UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, *et al.*,

Plaintiffs,

-v.-

UNITES STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Defendants

and CROPLIFE AMERICA, *et al.*,

Intervening Defendants.

03 Civ. 7155 (GEL)

NATIONAL RESOURCES DEFENSE COUNCIL, *et al.*,

Plaintiffs,

-v.-

MICHAEL O. LEAVITT, Administrator, *et al.*,

Defendants,

and CROPLIFE AMERICA, *et al.*,

Intervening Defendants.

03 Civ. 7176 (GEL)

OPINION AND ORDER

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03Civ.7155(GEL)
03Civ.7176(GEL)

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GERARD E. LYNCH, District Judge:

Plaintiffs — the States of New York, New Jersey, Connecticut and Massachusetts (the "State plaintiffs"), and the National Resources Defense Council, along with eleven other nongovernmental public health, environmental, religious, and farmworker organizations (the "NRDC plaintiffs") — filed two separate actions challenging the Environmental Protection Agency's ("EPA") determinations on its reassessment of the safety of various pesticide residues on foods under the Food Quality Protection Act, Pub. L. No. 104-170, 110 Stat. 1489 (1996). The complaints were consolidated on April 22, 2004. Intervenor-defendant CropLife America, an association of companies involved in the manufacture and distribution of pesticides, and several of its member companies filed a motion to intervene in the case, which was granted on May 29, 2004. The EPA and the CropLife defendants each moved to dismiss, and briefing was conducted on a coordinated schedule. Because the Court lacks subject matter jurisdiction over the action, defendants' motions will be granted.

BACKGROUND

Agricultural pesticides are regulated under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y, and the Federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-394.[1] The regulatory scheme requires that before a particular food treated with pesticide may be moved in interstate commerce, the EPA must set a "tolerance," or maximum permissible level of pesticide residue, that has been determined to be "safe" for use on that food; alternatively, the EPA may allow for an "exemption" from that tolerance. 21 U.S.C. §§ 331(a), 342(a)(2)(B), 346a(a)(1)-(2), (b)(2)(A)(i). The EPA must set a separate tolerance for each pesticide's use on each food. Thus, if a particular pesticide is to be used on apples, pears, and grapes, a separate tolerance must be set for each.

In 1996, Congress enacted the Food Quality Protection Act ("FQPA"), Pub. L. No. 104-170, 110 Stat. 1489 (1996), which amended this regulatory scheme to require the EPA to reevaluate on a set time-schedule the safety of all extant pesticide tolerances. Id. § 103, 110 Stat. at 1490, § 405, 110 Stat. at 1514-35 (codified at 7 U.S.C. § 136a-1(g)(2); 21 U.S.C. § 346a(q)). In undertaking this reevaluation, the EPA was to take into account a set of risk factors, including not only those resulting from exposure to pesticides in food, but also "all other exposures for which there is reliable information." Id. § 405, 110 Stat. at 1514-35 (codified at 21 U.S.C. § 346a(b)(2)(A)(ii)). The FQPA provided that in conducting its reassessments, the EPA must apply a presumptive "tenfold margin of safety in order to take into account potential pre- and

[1] FIFRA and FDCA are interconnected. FIFRA requires registration of all pesticides prior to distribution or sale, and provides that a pesticide may not be registered unless the EPA determines that "it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). "Unreasonable adverse effects" are defined in part by reference to the safety standards set in section 408 of the FDCA, 21 U.S.C. § 346a. 7 U.S.C. § 136(bb).

post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." Id. (codified at 21 U.S.C. § 346a(b)(2)(C)(ii)). The statute permits the Administrator to use a different factor "only if, on the basis of reliable data, such margin will be safe for infants and children." Id.

It is the Administrator's departure from the presumptive tenfold margin in its reassessment of permissible tolerances with respect to certain pesticides that plaintiffs principally challenge here.[2] Specifically, plaintiffs argue that in leaving certain existing tolerances in place for these pesticides without applying the tenfold margin of safety, the EPA failed to take into account scientific data demonstrating serious safety risks, or otherwise acted in the absence of "reliable data" that the departure from the tenfold margin would be "safe for infants and children." Id. The NRDC plaintiffs raise the additional claims that the EPA failed to designate farmworkers' children as a special subpopulation with heightened vulnerability to pesticide exposure, that it approved several tolerances that exceeded the agency's own calculated safe level for children's exposure, that it reduced its estimate of the acute health threats of certain pesticide uses based on percentage of crop treated, and that it relied on a "secret, industry-developed computer model" in conducting its reassessments, in violation of FIFRA, 7 U.S.C. § 136h(d). (NRDC Compl. ¶¶ 104-110, 145-47.)

Defendants move to dismiss on the ground of lack of subject matter jurisdiction, arguing that the challenged acts are not subject to review under the Administrative Procedure Act ("APA"), and that plaintiffs failed to exhaust administrative remedies. Because defendants are

[2] The State plaintiffs challenge the tolerance reassessments for alachlor, chlorothalonil, methomyl, metribuzin and thiodicarb. The NRDC plaintiffs challenge the tolerance reassessments for diazinon, disulfoton, oxydemeton methyl, alacor, and captan.

correct that, under the terms of the FDCA, this is neither the proper forum nor the proper time for plaintiffs' claims, the motions to dismiss will be granted.

DISCUSSION

I. Standard of Review

On a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) when the defendant challenges the legal sufficiency of the plaintiff's assertion of jurisdiction, the court must accept all facts alleged in the complaint as true and draw all reasonable inferences in the plaintiff's favor.[3] Sweet v. Sheahan, 235 F.3d 80, 83 (2d Cir. 2000). Dismissal is only appropriate when "it appears beyond doubt that the plaintiff can prove no set of facts which would entitle him or her to relief." Id.

II. Judicial Review under the APA

Plaintiffs assert jurisdiction under the federal question statute, 28 U.S.C. § 1331, which, in combination with the APA, 5 U.S.C. § 702, provides for judicial review of federal administrative actions. See Califano v. Sanders, 430 U.S. 99, 105-07, (1977)[4]; Lunney v. U.S.,

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[3] Defendants argue that plaintiffs bear the burden of establishing jurisdiction by a preponderance of the evidence. This is only true where the factual basis asserted for jurisdiction has been challenged. Robinson v. Gov't of Malaysia, 269 F.3d 133, 140 (2d Cir. 2001). "How the district court proceeds to resolve the motion to dismiss depends upon whether the motion presents a factual challenge." Id. (quotation and alteration omitted). "[W]here evidence relevant to the jurisdictional question is before the court, the district court may refer to that evidence," but "[i]f the defendant challenges only the legal sufficiency of the plaintiff's jurisdictional allegations, the court must take all facts alleged in the complaint as true and draw all reasonable inferences in favor of plaintiff." Id. (citations and quotations omitted). Because defendants here challenge only the legal sufficiency of plaintiffs' jurisdictional claims and have submitted no extrinsic evidence to the Court, plaintiffs are subject to no heightened burden of proof, and their factual allegations will be accepted as true.

[4] Califano held that the APA does not constitute an affirmative grant of jurisdiction, but allowed that jurisdiction over challenges to agency action brought pursuant to the APA would be

319 F.3d 550, 557-58 (2d Cir. 2003). The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof," and waives the government's sovereign immunity in actions for relief "other than money damages" against officials acting in their official capacity. 5 U.S.C. § 702; see also Department of Army v. Blue Fox, Inc., 525 U.S. 255, 260-61 (1999) (recognizing APA's waiver of sovereign immunity). The cause of action provided under the APA applies to "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

The Supreme Court has specified that "the Administrative Procedure Act's generous review provisions must be given a hospitable interpretation." Abbott Laboratories v. Gardner, 387 U.S. 136, 140-41 (1967) (citations and quotations omitted), overruled on other grounds by Califano, 430 U.S. 99, 105-07. The waiver of immunity is not unlimited, however, as the APA carves out exceptions in cases where "(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). These exceptions are to be construed narrowly in light of the APA's strong presumption in favor of judicial review, and claims should be considered precluded "only upon a showing of 'clear and convincing evidence' of a contrary legislative intent." Abbott Labs., 387 U.S. at 141 & n.2.

Defendants advance three challenges to the Court's jurisdiction under the APA. Their principal argument is that the agency actions at issue fall under the APA's exception in 5 U.S.C. § 701(a)(1) for actions precluded from judicial review by statute, because section 408(h) of the FDCA sets forth an exclusive procedure for obtaining review of certain agency actions. See 21

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proper under 28 U.S.C. § 1331.

U.S.C. § 346a(h). They argue in the alternative that even if the APA's actions are not insulated from district court review by the FDCA, the challenged tolerance determinations do not qualify as "final agency action" subject to judicial review under section 704 of the APA. And finally, they argue that plaintiffs should be required to exhaust their administrative remedies, under both the express statutory terms of section 408(h) of the FDCA, 21 U.S.C. § 346a(h), and the prudential doctrine of exhaustion.

In approaching these objections, it is appropriate to consider first whether the APA's general judicial review provision applies to the plaintiffs' claims, and then, if it does, whether they fall under the exception in section 702(a)(1) because either the FDCA or FIFRA precludes judicial review. If review is precluded, the prudential exhaustion argument need not be reached.

A. Application of the APA

According to defendants, the APA does not apply to plaintiffs' claims at all because the EPA's determinations to leave the challenged tolerances in place are not "final agency actions." Defendants raise three reasons those determinations should not be considered final: (1) they were not accomplished through the issuance of a new regulation that "modified or revoked" a tolerance, but rather, left existing tolerances in place; (2) they were issued through "Reregistration Eligibility Decisions" ("REDs") rather than through regulations; and (3) they may be challenged administratively under section 408(h) of the FDCA, 21 U.S.C. § 346a(h), the provision governing review of certain agency actions. None of these arguments is dispositive on the issue of finality.

In determining whether an agency action qualifies as "final" for purposes of the APA, the courts "have interpreted the 'finality' element in a pragmatic way." Abbott Labs., 387 U.S. at

149. As the Supreme Court has explained, "two conditions must be satisfied for agency action to be 'final': First, the action must mark the consummation of the agency's decisionmaking process — it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (quotations and citations omitted).

Defendants' assertion that the EPA's actions were not "final" because they left in place existing tolerances, rather than modifying or revoking them through new regulations, is unavailing. As the NRDC plaintiffs correctly point out, "the fact that the EPA maintained the same tolerances for these foods at the conclusion of what the agency itself calls an 'exhaustive scientific and regulatory effort' does not strip the agency's actions of finality or effect." (NRDC Br. 25.) Courts reviewing agency determinations to preserve existing regulations have routinely found that such determinations may be subject to review. See, e.g., Radio-Television News Directors Ass'n v. F.C.C., 184 F.3d 872, 880 (D.C. Cir. 1999) (Federal Communications Commission's deadlocked vote on a proposal to repeal a rule "constitutes reviewable final agency action in support of the status quo"); Center for Auto Safety v. Nat'l Highway Traffic Safety Admin., 710 F.2d 842, 846 (D.C. Cir. 1983) ("[A]n agency decision to terminate its rulemaking proceedings usually is ripe for review as final agency action [when] the agency explicitly indicates that its decision . . . is intended as a means of choosing the status quo over other reasonable alternatives."); Center for Biological Diversity v. Pirie, 191 F. Supp. 2d 161, 176-77 (D. D.C. 2002), vacated as moot by Center for Biological Diversity v. England, Nos. 02-5163, 02-5180, 2003 WL 179848 (D.C. Cir. Jan. 23, 2003) (agency decision to continue live fire military exercises in Pacific, in alleged violation of Migratory Bird Treaty Act, was final

agency action subject to APA review). The fact that the agency chose to leave the existing tolerances in place in these cases, therefore, does not by itself preclude judicial review.

Defendants' further contention that the challenged determinations were not final because they were announced through the issuance of a RED, rather than a regulation (D. Br. 19-21), is equally meritless. The EPA usually announces its determination upon completion of the reevaluation process through the issuance of a RED. Defendants offer no support for their assertion that REDs are in any way "tentative or interlocutory." 520 U.S. at 177-78. Their only attempt is the inapposite citation of two cases in which the agency actions under challenge, neither of them REDs, were clearly incomplete. See Air Espana v. Brien, 165 F.3d 148, 152-53 (agency action not final where statute stayed operation of ruling pending appeal process); Action on Smoking and Health v. Department of Labor, 28 F.3d 162, 165 (D.C. Cir. 1994) (agency action not final where notice and comment period still underway). By contrast, the issuance of a RED, whether it be one revoking, modifying, or leaving in place a tolerance, constitutes the agency's final determination, at the conclusion of a statutorily mandated review process, on the safety of the tolerance in question. There is nothing that would indicate that such a determination is merely "tentative or interlocutory": Once the RED has been issued, no further action is required of the agency, absent the filing of a petition appealing that tolerance. The challenged determinations thus marked the culmination of the review process mandated under section 408(q), and discharged the EPA's legal duty under the FQPA to reassess tolerances according to a new, more stringent set of criteria. Moreover, the determinations clearly have a direct impact on legal rights and obligations: They determine the continued permissibility of moving the treated foods in interstate commerce, and provide the EPA's official assurance that these foods,

when treated at the established tolerance levels, are safe.

Defendants' assertion that the challenged actions are not final is further belied by the EPA's own earlier description of the actions: As it announced in the Federal Register "the EPA believes it is appropriate to consider these tolerances reassessed for the purposes of the FQPA section 408(q) as of today's date . . . . The agency's assessment of these tolerances is effectively complete and the tolerances are considered reassessed." 67 Fed. Reg. 35,993 (May 22, 2002), 46,974 (July 17, 2002), 52,990 (Aug. 14, 2002), 56,558-59 (Sept. 5, 2002), & 62,556 (Sept. 5, 2002) (announcing completion of reassessment process for organophosphate pesticides diazinon, disulfoton, and oxydementon). This characterization hardly describes an agency decision that is "merely tentative or interlocutory." Defendants' attempt, in the face of litigation, to depict these determinations as "non-actions" is thus as disingenuous as it is inaccurate.

Finally, defendants' claim that reassessment determinations are not "final" because the statute provides a process for administrative appeal is directly contradicted by the language of the APA and by controlling Supreme Court authority. The APA specifies:

> Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, *unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.*

5 U.S.C. § 704 (emphasis added). The APA thus, "by its very terms, limit[s] the availability of the doctrine of exhaustion of administrative remedies to that which the statute or rule clearly mandates." Darby v. Cisneros, 509 U.S. 137, 146 (1993). The mere availability of an internal review process does not automatically foreclose judicial review. On the contrary, the Supreme

Court has required a clear indication by Congress of its intention to preclude review in order for 702(a)(1) to apply. See Id. at 144, 146-47 (1993).

In arguing that the availability of administrative review under the FDCA negates finality, defendants conflate two separate inquiries. Defendants' finality argument is essentially the same as that made in support of the assertion that review falls under the APA's statutory preclusion exception in section 702(a)(1). See infra Part II.B. But "the judicial doctrine of exhaustion of administrative remedies is conceptually distinct from the doctrine of finality." Darby, 509 U.S. at 144. As the Supreme Court has explained this distinction, "the finality requirement is concerned with whether the initial decisionmaker has arrived at a definitive position on the issue that inflicts an actual, concrete injury; the exhaustion requirement generally refers to administrative and judicial procedures by which an injured party may seek review of an adverse decision and obtain a remedy if the decision is found to be unlawful or otherwise inappropriate." Williamson County Regional Planning Comm'n v. Hamilton Bank, 473 U.S. 172, 193 (1985); see also Top Choice Distributors, Inc. v. U.S. Postal Service, 138 F.3d 463, 466 (2d Cir. 1998) ("Finality is an explicit requirement of the APA, while exhaustion is a judge-made creation, and the Supreme Court in Darby limited the applicability of the exhaustion of remedies doctrine in cases brought pursuant to the APA."). Thus, whether or not further administrative appeals are *available* to challenge agency action, the APA's presumption of judicial review applies so long as the determination is "final" under the APA; whether the statute otherwise precludes review, either by setting forth an exclusive review procedure or by foreclosing it altogether, is a separate inquiry.

The tolerance determinations challenged here clearly meet the requirements of finality set forth in Bennett: they "mark the culmination of the agency's decisionmaking process" and

represent decisions "by which rights or obligations have been determined, [and] from which legal consequences will flow." 520 U.S. 177-78. The APA's provision for judicial review thus applies absent demonstrated congressional intent to the contrary.

B. Exception under APA section 701(a)(1)

The standards governing whether a particular agency action is immune from APA review are relatively strict. In order for section 701(a)(1) to apply, defendants must show a "persuasive reason to believe that such was the purpose of Congress." Abbott Labs., 387 U.S. at 140. Congressional intent to preclude review must also be specific: The fact that a statute precludes review of a particular category of determinations does not mean that Congress intended to preclude review of other types of determinations covered by the same statute. Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667, 674, 680-81 (1986). "Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." Block v. Community Nutrition Institute, 467 U.S. 340, 345 (1984). The presumption in favor of judicial review may be overcome where "the congressional intent to preclude judicial review is 'fairly discernible in the statutory scheme.'" Id. at 351, quoting Data Processing Service v. Camp, 397 U.S. 150, 157 (1970). However, "where substantial doubt about the congressional intent exists, the general presumption favoring judicial review of administrative action is controlling." Id.

Courts applying this standards to the FDCA have recognized that the Act "contains no single, overarching provision governing judicial review." Cutler v. Hayes, 818 F.2d 879, 888 n.61 (D.C. Cir. 1987); accord Alabama Tissue Ctr. v. Sullivan, 975 F.2d 373, 376 (7th Cir. 1992);

Nader v. United States EPA, 859 F.2d 747, 754 (9th Cir. 1988). Rather, "Agency action taken under sections silent in this respect are directly reviewable in a district court under some appropriate head of its jurisdiction, for courts of appeals have only such jurisdiction as Congress has chosen to confer upon them." Cutler, 818 F.2d at 888 n.61 (citations omitted).

The statute does contain a provision, however, vesting jurisdiction over certain agency determinations in the Courts of Appeals. Subsection 408(h)(1) provides:

> In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C) of this section, or any order issued under subsection (f)(1)(C) or (g)(2)(C) of this section, or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

21 U.S.C. § 346a(h)(1). Significantly, as will be discussed more fully below, by its reference to subsection (g)(2)(C), subsection 408(h)(1) directs to the Courts of Appeals petitions for judicial review of the outcomes of the internal administrative review process established in subsection 408(g).[5] Subsection 408(h)(1) further provides that "[a]ny issue as to which review is or was

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[5] Subsection 408(g)(2)(A) provides:

> Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C) of this section, any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1) of this section, a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

21 U.S.C. § 346a(g)(2)(A). Subsection (g)(2)(C) requires the Administrator to issue an order "as

obtainable under this subsection shall not be the subject of judicial review under any other provision of law." Id. § 346a(h)(5) (emphasis added). Defendants argue that this provision brings the challenged tolerance determinations within APA section 701(a)(1)'s exception for agency actions as to which review is precluded by statute. Plaintiffs counter that subsection 408(h) does not reach the particular agency actions challenged here.

Defendants are correct that subsection 408(h), by its terms, both vests review of any provision to which it applies exclusively in the Courts of Appeals and forecloses such review prior to exhaustion of administrative remedies. Congress's intent to preclude review in any other forum is apparent in the text of the statute, which provides that challenges brought pursuant to subsection (h) "shall not be the subject of judicial review under any other provision of law." This clearly demonstrates Congress's intent to preclude other avenues of review for determinations issued under the subsections to which it applies. Moreover, the provision's broad language, specifying that it covers "any issue as to which review *is or was obtainable*," indicates an intention to sweep in any challenge to an agency action that could have been appealed through the procedures it references, regardless of whether such internal review was actually pursued. That is, subsection 408(h) explicitly applies not merely to cases in which administrative review was pursued, such that appellate review *is* obtainable under subsection 408(h)(1), but also to cases in which such review *was* obtainable had the appropriate steps been taken. A litigant challenging an administrative decision governed by these provisions thus cannot, by skipping the internal review procedures of subsection 408(g), avoid the jurisdiction of the Courts of Appeals and proceed

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soon as practicable after receiving the arguments of the parties . . . stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted." 21 U.S.C. § 346a(g)(2)(C).

instead to the District Courts under the APA, by arguing that, in the absence of an order under subsection 408(g)(2)(C), subsection 408(h)(1) is inapplicable.

Particularly in light of the regime established by subsections 408(g) and 408(h), the text of subsection 408(h) constitutes the type of language courts have insisted upon in demonstrating congressional intention to require exhaustion of administrative remedies. See, e.g., S.E.C. ex rel. Glotzer v. Stewart, No. 03-3125, 2004 WL 1489921, at *4 (2nd Cir. Jul. 6, 2004) (exhaustion required under statute providing that "[a]ny person aggrieved" by the SEC's refusal to authorize compliance with a subpoena must, as "a prerequisite to the seeking of judicial review," first file a petition with the SEC); Bastek v. Federal Crop Ins. Corp., 145 F.3d 90, 93 (2d Cir. 1998) (exhaustion required under statute providing that "a person shall exhaust all administrative appeal procedures established by the Secretary [of Agriculture] or required by law before the person may bring an action in a court of competent jurisdiction"). Congress's intent to provide a comprehensive administrative appeal process for challenges to tolerance reassessments is thus "fairly discernable in the statutory scheme." Community Nutrition Institute, 467 U.S. at 345 (quotation and citation omitted). Accordingly, review "under any other provision of law" of any claim to which this provision applies would be precluded, even in the Court of Appeals, absent exhaustion of the internal procedures set forth in the statute. Cf. Nader, 859 F.2d 747 (interpreting parallel pre-FQPA provision of FDCA as requiring exhaustion of internal procedures before challenging denial of petition for rulemaking in Court of Appeals).

As previously established, subsection (h)'s coverage is limited to the categories of agency action it specifically delineates. Of the actions listed in this subsection, subsection (g)(2)(C) is

controlling.[6] The question remaining, then, is whether or not review of the actions challenged here could have been obtained through the administrative review procedures set forth in subsection (g). However, because that provision itself incorporates by reference other subsections, which, in turn, refer to yet others, a brief tour through the statute is necessary in order to determine whether the challenged actions are subject to the exclusive review provision of subsection 408(h)(5).

Subsection (g) applies to regulations issued by the Administrator on his or her own initiative under subsection (e)(1), as well as determinations on petitions filed under subsection (d)(4). It is the latter subsection, which sets forth the procedure for filing objections to any existing tolerance or exemption, that is relevant here.[7] Paragraph (d)(1) provides in pertinent part

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[6] The other sections included in subsection 408(h)(1) are (1) regulations issued under subsection (e)(1)(C), (2) orders issued under subsection (f)(1)(C), or "any regulation that is the subject of such an order." Subsection 408(e)(1)(c) authorizes the Administrator of the EPA to issue regulations establishing "general procedures and requirements" to implement the regulation of tolerances. Subection (f)(1)(c) authorizes the Administrator of the EPA to institute procedures, after a period of notice and comment, to obtain "additional data or information . . . reasonably required to support the continuation of a tolerance or exemption" through publication of certain information in the Federal Register. 21 U.S.C. §§ 346a(e)(1)(C), (f)(1)(C).

[7] Subection 346a(d)(4) provides:

> The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator — (i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment); (ii) issue a proposed regulation under subsection (e) of this section, and thereafter issue a final regulation under such subsection; or (iii) issue an order denying the petition.

21 U.S.C. §346a(d)(4).

that "any person may file with the Administrator a petition proposing the issuance of a regulation . . . establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food." 21 U.S.C. § 346a(d)(1). Paragraph (d)(4), which governs the Administrator's determination of such petitions, requires the Administrator, upon "due consideration to a petition filed under paragraph (1)," to either issue a final or proposed regulation establishing, modifying, or revoking the challenged tolerance or exemption, or to issue an order denying the petition altogether. This type of order may in turn be challenged through the objection procedures set forth in subsection (g).

Paragraph (g)(2)(C) governs what is required of the Administrator upon receiving an objection to the disposition of such a petition. Specifically, it requires the Administrator to issue an order "as soon as practicable after receiving the arguments of the parties . . . stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted." 21 U.S.C. § 346a(g)(2)(C). It is this category of order, representing the culmination of the administrative review procedure available under the statute to those wishing to challenge existing tolerances or exemptions, that therefore falls under subsection 408(h)(5)'s limited review provision.

Plaintiffs advance several arguments in support of their position that the petition and administrative review procedure does not apply to the claims at issue. First, they argue that this procedure does not apply to determinations made pursuant to the reassessment process established by the FQPA in subsection (q), because neither subsection 408(h) nor 408(g) refers specifically to 408(q). According to plaintiffs, because "subsection (q) provides for a prospective *en masse* reassessment of tolerances for all pesticides already in use," unlike the procedure for establishing

tolerances in the first instance or reviewing them piecemeal in response to petitions filed under subsection (d), the petition and objection procedures set forth in paragraphs (d) and (g) are not applicable to reassessments performed under (q).

This position is unsupported by the language of the statute. While it is true that subsection (g) does not list subsection (q) among the subsections to which it applies, it does not follow that determinations made pursuant to subsection (q) are necessarily excluded from its coverage. To the contrary, the subsections that it does list clearly incorporate such determinations. Subsection (g) explicitly covers determinations issued pursuant to (e)(1), the general provision authorizing the Administrator to issue regulations setting tolerances or exemptions in the absence of a petition. Subsection (q), in turn, specifies that regulations issued by the Administrator to modify or revoke tolerances are issued pursuant to the authority in subsection (e)(1). See 21 U.S.C. § 346(q)(1) (providing that if a pesticide fails to meet the FQPA's statutorily-mandated safety requirements, "the Administrator shall . . . issue a regulation under subsection (d)(4) or (e)(1) of this section to modify or revoke the tolerance or exemption"). Subsection (g) would thus incorporate any challenge to a determination by the Administrator to modify or revoke a tolerance pursuant to subsection (q), because such determinations are made pursuant to subsection (e)(1). The reassessment process is squarely covered by the administrative review procedures, and therefore, by subsection (h)'s prohibition on any other avenue of review besides that available in the Courts of Appeals following the exhaustion of available administrative remedies. The statute evinces no indication of Congress's intent for the FQPA to short-circuit these procedures.

Plaintiffs further fail to offer any principled reason why determinations made pursuant to subsection (q) to leave tolerances in place should be treated any differently than decisions to

modify or revoke them. Plaintiffs argue that such determinations are unreviewable because when the Administrator decides to leave a tolerance in place, no new regulation is issued, and therefore, "there is no separate order or regulation that could be challenged pursuant to [subsection (g)]." (State Br. 14.) This is incorrect. Even assuming arguendo that an objection to such a determination would not be accepted by the agency under subsection (g), plaintiffs would still have recourse. As outlined above, a determination to leave an existing tolerance in effect would be reviewable in exactly the same manner as any existing tolerance: by "any person" filing a petition pursuant to subsection (d) to modify or revoke the challenged tolerance. The EPA would issue a determination pursuant to subsection (d)(4); the petitioner could then follow by filing an objection to this determination under subsection (g).[8]

In an effort to escape from the requirements of these procedures, plaintiffs attempt to portray their claims as a general challenge to the agency's "perva[sive]" failure to apply the required tenfold safety factor with respect to the tolerances at issue (State Br. 10), rather than a challenge to the outcome of specific reassessments. Their claims arise, they argue, not from their disagreement with the results of the reassessment with respect to any particular tolerance, but from their conviction that the review process itself violated the FQPA's explicit statutory

[8] Plaintiffs argue that requiring them to file a petition to modify or revoke a tolerance under subsection (d) would add an unnecessarily duplicative step to challenges to tolerances left in place, and thus, "would create a special category of tolerances for which in-depth review would have to happen *three times* before an aggrieved party could seek judicial review." (NRDC Br. 19.) Defendants contest this interpretation, arguing that the procedures established for reassessing tolerances would put petitions challenging decisions to leave tolerances in place on parallel footing to those challenging tolerance modifications or revocations. (D. Br. 20.) The Court need not resolve this procedural dispute. Even assuming that plaintiffs are correct and an additional step would be required, it would not be the place of this Court to judge the wisdom or efficiency of a particular procedure mandated by Congress.

mandates to apply a particular set of criteria and to take into account specific data. Plaintiffs assert that the petition process in subsection (d) is geared towards challenging the results of specific reassessment determinations, rather than the processes by which those determinations were reached, and that the petition procedure is therefore inapplicable to their claims.[9]

Plaintiffs' interpretation of their claims is borne out neither by the language of the statute nor by the substance of the complaints themselves. Their allegation is not that the EPA has an across-the-board policy of refusing to apply the tenfold factor. Rather, the complaints state that the agency failed to use the ten-fold safety factor in its reassessment of specific pesticide tolerances that it ultimately decided to leave in place. The State plaintiffs' complaint specifically states that "[w]hile EPA has failed to apply the tenfold safety factor for *a number of additional pesticide chemicals* to date, the States seek relief at this time only for these five pesticides which are widely used on children's food." (State Compl. ¶ 3, emphasis added.) The NRDC complaint states that it "specifically challenges EPA's failure to carry out the dictates of the FQPA to protect Plaintiffs' members . . . from the health threats posed by five high risk pesticides" (NRDC Compl. ¶ 4), and asserts that "[f]or each of the pesticides that are the subject of this complaint . . . EPA has waived the statutory tenfold safety factor even though reliable data do not exist to prove that a less protective margin of safety is safe for infants and children." (Id. ¶ 45.) And although the complaints each point to various problems in the EPA review process resulting in challenges to

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[9] Plaintiffs further argue that the petition procedures in (d) are aimed at manufacturers, and that they would be "entirely unable to muster the kind of technical support" required to modify or revoke a tolerance. (State Br. 12.) This is belied by the State plaintiffs' own concession that "plaintiff the State of New York has repeatedly utilized available administrative process to raise the instant claim by submitting written comments challenging EPA's failure to apply the tenfold safety factor in a number of tolerance reassessment administrative proceedings." (State Br. 18.)

numerous tolerances, the claims for relief all deal with tolerances set in connection with these specific pesticides. (See NRDC Compl. ¶¶ 148-157; State Compl. ¶¶29-66.) If plaintiffs' challenges were to the processes in general, the tolerances that were modified or revoked would presumably have suffered from the same procedural failing as those that were left in place; plaintiffs' challenge, however, is only to the latter.

It is thus clear that the complaints, at the very least, challenge the EPA's policy failures as embodied in particular tolerance reassessments, not simply on a systematic or abstract level. The same is true of the additional claims brought by the NRDC — that the agency failed to designate farmworkers' children as a special subpopulation, that it approved tolerances in excess of the calculated safe level, that it reduced its estimate of health threats based on percentage of crop treated, and that it relied on a "secret industry developed computer model" in conducting its reassessments. All of these separate counts ultimately challenge the outcome of a particular set of tolerance reassessments, even though the basis for the challenge is an objection to the methodologies used in reaching those tolerances. (See NRDC Compl. ¶ 129 (challenging 146 tolerances for failure to designate farmworkers' children as subpopulation); ¶ 136 (challenging 11 tolerances as exceeding safe level for children's exposure); ¶ 141 (challenging 120 tolerances for reducing risk based on percentage of crop treated); ¶ 146 (challenging 118 tolerances for using confidential model).)

Plaintiffs have failed to offer any support in the language of the statute for their assertion that the petition procedure in subsections (g) or (d) should not apply to their claims. Both are drafted in the broadest possible terms. Subsection (g) permits "any person" to file objections "specifying with particularity the provisions of the regulation or order deemed objectionable and

stating reasonable grounds therefor." 21 U.S.C. § 346a(g)(2)(A). Subsection (d) permits "any person" to petition for an existing tolerance (or exemption) to be established, modified, or revoked. 21 U.S.C. § 346a(d)(1). Neither provision restricts the grounds on which petitions or objections may be filed, limits them to challenges based on disagreement with the specific tolerance level set in a particular reassessment determination, or specifies that challenges to the methods used in establishing specific tolerances will not be entertained. On the contrary, the statute provides an expansive administrative appeal process for review of tolerance reassessments.

Plaintiffs' only textual argument is that subsection (d) is inapplicable to their claims because they do not ask the court to "modify or revoke" any tolerances, or to set any specific tolerance level, but rather, to vacate the reassessment determinations and remand to the agency with instructions to apply the proper criteria. This argument fails for two reasons. First, as stated above, the statute nowhere requires that a petitioner under subsection (d) must propose a particular tolerance level — it requires merely that the petition ask the tolerance to be changed or revoked. Second, plaintiffs' demand for vacatur and remand is tantamount to a request for a modification or revocation: Accepting the facts alleged in the complaint as true, application of the proper standards would de facto result in a reduction or outright revocation of the challenged tolerances. That plaintiffs have not proposed a particular tolerance level, or even explicitly demanded modification or revocation, does not change the essence of their claims: that the agency reached an incorrect result in reassessing these tolerances due to its failure to apply the correct standards.

Plaintiffs cite several cases in support of their argument that their claims are not precluded by the statute. See Cutler, 818 F.2d 879; NRDC v. Whitman, No. C 99-03701, 2001 WL

1221774 (N.D. Cal. Sept. 24, 2001); Amer. Farm Bureau, 121 F. Supp. 2d 84; California ex rel. Van de Kamp v. Reilly, 750 F. Supp. 433 (E.D. Cal. 1990). But none of these cases compels a different result, because none addresses the precise question of whether agency decisions to leave tolerances in place following the reassessment process mandated in subsection (q) are subject to the limited review provision in subsection (h).

In Cutler, the D.C. Circuit held that the district court had properly exercised jurisdiction over a challenge to the FDA's handling of new drug applications under another provision of the FDCA because the statute did not specifically preclude district court review of such applications. 818 F.2d at 888 n.61. However, Cutler did not interpret the particular provision at issue here, but rather, a section of the FDCA unrelated to pesticides. See 21 U.S.C. § 355. Moreover, the case was decided prior to the passage of the FQPA and the resulting addition of subsection (h)(5)'s limited review provision to that statute. See Pub. L. No. 104-170, sec. 405, 110 Stat. 1489, 1524 (1996). Plaintiffs' invocation of California ex rel Van de Kamp v. Reilly, 750 F. Supp. 433, suffers from a similar failing. The court there found jurisdiction over a challenge to the EPA's refusal to apply a statutory provision specifying that pesticides that caused cancer "when ingested by man or animal" were not "safe." Id. at 436. Jurisdiction in that case, which was decided six years prior to the FQPA's passage, was based on section 409, not section 408. Because the exception for judicial review in 701(a)(1) is entirely tied to the specific statutory provision in question, preclusion cannot be found by analogy either to different statutory provisions or to previous incarnations of the same statutory provision. Cf. Nader, 859 F.2d at 754 ("Since jurisdiction in these cases is wholly a creature of statute, we are not at liberty simply to apply the [Supreme] Court's reading of one statute to a separate, dissimilar statute.").

Of the two cases based on section 408 and decided after the passage of the FQPA, both turned on arguments different than those presented in the case at bar. NRDC v. Whitman, 2001 WL 1221774, concerned challenges to the EPA's failure to follow the schedule established in subsection 408(q)(3). In that case, plaintiffs challenged the agency's failure to issue reassessment determinations in a timely fashion in the first instance, rather than any determinations issued; the case was decided on grounds that the agency's actions had been "unlawfully withheld or unreasonably delayed" under the APA, 5 U.S.C. § 706(1). See id. at *10. The petition procedure set forth in subsection 408(d) was therefore not applicable, as there were no determinations to challenge administratively. Indeed, in that case, which was decided in the context of approving a proposed settlement over the objections of certain intervenors, the issue of statutory preclusion under subsection 408(h) was not even discussed.

In American Farm Bureau, 121 F. Supp. 2d 84, the other post-FQPA case cited by plaintiffs, the court found jurisdiction over plaintiffs' claims, notwithstanding subsection 408(h)'s limited review provision. In that case, plaintiffs brought several challenges to EPA procedures used in the course of the reassessment process, as well as to the agency's failure to conform to the time-table established in subsection 408(q)(1). Like the present case, American Farm Bureau also concerned "'*ad hoc* changes' to EPA's policy of applying the FQPA's tenfold safety factor when assessing a pesticide's dietary risk to infants and children in the tolerance-setting process," as well as the EPA's policy of using the "99.9th percentile of acute dietary exposure (the amount of pesticide reside that a person might be exposed to over a single day) in performing the risk assessments necessary to set pesticide tolerances and determine whether those tolerances meet the

FFDCA safety standard."[10] Id. at 104. Plaintiffs in American Farm Bureau argued that the EPA's refusal to use the proper criteria in performing reassessments amounted to the adoption of a "legislative rule" in violation of the notice and comment procedures required by the APA, 5 U.S.C. § 533(b). The EPA countered that its procedures fell under the limited review provision of subsection 408(h) because they were issued pursuant to subsection (e)(1)(C), which authorizes the Administrator to issue regulations pertaining to general procedures, and further, that plaintiffs' claims should be dismissed because the challenged procedures did not constitute final agency actions subject to review under the APA. The court held that district court review was proper, because the challenged actions did not in fact qualify as "general procedures," and were therefore not adopted pursuant to subsection (e)(1)(C). Id. at 93-94. It further found that the plaintiff had adequately alleged that the adoption of these policies qualified as a final agency action for purposes of surviving a motion to dismiss.

In American Farm Bureau, however, unlike the present case, the plaintiffs did not challenge particular tolerances at all. Rather, they challenged the agency's alleged adoption of a policy of failing to apply the statutorily mandated safety factor without conforming to the applicable notice and comment procedures mandated by the APA. In other words, the "agency action" challenged there was the adoption of a policy in violation of the APA, rather than the

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[10] Plaintiffs in American Farm Bureau also brought challenges related to the agency's conformance to various other mandates of the FQPA and FIFRA. The court ultimately dismissed for lack of standing under Lujan v. Defenders of Wildlife, 504 U.S. 555, plaintiffs' claims that the agency had failed to develop and implement the estrogenic substances screening program as required in 21 U.S.C. § 346a(p)(1). See 121 F. Supp. 2d at 97-101. Several counts, alleging various failures to conform with the data requirements in subsections 408(d)(2), (f)(1), and (c)(2), as well as FIFRA, were dismissed as impermissible programmatic challenges under Lujan v. National Wildlife Federation, 497 U.S. 871, and its progeny. 121 F. Supp. 2d at 101-04.

Administrator's final determination on any particular group of reassessment determinations. As in NRDC v. Whitman, the potential application of subsections (d) or (g) was therefore not discussed, because no tolerance determinations were challenged.

As established above, plaintiffs' complaints in the present action, unlike those in either NRDC v. Whitman or American Farm Bureau, do not merely challenge general "policies" of the agency, but rather, its failure to apply the correct standard to particular reassessments. This pleading decision reflects a double bind faced by the plaintiffs here. The Supreme Court has made clear that "generic challenge[s]" to an agency's policies do not satisfy the APA's requirement for "final agency action," see Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 890 n.2 (1990), and that plaintiffs asserting such challenges may not have standing to sue. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 571-78 (1991). Thus, in order to proceed, a plaintiff must allege that he or she suffered an actual injury from a specific agency action, and not simply from a "wholesale" defect in an agency's program. Lujan v. Nat'l Wildlife Fed'n, 497 U.S. at 891. This problem is reflected in American Farm Bureau. There, the court dismissed, among other claims, the plaintiffs' complaint that the EPA had failed to conform to the schedule established in subsection 408(q). 121 F. Supp. 2d at 94-96. Because plaintiffs there had not "identified any specific pesticide tolerance or exemption that ha[d] not been reassessed in a timely manner" or "alleged what obligations the schedule created that the EPA ha[d] failed to fulfill," the court determined that plaintiffs had only suffered the general type of procedural injury barred under Lujan v. Defenders of Wildlife and therefore lacked standing. Id. at 96-97.

By challenging a specific group of tolerance reassessments, the plaintiffs here have met this burden: Their complaints do not represent a "programmatic" challenge to the EPA's general

policies, but rather, to a group of related but discrete agency decisions that, in the aggregate, "have repetitive application 'across the board' to all agency determinations of a certain type."[11] (Sur-Reply at 3, quoting Lujan v. Nat'l Wildlife Fed'n, 497 U.S. at 890 n.2.) See, e.g., Center for Biological Diversity, 191 F. Supp. at 176-77 (holding that challenge to live-fire military training exercises in Pacific, in alleged violation of Migratory Bird Treaty "differs from those programmatic challenges that courts have held fall outside the scope of a 'final agency action' under the APA"); San Juan Audubon Soc'y v. Veneman, 153 F. Supp. 2d 1, 5-6 (D. D.C. 2001) (plaintiffs' challenge to EPA's failure to use maps in registering sodium cyanide ejectors used in controlling predators of endangered species, as required by FIFRA, was sufficiently specific to survive motion to dismiss). If plaintiffs' characterization of their claims as general policy challenges were accurate, and if they did not in fact challenge the outcome of the identified tolerance determinations, it is unlikely that they would be able to carry the burden of

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[11] Defendants do not raise any serious challenge to plaintiffs' standing in this case, noting merely that if plaintiffs' suit really only constituted a general challenge to EPA procedures, rather than to specific tolerance determinations, this would jeopardize their standing to sue. (D. Reply 10-11; Intervenor Reply 2 n.3.) Nonetheless, because federal courts lack jurisdiction to entertain a suit in the absence of a "case or controversy," the Court has an independent obligation to establish that standing indeed exists. The Court finds that plaintiffs here have challenged a specific action or group or actions, and alleged actual, concrete injury that is traceable to those actions and that would be likely to be redressed by a favorable decision. See Lujan v. Defenders of Wildlife, 504 U.S. at 560 -561. Plaintiffs adequately allege that the agency's decision to leave the challenged tolerances in place has directly harmed their members and their members' children by exposing them to increased and potentially unsafe levels of certain pesticides. Accepting the facts alleged in the complaint as true, as is required on this motion to dismiss, the requested remand and injunction requiring application of the tenfold safety factor would doubtless result in the modification or revocation of the vast majority of these tolerances. Accord NRDC v. Whitman, No. C 99-03701, 2001 WL 1221774, at *10 (N.D. Cal. Sept. 24, 2001) (holding that plaintiffs asserting claims under 21 U.S.C. § 346a(q) asserted cognizable injury in alleging "that members of their groups, such as farm workers, are regularly exposed to harmful pesticides").

demonstrating actual injury sufficient to satisfy the requirements of the APA or the constitution.

Nonetheless, in attempting to avoid the problem of standing by challenging a specific group of tolerance determinations, plaintiffs have run up against the problem of potential statutory preclusion. Their attempt to have it both ways by identifying a specific set of tolerances in their pleadings, while insisting in their briefing that their challenge was really to the process rather than the outcome of the determination, is ultimately unconvincing. In sum, plaintiffs do not adequately explain why their claims should be considered a procedural challenge, or even if they are, why they should be exempt from the petition and objection processes set forth in subsection 408 (g) and (d) and the limited review provision of subsection 408(h) of the FDCA.

Accordingly, the statutory provisions make clear that plaintiffs' challenges are properly channeled under subsection 408(h)(1), through the administrative review procedures provided in subsection 408(g), to the Courts of Appeals. Since challenges subject to this system of review "shall not be the subject of judicial review under any other provision of law," 21 U.S.C. 346a(h)(5), review in this Court under the APA is precluded.

III. FIFRA

Plaintiffs claim that FIFRA provides an alternative ground for jurisdiction. The pertinent section of FIFRA provides. "[e]xcept as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States." 7 U.S.C. § 136n.

In light of subsection 408(h)'s limited review provision, which specifies that "[a]ny issue as to which review *is or was obtainable* under this subsection shall not be the subject of judicial review *under any other provision of law*," id. § 346a(h)(5) (emphasis added), FIFRA's grant of jurisdiction is irrelevant. Plaintiffs challenge the registration of pesticides under FIFRA only through their challenge to the tolerances set under the FDCA. Although the two are linked, see 7 U.S.C. § 136(bb), the instant complaints do not make out a challenge to pesticide registrations on any other grounds. Their allegation that the EPA relied on a "secret" model in violation of a separate section of FIFRA is not to the contrary. Plaintiffs have alleged violations of several substantive provisions of the FDCA and FIFRA. However, as discussed above, these all amount to challenges to the methodologies used in reaching the reassessment determinations at issue, and such challenges are covered by the statute's procedures for administrative review. See supra Part II.B. Because plaintiffs' challenges rest entirely upon alleged violations under the FQPA and FIFRA for which review could have been obtained under section 408, subsection (h) precludes district court review "*under any other provision of law.*" FRA's provision for district court review is therefore inapplicable to plaintiffs' claims, which are reviewable only in the Courts of Appeals, and then, only after plaintiffs have availed themselves of the statutory provisions for administrative review.

CONCLUSION

Because the Court lacks subject matter jurisdiction to entertain plaintiffs' claims, the defendants' motions to dismiss are granted.

SO ORDERED:

Dated: New York, New York
July 29, 2004

GERARD E. LYNCH
United States District Judge