UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

ORGANIC PASTURES DAIRY COMPANY, LLC, Plaintiff, v. KATHLEEN SEBELIUS, et al., Defendants.	Case No. 1:12-cv-02019-SAB ORDER DENYING PLAINTIFF'S MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD ECF NO. 57

On August 9, 2013, Plaintiff Organic Pastures Dairy Company, LLC ("Organic Pastures") filed a motion to supplement the administrative record in this action. (ECF No. 57.) A hearing on this matter took place on August 28, 2013.

For the reasons set forth below, the Court finds that Organic Pastures has failed to demonstrate grounds to supplement the administrative record.

I.

BACKGROUND

In this lawsuit, Organic Pastures seeks judicial review of Defendant United States Food and Drug Administration's ("FDA") denial of Organic Pastures' citizen petition. Organic Pastures filed a citizen petition with the FDA on December 22, 2008. The citizen petition sought modification of 21 C.F.R. § 1240.61, which prohibits the sale of unpasteurized milk (also known

as "raw milk") across state lines. Organic Pastures requested an exemption that permitted the sale of raw milk across state lines so long as the sale was legal in both the seller's state and the destination state.

Organic Pastures initially filed this action in federal court on December 12, 2012 seeking a writ of mandamus to compel the FDA to respond to the citizen petition. (ECF No. 1.) On February 26, 2013, after this action was filed, the FDA denied the citizen petition. Organic Pastures then filed an amended complaint seeking judicial review of the FDA's denial of the citizen petition. Organic Pastures contends that the FDA's denial was arbitrary and capricious.

In May 2013, Organic Pastures submitted a subsequent petition to the FDA to modify the FDA's response, which included additional documents that Organic Pastures contends the FDA should have considered in connection with the original citizen petition.

The administrative record was filed in this action on July 3, 2013. (ECF No. 53.) The administrative record consists of the FDA's records related to their February 26, 2013 final response to Organic Pastures' citizen petition. However, the administrative record does not include the additional documents submitted by Organic Pastures in its May 2013 petition to modify.

Organic Pastures now seeks to supplement the administrative record in this action to include the additional documents submitted by Organic Pastures in its May 2013 petition to modify. At the hearing on this matter, Organic Pastures conceded that it had not previously attempted to submit the additional documents now at issue to the FDA when the FDA was responding to the citizen petition.

II.

LEGAL STANDARDS

In this action, Organic Pastures seeks judicial review of agency action under the Administrative Procedures Act. See 7 U.S.C. § 702 ("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.").

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When a plaintiff challenges a final agency action, judicial review normally is limited to the administrative record in existence at the time of the agency's decision. Friends of the Clearwater v. Dombeck, 222 F.3d 552, 560 (9th Cir. 2000). "In these cases, the agency must justify its final action by reference to the reasons it considered at the time it acted." Id. However:

> In limited circumstances, district courts are permitted to admit extra-record evidence: (1) if admission is necessary to determine "whether the agency has considered all relevant factors and has explained its decision," (2) if "the agency has relied on documents not in the record," (3) "when supplementing the record is necessary to explain technical terms or complex subject matter," or (4) "when plaintiffs make a showing of agency bad faith."

Lands Council v. Powell, 395 F.3d 1019, 1030 (9th Cir. 2004) (quoting Southwest Center for Biological Diversity v. U.S. Forest Service, 100 F.3d 1443, 1450 (9th Cir. 1996)). At the hearing on this matter, Organic Pastures stated that they sought to supplement the administrative record in this case under the first (whether the agency considered all relevant factors) and fourth (bad faith) exceptions.

"Though widely accepted, these exceptions are narrowly construed and applied." Id.; see also Cactus Corner, LLC v. U.S. Dept. of Agriculture, 346 F. Supp. 2d 1075, 1105 (E.D. Cal. 2004) ("Supplementation of an administrative record is the exception, not the rule."). "Were the federal courts routinely or liberally to admit new evidence when reviewing agency decisions, it would be obvious that the federal courts would be proceeding, in effect, de novo rather than with the proper deference to agency processes, expertise, and decision-making." Id.

A district court's decision whether to admit extra-record evidence is reviewed for abuse of discretion. Southwest Center for Biological Diversity, 100 F.3d at 1447.

III.

DISCUSSION

A. The FDA's Four Year Delay In Issuing A Response to Organic Pastures' Citizen Petition Does Not Exhibit Bad Faith

Organic Pastures argues that the Court should look at evidence beyond the administrative record because the FDA acted in bad faith in denying Organic Pastures' citizen petition. (Pl.'s

Mem. in Supp. of Mot. to Suppl. the Admin. Rec. ("Pl.'s Mem.") 4:15-5:22.) For the bad faith exception to apply, there must be a strong showing of bad faith or improper behavior. Animal Defense Council v. Hodel, 840 F.2d 1432, 1437 (9th Cir. 1988).

Organic Pastures contends that the FDA exhibited bad faith by delaying their response to Organic Pastures' citizen petition for four years. Organic Pastures contends that the FDA "failed to provide for any meaningful process in reaching its denial, such as engaging in discussions with Organic Pastures or holding public hearings" during this four year period. (Pl.'s Mem. 5:2-4.) Organic Pastures also contends that the FDA "failed to update its record of documents and information before deciding against the petition." (Pl.'s Mem. 5:5-6.) Organic Pastures contends that new and relevant information has become available in the four year period that the FDA did not consider in reaching its decision. (Pl.'s Mem. 5:7-22.)

Organic Pastures cites Tummino v. Torti, 603 F. Supp. 2d 519 (E.D.N.Y. 2009) in support of its argument that the administrative record should be supplemented due to the FDA's bad faith. In Tummino, the plaintiffs submitted a citizen petition to the FDA regarding the Plan B contraceptive. Id. at 522-23. The court permitted the introduction of extra record evidence based upon the bad faith exception. Id. 543-44. The court's bad faith finding was based upon 1) "the unusual involvement of FDA upper management in the review process," 2) "evidence that FDA officials were motivated by 'improper concerns about the morality of adolescent sexual activity,'" 3) "evidence that the decision not to approve the OTC switch was made before review staff had completed their reviews," 4) "the refusal to adopt the recommendations of professional review staff and the Advisory Committee," 5) the resignations of officials within the agency in connection with the matter addressed in the citizen petition, and 6) "the GAO's findings of procedural irregularities..." Id. at 544.

The facts here are distinguishable to those in Tummino. In this case, Organic Pastures' bad faith argument is premised entirely on the FDA's delayed response to Organic Pastures' citizen petition. Here, there is no suggestion that the FDA was motivated by improper political concerns and there is no evidence of procedural irregularities. Moreover, the extra-record evidence that Organic Pastures seeks to introduce has no relationship to the alleged bad faith

delay. In Tummino, introduction of extra-record evidence was necessary to determine whether the FDA acted in bad faith. See also Nehemiah Corp. of America v. Jackson, 546 F. Supp. 2d 830, 848 (E.D. Cal. 2008) (permitting introducing of extra-record evidence that agency improperly prejudged the merits of a proposed rule).

The extra-record evidence in this case does not evidence bad faith. In fact, the extra-record evidence in this case is inconsistent with Organic Pastures' bad faith argument. Organic Pastures contends that much of the extra-record evidence consists of new information that became available after Organic Pastures submitted its citizen petition in 2008. Had the FDA responded to Organic Pastures' citizen petition in a more timely manner, it could have avoided consideration of this extra-record evidence by issuing a decision before the extra-record evidence came into existence. In other words, if the new information was favorable to Organic Pastures' position, it is unclear how the FDA acted in bad faith by delaying and allowing this information to become available before issuing its decision. Organic Pastures does not identify any other bad faith motive behind the FDA's delay. Accordingly, the FDA's four year delay in responding to Organic Pastures' citizen petition does not demonstrate bad faith warranting consideration of extra-record evidence.

Based upon the foregoing, the Court finds that the FDA did not delay its response to the citizen petition in bad faith, warranting expansion of the administrative record.

B. There Insufficient Evidence Supporting Organic Pastures' Claim That The FDA Negligently Or Intentionally Excluded Material Documents From The Record

Organic Pastures argues that the Court should consider extra-record evidence because the FDA negligently or intentionally excluded material documents from the record. (Pl.'s Mem. 5:23-9:23.) Courts have treated an administrative agency's exclusion of documents from the administrative record as falling under the bad faith exception discussed above. See, e.g., McCrary v. Gutierrez, 495 F. Supp. 2d 1038, 1043 (N.D. Cal. 2007). Thus, as discussed above, Organic Pastures must make "a strong showing of bad faith or improper behavior" with respect to the exclusion of documents in order to invoke the exception. Animal Defense Council, 840 F.2d at 1437; McCrary, 495 F. Supp. 2d at 1043.

Organic Pastures contends that the FDA excluded documents from the administrative record in bad faith because some of the excluded documents were in the possession of the FDA or in the possession of other agencies within the Department of Health and Human Services ("HHS").[1] However, the cases cited by Organic Pastures are distinguishable from the facts in this case. In Kent County, Delaware Levy Court v. U.S. E.P.A., 963 F.2d 391, 396 (D.C. Cir. 1992), the court found that the EPA negligently failed to examine "the Region III CERCLA files" for relevant information. The court acknowledged it was not "the EPA's responsibility to find *all* documents ... located in *any* office of the EPA." Id. (italics in original). However, the court found it inexcusable that the regional EPA office that issued the decision failed to examine its own files for relevant documents.

In this case, several documents identified by Organic Pastures are documents that were authored outside the FDA. Although some of these agencies are other Operating Divisions under the umbrella of HHS, Organic Pastures does not demonstrate how it constitutes bad faith for the FDA to exclude these documents from the administrative record.[2]

With respect to the FDA authored documents, Organic Pastures fails to demonstrate that the extra-record evidence was located somewhere that the FDA should have looked before issuing its response to Organic Pastures' citizen petition. Several of these documents are only remotely relevant to the raw milk citizen petition. Organic Pastures claims that FDA documents such as "FDA Food Facts: Food Allergies," "Letter to Cantaloupe Industry on Produce Safety," and "FDA Investigates a Multistate Outbreak of listeria," should have been included in the administrative record because the FDA allegedly was inconsistent in its regulation of different food products. Irrespective of the merits of this line of argument, there is no suggestion that there was any bad faith motive on the FDA's part by their failure to consider these documents.

[1] The FDA is an Operating Division under the umbrella of HHS. HHS Leadership: Open Government at HHS, http://www.hhs.gov/open/contacts/index.html#od (last visited Aug. 22, 2013). Organic Pastures contends that relevant evidence was in the possession of other sub-agencies under HHS, such as the National Institute of Health and the Center for Disease Control. Id.

[2] One document was authored by the Government Accountability Office ("GAO"), which is not an Operating Division under HHS. Organic Pastures does not offer any theory as to why the FDA should have considered documents authored by GAO when responding to the citizen petition.

Had Organic Pastures expressly asked the FDA to compare raw milk to cantaloupes, Organic Pastures' argument may have some merit. However, short of that, the Court does not find any suggestion of bad faith on the FDA's part by their failure to isolate cantaloupes for comparison to raw milk

The FDA's report on "Food Facts: The Dangers of Raw Milk" is the only document that appears to be facially relevant to the issue raised in the citizen petition and authored by the FDA. However, Organic Pastures does not present sufficient evidence that this omission was done in bad faith. There is no evidence that this particular document was physically located somewhere the FDA would have been expected to look when researching its response to the citizen petition. There is also no convincing evidence that the FDA's failure to include the document in the administrative record was done for improper reasons. At the hearing, Organic Pastures contended that the Dangers of Raw Milk document was adverse to the FDA's position because it conceded that the health risks from consuming homemade ice cream may be caused by the use of raw eggs, rather than from the raw milk. Given the relatively minor concession in a document that, based on its title, appears to be generally supportive of the FDA's position, the Court cannot conclude that the Dangers of Raw Milk document was deliberately omitted by the FDA in bad faith.

Organic Pastures' argument that the FDA negligently or deliberately excluded evidence that was adverse to its position is undermined by the fact that Organic Pastures initiated the administrative proceedings by challenging the FDA's regulations through a citizen petition. Organic Pastures does not dispute that it could have submitted additional evidence along with its citizen petition. Organic Pastures argues that the omission of documents at the time the citizen petition was filed is attributable to the fact that Organic Pastures was not represented by legal counsel at the time. However, the pertinent regulations permit Organic Pastures to supplement the administrative record at any time before the FDA's decision. 21 C.F.R. 10.30(g). It is undisputable that Organic Pastures was represented by legal counsel at the time the petition for a writ of mandamus was filed in this action on December 12, 2012. Organic Pastures provides no explanation why they made no attempt to supplement the administrative record at that time.

Based upon the foregoing, the Court finds that the FDA did not negligently or deliberately exclude documents from the administrative record. Therefore, expansion of the administrative record is not warranted.

C. There Is Insufficient Evidence Supporting Organic Pastures' Claim That Admission Of Extra-Record Evidence Is Necessary To Determine Whether The FDA Considered All Relevant Factors

Organic Pastures argues that admission of extra-record evidence is necessary to determine whether the FDA has considered all relevant factors in reaching is decision on the citizen petition. Lands Council, 395 F.3d at 1030 (quoting Southwest Center for Biological Diversity, 100 F.3d at 1450). "[T]o satisfy the 'relevant factors' exception, a plaintiff must establish more than just that the document is relevant. In fact, the document in question must do more than raise 'nuanced points' about a particular issue; it must point out an 'entirely new' general subject matter that the defendant agency failed to consider." Pinnacle Armor, Inc. v. U.S., No. 1:07-cv-01655 LJO DLB, 2013 WL 509047, at *4 (E.D. Cal. Feb. 12, 2013) (citing In re Delta Smelt Consolidated Cases, No. 1:09-cv-1053 OWW DLB, 2010 WL 2520946, at *5 (Jun. 21, 2010)).

Here, Organic Pastures fails to convincingly demonstrate that the extra-record evidence at issue concerns an entirely new general subject matter not previously considered by the FDA. Organic Pastures contends that the relevant factor that the FDA failed to consider was "the Defendants' arbitrary treatment of unpasteurized dairy products intended for human consumption relative to other foods, including but not limited to pasteurized dairy products." (Pl.'s Reply to Defs.' Opp'n to Pl.'s Mot. to Suppl. the Admin. Rec. ("Pl.'s Reply") 4:23-26.)

The issue raised by Organic Pastures is merely a "nuanced point" about the broader issue of whether raw milk is deemed safe for human consumption. Organic Pastures does not deny that the FDA addressed the issue of safety in its response to the citizen petition. Organic Pastures contends that the FDA's treatment of raw milk relative to other foods presents an entirely new general subject matter. However, Organic Pastures fails to cite any legal authority that suggests that the FDA has an independent obligation to perform relative comparisons between raw milk and other food products.

Moreover, it is worth noting that Organic Pastures' own citizen petition did not frame the relative treatment of raw milk compared to other foods as an "entirely new general subject matter that the agency failed to consider." In the "Action requested" section of the citizen petition, Organic Pastures sought an amendment of the regulation prohibiting the interstate sale of raw milk. (Defs.' Opp'n to Pl.'s Mot to Suppl. the Admin. Rec. ("Defs.' Opp'n") Ex. A, at pg. 1.) The "Statement of grounds" section does conclude with the argument that:

> No other foods have been singled out for state line FDA prohibition. Raw milk stands alone as the single food that can not be taken across state lines and consumed. There is no rational argument that can be made to defend this regulation.

(Defs.' Opp'n Ex. A, at pg. 6.) However, the citizen petition makes no argument that the differential treatment of raw milk is an entirely new subject matter and ground to amend the raw milk regulations. The citizen petition does not expressly ask the FDA to compare its regulation of raw milk to its regulation of other foods. Taken in context, the statement that raw milk had been "singled out" was presented by Organic Pastures more as a sub-argument in support of the general proposition that raw milk is safe enough to transport across state lines rather than an "entirely new" subject matter justifying expansion of the administrative record.

Organic Pastures argues that the FDA treats raw milk differently than it treats other foods and that the FDA singled out raw milk as the only product subject to a prohibition on interstate sale. However, this argument speaks to the merits of Organic Pastures' petition for judicial review rather than the present issue of whether the administrative record should be supplemented with additional evidence.

In a case analogous to this case, the district court for the District of Columbia held that the "relevant factors" exception did not apply when plaintiffs sought to introduce evidence from a separate case for the purpose of comparing the agency's actions in the separate case to the case at bar. Marcum v. Salazar, 751 F. Supp. 2d 74, 81 (D.D.C. 2010). In a case involving judicial review of the United States Fish & Wildlife Service's ("the Service") denial of plaintiffs' elephant trophy import application, the plaintiffs argued that the administrative record should be supplemented with the record from a prior case involving elephant trophy imports. The court

held that "[t]he Service was not obliged to consider the [prior case records] in the present case, which involves different plaintiffs challenging different permit denials." Id. at 82.

In this case, the FDA considered the health hazards presented by raw milk in reaching its decision on the citizen petition. The additional evidence proposed by Organic Pastures pertaining to the risks posed by other foods merely provides a "nuanced point" on the same issue. Accordingly, such evidence does not qualify as an exception to the general rule that this Court should not look beyond the administrative record in reviewing the FDA's response to the citizen petition.

More importantly, as discussed above, Organic Pastures framed the issues associated with this present case. They filed their first citizen petition in 2008 and never sought to amend or supplement the petition. Instead they chose judicial intervention under the APA, which is limited in scope and is not intended for Court's to substitute their judgment for that of the administrative agency. Organic Pastures then filed a petition to modify in May 2013 addressing the issues now being raised more succinctly. The Court's role is to review the FDA's response to the original citizen petition, not preempt the FDA's response to the petition to modify. To merely supplement the record by adding the documents at Organic Pastures request would be the equivalent of usurping the FDA's role in responding to the petition to modify filed by Organic Pastures. This Court will review the FDA's decision of February 2013 under the APA in the manner framed by the Plaintiff.

IV.

CONCLUSION AND ORDER

For the reasons set forth below, the Court finds that there exist no grounds to supplement the administrative record with the evidence proposed by Organic Pastures.

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Accordingly, it is HEREBY ORDERED that Organic Pasture's motion to supplement the administrative record is DENIED.

IT IS SO ORDERED.

Dated: **August 29, 2013**

UNITED STATES MAGISTRATE JUDGE