

FOR PUBLICATION

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

COMPASSION OVER KILLING, a non-profit organization; ANIMAL LEGAL DEFENSE FUND, a non-profit organization; ELIZABETH BARRETT; ANDREA BOCK; LINDA CALBREATH; JASON CANADA; JERI OPALK; HUMBERTO RETANA,

Plaintiffs-Appellants,

v.

U.S. FOOD & DRUG ADMINISTRATION; MARGARET HAMBURG, M.D., Commissioner; AGRICULTURE MARKETING SERVICE; DAVID R. SHIPMAN, Administrator; FOOD SAFETY AND INSPECTION SERVICE; ALFRED V. ALMANZA, Administrator; FEDERAL TRADE COMMISSION; EDITH RAMIREZ, Chairwoman,

Defendants-Appellees.

No. 15-15107

D.C. No.
3:13-cv-01385-
VC

OPINION

Appeal from the United States District Court
for the Northern District of California
Vince G. Chhabria, District Judge, Presiding

Argued and Submitted December 14, 2016
San Francisco, California

Filed February 27, 2017

Before: Michael Daly Hawkins, Marsha S. Berzon,
and Mary H. Murguia, Circuit Judges.

Opinion by Judge Murguia

SUMMARY*

Rulemaking

The panel affirmed the district court's summary judgment in favor of federal agencies in a lawsuit alleging that the agencies acted arbitrarily and capriciously in dismissing plaintiffs' rulemaking petitions, which requested that each agency promulgate regulations that would require all egg cartons to identify the conditions in which the egg-laying hens were kept during production.

The panel held that the Food Safety and Inspection Service did not act arbitrarily or capriciously in denying plaintiffs' rulemaking petition because the agency correctly concluded that it lacked authority to promulgate plaintiffs' proposed labeling regulations for shell eggs. The panel also held that the Agricultural Marketing Service did not act arbitrarily or capriciously in denying plaintiffs' rulemaking

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

petition because the agency correctly concluded that it lacked the authority to promulgate mandatory labeling requirements for shell eggs.

The panel held that the Federal Trade Commission did not act arbitrarily or capriciously in denying plaintiffs' rulemaking petition. Specifically, the panel held that the FTC reasonably denied plaintiffs' petition in light of the limited evidence before the FTC showing any "prevalent" unfair or deceptive practices. The panel further held that the FTC reasonably denied plaintiffs' rulemaking petition based on its discretion to combat any potentially misleading egg labeling through ad hoc enforcement proceedings.

The panel held that the Food and Drug Administration barely met its low burden to clearly indicate that it considered the potential problem identified in plaintiffs' petition, and provide a reasonable explanation for not initiating rulemaking.

COUNSEL

Monte M.F. Cooper (argued), Orrick Herrington & Sutcliffe LLP, Menlo Park, California; Karen G. Johnson-McKewan, Orrick Herrington & Sutcliffe LLP, San Francisco, California; for Plaintiffs-Appellants.

Jeffrey E. Sandberg (argued) and Mark B. Stern, Attorneys, Appellate Staff; Brian Stretch, Acting United States Attorney; Benjamin C. Mizer, Principal Deputy Assistant Attorney General; Civil Division, United States Department of Justice, Washington, D.C.; for Defendants-Appellees.

OPINION

MURGUIA, Circuit Judge:

Plaintiffs Compassion Over Killing, the Animal Legal Defense Fund, and six individual egg consumers submitted rulemaking petitions to Defendants U.S. Food and Drug Administration (“FDA”), Federal Trade Commission (“FTC”), Agricultural Marketing Service (“AMS”), and Food Safety and Inspection Service (“FSIS”), requesting that each agency promulgate regulations that would require all egg cartons to identify the conditions in which the egg-laying hens were kept during production. Each agency denied Plaintiffs’ rulemaking petition. Plaintiffs initiated the underlying lawsuit claiming that each agency had acted arbitrarily and capriciously in dismissing their rulemaking petitions. The district court concluded that Defendants had each acted reasonably in denying Plaintiffs’ petitions and granted summary judgment in favor of Defendants. We have jurisdiction pursuant to 28 U.S.C. § 1291, and we affirm.¹

I.

Plaintiffs submitted similar rulemaking petitions to the FDA, FTC, AMS, and FSIS requesting that each agency

¹ We grant Plaintiffs’ request for judicial notice of documents that were omitted from the administrative record (Doc. No. 50). *See* Fed. R. App. P. 10(e)(2)(C).

We deny Plaintiffs’ request for judicial notice of two recent newspaper articles (Doc. No. 67). These articles were not part of the administrative record on which the agencies based their decisions to deny Plaintiffs’ rulemaking petitions, and Plaintiffs have not “met [their] heavy burden to show that the additional materials . . . are necessary to adequately review” the agencies’ decisions. *See Fence Creek Cattle Co. v. U.S. Forest Serv.*, 602 F.3d 1125, 1131 (9th Cir. 2010).

“take regulatory action to revise the current labeling requirements for eggs at [21 C.F.R. §§ 101, 115, 160], and/or to promulgate new regulations” that would require all egg cartons to identify the conditions in which the egg-laying hens were kept during production. The petitions specifically proposed that each agency develop regulations that would require all egg cartons to bear the labels “Free-Range Eggs,” “Cage-Free Eggs,” or “Eggs from Caged Hens,” consistent with the living conditions of the hens. In support of the proposed regulations, Plaintiffs argued that there is a strong consumer interest in buying eggs that are produced in cage-free environments. Plaintiffs also argued that, without the proposed regulations, consumers are being misled by certain statements and images on egg cartons that imply that the hens are being raised in cage-free environments. Plaintiffs provided several examples of various egg labels that present images of uncaged hens and contain phrases such as “all natural” or “animal friendly,” arguing that these images and phrases likely mislead a consumer to believe that the hens are not being raised in cages. Plaintiffs also maintained that their proposed regulations are necessary because eggs from caged hens are nutritionally inferior to and carry a greater risk of Salmonella contamination than eggs from free-range hens.

Each agency denied Plaintiffs’ petition for rulemaking. The FSIS and AMS explained that they could not promulgate the proposed regulations because they lacked the authority to take the requested action. The FTC explained that, based on the information Plaintiffs provided in the petition, it could not conclude that current egg-labeling practices were either “unfair or deceptive.” The FTC also concluded that the petition had not sufficiently demonstrated that any misleading practice was “prevalent,” as statutorily required for rulemaking. Lastly, the FTC explained that the

agency's resources would be better used by combating any potentially deceptive practices through individual enforcement actions, rather than by promulgating new regulations.

The FDA denied Plaintiffs' request for rulemaking because it determined that Plaintiffs had failed to show that current egg labels omitted a "material" fact by not indicating the living conditions of the egg-laying hens. The FDA specifically explained that it could not determine that this information was material because Plaintiffs had not provided persuasive evidence that eggs from caged hens are either less nutritious or more likely to be contaminated with Salmonella than eggs from uncaged hens. The FDA also explained that consumer interest in the hens' living conditions, alone, is insufficient to establish that egg-production methods are a material fact that would permit the FDA to issue the requested regulations. Lastly, the FDA stated that it declined to promulgate the proposed labeling regulations because it could bring individual enforcement actions against any misbranded eggs, and "it would choose to use its limited resources on rulemakings of higher priority, such as those that are of greatest public health significance or are statutorily-mandated."

Plaintiffs filed this lawsuit, alleging that the FSIS, AMS, FTC, and FDA had each acted arbitrarily and capriciously in dismissing their rulemaking petitions. Plaintiffs moved for summary judgment, and Defendants filed a cross-motion for summary judgment, arguing that each agency had acted reasonably in denying Plaintiffs' rulemaking requests. The district court granted summary judgment for Defendants. Plaintiffs timely appealed.

II.

This Court reviews challenges to final agency action decided on summary judgment de novo and pursuant to Section 706 of the Administrative Procedure Act (“APA”). *Turtle Island Restoration Network v. Nat’l Marine Fisheries Serv.*, 340 F.3d 969, 973 (9th Cir. 2003). The APA requires the Court to “hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2). When an agency refuses to exercise its discretion to promulgate proposed regulations, the Court’s review “is ‘extremely limited’ and ‘highly deferential.’” *Massachusetts v. EPA*, 549 U.S. 497, 527–28 (2007) (quoting *Nat’l Customs Brokers & Forwarders Ass’n of Am., Inc. v. United States*, 883 F.2d 93, 96 (D.C. Cir. 1989)); see also *Nat’l Mining Ass’n v. Mine Safety & Health Admin.*, 599 F.3d 662, 667 (D.C. Cir. 2010) (stating that an “‘agency’s refusal to institute rulemaking proceedings is at the high end of the range’ of levels of deference we give to agency action under our ‘arbitrary and capricious’ review” (quoting *Defenders of Wildlife v. Gutierrez*, 532 F.3d 913, 919 (D.C. Cir. 2008))).

A.

Plaintiffs argue that the FSIS acted arbitrarily and capriciously by denying their rulemaking petition based on the agency’s conclusion that it lacks the authority to promulgate the proposed regulations. Plaintiffs specifically argue that the FSIS has the authority to regulate the labeling of shell eggs under the Egg Products Inspection Act (“EPIA”), 21 U.S.C. §§ 1031–56.

The FSIS correctly concluded that it lacks the authority to promulgate Plaintiffs’ proposed labeling regulations for

shell eggs. The EPIA expressly distinguishes between the terms “egg products” and “eggs,” and grants broad authority to the FSIS to regulate the labeling only of “egg products.” *See* 21 U.S.C. § 1036(a) (stating that the FSIS may promulgate regulations mandating the disclosure of information “to assure that [egg products] will not have false or misleading labeling”); *see also id.* § 1033(f) (defining “egg product” as “any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion”); *id.* § 1033(g) (defining “egg” as “the shell egg of the domesticated chicken, turkey, duck, goose, or guinea”). Because Plaintiffs’ proposed labeling regulations concern only shell eggs, they fall outside of the FSIS’s labeling jurisdiction under the EPIA. Accordingly, we conclude that the FSIS did not act arbitrarily or capriciously in denying Plaintiffs’ rulemaking petition.

B.

Plaintiffs also argue that the AMS acted arbitrarily and capriciously in denying their rulemaking petition based on the agency’s conclusion that it lacks the authority to promulgate mandatory labeling regulations. Plaintiffs maintain that the AMS has the authority to issue their proposed regulations under the Agricultural Marketing Act of 1946 (“AMA”), 7 U.S.C. §§ 1621–39j.

The AMS correctly concluded that it lacks the authority to promulgate mandatory labeling requirements for shell eggs. The relevant grant of authority in the AMA only authorizes the AMS “[t]o develop and improve standards of quality, condition, quantity, grade, and packaging, and *recommend* and demonstrate such standards in order to encourage uniformity and consistency in commercial practices.” 7 U.S.C. § 1622(c) (emphasis added). There is no

indication from this statutory language that Congress intended to authorize the AMS to promulgate mandatory labeling requirements for all shell eggs. Further, although Plaintiffs correctly note that the AMS has previously developed voluntary programs related to food labels, these programs do not demonstrate that the AMS has the authority to promulgate the mandatory regulations Plaintiffs sought. *See, e.g.*, Regulations Governing the Voluntary Grading of Shell Eggs, 7 C.F.R. pt. 56. We therefore conclude that the AMS also did not act arbitrarily or capriciously in denying Plaintiffs' rulemaking petition because the agency correctly concluded that it lacks the authority to promulgate mandatory labeling requirements for shell eggs.

C.

Plaintiffs argue that the FTC acted arbitrarily and capriciously by denying their rulemaking petition without completing an appropriately substantive analysis of the petition. Plaintiffs also argue that, because the FTC did not appropriately review the rulemaking petition, the agency should not be permitted to exercise its discretion to address any misleading egg labeling through ad hoc enforcement actions.

The Federal Trade Commission Act ("FTCA"), 15 U.S.C. §§ 41–58, authorizes the FTC to prescribe "rules which define with specificity acts or practices which are unfair or deceptive" and "requirements . . . for the purpose of preventing such acts or practices." 15 U.S.C. § 57a(a)(1)(B). The FTC may initiate such rulemaking proceedings, however, "only where it has reason to believe that the unfair or deceptive acts or practices . . . are prevalent." *Id.* § 57a(b)(3). The FTCA states that an act or practice is "prevalent" if the FTC has previously issued cease-and-desist orders regarding the act or practice, or if

“any other information available to the [FTC] indicates a widespread pattern of unfair or deceptive acts or practices.” *Id.* § 57a(b)(3)(A)–(B).

In its letter denying Plaintiffs’ petition, the FTC explained that it could not conclude that the potentially unfair or deceptive labeling practices Plaintiffs challenge are “prevalent” as that term is used in the FTCA. The FTC specifically concluded, and Plaintiffs do not dispute, that the agency has not issued any cease-and-desist orders concerning the egg-labeling practices identified in their petition. The FTC also reasonably concluded that Plaintiffs had submitted insufficient evidence to establish that any potentially unfair or deceptive egg-labeling practices were “widespread.” While Plaintiffs submitted isolated examples of potentially misleading egg labels and survey evidence concerning consumer confusion over the word “natural,” Plaintiffs have not identified any evidence submitted to the FTC tending to indicate that such practices were sufficiently widespread to justify promulgating their proposed regulations. In light of the limited evidence before the FTC showing any “prevalent” unfair or deceptive practices, the FTC’s decision to deny Plaintiffs’ petition on this basis was reasonable. *See Massachusetts*, 549 U.S. at 533 (requiring a “reasonable explanation as to why [an agency] cannot or will not exercise its discretion” to decline rulemaking).

The FTC also reasonably denied Plaintiffs’ rulemaking petition based on its discretion to combat any potentially misleading egg labeling through ad hoc enforcement proceedings. *See SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947) (“[T]he choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency.”). Here, the FTC explained that it has been

successful in pursuing individual enforcement efforts concerning misleading shell egg labeling in the past. Further, the FTC considered its “limited . . . resources” and explained that, in light of the numerous statutory requirements for rulemaking under the FTCA, the “resource commitment necessary to adopt a rule” similar to what Plaintiffs requested “would be considerable.” These considerations provide a separate, reasonable basis for denying Plaintiffs’ rulemaking request that is also sufficient to withstand judicial review. *See Massachusetts*, 549 U.S. at 527 (“[A]n agency has broad discretion to choose how best to marshal its limited resources and personnel to carry out its delegated responsibilities.”). We therefore conclude that the FTC did not act arbitrarily or capriciously in denying Plaintiffs’ rulemaking petition.

D.

Plaintiffs argue that the FDA acted arbitrarily and capriciously in denying their rulemaking petition because the agency failed to consider their claims that egg cartons are widely misbranded not only because their labels omit material information, but also because current labeling practices *affirmatively* misrepresent the nature of the hens’ living conditions. Plaintiffs also argue that the FDA improperly rejected their scientific evidence that the egg-laying hens’ living conditions increase the risk of Salmonella-contamination and negatively affect the nutritional value of the eggs. Lastly, Plaintiffs contend that because the FDA failed to appropriately review their petition, the agency should not be permitted to summarily exercise its discretion to prioritize other agency goals in order to avoid addressing Plaintiffs’ request for rulemaking.

The Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301–399f, prohibits the sale of misbranded

food items. *See* 21 U.S.C. §§ 331(a). The FDA possesses discretionary authority to “promulgate regulations for the efficient enforcement of [the FDCA].” *Id.* § 371(a). Under the FDCA a food item is “misbranded” if its label “is false or misleading in any particular.” *Id.* § 343(a)(1). Food labeling may be misleading through affirmative representations or through an omission of a material fact. *See id.* § 321(n).

To the extent Plaintiffs’ petition argued that egg production methods were an omitted material fact that required disclosure because the hens’ living conditions affect the likelihood of Salmonella-contamination or the nutritional value of the eggs, the FDA explained that Plaintiffs had provided insufficient reliable scientific evidence to support these claims. While Plaintiffs dispute the FDA’s decision to reject their scientific evidence, the Court will not second guess the FDA’s conclusion that these studies were insufficiently reliable, largely because they failed to control for relevant variables. *See N. Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1075 (9th Cir. 2011) (“A court generally must be ‘at its most deferential’ when reviewing scientific judgments and technical analyses within the agency’s expertise.” (quoting *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983))).

To the extent Plaintiffs’ petition argued that egg-production methods were an omitted material fact that required disclosure in light of misleading affirmative representations that appear on egg cartons, the FDA explained that it could bring individual enforcement actions against any such misbranded food, as it has done in the past. The FDA also detailed its competing priorities given its limited resources and explained it had determined that, even

if certain egg-labeling practices are misleading, proposed rulemaking was not the best use of its limited resources.

The decision to take enforcement action against misbranded eggs on a case-by-case basis, as opposed to promulgating regulations that would apply to all egg producers, is left to the broad discretion of the FDA. *See Chenery Corp.*, 332 U.S. at 203. Similarly, the agency’s decision to prioritize other projects is entitled to great deference by a reviewing court. *See Massachusetts*, 549 U.S. at 527; *see also In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (“[W]e have no basis for reordering [the FDA’s] priorities. The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way.”).

We note, however, that such broad discretion should not be construed as providing a blanket exception to APA review in any matter involving the allocation of agency resources. *See WWHT, Inc. v. F.C.C.*, 656 F.2d 807, 814 (D.C. Cir. 1981) (“[W]e reject the suggestion that agency denials of requests for rulemaking are exempt from judicial review.”). In denying a petition for rulemaking, an agency must, at a minimum, clearly indicate that it has considered the potential problem identified in the petition and provide a “reasonable explanation as to why it cannot or will not exercise its discretion” to initiate rulemaking. *Massachusetts*, 549 U.S. at 533; *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv.*, 807 F.3d 1031, 1042–43 (9th Cir. 2015) (stating that an agency action is considered “arbitrary and capricious” if the agency has “entirely failed to consider an important aspect of the problem” (quoting *Pac. Coast Fed’n of Fisherman’s Ass’ns v. Nat’l Marine Fisheries Serv.*, 265 F.3d 1028, 1034 (9th Cir. 2001))).

Here, the FDA's explanation for denying Plaintiffs' rulemaking petition barely meets this low burden. The FDA could have better addressed Plaintiffs' evidence of misleading representations that appear on egg cartons to demonstrate that the agency fully appreciated one of the primary bases for Plaintiffs' rulemaking petition—that information concerning egg-laying hens' living conditions is necessary in order to correct the affirmative representations that frequently appear on egg labels and convey misleading information. The FDA's denial letter, however, reflects that the agency did consider Plaintiffs' evidence of affirmative misrepresentations that appear on egg labels but ultimately decided that individual enforcement actions would be preferable to promulgating the proposed regulations. Because the FDA is generally free to choose its procedural mode of administration and prioritize agency goals, we see no reason to remand the matter to the FDA to reconsider Plaintiffs' petition in this case.

III.

For the reasons stated above, the FSIS, AMS, FTC, and FDA each acted reasonably in denying Plaintiffs' rulemaking petitions. Accordingly, we affirm the district court's grant of summary judgment to Defendants.

AFFIRMED.