIFRA violations. The options listed in EPA’s FIFRA Enforcement Response Policy (“Policy”) include, *inter alia*, “Stop Sale, Use, or Removal Orders” (“SSUROs”), civil administrative penalties, referrals for criminal proceedings and recalls. Env’tl. Prot. Agency, *FIFRA Enforcement Response Policy* 5 (Dec. 2009), <https://www.epa.gov/sites/production/files/documents/fifra-erp1209.pdf>. Pursuant to the Policy, SSUROs can be issued whenever the “EPA has *reason to believe* that [a] product is in violation of [FIFRA].” *Id.* at 7 (emphasis in original). Civil penalties can be issued where violations are committed by FIFRA registrants, commercial applicators, wholesalers, dealers, retailers or other distributors, or by a private applicator or other person who has received a warning or citation for a FIFRA violation. *Id.* at 10. The Policy provides for increases to civil penalties for “knowing or willful” violations of FIFRA and notes that EPA may consider criminal proceedings for such violations. *Id.* at 34-35. The Policy provides that EPA can “only request a recall where the evidence clearly supports the need for such action,” and that “[a]ll information supporting a recall decision should be included in the official file.” *Id.* at 12. The Policy distinguishes between mandatory and voluntary recalls. *Id.* at 12-13.

Prior to receiving the Letter from EPA, Plaintiff had concluded that the Website’s reference to surfaces should be removed and took steps to remove that reference. Plaintiff believes all references to surfaces in the description on the Website were removed by the first week of September 2020.

After Plaintiff notified EPA of the revised description on the Website, EPA continued to focus on the phrase “Use it Anytime, Anywhere” and asked Plaintiff to recall and destroy all inventory of the Product with that phrase. On September 10, 2020, EPA emailed Plaintiff stating that the Product’s label needs to be clear that the Product is intended for use only on hands and noting that the front of the Product’s label does not mention that the Product is intended for use on hands.

Plaintiff and EPA discussed the Product and its label in a series of phone calls and e-mails through December 2020. Plaintiff designed a new label for the Product and sent the revised label to EPA. EPA declined to comment on the revised label. Plaintiff sought “substantive discussions” with EPA to address EPA’s concerns before it issued a Stop Sale, Use and Removal Order (“SSURO”). EPA denied Plaintiff’s request for a meeting and instead requested that Plaintiff prepare a plan for a voluntary recall by January 8, 2021. EPA stated that if Plaintiff did not initiate a voluntary recall, then EPA would issue an SSURO.

The Complaint primarily seeks (i) a declaration that “EPA’s recall demand and threatened SSURO requiring Tzumi to either destroy [the Product] or register the [P]roduct as a pesticide” is unlawful; (ii) a declaration that “EPA’s attempted change of regulatory direction” regarding the division of regulatory authority between EPA and the Food and Drug Administration over hygienic wipes is unlawful; (iii) an order setting aside the recall demand and threatened SSURO; and (iv) an order preliminarily and permanently enjoining EPA from taking enforcement actions in connection with Plaintiff’s sale of the Product.

II. STANDARD

On a motion to dismiss, a court accepts as true all well-pleaded factual allegations and draws all reasonable inferences in favor of the non-moving party, *Montero v. City of Yonkers*, N.Y., 890 F.3d 386, 391 (2d Cir. 2018), but gives “no effect to legal conclusions couched as

factual allegations,” *Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 35 (2d Cir. 2017). To withstand a motion to dismiss, a pleading “must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Iqbal*, 556 U.S. at 678. It is not enough for a plaintiff to allege facts that are consistent with liability; the complaint must “nudge[]” claims “across the line from conceivable to plausible.” *Twombly*, 550 U.S. at 570. “To survive a motion to dismiss, plaintiffs must provide the grounds upon which [their] claim rests through factual allegations sufficient to raise a right to relief above the speculative level.” *Rich v. Fox News Network, LLC*, 939 F.3d 112, 121 (2d Cir. 2019) (internal quotation marks omitted) (alteration in original).

“A suit brought in federal court is ‘properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it.’” *Citizens for Resp. & Ethics in Wash. v. Trump*, 939 F.3d 131, 142 (2d Cir. 2019) (quoting *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000)). Plaintiff bears the burden of establishing standing. *See Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547(2016), *as revised* (May 24, 2016). When the parties are disputing standing based solely on the pleadings, “all material allegations of the complaint” are accepted as true and the complaint is construed “in favor of the complaining party.” *Am. Psychiatric Ass’n v. Anthem Health Plans, Inc.*, 821 F.3d 352, 357 (2d Cir. 2016); *accord MSP Recovery Claims, Series LLC v. Tech. Ins. Co., Inc.*, No. 18 Civ. 8036, 2020 WL 91540, at *1 (S.D.N.Y. Jan. 8, 2020).

III. MOTION TO DISMISS

A. Arbitrary & Capricious Agency Actions Claim

The Complaint alleges that EPA violated the APA and FIFRA by arbitrarily and capriciously (1) concluding that the Product is a pesticide under FIFRA, (2) demanding that Plaintiff provide a recall plan for the “Wipe Out!” product and (3) threatening future enforcement action in relation to the Product. EPA argues that this claim is not justiciable because none of those actions are final agency action and the claim is not ripe. For the reasons discussed below, the claim is dismissed as to EPA’s threat of future enforcement action but survives as to EPA’s determination that the Product is a pesticide and EPA’s recall demand.

1. Final Agency Action

EPA’s determination that the Product is a pesticide under FIFRA and demand for a recall of the Product are final agency actions because they mark the consummation of EPA’s decision-making process and legal consequences flow from those actions. The APA limits judicial review to “final agency action for which there is no other adequate remedy in court.” 5 U.S.C. § 704. An agency’s action is final if it (1) “mark[s] the consummation of the agency’s decisionmaking process” and (2) is “one by which rights or obligations have been determined, or from which legal consequences will flow.” *Salazar v. King*, 822 F.3d 61, 82 (2d Cir. 2016) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)); accord *Doe v. U.S. Immigr. and Customs Enf’t*, 490 F. Supp. 3d 672, 687 (S.D.N.Y. 2020). Ultimately, the finality inquiry is a pragmatic one. See *Salazar*, 822 F.3d at 82; *Paskar v. U.S. Dep’t of Transp.*, 714 F.3d 90, 97-98 (2d Cir. 2013) (considering the “substantial practical impact” of an agency’s letter in deciding if it was a final agency decision).

The Letter refers to the Product as among “unregistered disinfectants and other antimicrobial products” and notes that “EPA is particularly concerned about the proliferation of

these types of pesticide and pesticide devices online.” The Letter demands a response within seven days to include a recall plan explaining “the date on which the unregistered pesticides and misbranded devices were removed from commerce and how you intend to lawfully dispose of any inventory of such products in your possession or control.” This definitive language marks the consummation of agency action. *See CSI Aviation Servs. v. U.S. DOT*, 637 F.3d 408, 412-13 (D.C. Cir. 2011) (finding letter constituted final agency action where it “effectively declared the company’s operations unlawful”); *NRDC, Inc. v. U.S. DOI*, 397 F. Supp. 3d 430, 446-447 (S.D.N.Y. 2019) (finding that an opinion with definitive language marked the consummation of an agency’s decision-making process).

EPA’s Policy provides further support to conclude that EPA’s actions were final because the Policy limits the conditions under which EPA can demand a recall. The Policy states that “EPA should only request a recall where the evidence clearly supports the need for such action.” *Envntl. Prot. Agency, FIFRA Enforcement Response Policy 12* (Dec. 2009), <https://www.epa.gov/sites/production/files/documents/fifra-erp1209.pdf>. The Policy imposes requirements for documenting recall decisions and specifies conditions for when a voluntary recall is appropriate. *Id.* at 12-13.

EPA’s arguments that the Letter does not mark the consummation of its decision-making process are not persuasive. EPA cites non-binding cases to argue that the Letter does not mark the consummation of the agency decision-making process, but the letters in those cases were equivocal about the agencies’ positions. *See Holistic Candles & Consumers Ass’n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012) (emphasizing that the letter used equivocal language and the agency’s procedures manual provided that the letter did not mark the consummation of the agency’s enforcement action); *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm’n*, 324 F.3d 726, 734 (D.C. Cir. 2003) (“[T]here has been no unequivocal statement of the

agency's position on the meaning of 'consumer product' or on the agency's jurisdiction over [plaintiff.]); *Air California v. U.S. DOT*, 654 F.2d 616, 620 (9th Cir. 1981) ("The [agency letter] was neither a definitive statement of the agency's position nor a document with the status of law."). EPA also argues that it has not finished its decision-making process because it has not decided whether to issue an SSURO. That the agency may take additional action, such as issuing an SSURO, does not make the unequivocal language of the letter any less final. *See Salazar*, 822 F.3d at 83-84 ("The APA does not require that the challenged agency action be the agency's final word on the matter for it to be 'final' for the purposes of judicial review."); *accord NRDC*, 397 F. Supp. 3d at 447.

Legal consequences flow from the Letter. Because the Letter affirmatively states that the Product is a pesticide, if Plaintiff is found in violation of FIFRA, it could be subject to either enhanced civil penalties for knowingly violating FIFRA or criminal penalties. The Policy provides for a gravity adjustment to civil penalties for "knowing or willful" violations of FIFRA and notes that EPA may consider criminal proceedings for knowing and willful violations. *Envtl. Prot. Agency, FIFRA Enforcement Response Policy* at 34-35. Increased civil and criminal penalties in a future enforcement action constitute legal consequences. *See U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1815 (2016) (finding agency action to be final where action warned regulated party it could be subject to "significant criminal and civil penalties" under certain circumstances); *Sackett v. EPA*, 566 U.S. 120, 126 (2012) (finding legal consequences flowed from an order because it exposed the regulated party "to double penalties in a future enforcement proceeding"). Legal consequences also flow from the Letter because it put Plaintiff in the position of complying with EPA's costly recall demand or risking enforcement action at some uncertain point in the future. *See CSI Aviation Servs.*, 637 F.3d at 412 (holding that the agency's letter "put the company to the painful choice between costly compliance and

the risk of prosecution at an uncertain point in the future” and that the “conundrum” was “the very dilemma the Supreme Court has found sufficient to warrant judicial review” (internal quotation marks omitted)).

On the other hand, EPA’s threat to issue an SSURO is not a final agency action. The threat does not mark the consummation of the agency’s decision-making process, and no rights or obligations have been determined by a possible future enforcement action. To the extent Plaintiff’s causes of action are based on the threat to issue an SSURO, they are dismissed and are not further addressed in this Opinion.

2. Ripeness

EPA’s determination that the Product is a pesticide and EPA’s recall demand are ripe for judicial consideration. A case is ripe when a court “can confidently say that (1) the issues are fit for judicial consideration[] and (2) withholding of consideration will cause substantial hardship to the parties.” *United States v. Villafane-Lozada*, 973 F.3d 147, 150 (2d Cir. 2020) (internal quotation marks omitted) (alteration in original). “The fitness analysis is concerned with whether the issues sought to be adjudicated are contingent on unknowable future events.” *Authors Guild, Inc. v. HathiTrust*, 755 F.3d 87, 104 (2d Cir. 2014); *accord Kemper Indep. Ins. Co. v. Haughey*, No. 20 Civ. 5945, 2021 WL 134565, at *3 (S.D.N.Y. Jan. 14, 2021). The hardship analysis asks “whether the challenged action creates a direct and immediate dilemma for the parties.” *Nat’l Org. for Marriage, Inc. v. Walsh*, 714 F.3d 682, 691 (2d Cir. 2013); *accord Kemper Indep. Ins. Co.*, 2021 WL 134565, at *3. Ripeness also includes a constitutional element that, like standing doctrine, requires a “plaintiff’s injury be imminent rather than conjectural or hypothetical.” *Lacewell v. Office of the Comptroller of the Currency*, 999 F.3d 130, 149 (2d Cir. 2021).

As stated above, EPA has made a final determination that the Product is a pesticide and issued a recall request. EPA's policy limits requesting recalls to situations where "the evidence clearly supports the need for such action" and requires documenting "[a]ll information supporting a recall decision." Env'tl. Prot. Agency, *FIFRA Enforcement Response Policy* at 12. EPA has declined to alter (1) its determination that the Product is a pesticide and (2) recall request since they were issued. The legality of that determination and that request are not contingent, so they are fit for consideration. See *United States v. Traficante*, 966 F.3d 99, 106 (2d Cir. 2020) ("[A] claim is not ripe if it depends upon contingent future events that may not occur as anticipated, or indeed may not occur at all." (internal quotation marks omitted)).

Withholding consideration will subject Plaintiff to continued substantial hardship regarding the uncertain legality of the Product, which generates \$100 million of revenue a year. This uncertainty creates a direct and immediate dilemma for how Plaintiff should proceed selling and marketing the Product. The dilemma is amplified because of EPA's unwillingness to advise if alternative labeling for the Product complies with FIFRA.

EPA's argument is unpersuasive that Plaintiff's injury is not imminent because EPA has not yet commenced enforcement proceedings. Plaintiff has already suffered, and will continue to suffer, injury from EPA's declaring Plaintiff's product a pesticide and demanding a recall. Plaintiff has been forced to seek regulatory counsel and advice, developed new labeling for its Product and expended resources to determine how to bring its product into compliance with FIFRA in the eyes of EPA. See *NRDC, Inc. v. United States FDA*, 710 F.3d 71, 85 (2d Cir. 2013) ("Even a small financial loss is an injury for purposes of Article III standing."); accord *Farina v. Metro. Transp. Auth.*, 409 F. Supp. 3d 173, 191 (S.D.N.Y. 2019). When the government subjects a plaintiff to action "there is ordinarily little question that the action or inaction has caused him injury" *United States v. Vazquez*, 145 F.3d 74, 81 (2d Cir. 1998) (quoting *Lujan v.*

Defenders of Wildlife, 504 U.S. 555, 561-62 (1992)); accord *Free Libertarian Party, Inc. v. Spano*, 314 F. Supp. 3d 444, 453 (E.D.N.Y. 2018).

B. FIFRA and Declaratory Judgment Claims – Counts I, V and VI

The Complaint challenges EPA’s finding that the Product is a pesticide and demand that Plaintiff institute a voluntary recall, asserting violations of the APA, FIFRA and the Due Process Clause of the Fifth Amendment of the U.S. Constitution. For relief, the Complaint seeks an order setting aside EPA’s recall demand and a declaration that the “recall demand . . . requiring Tzumi to either destroy [the Product] or register the product as a pesticide” is unlawful.

Plaintiff has standing to assert these claims and pursue declaratory relief. To pursue declaratory relief, a plaintiff must establish “the three familiar elements of standing: injury in fact, causation, and redressability.” *Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011) (citing *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009)). “A plaintiff seeking injunctive or declaratory relief cannot rely on past injury to satisfy the injury requirement” *McCormick ex rel. McCormick v. Sch. Dist. of Mamaroneck*, 370 F.3d 275, 284 (2d Cir. 2004) (quoting *Deshawn E. ex rel. Charlotte E. v. Safir*, 156 F.3d 340, 344 (2d Cir. 1998)); accord *In re Welspun Litig.*, No. 16 Civ. 6792, 2019 WL 2174089, at *6 (S.D.N.Y. May 20, 2019). Instead, “[t]o obtain prospective relief, such as a declaratory judgment or an injunction,” “a plaintiff must show . . . ‘a sufficient likelihood that he [or she] will again be wronged in a similar way.’” *Marcavage v. City of N.Y.*, 689 F.3d 98, 103 (2d Cir. 2012) (quoting *City of L.A. v. Lyons*, 461 U.S. 95, 111 (1983)); accord *Dorce v. City of N.Y.*, 460 F. Supp. 3d 327, 342 (S.D.N.Y. 2020). Alleging “possible future injury” is insufficient. *Am. Civil Liberties Union v. Clapper*, 785 F.3d 787, 800 (2d Cir. 2015) (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013)).

The Complaint alleges that EPA violated FIFRA and Plaintiff’s due process rights when it issued the Letter and demanded a recall, and that EPA will violate FIFRA and Plaintiff’s due

process rights again when it issues an SSURO. The Complaint adequately pleads a likelihood that Plaintiff will be wronged again because it alleges that EPA has not backed down from its claim that the Product is a pesticide. EPA said that if Plaintiff did not provide a plan for a voluntary recall by January 8, 2021, EPA would issue an SSURO, EPA refused further meetings with Plaintiff, Plaintiff did not provide a plan for a voluntary recall by the EPA deadline and Plaintiff continues to sell the Product, “currently [with] 9 million units of [the Product] with the old label on the shelves with retailers” The Complaint also alleges that an SSURO would cause Plaintiff significant lost revenue and other costs.

Viewed in the light most favorable to Plaintiff, these allegations plead a sufficient likelihood of a repeated injury to Plaintiff. *See J & J Prods., Inc. v. Patin*, 358 F. Supp. 3d 318, 321-22 (S.D.N.Y. 2019) (finding risk of future civil liability sufficient for standing to seek a declaratory judgment).

EPA argues that declaratory relief is impermissible under the APA because such relief would interfere with action that is committed to its discretion by law. EPA is correct that a decision to issue an SSURO is committed to its prosecutorial discretion, but declaratory relief related to the recall demand would not interfere with EPA’s discretion because EPA has already made the decision to act and demand a recall.

C. Unlawful Change in Regulatory Position & Unlawful Rulemaking Claims – Counts II and III

Plaintiff’s rulemaking claims are dismissed because the Complaint fails to allege that EPA has made any change to its regulatory position or unlawfully promulgated rules. The Complaint alleges EPA changed its regulatory position by deciding to regulate hand sanitizing products and by enforcing a reinterpretation of what constitutes “intention that a product be used as a pesticide” under FIFRA. These conclusory allegations are insufficient to allege that EPA has

made any change to its regulatory position because they fail to show that EPA has changed its approach to regulating any product other than the Product and its particular labeling. Even if EPA had changed its position, the Complaint fails to allege any changes to rules for which notice-and-comment rulemaking is required. *See* 5 U.S.C. § 553(b)(3)(A) (providing that notice is not required for “interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice”); *accord Gonnella v. U.S. SEC*, 954 F.3d 536, 546 (2d Cir. 2020). Plaintiff’s unlawful rulemaking and unlawful change in regulatory position claims are dismissed. Because these claims are dismissed, the related demands for declaratory relief are also dismissed.

D. Executive Order 13892 Claim – Count IV

Plaintiff’s claim under Executive Order 13892 is dismissed because the Executive Order did not create a private right of action. The Executive Order states “[t]his order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.” Exec. Order No. 13892, 84 Fed. Reg. 55239, 55242 (Oct. 9, 2019). This type of language in an Executive Order precludes a private right of action. *See, e.g., Valentine Props. Assocs., LP v. U.S. HUD*, 785 F. Supp. 2d 357, 368 (S.D.N.Y. 2011); *Calef ex rel. Calef v. Barnhart*, 309 F. Supp. 2d 425, 433 (E.D.N.Y. 2004). In any event, as Plaintiff concedes, the Executive Order was revoked on January 20, 2021, by Executive Order 13992, Revocation of Certain Executive Orders Concerning Federal Regulation, 86 Fed. Reg. 7049 (Jan. 20, 2021).

IV. MOTION FOR PRELIMINARY INJUNCTION

Plaintiff’s motion for a preliminary injunction is denied because it has not shown a likelihood of success on the merits. To obtain a preliminary injunction against governmental

action taken pursuant to a statute, Plaintiff must demonstrate (1) “irreparable harm absent injunctive relief,” (2) a “likelihood of success on the merits,” (3) “public interest weighing in favor of granting the injunction” and (4) “that the balance of equities tips in [their] favor.” *Yang v. Kosinski*, 960 F.3d 119, 127-28 (2d Cir. 2020) (internal citations omitted); *see also Trump v. Deutsche Bank AG*, 943 F.3d 627, 635-41 (2d Cir. 2019) (holding that the “more rigorous standard of a likelihood of success on the merits” applies to injunctions against government action), *vacated on other grounds*, 140 S. Ct. 2019 (U.S. 2020). For the reasons below, Plaintiff has not shown a likelihood of success on the merits, and the Court need not address the other elements.

Plaintiff seeks a preliminary injunction on the grounds that EPA’s finding in the Letter that the Product is a pesticide is contrary to law and arbitrary and capricious. An agency’s decision is arbitrary and capricious where it “has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency,” or its decision “is so implausible that it could not be ascribed to a difference in view of the product or agency expertise.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *accord Alzokari v. Pompeo*, 973 F.3d 65, 70-71 (2d Cir. 2020). Under FIFRA, a pesticide is “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest” and a pest is a “virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals)” which EPA declares to be a pest. 7 U.S.C. § 136(t)-(u). A substance is considered “to be a pesticide requiring registration, if: (a) “[t]he person who distributes or sells the substance claims, states, or implies (by labeling or otherwise) . . . [t]hat the substance . . . can or should be used as a pesticide.” 40 C.F.R.

§ 152.15. Labeling is broadly defined as “all labels and other written, printed or graphic matter (A) accompanying the pesticide . . . at any time.” 7 U.S.C. § 136(p).

Plaintiff has not shown that it is likely it can prove the Letter was arbitrary and capricious. The Letter claims the Product is a pesticide because, in part, the Website stated that it could be used on surfaces to kill viruses and bacteria. Under FIFRA, a product is a pesticide when it is advertised as intended for preventing or destroying a virus, bacteria or other-micro-organism unless that micro-organism is on or in living man. 7 U.S.C. § 136(t)-(u); 40 C.F.R. § 152.15. Plaintiff does not dispute that the Website claimed the Product could be used to kill bacteria and viruses on non-human surfaces. Because the Letter explains that this claim on the Website, in part, provided a basis for EPA’s decision and that decision is supported by the plain-meaning of the statute and regulation, Plaintiff is unlikely to prove that EPA’s Letter was arbitrary and capricious.

Plaintiff’s argument that EPA should not regulate the Product because it is a hand sanitizer regulated exclusively by the FDA is not persuasive. Plaintiff contends that a 1971 Memorandum of Understanding between EPA and the FDA’s parent agency memorializes a division of regulatory responsibility between EPA and the FDA in which EPA ceded jurisdiction over hand wipes to the FDA. The Memorandum of Understanding provides for a dual-regulatory scheme in which products can be considered both a drug regulated by the FDA and a pesticide regulated by EPA, including allocation of primary and secondary jurisdiction. Plaintiff’s memorandum in support of its motion for preliminary injunction quotes the portion of the Memorandum in which EPA and the FDA recognized their dual-jurisdiction over “disinfectants and sanitizers intended for use on inanimate objects but including claims for use on humans.” The Memorandum does not provide a basis for arguing that EPA ceded jurisdiction over the Product to the FDA.

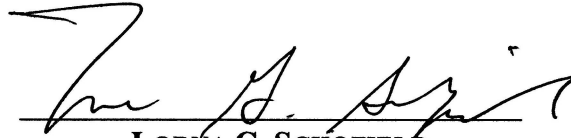
V. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is GRANTED IN PART and DENIED IN PART, and Plaintiff's motion for a preliminary injunction is DENIED. Counts II (Violation of the APA for Alleged Change in Regulatory Position), III (Violation of the APA for Unlawful Rulemaking) and IV (Violation of Executive Order 13892) are DISMISSED. For clarity, the following claims survive: Count I (Violation of the APA for finding the Product is a pesticide and EPA's recall demand), Count V (Declaratory Judgment -- Violation of FIFRA) and Count VI (Declaratory Judgment -- Violation of Due Process).

Plaintiff's motion for a preliminary injunction is DENIED.

The Clerk of Court is respectfully directed to close Dkt. Nos. 23 & 31.

Dated: July 30, 2021
New York, New York



LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE