UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR ENVIRONMENTAL HEALTH, et al.,

Plaintiffs,

v.

TOM VILSACK, et al.,

Defendants.

Case No. 15-cv-01690-JSC

ORDER RE: CROSS-MOTIONS FOR SUMMARY JUDGMENT

Re: Dkt. Nos. 57 & 59

Three environmental nonprofits contend that the United States Department of Agriculture ("USDA") violated the Administrative Procedures Act ("APA") by issuing a guidance document without providing public notice and comment. Plaintiffs insist that formal rulemaking was required because the document amended existing national organic food regulations to permit certified organic producers to use compost materials that contain synthetic pesticides. The parties' cross-motions for summary judgment are now pending before the Court. (Dkt. Nos. 57 & 59.) Having considered the parties' submissions, and having had the benefit of oral argument on May 26, 2016, the Court GRANTS Plaintiffs' motion and DENIES Defendants' cross-motion.[1] The guidance document at issue is a legislative rule subject to the APA's notice and comment requirements.

STATUTORY AND REGULATORY FRAMEWORK

The Organic Foods Production Act, 7 U.S.C. § 6501 et seq., ("the Organic Foods Act") required the Secretary of Agriculture to "establish an organic certification program for producers

[1] All parties have consented to the jurisdiction of a magistrate judge pursuant to 28 U.S.C. § 636(c). (Dkt. Nos. 17 & 18.)

and handlers of agricultural products that have been produced using organic methods." 7 U.S.C. § 6503. The certification program is known as the National Organic Program or NOP. 7 C.F.R. § 205 et seq.

The Organic Foods Act established standards an agricultural product must satisfy to be sold or labeled as organic. See 7 U.S.C. § 6504. Specifically, the agricultural product must:

> (1) have been produced and handled without the use of synthetic chemicals, except as otherwise provided in this chapter;
>
> (2) except as otherwise provided in this chapter and excluding livestock, not be produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the 3 years immediately preceding the harvest of the agricultural products; and
>
> (3) be produced and handled in compliance with an organic plan agreed to by the producer and handler of such product and the certifying agent.

Id. The Organic Foods Act also directed the establishment of a "National List" of approved and prohibited synthetic substances for use in organic production. 7 U.S.C. § 6517(a) & (b); 7 C.F.R. § 205.601. National Organic Program regulations specifically prohibit use of "[a]ny fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production." 7 C.F.R. § 205.203(e)(1).

Compliance with the National Organic Program is monitored pursuant to a USDA program which accredits individuals and state officials as agents "for the purpose of certifying a farm or handling operation as a certified organic farm or handling operation." 7 U.S.C. § 6514(a). Producers seeking organic certification must demonstrate their compliance with the Organic Program requirements to these certifying agents, subject to appeal. See 7 C.F.R. §§ 205.400-205.406, 205.681. The certifying agents may also investigate compliance with National Organic Program regulations. See 7 C.F.R § 205.661.

BACKGROUND

The California Department of Food and Agriculture (CDFA) is the California agency certified to administer the National Organic Program. See Cal. Food & Agric. Code § 46000(a). In August through October 2009, CDFA inspectors found detectable levels of bifenthrin—a

residential insecticide—in three compost products listed for use in organic agriculture. (Administrative Record ("AR") 726-27, 927.) As bifenthrin is not on the National List of approved synthetic substances, and National Organic Program regulations prohibit any compost used in organic production from containing a synthetic substance not on the National List, 7 C.F.R. § 205.203(e)(1), the CDFA banned all three compost products from use in organic production. (Id.)

Nortech Waste LLC ("Nortech"), a producer of one of the banned composts, thereafter contacted the National Organic Program to ask whether the National Organic Program was going to "back the action of the [CDFA]". (AR 659-60.) Mark Bradley, Chief of National Organic Program Accreditation, responded that "[b]ifenthrin is a synthetic substance which is not on the NOP National List of Allowed and Prohibited Substances. We have consulted with the State of California on this issue and concur that compost containing the substance bifenthrin is not eligible for use in organic farming operations." (AR 662.) Nortech replied that "[b]ifenthrin in compost is going to become a nationwide problem and just saying that contaminated compost can not be used in organic agriculture is not the answer." (AR 661.) Mr. Bradley responded that he had advised the new Deputy Administrator of the National Organic Program of the situation. (Id.)

Several months later, the USDA issued the guidance document at issue in this lawsuit—NOP 5016. NOP 5016, entitled "Guidance Allowance of Green Waste in Organic Production Systems," states that its purpose is to "provide[] clarification on the allowance of green waste and green waste compost in organic production systems under the National Organic Program (NOP) regulations." (AR 1103.) It recites the regulation's requirement that "[t]he producer must not use: (1) Any fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production." (AR 1104 (citing 7 C.F.R. § 205.203(e).) The Guidance then notes:

> However, the NOP regulations were established with recognition that background levels of synthetic pesticides may be present in the environment and, therefore, may be present in organic production systems. This is referred to as unavoidable residual environmental contamination (UREC) in the regulations. Furthermore, the NOP standards are process based and do not mandate zero tolerance for synthetic pesticide residues in inputs, such as compost. Compost that is produced from the approved feedstocks, listed above, is

> acceptable for use in organic production, provided that any residual pesticide levels do not contribute to the contamination of crops, soil or water.
>
> Green waste and green waste compost that is produced from approved feedstocks, such as, non-organic crop residues or lawn clippings may contain pesticide residues. Provided that the green waste and green waste compost (i) is not subject to any direct application or use of prohibited substances (i.e. synthetic pesticides) during the composting process, and (ii) that any residual pesticide levels do not contribute to the contamination of crops, soil or water, the compost is acceptable for use in organic production.

(Id.)

PROCEDURAL HISTORY

Plaintiffs filed this lawsuit nearly five years later contending that NOP 5016 "changed the legal status of bifenthrin and other pesticides that are prohibited for use in organic production but are now being allowed in green waste used in organic production." (Dkt. No. 1 ¶ 54.) Plaintiffs allege that Defendants, the USDA and various governmental officials and agencies (collectively "Defendants" or "the Agency") violated the APA by issuing NOP 5016 without first providing the notice and comment period required by the APA's rulemaking provisions. Plaintiffs seek remand and vacatur of NOP 5016 until the proper procedures are followed.

Defendants responded to the complaint by moving to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) on the grounds that Plaintiffs lacked standing and that the challenged decision was exempt from APA rulemaking as either a general statement of policy or as an interpretive rule. (Dkt. No. 24.) The Court denied Defendants' motion. (Dkt. No. 41.)

The now pending cross-motions for summary judgment followed. (Dkt. Nos. 57 & 59.) The day after the last brief on the cross-motions was filed, the Western Growers Association moved for leave to appear as amicus curiae and file a brief in support of Defendants. (Dkt. No. 63.) Nearly a week later, the California Certified Organic Farmers and the Organic Trade Association asked to appear as amici curiae and submit declarations joining in the Western Grower's Association brief. (Dkt. No. 72.) Plaintiffs objected to both requests as untimely, prejudicial, and as not useful to the Court. (Dkt. Nos. 70 & 73.) The Court subsequently granted in part the motions to appear as amici in connection with the appropriate remedy should the Court find an APA violation. (Dkt. No. 75.)

LEGAL STANDARD

The APA provides for judicial review of final agency decisions. 5 U.S.C. §§ 702, 706. Courts routinely resolve APA challenges to agency administrative decisions by summary judgment. *Nw. Motorcycle Ass'n v. U.S. Dept. of Agric*., 18 F.3d 1468, 1481 (9th Cir. 1994). "Because the presence of the administrative record, which the parties have stipulated to, usually means there are no genuine disputes of material fact, it allows the Court to decide whether to set aside the agency determination on summary judgment without a trial." Sodipo v. Rosenberg, 77 F. Supp. 3d 997, 1001 (N.D. Cal. 2015) (citing Camp v. Pitts, 411 U.S. 138, 142 (1973) (per curiam)).

Under the APA, a court may set aside an agency's final action if the action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This is a "highly deferential" standard under which there is a presumption that the agency's action is valid "if a reasonable basis exists for its decision." Kern Cnty. Farm Bureau v. Allen, 450 F.3d 1072, 1076 (9th Cir. 2006). A reviewing court may also "hold unlawful and set aside agency action, findings, and conclusions" that are "without observance of procedure required by law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C), (D). Unlike substantive challenges, "review of an agency's procedural compliance is exacting, yet limited." Kern Cty. Farm Bureau, 450 F.3d at 1076. The reviewing court determines "the adequacy of the agency's notice and comment procedure, without deferring to an agency's own opinion of the . . . opportunities it provided." Id. (internal citation and quotation marks omitted).

DISCUSSION

This case asks whether the Agency was required to give public notice and an opportunity to comment prior to adoption of NOP 5016. Plaintiffs contend that because NOP 5016 altered a practice that was previously prohibited by the Organic Foods Act and its implementing regulations—use of compost that contains pesticides—it is a legislative rule which triggered the APA's notice and comment requirements. Defendants counter that NOP 5016 was exempt from

formal rulemaking because it merely clarified that organic producers can use green waste compost with de minimis background levels of pesticide residue such that NOP 5016 qualifies as an interpretive guidance, or alternatively, a general statement of policy for which formal rulemaking is not required.

I. The APA's Rulemaking Requirements

The APA requires a federal agency to follow specific procedures before issuing a rule. "These procedures include: (1) publication of notice of the proposed rule in the Federal Register, 5 U.S.C. § 553(b); (2) a period for interested individuals to comment on the proposed rule, id. § 553(c); and (3) publication of the adopted rule not less than thirty days before its effective date, id. § 553(d)." Mora–Meraz v. Thomas, 601 F.3d 933, 939 (9th Cir. 2010). Whether the procedures apply depends on whether a rule is "substantive" or "legislative" or instead "interpretative." If a rule is substantive or legislative, the agency must use the notice and comment procedure unless "it publishes a specific finding of good cause documenting why such procedures 'are impracticable, unnecessary, or contrary to the public interest.'" *Hemp Indus. Ass'n v. Drug Enf't Admin*., 333 F.3d 1082, 1087 (9th Cir. 2003) (quoting 5 U.S.C. § 553(b), (b)(B)). The notice and comment requirement does not apply to "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(3)(A). The exceptions to the APA's notice and comment requirements "will be narrowly construed and only reluctantly countenanced." Alcaraz v. Block, 746 F.2d 593, 612 (9th Cir. 1984) (internal citation and quotation marks omitted). "This is consistent, of course, with Congress's clear intent to preserve the statutory purpose of informal rulemaking by making sure those exceptions did not become 'escape clauses,' which an agency could utilize at its whim." Id. (internal citation and quotation marks omitted).

A. NOP 5016 is a Legislative Rather Than Interpretative Rule

"Generally, agencies issue interpretive rules to clarify or explain existing law or regulations so as to advise the public of the agency's construction of the rules it administers." Gunderson v. Hood, 268 F.3d 1149, 1154 (9th Cir. 2001). "[I]nterpretive rules merely explain, but do not add to, the substantive law that already exists in the form of a statute or legislative rule.

Legislative rules, on the other hand, create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress." *Hemp Indus. Ass'n*., 333 F.3d at 1087 (internal citation omitted). Legislative rules, unlike interpretative rules, have the force of law. See Erringer v. Thompson, 371 F.3d 625, 630 (9th Cir. 2004). A rule has the "force of law":

> (1) when, in the absence of the rule, there would not be an adequate legislative basis for enforcement action;
>
> (2) when the agency has explicitly invoked its general legislative authority; or
>
> (3) when the rule effectively amends a prior legislative rule.

Hemp Industries, 333 F.3d at 1087 (internal quotation marks and citation omitted). "If the answer to any of these questions is affirmative," the rule is legislative, not interpretive. Oregon v. Ashcroft, 368 F.3d 1118, 1133 (9th Cir. 2004) (internal quotation marks and citation omitted), *aff'd sub nom.* Gonzales v. Oregon, 546 U.S. 243 (2006).

1) NOP 5016 Amends the Existing Regulation

Section 205.203(e)(1) prohibits the use in organic production of any compost "that contains a synthetic substance not on the National List" of approved synthetic substances. In contrast, NOP 5016 states that an organic producer can use a synthetic substance even if it is not on the National List provided the synthetic substance (1) is not applied during or used in the composting process, and (2) does not contaminate crops, soil, or water. Whereas before the adoption of NOP 5016 an organic producer could not use compost if it contained a synthetic substance not on the National List, under NOP 5016 it can so long as (1) the synthetic substance was not directly applied and (2) does not "contribute to contamination." (AR 1104.) NOP 5016 therefore amends Section 205.203(e)(1) by creating an exception to the prohibition on the use of compost that contains unapproved synthetic substances.

Defendants' insistence that NOP 5016 merely clarifies the meaning of the word "contains" in Section 205.203(e)(1) is unpersuasive. Defendants contend that "administrative practicability demands" that "contains" mean something "less than [to] categorically forbid the presence of any scintilla of any synthetic substance not on the National List." (Dkt. No. 59 at 19:21-23.[2]) Thus,

[2] Record citations are to material in the Electronic Case File ("ECF"); pinpoint citations are to the

according to Defendants, NOP 5016 sought to define "contains" in the context of green waste compost such that the compost only "contains" a non-approved synthetic substance if it was added during the composting process or it will contribute to contamination of crops, soil, or water. In other words, NOP 5016 "clarifies that an organic famer may use green waste compost with a pre-existing, de minimis amount of non-approved synthetic substances, because in that scenario the compost does not 'contain' a synthetic substance that is not allowed per the National List." (Dkt. No. 59 at 22:3-6.) Not so.

First, nowhere does NOP 5016 itself suggest that it is defining the word "contains" as used in section 205.203(e)(1). "Contains" is used twice in NOP 5016. It states that "[t]he NOP does not allow the use of compost that **contains** synthetic substances that are not on the National List." (AR 1004 citing 7 C.F.R. § 205.203(e) (emphasis added).) It also recites that "[g]reen waste and green waste compost that is produced from approved feedstocks, such as, non-organic crop residues or lawn clippings may **contain** pesticide residues." (AR 1004 (emphasis added).). Neither use of "contains" suggests that NOP 5016 is defining the word as used in the regulation. Indeed, elsewhere NOP 5016 defines the terms "green waste" and "feedstocks" which suggests that Defendants recognized that it should explicitly define terms where needed. It did not define "contains" in NOP 5016.

NOP 5016's assertion that "green waste" and "green waste compost" that contain pesticide residues can be used in organic production provided the pesticides are not applied during the composting process and do not contribute to the contamination of crops, soil or water is further evidence that Defendants were not interpreting the word "contains" as used in section 205.203(e)(1). The regulation prohibits any compost, not just green waste compost, from "containing" a non-listed synthetic substance. 7 C.F.R. § 205.203(e)(1). If Defendants were actually clarifying the meaning of "contains" as used in the regulation, as they now claim, then NOP 5016 should apply to all compost, not just green waste compost. That NOP 5016 is limited to green waste compost is consistent with Defendants making an exception, that is, an amendment,

ECF-generated page numbers at the top of the documents.

to section 205.203(e)(1), rather than clarifying it.

Indeed, NOP 5016 uses "contains" in a manner inconsistent with the meaning the Agency now ascribes to the word. NOP 5016 states: "Green waste and green waste compost that is produced from approved feedstocks . . . may **contain** pesticide residues." (AR 1104.) The next sentence states that "[p]rovided that the green waste and green waste compost" are not directly applied or used during the composting process and do not otherwise contaminate the environment, "the compost is acceptable for use in organic production." (Id.) In other words, NOP 5016 itself states that even if the compost **contains** a non-approved synthetic substance, it can still be used in certain circumstances. NOP 5016 thus uses "contains" to mean "is found in" or "is present in" the compost; it never defines "contains" to mean more than a de minimis amount.

Second, Defendants' purported clarification of "contains" in NOP 5016 is inconsistent with Defendants' own prior interpretation of the rule. After CDFA banned the three composts containing bifenthrin, the National Organic Program repeatedly confirmed that because bifenthrin is a synthetic substance not on the National List, compost containing the substance bifenthrin was not eligible for use in organic farming. (AR 662; 741; 786; 848.) There is nothing in the administrative record that suggests that prior to NOP 5016 the Agency ever interpreted section 205.203(e)(1) as allowing compost that contains any unapproved synthetic substance.

Third, the Agency's December 21, 2000 final rulemaking commentary undermines Defendants' currently proffered definition of "contains." In discussing the compost practice standard, the Agency stated:

> The [organic] producer's first responsibility is to identify the source of the feedstocks used in the composting system. This requirement ensures that only allowed plant and animal materials are included in the composting process, that they are not contaminated with prohibited materials, and that they are incorporated in quantities suitable to the design of the composting system. Certifying agents will exercise considerable discretion for evaluating the appropriateness of potential feedstock materials and may require testing for prohibited substances before allowing their use. For example, a certifying agent could require a producer to monitor off-farm inputs such as leaves collected through a municipal curbside program or organic wastes from a food processing facility. Monitoring may be necessary to protect against contamination from residues of prohibited substances such a motor oil or heavy metals, or gross inert materials such as glass shards that can enter the

organic waste stream.

(AR 480; see also AR 347 (the proposed rules "prohibit the use of any commercially blended fertilizer product that contains a prohibited substance"); id. ("We acknowledge the need to examine carefully commercial blended fertilizers and soil amendments to ensure that such products do not contain prohibited substances" (emphasis added)).) In the rulemaking process, the Agency's focus was on ensuring that compost material did not contain any prohibited substance; not, as it now suggests, on whether whatever prohibited substance found in the compost not cause some undefined contamination of crops, soil or water. There is no suggestion in the record that the potentially required testing of the feedstock was to determine whether the prohibited substance was directly applied during the composting process or whether the prohibited substance found in the feedstock when used in compost will contaminate food, soil or water; instead, the Agency's focus was on ensuring that the compost does not contain a prohibited substance, consistent with the plain language of the rule ultimately adopted.

Fourth, the unavoidable residual environmental contamination (UREC) rules do not support Defendants' position. The Organic Foods Act provides that an "agricultural product shall not be sold or labeled as organically produced" if it contains a residue that is "(A) the result of intentional application of a prohibited substance; or (B) present at levels that are greater than unavoidable residual environmental contamination." 7 U.S.C. § 6511(c)(2). Unavoidable residual environmental contamination is defined as "[b]ackground levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances." 7 C.F.R. § 205.2. Defendants argue that because the UREC rules contemplate that some unavoidable contamination of products will be tolerated, it makes sense for Defendants to interpret section 205.203(e)(1) as allowing compost to contain prohibited synthetic substances provided they are not directly applied or do not contaminate crops, soil or food. The UREC rules, however, apply to the final product—the organic produce. Further, they only apply to "unavoidable" residues that are below certain levels. There is nothing inconsistent about the Agency prohibiting an organic producer from using a compost that contains a synthetic substance (something the producer can avoid), while at the same time acknowledging that some amount of prohibited substance may nonetheless be found in the finished product and therefore

will be tolerated provided it is below certain levels.

In any event, even if Defendants could adopt some UREC standard for compost, they did not do so. NOP 5016 is not limited to "unavoidable" contamination of compost; rather, even if having the compost contain the pesticide is avoidable, NOP 5016 allows the synthetic substance. More problematic for Defendants' argument, however, is that in response to the concerns of the banned compost producers, Defendants contemplated adopting a UREC for compost. (AR 741,749-50, 783, 786, 790.) Specifically, on October 14, 2009, the National Organic Program circulated internally a first "draft policy for pesticide residues in compost." (AR 748.) It proposed applying UREC standards to compost with the threshold level of UREC in compost set at 5% of the lowest tolerance level of that pesticide in food as established by the Environmental Protection Agency (EPA). (AR 749-50.) Two days later, the Program circulated a revised draft which omitted reference to the UREC standard and just proposed applying the EPA standard to compost; that is, the lowest tolerance level of that pesticide in food. (AR 757-59.) The National Organic Program ultimately rejected this approach, however, because to "establish a tolerance for compost and other inputs we should obtain lots of scientific justification for the levels that we establish, have the NOSB approve of the tolerance levels, and go through a rule making process." (AR 771 (emphasis added).)

The Program then adopted NOP 5016 which provides "no tolerance levels for pesticide contaminants in compost." (AR 763, 867.) This was done, not as a matter of scientific judgment or in the exercise of technical expertise, but because the Agency determined that it would be too difficult and too time consuming to set tolerance levels. While Defendants refer to NOP 5016 as only allowing de minimis amounts of non-approved substances, under NOP 5016 there are no tolerance levels. Indeed, even if the Court were to accept Defendants' suggestion that de minimis levels of residue have always been allowed, the levels of bifenthrin at issue here are not de minimis. (AR 741 "the bifenthrin residue amounts found range from 0.07 to 0.41 ppm. The EPA tolerance level for bifenthrin varies depending upon the crop (e.g. 0.05 ppm for peanuts, pistachio; 0.10 ppm for root vegetables. The bifenthrin residues in the compost exceed the EPA tolerance level and the UREC level."). If the Agency believed rulemaking is required to go from no

unapproved synthetic substances in compost to adopting tolerance levels for those synthetic substances, it certainly requires rulemaking to change from no synthetic substances to synthetic substances allowed with no tolerance levels and, indeed, with synthetic substances present in amounts greater than that allowed under the UREC standards for agricultural products.

Defendants' insistence that an agency can change its mind misses the point. The question here is not whether NOP 5016 would pass muster under an APA substantive challenge; rather, the question is whether it was adopted consistent with the APA's procedural requirements. Indeed, it is telling that the cases Defendants cite on this issue involved an agency "changing its mind" following formal rulemaking. See Navarro v. Encino Motorcars, LLC, 780 F.3d 1267, 1273 (9th Cir. 2015), cert. granted, 136 S. Ct. 890 (2016), and vacated and remanded, (U.S. June 20, 2016); *Nat'*l Ass'n of Home Builders v. E.P.A., 682 F.3d 1032 (D.C. Cir. 2012). That is what the Agency was required to do here.

* * *

"An agency is not allowed to change a legislative rule retroactively through the process of disingenuous interpretation of the rule to mean something other than its original meaning." Hemp Indus. Ass*'n*, 333 F.3d at 1091. National Organic Program regulations (legislative rules) specifically prohibit use of "[a]ny fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production." 7 C.F.R. § 205.203(e)(1). Pesticide residues are not on the National List. Thus, NOP 5016's assertion that "green waste and green waste compost" can contain pesticide residues "[p]rovided that the green waste and green waste compost (i) is not subject to any direct application or use of prohibited substances (i.e. synthetic pesticides) during the composting process, and (ii) that any residual pesticide levels do not contribute to the contamination of crops, soil or water" amends Section 205.203(e). It is legislative, not interpretative, and required formal rulemaking.

B. NOP 5016 is Not a General Statement of Policy

Defendants contend that even if NOP 5016 is not exempt from formal rulemaking as an interpretative rule, it is exempt because it is a general statement of policy. "The critical factor to

determine whether a directive announcing a new policy constitutes a rule or a general statement of policy is the extent to which the challenged [directive] leaves the agency, or its implementing official, free to exercise discretion to follow, or not to follow, the [announced] policy in an individual case." Mada-Luna v. Fitzpatrick, 813 F.2d 1006, 1013 (9th Cir. 1987) (internal quotation marks and citation omitted). "To the extent that the directive merely provides guidance to agency officials in exercising their discretionary powers while preserving their flexibility and their opportunity to make 'individualized determination[s],' it constitutes a general statement of policy." Id. "In contrast, to the extent that the directive 'narrowly limits administrative discretion' or establishes a 'binding norm' that 'so fills out the statutory scheme that upon application one need only determine whether a given case is within the rule's criterion,' it effectively replaces agency discretion with a new 'binding rule of substantive law.' In these cases, notice-and-comment rulemaking proceedings are required, as they would be for any other substantive rule, and they will represent the only opportunity for parties to challenge the policy determinations upon which the new rule is based." Id. Thus, to qualify for the "statement of policy" exception to formal rulemaking two requirements must be satisfied: (1) the policy operates only prospectively, and (2) the policy does "not establish a binding norm, or be finally determinative of the issues or rights to which [it] address[es]" and instead leaves officials "free to consider the individual facts in the various cases that arise." Id. NOP 5016 is not a general statement of policy.

As a preliminary matter, the Agency has not explained how NOP 5016 can be a general statement of policy if the Court rejects (as it has) the Agency's first argument that it is interpretative rather than legislative. In other words, having concluded that NOP 5016 amended 7 C.F.R. § 205.203(e)(1) and thus has the force of law, it cannot merely be a general statement of policy.

In any event, NOP 5016 does not satisfy either of the two requirements of a general statement of policy. First, it operates retroactively as well as prospectively. For this, the Court need look no further the National Organic Program's repeated observation that if the guidelines set forth in NOP 5016 were adopted, CDFA would have to withdraw the ban on the three compost products found to contain bifenthrin. (See, e.g., AR 759 ("CDFA would have to rescind their

orders and the compost with bifenthrin residues would be allowed in organic crop production"); AR 763 (CDFA "will need to withdraw the notices prohibiting the 3 California compost products").) Rescission is necessarily retroactive. See *Welles v. Turner Entm't Co*., 503 F.3d 728, 738 (9th Cir. 2007) ("rescind [] conveys a retroactive effect"); *Am. Bus Ass'*n v. United States, 627 F.2d 525, 531 (D.C. Cir. 1980) (concluding that the Interstate Commerce Commission's determination that "restrictions previously imposed on carriers' freedom have been lifted" necessarily operated retroactively).

Second, NOP 5016 creates a binding norm. Defendants' argument that the lack of any tolerance level in NOP 5016 means that implementation is left to each individual certifying agent's discretion ignores the Guidance and how the Agency itself interpreted it. The certifying agents no longer have discretion to ban products which contain synthetic substances not on the National List unless the presence of the synthetic substances contributes to contamination or was directly applied. "[C]abining of an agency's prosecutorial discretion can in fact rise to the level of a substantive, legislative rule." Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 948 (D.C. Cir. 1987). Indeed, that is precisely how the Agency interpreted the Guidance. In considering the effect of a guidance document that states "that there are no tolerance levels for pesticide contaminants in compost," Miles McEvoy, the Deputy Administrator of the National Organic Program, reasoned that such document would require the Program to notify the CDFA that

> they should not prohibit compost that contains bifenthrin residues unless they have evidence that the compost is contaminating the crops, soil or water. So far I have not seen any evidence the bifenthrin is contaminating the crops, soil or water. They will need to withdraw the notices that prohibited the 3 California compost products.

(AR 763 (emphasis added); see also AR 759 ("CDFA would have to rescind their orders and the compost with bifenthrin residues would be allowed in organic crop production"). Thus, according to the National Organic Program, in light of NOP 5016 certifying agents do not have discretion to ban compost that contains unapproved synthetic substances; instead, they must withdraw the bans on those products. "If it appears that a so-called policy statement is in purpose or likely effect one that narrowly limits administrative discretion, it will be taken for what it is—a binding rule of

substantive law." *Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp.,* 589 F.2d 658, 666 (D.C. Cir. 1978).

*Nat'l Min. Ass'*n v. McCarthy, 758 F.3d 243 (D.C. Cir. 2014), is distinguishable. There, the DC Circuit held that a final guidance document was a general statement of policy because it did "not tell regulated parties what they must do or may not do in order to avoid liability. The Final Guidance imposes no obligations or prohibitions on regulated entities. State permitting authorities 'are free to ignore it.'" Id. at 252. Here, in contrast, neither state certifying agents nor organic producers are "free to ignore" NOP 5016. Id.; see also Appalachian Power Co. v. E.P.A., 208 F.3d 1015, 1023 (D.C. Cir. 2000) ("[the guidance] reads like a ukase. It commands, it requires, it orders, it dictates. Through the Guidance, EPA has given the States their "marching orders" and EPA expects the States to fall in line, as all have done, save perhaps Florida and Texas.").

For the same reason, the Court rejects Defendants' suggestion that NOP 5016 is nothing more than a "field-level instructional guide" because it is part of the "National Organic Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations" which seeks to "provide standard operating procedures and specific review and enforcement approaches to help ensure that all parties implement the program's mandate in an effective, fair, and consistent manner." (Dkt. No. 59 at 28:24-26.) Although Defendants emphasize that the handbook contains a disclaimer suggesting that its policies are not legally binding, the Court is not required to accept the Agency's interpretation of the legal effect of the guidance. See Hemp Indus. *Ass'n*, 333 F.3d at 1088 ("fact that an agency claims that its rule does not bind tribunals outside the agency, however, does not end the inquiry into whether the rule is legislative."); see also Columbia Riverkeeper v. U.S. Coast Guard, 761 F.3d 1084, 1094-95 (9th Cir. 2014) ("courts consider whether the practical effects of an agency's decision make it a final agency action, regardless of how it is labeled.").

Finally, Defendants make a confusing argument that NOP 5016 is a general statement of policy because it only binds lower-level implementing agents and the Secretary of the USDA has the discretion as to how to implement the Organic Foods Act. The cases upon which Defendants rely, however, are inapposite. For example, Erringer v. Thompson, 371 F.3d 625, 631 (9th Cir.

2004), involved whether a rule was interpretative, not a general statement of policy. In any event, the court held the rule was interpretative rather than legislative because it did not amend an existing legislative rule; here, in contrast, NOP 5016 amends a regulation and thus has the force of law. In Nguyen v. United States, 824 F.2d 697, 702 (9th Cir. 1987), the court reiterated that "notice must be given both to make and to change [a] 'law.'" Here, NOP 5016 changed the law, 7 C.F.R. § 205.203(e)(1). The Agency did not have the discretion to amend an existing regulation without formal rulemaking.

Further, to hold that because the Agency could change NOP 5016 at any time it has no binding effect would allow an agency to perpetually amend the rules and evade the APA's procedural requirements. "[A]n agency's characterization of its action as being provisional or advisory is not necessarily dispositive, and courts consider whether the practical effects of an agency's decision make it a final agency action, regardless of how it is labeled." Columbia Riverkeeper, 761 F.3d at 1094-95; see also Appalachian Power Co., 208 F.3d at 1022 (rejecting an argument that "because the Guidance, is subject to change, it is not binding and therefore not final action" because "all laws are subject to change. Even that most enduring of documents, the Constitution of the United States, may be amended from time to time. The fact that a law may be altered in the future has nothing to do with whether it is subject to judicial review at the moment."). Defendants' interpretation of the general statement of policy exception to the APA's rulemaking provisions would effectively insulate agency decisions from review by requiring deference to senior officials' interpretation of rules even where those interpretations represent a substantive change to that rule. The APA is not so toothless.

* * *

NOP 5016 amended 7 C.F.R. § 205.203(e)(1) and was therefore a legislative rule change. Because it was not accompanied by a "specific finding of good cause documenting why such procedures 'are impracticable, unnecessary, or contrary to the public interest,'" it was subject to the APA's notice and comment provisions. See Hemp Industries, 333 F.3d at 1087 (quoting 5 U.S.C. § 553(b), (b)(B)). Defendants' failure to follow these procedural rulemaking requirements was unlawful. See 5 U.S.C. § 706(2)(D).

II. Remedy

There remains the question of remedy. The parties agree that if the Court finds that Defendants violated the APA the appropriate remedy is remand; however, their views diverge as to the status of NOP 5016 during remand. Plaintiffs argue for vacatur whereas Defendants request that the Agency be allowed to cure the procedural error while leaving NOP 5016 in place.

The remedy for a procedural APA violation is for the reviewing court to "hold unlawful and set aside agency action." 5 U.S.C. § 706(2). Thus, where an agency's "finding is not sustainable on the administrative record made, then the [] decision must be vacated and the matter remanded [to the agency] for further consideration." Camp v. Pitts, 411 U.S. 138, 143 (1973). In the Ninth Circuit, remand without vacatur is the exception rather than the rule. See California Communities Against Toxics v. U.S. E.P.A., 688 F.3d 989, 994 (9th Cir. 2012)("we have only ordered remand without vacatur in limited circumstances."); *Humane Soc'y v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010) ("In rare circumstances, when we deem it advisable that the agency action remain in force until the action can be reconsidered or replaced, we will remand without vacating the agency's action."); Ctr. for Food Safety v. Vilsack, 734 F.Supp.2d 948, 951 (N.D. Cal. 2010) ("[T]he Ninth Circuit has only found remand without vacatur warranted by equity concerns in limited circumstances, namely serious irreparable environmental injury."). Courts "leave an invalid rule in place only when equity demands that we do so." Pollinator Stewardship Council v. U.S. E.P.A., 806 F.3d 520, 532 (9th Cir. 2015). "When determining whether to leave an agency action in place on remand, [courts] weigh the seriousness of the agency's errors against the disruptive consequences of an interim change that may itself be changed." Id. (internal citation and quotation marks omitted).

A. Seriousness of the Agency's Errors

The error here is serious. In issuing NOP 5016, the Agency effectively amended Section 205.203(e) and withdrew a prior basis for enforcement without the APA-required notice and comment. While the record reflects that the prevalence of bifenthrin in green waste compost is—or was in 2010—an emerging issue which the National Organic Program may not have considered when these regulations were adopted, these circumstances do not excuse the Agency from the

notice and comment requirement. This result is especially true where, as here, the reach of the Agency's new rule stretches beyond bifenthrin and instead allows green waste or green waste compost used in organic production to contain any synthetic pesticide of which bifenthrin is just one example. (AR 1103-1104.) Moreover, if the presence of bifenthrin was unexpected and created an issue that had to be addressed immediately, the APA exempts an agency from the notice and comment requirement if "the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b). The Agency chose not to invoke this exemption.

"In enacting the APA, Congress made a judgment that notions of fairness and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment." Paulsen v. Daniels, 413 F.3d 999, 1004 (9th Cir. 2005) (internal citation and quotation marks omitted). Defendants may be correct that they could adopt the same rule on remand, but whether they will do so after the required notice and comment procedures is far from certain. Under these circumstances, the severity of the error weighs in favor of vacatur.

B. Consequences of Vacatur

"In considering whether vacatur is warranted, [the Court] must balance the [Agency's] errors against the consequences of such a remedy." California Communities Against Toxics, 688 F.3d at 993. Defendants contend that in the absence of NOP 5016 there would be significant environmental harms because the green waste currently being used for green waste compost would be dumped in landfills rather than contributing to compost nutrient cycling. They suggest further that even if this were not the result, and the green waste was instead sold for use in non-organic agriculture, there would be fewer incentives to produce environmentally friendly compost. Plaintiffs counter that there is little evidentiary support for Defendants' arguments and that the record reflects that only a small portion of green waste compost is actually used by organic farmers as it is. Further, Plaintiffs suggest that there are several sources of synthetic-substance free compost available on the market. Plaintiffs identify testing performed by the Washington State Department of Agriculture (which tests for pesticide contamination because it is required for

Canadian organic certification) that showed of the 13 tested composts, only 5 had pesticide residues. (AR 1115.)

The Court is not persuaded that vacating NOP 5016 pending formal rulemaking will result in environmental harm sufficient to warrant leaving the invalid rule in place. Those "limited circumstances" in which the Ninth Circuit has declined to vacate on remand because of the potential for interim environmental harm involved irreparable injuries such as the potential extinction of an animal species. See, e.g., *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995) (concluding that equity warranted leaving the rule in place during remand because of the potential extinction of a snail species); Pollinator Stewardship Council, 806 F.3d at 532 (concluding that "given the precariousness of the bee population, leaving the EPA's registration of sulfoxaflor in place risks more potential environmental harm than vacating it."). Ensuring a secondary use for green waste is certainly an important environmental cause, but the record does not establish that a significant a share of that market is represented by the organic community. (AR 846.) The record also does not suggest that the result of vacatur will be a lack of available compost for organic producers, especially given the State of Washington's experience.

The Court thus turns to the thrust of the parties' and amici's arguments—economic harm. The Ninth Circuit has declined vacatur because of potential economic consequences (among others) at least once. In California Communities Against Toxic, the EPA admitted its rulemaking process had been flawed and voluntarily sought remand following the plaintiffs' APA challenge. Id. at 992-93. The court remanded without vacatur because the "delay and trouble vacatur would cause [was] severe" as it would have delayed construction of a Southern California power plant. Id. at 993. Without the power plant, the region might not have had enough power which could have resulted in rolling blackouts and such blackouts have negative environmental consequences which the Clean Air Act sought to avoid. Id. Further, the consequences of vacatur would be "economically disastrous [because] [t]his is a billion-dollar venture employing 350 workers." Id. at 994.

Defendants contend that the organic industry will likewise suffer significantly if NOP 5016 is vacated because organic growers will no longer be able to use green waste compost and

composting operations will lose a significant market for their products. However, there is insufficient evidence in the record to support their assertion, let alone quantify it. Defendants also suggest that because NOP 5016 was adopted five years ago and organic farmers have since applied the compost to their soil there is considerable uncertainty regarding what will happen with a farmer's organic certification if the rules change. Plaintiffs, however, limit their request to prospective vacatur only such that any compost purchased and/or used between 2010 and the Court's Order would be grandfathered in and the Court is not going to order otherwise.

The amici, for their part, contend that withdrawing NOP 5016 would cause "profound disruptions to the organic industry" (Dkt. No. 72-1 at ¶ 8 (Declaration of Laura Batcha, Executive Director of the Organic Trade Association)), would "impose an irreparably harmful burden on certifying agents" by forcing them to develop an "astronomical...testing regime" (AR 64-3 at ¶¶ 10-11 (Declaration of Jake Lewin, President of CCOF Certification Services), and could make it "immediately necessary to halt shipments of crops presently in the field until USDA sorts out the compliance plan" (AR 64-1 at ¶ 14 (Declaration of Hank Giclas, Senior Vice President with Western Growers Association)). Amici contend that these harms will occur because in the absence of NOP 5016 (1) they would be required to develop a new compost testing regime which would be impossible or at least impossibly expensive, (2) the bulk of this burden would fall on organic farmers who can ill-afford it, and (3) Plaintiffs have not shown that NOP 5016 has had any negative environmental impacts in the five years since it was adopted. Amici suggest that even if the testing only cost $100/ton because compost is applied at a rate of 1-8 tons per acre and Western Growers Association members use more than a million acres, the cost to its members alone could be as high as $100 million per year.

These arguments are not supported by the record or the law. Vacatur merely reinstates the status quo. See Paulsen, 413 F.3d at 1008 ("The effect of invalidating an agency rule is to reinstate the rule previously in force."). From 2000 through 2010—before the adoption of NOP 5016—the organic industry thrived. Moreover, as NOP 5016 did not rescind some sort of mandatory testing regime, vacating the guidance does not re-impose a mandatory testing regime; instead, as always, testing is performed at the discretion of certifiers and state organic programs

"when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods." 7 C.F.R. § 205.670(b**)**. Further, some states like California and Washington have pre-existing residue testing programs. The Washington State Department of Agriculture's program for residue testing reviews inputs (including compost) at the expense of the commercial compost producer to insure that the inputs are not contaminated with prohibited substances and provides a list of approved composts for organic farmers. (AR 1115-1116.) Additionally, the National Organic Program issued a final rule requiring organic certifiers to periodically test organic products for residues of prohibited substances in 2012—just two years after NOP 5016. See Final Rule, Periodic Residue Testing, 77 Fed. Reg. 67,239 (November 9, 2012).[3] And, any such testing is performed at the certifiers' expense, not that of the farmer. 7 C.F.R. § 205.670(b**)**. ("Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense."). The burden then is on the certifier and not the farmer to ensure that all inputs (such as commercially made compost) meet the requirements for labeling as organic. 7 C.F.R. §§ 205.201, 205.670. Amici's testing argument makes no sense.

Finally, any argument regarding the disastrous effect of vacatur of the rule is undermined by the fact that any prospective vacatur would put the industry in the same position the California organic industry was in from 2009-2010 between the time when CDFA prohibited the three compost products containing bifenthrin for use in organic production and NOP 5016 was enacted. When asked about how the industry fared during this time at oral argument, amici stated that the compost manufacturer whose compost was banned "stopped selling, and they found other composts" and "it was just business as usual while this worked itself out." (Transcript at 52:19-

[3] The purpose of the rule is to "clarify[y] a provision of OFPA and the regulations issued thereunder that requires periodic residue testing of organically produced agricultural products by accredited certifying agents. The rule ensures consistency of the regulations with OFPA by ensuring that all certifying agents are conducting residue testing of organic products on a regular reoccurring basis. Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the NOP and by discouraging the mislabeling of agricultural products. This action further ensures the integrity of products produced and handled under the NOP regulations." National Organic Program; Periodic Residue Testing, 77 FR 67239-01.

23.) In other words, the sky did not fall.

In sum, Defendants' and the amici's arguments regarding the severity of the consequences of vacatur are overstated, at best. Given the apparent prevalence of bifenthrin in green waste, vacating NOP 5016 will likely affect the availability of this green waste for use in organic compost. But neither Defendants nor the amici have demonstrated that this would be unacceptably harmful to the environment or the organic industries' economy or that the consequences are anywhere near the level of the consequences in California Communities Against Toxics. On the other hand, Plaintiffs did not challenge NOP 5016 until nearly five years after its adoption and this delay must factor into the Court's analysis. Ultimately, however, given that vacatur is the presumptive remedy for a procedural violation such as this, it is Defendants' burden to show that vacatur is unwarranted. Defendants have not done so. The Agency's unlawful rulemaking must be set aside and the matter remanded for compliance with 5 U.S.C. § 553.

CONCLUSION

For the reasons stated above, Plaintiffs' Motion for Summary Judgment is GRANTED and Defendants' cross-motion is DENIED. (Dkt. Nos. 57 & 59.) NOP 5016 is VACATED prospectively and the matter is REMANDED to the Agency for compliance with the APA. The Court's vacatur is effective as of August 22, 2016. Any green waste compost purchased or used between 2010 and August 22, 2016 is grandfathered in and not subject to this Order.

IT IS SO ORDERED.

Dated: June 20, 2016

JACQUELINE SCOTT CORLEY
United States Magistrate Judge