Center for Food Safety v. Becerra

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WHY IT MADE THE LIST

Occasionally, important cases are those that maintain, rather than alter, the status quo. This case[1] is included in this volume because it does just that: it maintains the voluntary notification procedure, created by the Food and Drug Administration (FDA), under which a manufacturer may inform FDA that a substance is generally recognized as safe (GRAS) for its intended use and therefore may be added to food, and declines to make the notification mandatory. This voluntary notification procedure has been unchanged for two decades, partially because, for much of that time, the procedure was set forth as policy (in a proposed rule) rather than in a final rule. In 2016, after FDA promulgated a final rule, it was promptly challenged by plaintiffs. This case presents the first instance in which a court considered, and affirmed, FDA's voluntary GRAS notification process.

BACKGROUND

A food additive is defined, in part, as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[2] As part of the 1958 Food Additive Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), Congress required "food additives" to undergo a premarket approval process.[3] This premarket approval process consists of a sponsor-submitted petition that "proposes the issuance of a regulation prescribing the conditions under which such additive may be safely used,"[4] and may result in FDA proposing a food additive regulation for the specific substance and intended use.

Ostensibly recognizing that certain substances should not be required to undergo a fulsome premarket review, Congress provided for an exception to the definition of "food additive" for substances that are:

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1 Ctr. for Food Safety v. Becerra, No. 17-CV-3833 (VSB), 2021 WL 4504472 (S.D.N.Y. Sept. 30, 2021).

2 21 U.S.C. § 321(s).

3 21 U.S.C. § 348(b)–(g).

4 21 U.S.C. § 348(b)(1).

> generally recognized, among experts qualified by scientific training and experience to evaluate their safety . . . as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of their intended use.[5]

The use of a substance falling under such exclusion because it is GRAS is not subject to the premarket review process for "food additives."

Since the passage of the Food Additives Amendments, FDA has implemented various approaches to identify those substances that are GRAS, including publication of a "GRAS list" by regulation,[6] which itself notes the impracticality of listing all substances that are GRAS for an intended use.[7] FDA initially issued non-binding (and generally private) "opinion letters"[8] and later progressed to a GRAS affirmation process, which included FDA review of safety and functionality data, a public notice-and-comment period, and FDA publication of the substance as either GRAS or not.[9] If FDA affirmed a substance to be GRAS, the agency added the substance to its list of GRAS substances, codified in 21 C.F.R. Parts 184 and 186.[10]

Importantly, from 1958 on, the focus of FDA's regulation of GRAS substances was on defining the scientific and legal standards that such substances had to meet, and these standards were tested in various court decisions. FDA recognized that, if a substance qualified as GRAS, then it was exempt from the food additive definition and FDA had no premarket authority over it. As such, FDA considered any procedure under which industry reported GRAS determinations to FDA to be voluntary; the agency has never tried to implement a mandatory GRAS reporting procedure.

Ultimately, in April 1997, FDA promulgated a proposed rule that, when implemented, would replace the GRAS affirmation procedure with a "notification procedure whereby any person may notify [FDA] of a conclusion that a particular use of a substance is GRAS."[11] However, FDA did not move to finalize the GRAS rule until 2016. During the intervening nineteen years, the agency effectively operated under the policy set forth in the proposed rule, allowing a manufacturer to voluntarily notify FDA of its determination that a substance is GRAS for a particular use. Following a 2010 U.S. Government Accountability Office (GAO) report that criticized FDA for failing to finalize its GRAS notification procedure, which "potentially detract[s] from the program's credibility,"[12] the agency issued the 2016 final rule (GRAS rule) that is the target of this litigation.

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[5] Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 54,963 (Aug. 17, 2016) (citing 21 U.S.C. § 321(s)).

[6] 21 C.F.R. Part 182.

[7] 21 C.F.R. § 182.1(a).

[8] 81 Fed. Reg. at 54,693.

[9] 81 Fed. Reg. at 54,693.

[10] 81 Fed. Reg. at 54,693–94.

[11] *Id.* (citing Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938 (Apr. 17, 1997) (proposed rule), https://www.govinfo.gov/content/pkg/FR-1997-04-17/pdf/97-9706.pdf).

[12] U.S. GOV'T ACCOUNTABILITY OFF., GAO-10-246, FOOD SAFETY: FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE (GRAS) (Feb. 2010), https://www.gao.gov/assets/gao-10-246.pdf [hereinafter GAO REPORT].

Under the GRAS rule, persons may voluntarily "notify FDA of a view that a substance is not subject to the premarket approval requirements [applicable to food additives] based on that person's conclusion that the substance is GRAS under the conditions of its intended use."[13] A GRAS notice must be supported by evidence of "general recognition of safety," based on the views of qualified experts and "generally available and accepted scientific data, information, and methods."[14] Following FDA review of the submission, the agency will publicly respond by letter and state that 1) it has "no questions" regarding the GRAS conclusion, 2) the submitter has provided an insufficient basis for a GRAS conclusion, or 3) it ceased to evaluate the notice on the submitter's request.[15]

It is important to note that under the policy set forth by the 1997 proposed rule, as formalized by the 2016 final rule, a manufacturer is not *required* to notify FDA of a GRAS conclusion.[16] Rather, entities may opt to make an "independent conclusion" of a substance's GRAS status and keep such determination proprietary.[17] In fact, food manufacturers had been "self-affirming" GRAS determinations in this way for many years, guided by the scientific standards in FDA's regulations. The notification process that FDA established in 1997 was an attempt to encourage manufacturers to voluntarily notify FDA of their self-affirmed GRAS determinations. The 1997 policy did not distinguish between a GRAS determination submitted to FDA and one that is not—the same content requirements applied to both[18]—but it did offer submitters the potential benefit of a "no questions" letter from FDA, which could make their new food formulations easier to sell in the marketplace.

DISCUSSION

In this case, Plaintiffs, all non-profit advocacy organizations,[19] alleged that the GRAS rule "allows FDA to abdicate its core duty under the FDCA . . . to be responsible for the safety of the food supply."[20] Specifically, Plaintiffs argued that, because the rule permits entities to reach independent GRAS conclusions without notifying FDA or keeping and retaining records regarding the basis of such determination, in effect, it permits "potentially unsafe chemical substances to be added

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[13] 21 C.F.R. § 170.205.

[14] 21 C.F.R. § 170.30(a)–(c).

[15] *About the GRAS Notification Program*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/generally-recognized-safe-gras/about-gras-notification-program (updated Jan. 4, 2018).

[16] 62 Fed. Reg. at 18,941–42.

[17] 81 Fed. Reg. at 54,984.

[18] 81 Fed. Reg. at 54,984.

[19] Plaintiffs were the Center for Food Safety, Breast Cancer Prevention Partners, Center for Science in the Public Interest, Environmental Defense Fund, and Environmental Working Group. The court subsequently dismissed the claims of Plaintiffs Breast Cancer Prevention Partners, Center for Science in the Public Interest, and Environmental Working Group for lack of standing. *See* Ctr. for Food Safety v. Becerra, No. 17-CV-3833 (VSB), Docket #44.

[20] Complaint at 2, Ctr. for Food Safety v. Becerra, No. 17-CV-3833 (VSB) (filed May 22, 2017), http://www.centerforfoodsafety.org/files/1-complaint-2017-5-22_69110.pdf.

to food based on conclusions by self-interested food . . . manufacturers . . . without FDA's oversight or knowledge."[21]

Plaintiffs sought a declaratory judgment that the GRAS rule: "(1) unlawfully subdelegates FDA's duty to ensure food safety in violation of the Constitution, the [Administrative Procedure Act (APA)], and the FDCA; (2) exceeds FDA's statutory authority and constitutes arbitrary and capricious agency action in violation of the FDCA and APA; and (3) conflicts with the FDCA."[22] The trial court considered, and rejected, each of these arguments in turn.

First, the court explained that the FDCA does not require manufacturers to submit GRAS conclusions, nor does it mandate that FDA review GRAS conclusions prior to marketing.[23] In contrast with the FDCA's premarket approval scheme for food additives, FDA's controls over GRAS determinations are entirely postmarket, and the agency retains discretion to pursue enforcement action if it does not agree with a manufacturer's conclusion that a substance is GRAS for a particular use.

It appears that the court was receptive to FDA's argument that the GRAS rule had no effect on its longstanding framework, and that even if FDA had not finalized the GRAS rule, manufacturers still could reach a self-affirmed GRAS determination on their own responsibility, without notifying the agency, and at the risk of enforcement in case FDA were to disagree. Although it found merit in Plaintiffs' concerns that the lack of public scrutiny and potential conflicts of interest on private GRAS expert panels (as noted by the 2010 GAO Report)[24] undercut the ability of FDA and the public at large to scrutinize decisions about chemical substances added to foods, the court ultimately disagreed that the public's inability to challenge private GRAS determinations rose to the level of a constitutionally unlawful subdelegation of powers.[25]

Second, the court concluded that the GRAS rule was a reasonable interpretation of the FDCA under the APA and the typical two-step *Chevron* analysis.[26] At the outset, Plaintiffs primarily argued that the FDCA plainly contradicts the GRAS rule because the Food Additives Amendment requires FDA, in making determinations of food additive safety, to consider the "cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet."[27] In Plaintiffs' view, permitting entities to make internal GRAS determinations frustrates this responsibility because the agency does not have full knowledge of all substances added to food. The court rejected this argument outright, noting that "it is dubious to think that Congress used such language to require manufactures to inform FDA of GRAS determinations without saying so."[28]

That said, the court found that the statutory text of the FDCA does not indicate that Congress clearly spoke to the precise question at issue: whether GRAS notifications

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[21] *Id.* at *2–3.

[22] Ctr. for Food Safety v. Becerra, 2021 WL 4504472 at *5.

[23] *Id.* at *7.

[24] GAO REPORT, *supra* note 14, at 14.

[25] Ctr. for Food Safety v. Becerra, 2021 WL 4504472 at *7–8.

[26] *Id.* at 8 (citing Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842 (1984)).

[27] 21 U.S.C. § 348(c)(5)(B).

[28] Ctr. for Food Safety v. Becerra, 2021 WL 4504472 at *9.

must be mandatory.[29] Although the court recognized that the FDCA broadly requires FDA to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled," the court also (repeatedly) highlighted Congress's express exemption of GRAS substances from the FDCA's rigorous statutory scheme for approving food additives. Given that the FDCA did not speak directly to this question, the court turned to *Chevron*'s step two.

At *Chevron*'s second step, the court determined that FDA's interpretation of the FDCA (set forth in the GRAS rule) was reasonable. In reaching this conclusion, it pointed to the following: 1) the FDCA does not specify that a GRAS notification must be mandatory; 2) the number of submitted GRAS notices actually increased during the time that the rule was pending; 3) FDA has a "long-standing record" of excluding GRAS substances from premarket review under the FDCA; and 4) mandatory GRAS submissions would require FDA to divert limited resources from other food safety activities.[30] In addition to the FDCA's silence on the issue of whether GRAS notifications must be mandatory, the court found particularly compelling that, again, Congress specifically exempted GRAS substances from premarket review and that Congress "remained silent for more than sixty years on whether GRAS submissions should be voluntary, and has amended the statute at issue when a voluntary system was in place."[31]

The court further noted that Plaintiffs' counterarguments could be distilled to one basic point: "if GRAS notifications were mandatory, FDA could obtain all of the information it needs to make food safety determinations before ingredients are placed into food."[32] In dismissing this argument, the court explained that, as recognized by FDA and GAO, it is unclear whether the FDCA even grants FDA the authority to make GRAS notifications mandatory in the first instance.[33]

Finally, the court considered, and rejected, Plaintiffs' claim that the GRAS rule unlawfully contradicts the FDCA criteria for determination of GRAS status. Notably, Plaintiffs argued that the GRAS rule fails to ensure that data, information, and methods used to support a GRAS conclusion are "generally recognized,"[34] specifically, the rule does not prohibit the use of unpublished information in support of a GRAS conclusion. Again, the court disagreed, explaining that unpublished material is just "one potential part of the GRAS determination," and in any case, the use of such material is not prohibited by the FDCA.[35] Moreover, the court similarly disagreed with Plaintiffs' contention that the GRAS rule runs afoul of the Delaney Clause,[36] explaining that such clause is applicable to food additives, not GRAS substances, and that in any case, the

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[29] *Id.* at *9–10.

[30] *Id.* at *11.

[31] *Id.* at *11–12.

[32] *Id.* at *12.

[33] *Id.* at *13.

[34] *Id.* at *14.

[35] *Id.* at *15.

[36] 21 U.S.C. § 348(c)(3)(A) (prohibiting FDA from approving food additives shown to cause cancer).

requirements for a GRAS determination would preclude a conclusion that such substance is GRAS.[37]

IMPACT OF THE DECISION

For twenty years, the FDA policy permitting manufacturers to voluntarily notify self-affirmed GRAS determinations went judicially untested and unreviewed; the court's blessing of this policy provides a degree of certainty and long-term stability to the current rule. However, even in a victory for FDA, the court appeared to give some credence to the Plaintiffs' concerns. For instance, it noted that Plaintiffs' concerns regarding potential conflicts of interest on GRAS panels were "valid," and repeated conclusions from a study cited by Plaintiffs showing that in "more than 450 GRAS determinations voluntarily reported to FDA, every determination was made by experts with financial ties to the manufacturer of the substance at issue."[38] Thus, there is still room for improvement (and FDA has issued guidance to reduce the risks posed by conflicts of interest). Moreover, the court's dicta may provide additional ammunition for proponents of mandatory GRAS notification with which to lobby Congress for statutory change.

As a practical matter, however, the GRAS notification program is a success in the sense that it has established a system that food companies can and do rely on when sourcing new ingredients. A "successful" GRAS notification can provide at least some assurance that a new ingredient meets acceptable safety standards. This promotes a stable supply chain: as the U.S. food ingredient supply chain grows ever more global, U.S. food companies seeking to ensure that ingredients used in their U.S.-marketed food products are lawful can rely—at least in part—on FDA's GRAS notification procedure.

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[37] Ctr. for Food Safety v. Becerra, 2021 WL 4504472 at *15–16 (citing to 21 C.F.R. § 170.30(a) ("General recognition of safety requires common knowledge throughout the scientific community . . . that there is a reasonable certainty that the substance is not harmful under the conditions of its intended use.")).

[38] *Id.* at *15. Note that FDA has published draft guidance regarding best practices for convening a GRAS panel. U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: BEST PRACTICES FOR CONVENING A GRAS PANEL (Nov. 2017), https://www.fda.gov/media/109006/download.