Case No. 22-16770

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

NATURAL GROCERS, CITIZENS FOR GMO LABELING, LABEL GMOS, RURAL VERMONT, GOOD EARTH NATURAL FOODS, PUGET CONSUMERS CO-OP, NATIONAL ORGANIC COALITION, AND CENTER FOR FOOD SAFETY

Plaintiffs-Appellants,

v.

THOMAS J. VILSACK, et al.,

Defendants-Appellees,

On Appeal from the United States District Court, Northern District of California Case No. 20-5151 (Hon. Judge James Donato)

NATURAL GROCERS, ET AL. PLAINTIFFS-APPELLANTS' OPENING BRIEF

CENTER FOR FOOD SAFETY
George A. Kimbrell
Amy van Saun
Meredith Stevenson
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
T: (415) 826-2770
gkimbrell@centerforfoodsafety.org
avansaun@centerforfoodsafety.org
mstevenson@centerforfoodsafety.org
Counsel for Plaintiffs-Appellants

Case: 22-16770, 09/05/2023, ID: 12786932, DktEntry: 18, Page 2 of 144

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Citizens for GMO Labeling, Label GMOs, National Organic Coalition, Rural Vermont, Good Earth Natural Foods, Puget Consumers Co-op, and Center for Food Safety certify that they have no parent corporations and that no publicly held corporation owns more than ten percent of these Plaintiffs-Appellants. Appellant Natural Grocers' parent company is Natural Grocers by Vitamin Cottage, Inc., and no publicly held corporation owns more than ten percent of Natural Grocers.

TABLE OF CONTENTS

CORPORA	ATE DISCLOSURE STATEMENT	i
TABLE OF	CONTENTS	ii
TABLE OF	AUTHORITIES	iv
GLOSSAR	Y OF ACRONYMS	X
STATEME	NT OF THE CASE	1
JURISDIC	TIONAL STATEMENT	8
ISSUES PR	RESENTED	8
FACTUAL	BACKGROUND	9
I.	CONSUMERS' LONG-STANDING DEMANDS FOR TRANSPARENCY CULMINATED IN THE DISCLOSURE ACT AND USDA'S FINAL RULES IMPLEMENTING THE ACT.	9
	A. The GE Labeling Movement.	9
	B. The Disclosure Act.	11
	C. USDA's Final Rules	15
II.	THE DISTRICT COURT RULED IN USDA'S FAVOR ON ITS HIGHLY REFINED EXEMPTION AND LIMITED TERMINOLOGY.	18
SUMMAR	Y OF ARGUMENT	21
STANDAR	D OF REVIEW	23

ARGUME.	NT			25
I.	RUE	BBERS	RICT COURT WAS WRONG TO TAMP USDA'S EXCLUSION OF MOST GE ENTS FROM LABELING.	25
	A.		Disclosure Act's Plain Text Requires Labeling on nly Refined Foods.	26
	В.	Inte	District Court Overlooked Numerous Statutory rpretation Tools Before Deferring to USDA's Post Hoconalization	32
		1.	The District Court Erred in Endorsing USDA's Litigation Position.	32
		2.	The District Court Overlooked the Disclosure Act's Unambiguous Requirement to Disclose Highly Refined Foods.	34
		3.	The District Court Failed to Give Effect to Legislative History and USDA's Interpretation of the Disclosure Act in Ascertaining Legislative Intent	38
	C.	The	District Court Erred in Deferring to USDA	41
II.			RICT COURT ERRED IN CONCLUDING USDA LY BANNED SIMILAR TERMS	49
III.			RICT COURT IMPROPERLY REMANDED THE EDISCLOSURE OPTION WITHOUT VACATUR	57
CONCLU	SION .			61

TABLE OF AUTHORITIES

I	Page(s)
Federal Cases	
Alexander v. Sandoval, 532 U.S. 275 (2001)	49
All. for the Wild Rockies v. USFS, 907 F.3d 1105 (9th Cir. 2018)	59, 60
Allied–Signal, Incorporated v. United States Nuclear Regulatory Commission, 988 F.2d 146 (D.C. Cir. 1993)	40, 57
Altera Corp. & Subsidiaries v. Comm'r of Internal Revenue, 926 F.3d 1061 (9th Cir. 2019)	38
Baldwin v. United States, 140 S. Ct. 690, 206 L. Ed. 2d 231 (2020))	42
Bostock v. Clayton Cnty., Georgia, 140 S. Ct. 1731 (2020)	26, 30
Buffington v. McDonough, 143 S. Ct. 14, 214 L. Ed. 2d 206 (2022)	42
Cheneau v. Garland, 997 F.3d 916 (9th Cir. 2021)	39
Chevron, U.S.A., Incorporated v. Natural Resources Defense Council, 467 U.S. 837 (1984)	41, 42
Conn. Nat'l Bank v. Germain, 503 U.S. 249 (1992)	36
Ctr. for Biological Diversity v. U.S. Dep't of Interior, 623 F.3d 633 (9th Cir. 2010)	
Ctr. for Biological Diversity v. Zinke, 900 F.3d 1053 (9th Cir. 2018)	

Federal Cases (Cont'd)	Page(s)
FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000)	24
Greater Yellowstone Coal., Inc. v. Servheen, 665 F.3d 1015 (9th Cir. 2011)	23, 24, 49
Heavenly Hana LLC v. Hotel Union & Hotel Indus. of Haw. Pension Plan, 891 F.3d 839 (9th Cir. 2018)	39
Kisor v. Wilkie, 139 S. Ct. 2400 (2019)	passim
Kokoszka v. Belford, 417 U.S. 642 (1974)	34
Lamie v. U.S. Tr., 540 U.S. 526 (2004)	37
Loper Bright Enters. v. Raimondo, 143 S. Ct. 2429 (2023)	42
Maine v. Thiboutot, 448 U.S. 1 (1980)	27
Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983)	33, 54, 56
Murphy v. Nat'l Collegiate Athletic Ass'n, 138 S. Ct. 1461 (2018)	31
Nat. Grocers v. Vilsack, 627 F. Supp. 3d 1130 (N.D. Cal. 2022)	8
Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519 (2012)	24
Nichols v. United States, 578 U.S. 104 (2016)	28

Federal Cases (Cont'd)	Page(s)
Nieves v. Bartlett, 139 S. Ct. 1715 (2019)	26
Okla. V. Castro-Huerta, 142 S. Ct. 2486 (2022)	24
Oliver v. Keller, 289 F.3d 623 (9th Cir. 2002)	23
Patel v. Garland, 142 S. Ct. 1614 (2022)	29
Philbrook v. Glodgett, 421 U.S. 707 (1975)	34
Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41 (1987)	34
Pollinator Stewardship Council v. EPA, 806 F.3d 520 (9th Cir. 2015)	57
Rotkiske v. Klemm, 140 S. Ct. 355 (2019)	27
S.D. Warren Co. v. Me. Bd. of Env't Prot., 547 U.S. 370 (2006)	28
Sale v. Haitian Ctrs. Council, Inc., 509 U.S. 155 (1993)	
SAS Inst., Inc. v. Iancu, 138 S. Ct. 1348 (2018)	29
SEC v. Chenery Corp., 332 U.S. 194 (1947)	33
Sierra Forest Legacy v. Sherman, 646 F.3d 1161 (9th Cir. 2011)	25, 58

Federal Cases (Cont'd)	Page(s)
Snoqualmie Indian Tribe v. FERC, 545 F.3d 1207 (9th Cir. 2008)	24
United States v. Gonzales, 520 U.S. 1 (1997)	29
United States v. Williams, 553 U.S. 285 (2008)	52
In re W. States Wholesale Nat. Gas Antitrust Litig., 715 F.3d 716 (9th Cir. 2013)	34
W. Watersheds Project v. McCullough, 2023 WL 4557742 (9th Cir. July 17, 2023)	25
Federal Statutes	
5 U.S.C.A. § 706	23, 52
5 U.S.C. § 702	8
7 U.S.C. § 1639(1)(A)	passim
7 U.S.C. § 1639(2)	5
7 U.S.C. § 1639b(a)(1)	passim
7 U.S.C. § 1639b(b)(2)(B)	32, 34, 40, 47
7 U.S.C. § 1639b(b)(2)(C)	5, 12, 35
7 U.S.C. § 1639c(c)	4, 14, 50
7 U.S.C. § 6511(c)(1)	37
7 U.S.C. § 6519(c)	52
7 U.S.C. § 6524	
28 U.S.C. § 1291	8

Federal Statutes (Cont'd)	Page(s)
28 U.S.C. § 1331	8
28 U.S.C. § 1346	8
28 U.S.C. § 2107(b)(2)	8
Rules	
Fed. R. App. P. 4(a)(1)(B)(ii)	8
Regulations	
7 C.F.R. § 66.9	33
7 C.F.R. pt. 340.1	53
7 C.F.R. § 66.1	6, 15, 42
7 C.F.R. § 66.5(c)	40, 47
7 C.F.R. § 66.102	16, 18
7 C.F.R. § 66.108	17
7 C.F.R. § 66.116(b)(1)	46
Other Authorities	
83 Fed. Reg. 65,814 (Dec. 21, 2018)	passim
162 Cong. Rec. H4830 (daily ed. July 13, 2016)	51
162 Cong. Rec. H4934 (daily ed. July 14, 2016)	51
162 Cong. Rec. H4936 (daily ed. July 14, 2016)	13
162 Cong. Rec. S4783 (daily ed. July 6, 2016)	12, 30, 38
162 Cong. Rec. S4873 (daily ed. July 7, 2016)	51
162 Cong. Rec. S4906 (daily ed. July 7, 2016)	31

Other Authorities (Cont'd)	Page(s)
162 Cong. Rec. S4994 (daily ed. July 12, 2016)	30, 31
A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 116 (2012)	29
Contain, Cambridge Dictionary (2023)	28
Contain, Mirriam-Webster (2023)	28
Executive Order 13563	56
Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 114th Cong. (2015)	13, 51
USDA, S. REP. 114-403	38
USDA, Frequently Asked Questions: Guidance of Testing Methods (July 7, 2020), https://www.ams.usda.gov/sites/default/files/media/NBFDS_FAQtestingMethods.pdf	46
USDA, Frequently Asked Questions: Guidance to Ensure Acceptable Validation of a Refining Process (July 2, 2020), https://www.ams.usda.gov/sites/default/files/media/NBFDS_FAQ refiningProcessValidation.pdf	42, 43
USDA, National Bioengineered Food Disclosure Standard; Guidance on Testing Methods (July 7, 2020,	
https://www.ams.usda.gov/sites/default/files/media/NBFDS_testingMethodology.pdf	44, 47

GLOSSARY OF ACRONYMS

AMS Agricultural Marketing Service

APA Administrative Procedure Act

BE Bioengineered

FDA Food & Drug Administration

GE Genetically Engineered

GMO Genetically Modified Organism

LOD Limit of Detection

PCR Polymerase Chain Reaction

QR Code Quick-Response Code

USDA United States Department of Agriculture

STATEMENT OF THE CASE

This case is the culmination of enduring efforts to enact a mandatory U.S. labeling standard for all genetically engineered (GE) foods, on packages, with familiar terminology, like sixty-four other countries around the world. And while the topic may sound complicated, the legal questions presented are simple and familiar: this is an administrative law case about whether an agency followed Congress's statutory commands or instead went rogue, contrary to Congress and to the detriment of U.S. shoppers and retailers. The lower court correctly held that the agency erred in one way, but let the agency off the hook in several other important ways requiring reversal.

Seven years ago, Congress passed the National Bioengineered Food Disclosure Act (Disclosure Act) to replace individual state GE labeling laws and provide a nationwide, mandatory labeling standard for all GE foods. Before this Court are the subsequent United States Department of Agriculture (USDA) regulations applying the Disclosure Act. However, those regulations created a labeling scheme covering only a far narrower scope of foods than that contemplated and mandated by Congress. And those rules purport to carry out a statute for labeling GE foods while *prohibiting* the most familiar terms for them, GE and GMO (genetically modified organism). And the rules allow packages to carry a smartphone "QR code" alone,

with no other labeling, despite USDA's own study concluding that was wholly insufficient for most shoppers. Essentially, the USDA labeling regulations actually require almost no labels, let alone labels consumers understand.

To understand how misaligned USDA's regulations are with Congress's commands, it is crucial to understand the movement that brought about the Disclosure Act. Beginning in the 1990s, American consumers began to view GMOs as the central pillar of an inherently unsustainable agricultural system: one that promoted pesticide use, depleted soils, and contaminated drinking water. In response, the GE labeling movement rapidly spread to such an extent that by 2010, polls showed over and over that 90% of Americans wanted transparency in how their foods are produced in the form of mandatory GE labels. 3-ER-531; 3-ER-590. The widespread calls for GE labeling prompted several organizations—some of which are Appellants here—to push for state and then federal laws creating mandatory labeling schemes, based on the genetic engineering process, that would require consistent, understandable labeling of all GE foods in the United States. And these efforts were successful: By 2016, several states had already enacted GE labeling laws substantially identical to each other, with dozens more states actively considering their own similar GE labeling bills.

Shortly after, in July 2016, stakeholders advocating for transparency in food production saw their decades-long efforts come to fruition in the Disclosure Act's passage. The Act created a broad national standard requiring disclosure not only for all "bioengineered foods" but even for foods that "may be bioengineered." 7 U.S.C. § 1639b(a)(1). Legislative history behind this broad requirement reveals that coverage of "highly refined" (processed) foods was critical to Congress and stakeholders, as by some estimates around 75% of GE ingredients in the United States are highly refined, such as sugar and oil, often found in snack foods and sodas. 2-ER-291; 2-ER-156; 2-ER-199; 2-ER-175. The Act also included requirements to ensure all consumers could access the forms of disclosure, provided authority to USDA to expand the scope of disclosure even further, and used and authorized the familiar, accurate terminology, GE and GMO.

Unfortunately, USDA, charged with implementing the Act, issued the National Bioengineered Food Disclosure Standard (2018 disclosure rules or rules), flouting the Disclosure Act's express mandate to label "any bioengineered food and any food that may be bioengineered," 7 U.S.C. § 1639b(a)(1), and limiting the acceptable language to only the brand-new, unfamiliar term, "bioengineered." That is, while the Act plainly requires disclosures on all foods "that contain[] genetic material that has been modified through in vitro recombinant deoxyribonucleic acid

(DNA) techniques," *id.* § 1639(1)(A), and even those that *may* contain it, *id.* § 1639b(a)(1), USDA's regulations require disclosures only for foods with "detectable" GE material based on unspecified testing methods, leaving out a significant number of GE foods. And while the Act itself uses longstanding, well-known terminology, GE and GMO, interchangeably with the new "bioengineered," *see*, *e.g.*, *id.* § 1639i(b) & *id.* § 1639c(c), USDA's rules for the first time prohibited the use of GE and GMO as alternatives. Finally, the regulations blessed standalone QR codes (digital links on packages for consumers to scan with smart phones or other devices) as a permissible disclosure form, despite USDA itself concluding QR codes provide insufficient access to consumers and Congress requiring "additional and comparable options" should USDA reach that very conclusion. *Id.* § 1639b(c)(4).

Accordingly, Appellants—public interest nonprofit organizations as well as grocery retailers—filed this challenge to USDA's regulations in district court.

Appellants' arguments relied on the Disclosure Act's plain text, which unambiguously requires that regulated entities label all bioengineered foods and foods that "may be bioengineered," including highly refined foods like oils and sweeteners; mandates that the disclosure form be accessible to consumers; and interchangeably uses the familiar terminology, GE and GMO. Appellants also highlighted the Disclosure Act's overarching statutory scheme and purpose, as well

as the Act's legislative history, all which support labeling all GE foods in a manner consumers understand. On summary judgment, the district court correctly held that USDA's decision to allow QR code disclosures alone was unlawful—a decision USDA does not cross-appeal—but nonetheless did not set those disclosures aside. And the court signed off on USDA's exemption from any labeling for the majority of GE ingredients, and USDA's refusal to honor the well-known GE/GMO terminology.

The district court made four errors requiring reversal. First, regarding the scope of coverage, the lower court failed to analyze the *only* two Disclosure Act provisions that USDA's rules relied on to support its exemption of "undetectable," highly refined foods from disclosure: (1) the Act's definition of "bioengineering," 7 U.S.C. § 1639(1)(A), and (2) the Act's authorization to establish additional factors and conditions under which USDA considers foods "bioengineered." *Id.* § 1639b(b)(2)(C). In so doing, the court violated core administrative law principles: It failed to exhaust statutory interpretation tools before deferring to USDA and deferred to USDA's *post hoc* rationalization to support its highly refined foods exemption. Had the district court actually considered the key provisions USDA cited during rulemaking, it would have concluded the provisions do not support the massive exemption. USDA lacked authority to whittle the scope of disclosure to a

nub far more narrow than Congress's mandate: to include not only foods that contain material that has been genetically modified, but also those that may contain it.

Second and relatedly, even if the plain text were ambiguous, the record flatly contradicts USDA's explanation for its "detectability" requirement. USDA asserts that highly refined foods "do[] not contain modified genetic material if the genetic material is not detectable," 7 C.F.R. § 66.1, yet a number of newer, more sensitive testing methods before USDA reveal that highly refined foods, as a matter of objective fact, "contain" genetic material that has been modified, per the statutory definition. Furthermore, USDA's decision to overlook these newer methods and allow regulated entities to avoid disclosure using older, less sensitive testing methods to "prove" that their highly refined foods do not "contain" GE material creates an arbitrarily shifting standard, allowing some highly refined foods to avoid disclosure and creating inconsistency in the marketplace.

Third, as to terminology, USDA and the district court erred in concluding that "bioengineered" covers a wholly different scope than GE or GMO and thus is the only proper term. Crucially, nothing in the record supports this conclusion.

Rather, Congress plainly defined "bioengineered foods" as those that "contain[] genetic material that has been modified," 7 U.S.C. § 1639(1)(A) (emphases added), and

USDA's decision to unduly restrict labeling to "bioengineered" starkly departs from USDA's past insistence on using GE and GMO both in other programs and in this very rulemaking, as USDA recognizes GE and GMO as the prominent terminology used by state governments, federal agencies, scientists, 64 other countries labeling GE foods, and the marketplace over the past two-plus decades.

Fourth and finally, as to remedy, despite holding that USDA's rules violated the Administrative Procedure Act (APA) and Disclosure Act by permitting standalone QR code disclosures, the court failed to vacate the rule in whole or even in part. The court acknowledged that USDA's violation was a "significant error," 1-ER-21, but nevertheless deferred to USDA's warning of alleged disruptive consequences, without any assessment of its own. In doing so, the lower court improperly conflated agency deference in the context of merits judicial review, with deference in consideration of *remedy* favored by the agency, after the APA violation had been found. Vacatur, the presumptive remedy, was instead proper here.

Accordingly, Appellants ask this Court to reverse the district court and vacate and remand the disclosure rules to the district court with instructions to remand to the agency to conduct further proceedings consistent with this Court's decision.

JURISDICTIONAL STATEMENT

This appeal follows the district court's final judgment issued September 13, 2022. *Nat. Grocers v. Vilsack*, 627 F. Supp. 3d 1130 (N.D. Cal. 2022). Appellants timely filed their Notice of Appeal on November 15, 2022. *See* 28 U.S.C. § 2107(b)(2); Fed. R. App. P. 4(a)(1)(B)(ii).

The district court had jurisdiction under 5 U.S.C. § 702, 28 U.S.C. § 1331, and 28 U.S.C. § 1346. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

ISSUES PRESENTED

- 1. In implementing a statute in which Congress unambiguously required USDA to label *any* food that "contains" or even *may* "contain" genetic material that has been modified, did the district court err in concluding that USDA could instead add a new requirement of detectability and thus omit a significant number of all GE foods from labeling?
- 2. Even if the statutory text were ambiguous, does the record support USDA's assertion that foods with "undetectable" GE material, based

¹ USDA previously took the position that the district court did not issue an appealable, final decision because it did not grant summary judgment in favor of USDA on several counts, only denied Appellants summary judgment on those counts. Appellants then filed a Motion for Indicative Ruling in the lower court, requesting an indicative ruling that the district court would grant a Rule 60(a) motion to modify its Order to specifically state that its decision to deny summary judgment on several counts is a final, appealable action and submitted a Joint Stipulation. Pls.' Mot. Indicative Ruling, *Nat. Grocers*, *et al. v. USDA*, No. 20-5151 (filed Mar. 30, 2023), ECF 69; Joint Stipulation, ECF 69-1. The district court denied the Motion, stating its decision had sufficient clarity and was final. Order, *id.* (June 1, 2023), ECF 70.

- on some older, less sensitive tests, do not "contain" genetic material that has been modified at some point during production?
- 3. Did the district court err in holding that USDA's decision to restrict mandatory terminology to solely "bioengineered" was reasonable, despite Congress interchangeably using the terms, GE and GMO, and expressly allowing for "similar terms," and despite one of the Act's main purposes to replace state labeling laws that used only GE or GMO, widespread common use of GE and GMO, and USDA's prior policy to use the same terms?
- 4. Did the district court err in remanding to USDA without vacatur the unlawful portion of the rules allowing for standalone QR code labeling despite holding the errors of law significant and the absence of any record support of disruptive consequences from vacatur?

FACTUAL BACKGROUND

I. CONSUMERS' LONG-STANDING DEMANDS FOR TRANSPARENCY CULMINATED IN THE DISCLOSURE ACT AND USDA'S FINAL RULES IMPLEMENTING THE ACT.

A. The GE Labeling Movement.

Genetically modified organisms, genetically engineered food, genetically modified food. At least sixty-four other countries around the world have used a version of these three terms to mandate uniform labeling of GE foods. 162 Cong. Red. H4936 (daily ed. July 14, 2016). And these terms make sense: For decades, food companies, scientists, governments, private labeling standards, policymakers, states, and even U.S. government agencies—including and specifically Appellees—have relied on these terms to accurately describe the processes by which

agrochemical companies genetically engineer seeds, largely to withstand pesticide application. These terms, by USDA's own account, "permeat[e] American culture," 3-ER-696, and are "nearly universally utilized, understood and communicated by all American journalists, broadcasters, public officials, and throughout culture and the public at large." 3-ER-695-66. The terms are ubiquitous, and people know what they mean.

It is unsurprising, then, that American consumers began demanding this same transparency in the United States that exists in dozens of other countries, including the European Union, Japan, Russia, China, and many more. Beginning as early as the 1990s, United States consumers submitted comments, filed petitions, and showed up at their state governments, all to request labels on GE and GMO foods, using the standard, known nomenclature. And elected representatives responded:

Over the span of two years from 2013 to 2015, more than thirty states introduced GE labeling legislation. 3-ER-464; 3-ER-615. Most successfully, Connecticut and Maine passed laws in 2013, albeit with clauses tying their effective dates to the passage of other state laws, 3-ER-554-57, and Vermont became the first state to pass a stand-alone law in 2014. 3-ER-601-609; see also 3-ER-552-53.

This call for transparency was well-received and supported by major food companies. Campbell Soup Company, 3-ER-498, Coca Cola, 2-ER-244, Danone, 2-

ER-247-52; 3-ER-499, Mars, 2-ER-253-57, and Unilever, 2-ER-268-76, all gave full-throated support to labeling all GE products in accordance with state laws: They began labeling their foods produced with GE ingredients even before the state laws took effect. To satisfy the state laws' transparency requirements, these companies placed labels on all foods produced with GE technology, used the terminology, GE or GMO, and placed the labels directly on packages, as prior government-mandated labels have always been displayed.

B. The Disclosure Act.

With major food companies already labeling and the Vermont law's effective date looming, Congress began diligently working on a federal statute that would encompass the state laws' scope and establish uniform federal regulations for all GE foods, in all states. Congress resoundingly rejected an earlier bill, H.R. 1599, that would have required only voluntary labels, replacing it with Senate bill, S. 764, requiring *mandatory* labels on GE foods, with a broad scope honoring state laws and decades of consumer demand for transparency. The Disclosure Act was then passed in late July 2016, promising a high level of transparency and accessibility for consumers.

First, the Disclosure Act broadly mandated labels on any "bioengineered food and any food that may be bioengineered." 7 U.S.C. § 1639b(a)(1) (emphasis added).

This includes *any food* "that contains genetic material that *has been* modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques," 7 U.S.C. § 1639(1)(A) (emphases added), including the 75% of GE ingredients, which are highly refined. *See, e.g.*, 162 Cong. Rec. S4783 (daily ed. July 6, 2016) (The Disclosure Act "provides authority to the USDA to label refined sugars and other processed products."); *see also infra* at 30–31. To further solidify this broad scope, the Act also granted authority to USDA to expand the scope of disclosure even further to include "other factors and conditions under which a food *is considered* a bioengineered food." 7 U.S.C. § 1639b(b)(2)(C) (emphasis added).

Second and relatedly, the Disclosure Act required labeling consistent with the 64 other countries that require GE labeling. Specifically, Congress instructed USDA to apply the law "in a manner consistent with [U.S.] obligations under international agreements," *id.* § 1639c(a), which in this context means the *Codex Alimentarius*, a collection of internationally recognized standards relating to food labeling published by the United Nations' Food and Agriculture section. *See* National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814, 65,835 (Dec. 21, 2018). The Codex's internationally accepted definition of modern biotechnology *includes* highly refined foods, and the vast majority of countries that label GE foods outside the U.S. do require disclosure of highly refined GE products. The European Union, for

example, has long included highly refined products in its scope and urged the U.S. to do the same. 3-ER-500-01 (EU comment: USDA should not burden trading partners with inconsistent labeling standards, such as not labeling highly refined foods); 2-ER-271 (British company, Unilever, one of the world's largest consumer goods companies, with over 400 brands in 190 countries: disclosing highly refined ingredients will assist trade because about sixty countries already label highly refined foods, including the EU, Russia, Turkey, Australia, and Brazil).

Third, because some states were requiring GE labeling but others (so far) had not, the Disclosure Act promised a *uniform* label to ensure no confusion for consumers under a "patchwork" of state laws. *See* A National Framework for the Review and Labeling of Biotechnology in Food: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 114th Cong. 2 (2015) ("Producers have the option to voluntarily label their GE foods. However, over 15 years after the implementation of this policy, very few products on the market have been labeled as being genetically engineered. Yet we all know there is a great number of GE foods on the market."); 162 Cong. Rec. H4936 (daily ed. July 14, 2016) ("It would be confusing for consumers to have 50 different State standards.").

<u>Fourth and finally</u>, the Disclosure Act mandated a labeling system consumers could access and understand. For one, Congress repeatedly used the familiar terms,

"genetically engineered" and "genetically modified," and the new, unfamiliar term, "bioengineered," interchangeably, see 7 U.S.C. § 1639c(c); id. § 1639i(b); id. § 6524, and then directed USDA in the rules to permit "any similar terms" to bioengineered in the implementing regulations. *Id.* § 1639(1).

In the same way, Congress specifically sought to ensure that all Americans can access the form of disclosure. While the Act allowed for three potential disclosure forms: text, symbol, or electronic link, *id.* § 1639b(b)(2)(D), Congress recognized that the unprecedented and controversial electronic QR code labeling might not work and required a study to analyze, among other things, the "potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods." *Id.* § 1639b(c)(1). If USDA determined in the study that "consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods," then Congress required that USDA "shall provide additional and comparable options" to ensure consumers have sufficient access. *Id.* § 1639b(c)(4).

C. USDA's Final Rules.

In December 2018, USDA issued disclosure rules bearing little resemblance to Congress's mandates in the Disclosure Act for a broad labeling scope and accessible labels. First, USDA simply exempted the vast majority of GE foods from disclosure. It added an extra-statutory requirement that to be included, GE ingredients must be "detectable" by a testing method (regardless of the given method's sensitivity). 7 C.F.R. § 66.1. This means that, on a practical level, highly refined GE foods need not bear disclosure, ² despite USDA estimating this resulting in as much as a 75 percent decrease in total GE ingredients requiring disclosure, 2-ER-291, and despite USDA previously assuring Congress it would include them. 162 Cong. Rec. S4994 (daily ed. July 12, 2016) (USDA's General Counsel, Jeffrey Prieto, stating the Act's scope includes "highly refined oils, sugars, or high fructose corn syrup that have been produced or developed from genetic modification techniques."); see also infra at 30-31. As an explanation, USDA provided only that foods "do[] not contain modified genetic material if the genetic material is not detectable." 7 C.F.R. § 66.1. It did not explain the myriad studies in the record

² To be clear, USDA did not technically exempt all highly refined foods from disclosure; rather, it exempted foods with "undetectable" GE material by any testing method. 7 C.F.R. § 66.1. But the practical result is the exemption of all highly refined foods because outdated, less-sensitive testing methods do not detect GE material after the refining process.

describing newer testing methods that *are* capable of detecting GE material in highly refined foods to a high degree of sensitivity, nor how its exemption satisfies the mandate to also disclose foods that "may be bioengineered." 7 U.S.C. § 1639b(a)(1).

Second, USDA prohibited the longstanding, well-known terminology, GE and GMO, from satisfying the disclosure rules. 7 C.F.R. § 66.102 ("A text disclosure must bear the text as described in this section."); *id.* (listing only "bioengineered foods," "bioengineered food," or "contains a bioengineered ingredient" as permissible disclosure options). In so doing, USDA claimed that "other terms such as genetic engineering or genetically modified organisms" that Congress used in the Act, "may create inconsistencies with the preemption provisions or muddy the scope of disclosure." 83 Fed. Reg. 65,837. Instead of acknowledging that Congress used the terms interchangeably and the universal use of GE or GMO, USDA provided a thin, one-sentence rationale that bioengineered "clearly and accurately describes the technology and provides consumers with the information they desire," 83 Fed. Reg. at 65,852, despite a mountain of evidence indicating the opposite.

And third, regarding the form of labeling, USDA still allowed QR codes alone, with no additional disclosure method required on the same package, despite determining that "consumers would not have sufficient access to the bioengineering disclosure through only electronic or digital means under ordinary shopping

conditions at this time." 83 Fed. Reg. at 65,828 (emphasis added). Instead, to "remedy" the failings the Congressionally mandated study found, USDA provided phone text message disclosures as a separate option. 83 Fed. Reg. at 65,828–29; see 7 C.F.R. § 66.108 (phone text message option); § 66.100(b)(1)–(4) (adding phone text message option to other options of on-package text, on-package symbol, and electronic or digital). That is, USDA still allowed companies to use QR codes alone.



Figure 1: Sample QR Code Linking QR Code Definition

USDA did not explain how this fixed the problems its study found, and which Congress required to be remedied: Its sole stated rationale was that the Act required a "comparable option to access the BE [bioengineered] disclosure, not that the option be comparable to on-package labeling." 83 Fed. Reg. at 65,856.

II. THE DISTRICT COURT RULED IN USDA'S FAVOR ON ITS HIGHLY REFINED EXEMPTION AND LIMITED TERMINOLOGY.

The district court ruled in USDA's favor on several claims and in Appellants' favor on one.³ First, the district court agreed with Appellants that USDA's standalone QR code labeling option violates the Disclosure Act because, in requiring a study on QR code disclosures, Congress intended for USDA to provide "additional and comparable options" to improve the accessibility of the electronic disclosure method, not just add another inaccessible option in addition to inaccessible QR codes. 1-ER-16-21. Since USDA's text message option did nothing to fix the access issues USDA found in the study, the Court found it a "significant

³ Appellants also brought a handful of constitutional claims, including that USDA's new rules violated retailers' First Amendment rights by restricting their ability to label all GE foods in their stores using familiar, accurate terminology beyond the narrow scope of the new USDA standard. This was mainly based on the regulations' statement that regulated entities could only use bioengineered and were prohibited from using GE and GMO, even voluntarily. See 7 C.F.R. § 66.102 ("A text disclosure must bear the text as described in this section.") (emphases added); id. (listing only "bioengineered foods," "bioengineered food," or "contains a bioengineered ingredient" as permissible disclosure options). However, USDA assented for the first time in litigation briefing that the Disclosure Standard rules actually did not attempt to prohibit the retailers' First Amendment speech beyond the new standard and retailers can still voluntarily use the accurate terminology, GE and GMO, on products and in stores and label highly refined foods with this terminology on a voluntary basis beyond the standard, without potentially being subject to USDA violation and fines. USDA's Opp'n, at 28-29, Nat. Grocers v. USDA, No. 20-5151 (filed Feb. 16, 2022), ECF 56. Accordingly, the district court then determined Appellants no longer had standing to pursue their First Amendment claims. 1-ER-13-16.

error." 1-ER-21. However, the court nonetheless declined to set aside the unlawful QR code disclosure provision, instead allowing products to continue bearing QR codes alone on market shelves, largely due to the agency's unsubstantiated concerns about costs to food companies, without further explanation. 1-ER-21.

Second, the district court deferred to USDA on its terminology restriction to "bioengineered" for mandatory disclosures largely because the Act does not *mandate* "similar terms," it only allows for them. 1-ER-21-22. The court accepted USDA's rationale that that allowing GE and GMO would "blur the scope of the regulations, and lead to inconsistent disclosures." 1-ER-22. In doing so, however, the court nowhere addressed or grappled with Congress's own decision to use these terms interchangeably in the statute and legislative history, nor USDA's additional explanation that "bioengineered" is "clear" to consumers, despite the massive weight of record evidence indicating consumers do not recognize the term.

And third, the district court sided with USDA on its exemption for GE foods without "detectable" GE material. 1-ER-22-23. For statutory support, the court zeroed in on a provision USDA never cited during rulemaking: its authority to "determine the amounts of a bioengineered substance that may be present in a food, as appropriate, in order for the food to be a bioengineered food." 1-ER-23 (quoting 7 U.S.C. § 1639b(b)(2)(B)). In focusing on this *post hoc* rationalization, the district

court overlooked the only two statutory provisions USDA actually did use to support its exemption during rulemaking: the "bioengineering" definition, 83 Fed. Reg. 85,816 (citing 7 U.S.C. § 1639(1)(A)), and its authority to establish additional factors and conditions under which foods *are* bioengineered. 83 Fed. Reg. 65,821 (citing 7 U.S.C. § 1639b(b)(2)(C)). Further, the district court overlooked Congress's mandate for USDA to require disclosure of "any bioengineered food and any food that *may be bioengineered*," 7 U.S.C. § 1639b(a)(1) (emphasis added), instead quickly deferring to USDA before even examining the substantial legislative history indicating Congressional intent to include highly refined foods, and USDA's own assurances to Congress that the rules would encompass highly refined foods.

And after deferring, nowhere did the district court explain the reasonableness of USDA's conclusions. See 1-ER-22-23. Namely, it failed to explain how exempting an entire class of foods could be described as USDA "determin[ing] the amounts" of a bioengineered substance for a food to be considered bioengineered, as USDA's exemption excludes *all* "undetectable" GE foods from disclosure, not foods with a certain *amount* of GE material. Instead, the court remarked only that detection of GE material is "impossible to obtain with existing technology," 1-ER-23, despite significant record evidence that illustrated otherwise.

SUMMARY OF ARGUMENT

The lower court made fundamental errors of statutory interpretation, administrative law, and remedies, each warranting reversal on appeal.

First: the fundamental principle to always begin with the plain text. The district court erred in letting USDA get away with eschewing the plain language of the Disclosure Act to exempt "undetectable" highly refined foods and to create a distinction between the terms GE/GMO and bioengineered. Regarding the highly refined exemption, agencies receive no deference for decisions that add new extrastatutory conditions they conjure out of the whole cloth: here, USDA's extrastatutory "detectability" prerequisite, and likewise its unreasonable, unsupported interpretation that highly refined foods do not "contain" genetic material that has been modified. The lower court further overlooked another critical tool of statutory interpretation, legislative history, in ignoring clear Congressional intent to include highly refined foods and allow for familiar terminology, GE and GMO. USDA, for its part, did not have the prerogative to usurp for itself decisions that Congress mandated and to ignore the Act's plain text.

Second: bedrock administrative law prohibits courts from deferring to the *post* hoc rationalizations agencies advance in litigation to defend their past actions. In determining USDA had authority to exempt highly refined foods from disclosure,

the lower court *did not even mention*, let alone critically assess, the key provisions on which USDA [mis]relied during rulemaking: the definition of "bioengineering," 7 U.S.C. § 1639(1)(A), and its authority to *expand* the scope of mandatory disclosure. *Id.* § 1639b(a)(1). Instead, the lower court deferred to USDA's *post hoc* litigation assertion that its authority to set threshold amounts of inadvertent material in GE foods allowed USDA to exempt the majority of GE foods. It did not.

Third: agencies must support their decisions with record evidence. Even if the statutory text were ambiguous (it is not), the district court erred in deferring to USDA's assertion that highly refined foods do not "contain" GE material, when numerous studies before USDA show the opposite. Additionally, the record sharply contradicts USDA's assertion that the term "bioengineered" covers a different scope than GE/GMO, instead revealing USDA's own interchangeable use of these terms in this rulemaking and other contexts. And nothing in the record supports USDA's assertion that the term, bioengineered, alone will not confuse and mislead consumers accustomed to only GE and GMO.

Fourth and finally: when courts hold agency actions unlawful, the standard, presumptive remedy, absent unusual circumstances and a strong evidentiary showing to the contrary, is vacatur. The district court erred in remanding the unlawful portion of the rules allowing for standalone QR code labeling to USDA without the

default remedy of vacating it, despite holding the errors of law "significant" and the absence of any evidence demonstrating disruptive consequences from vacatur. As a result, products remain on market shelves "labeled" with QR codes alone, despite USDA's own admission that most consumers cannot access the crucial information Congress sought to disclose.

STANDARD OF REVIEW

A district court's grant of summary judgment is reviewed *de novo*. Oliver v. Keller, 289 F.3d 623, 626 (9th Cir. 2002).

Judicial review of agency action proceeds according to the APA's standards, under which reviewing courts "decide all relevant questions of law [and] interpret ... statutory provisions," and "shall ... set aside" agency actions that are either "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(a). In reviewing whether an agency decision is arbitrary or capricious, courts must "ensure that the agency considered the relevant factors and articulated a rational connection between the facts found and the choices made." Greater Yellowstone Coal., Inc. v. Servheen, 665 F.3d 1015, 1023 (9th Cir. 2011) (citation omitted). "[A]n agency rule would be arbitrary and capricious if the agency ... entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is

so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).

Courts begin with a statute's plain text. See Snoqualmie Indian Tribe v. FERC, 545 F.3d 1207, 1212 (9th Cir. 2008) (An agency's interpretation or application of a statute is a question of law reviewed de novo.). If the text is plain, this review can "begin" and "end" with a statute's "text and structure." Okla. V. Castro-Huerta, 142 S. Ct. 2486, 2496–2497 (2022) (quoting Alexander v. Sandoval, 532 U.S. 275, 287–288 (2001)). In order to respect the intent of Congress, courts are to "exhaust all the 'traditional tools' of construction," including a statute's "text, structure, history, and purpose" before deferring to agencies. Kisor v. Wilkie, 139 S. Ct. 2400, 2415 (2019) (citations omitted); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000). This is because "the best evidence of Congress's intent is the statutory text."

But even if after exhausting all tools of statutory construction and still finding plain text ambiguous, courts "need not defer to the agency when the agency's decision is without substantial basis in fact." *Ctr. for Biological Diversity v. Zinke*, 900 F.3d 1053, 1067 (9th Cir. 2018) (citing *Ariz. Cattle Growers' Ass'n v. Salazar*, 606 F.3d 1160, 1163 (9th Cir. 2010)). This Court has accordingly "insisted that agencies

support and explain their conclusions with evidence and reasoned analysis." Ctr. for Biological Diversity v. U.S. Dep't of Interior, 623 F.3d 633, 648 (9th Cir. 2010).

Regarding remedy, USDA receives no deference. Once a court determines that the agency action was arbitrary, capricious, or otherwise not in accordance with law, the appropriate remedy is not a matter within the agency's discretion, and no deference is owed. See, e.g., Sierra Forest Legacy v. Sherman, 646 F.3d 1161, 1185–86 (9th Cir. 2011) (declining to defer on remedy). This Court reviews the district court's decision to remand without vacatur for an abuse of discretion. See W. Watersheds Project v. McCullough, 2023 WL 4557742, at *3 (9th Cir. July 17, 2023).

ARGUMENT

I. THE DISTRICT COURT WAS WRONG TO RUBBERSTAMP USDA'S EXCLUSION OF MOST GE INGREDIENTS FROM LABELING.

USDA's exemption for highly refined foods is contrary to statute for several reasons. First, this exemption requires insertion of the extra-statutory requirement that GE material must be "detectable" to require disclosure. Second, USDA's separate and distinct authority to set threshold amounts of inadvertent presence of GE material in foods cannot support the "undetectable" GE foods exemption because it is a *post hoc* rationalization, nowhere mentioned during rulemaking (and even if it *had* been a ground on which the agency relied, the provision covers a different topic that does not support the wholesale exemption of all highly refined

foods). And finally, even if the text of the Disclosure Act were ambiguous, USDA's assertion that highly refined GE foods do not "contain" GE material runs headlong into the record evidence: Numerous studies before the agency indicate that they *do* contain GE material. USDA's refusal to require labeling of all GE foods is contrary to law and arbitrary and capricious.

A. The Disclosure Act's Plain Text Requires Labeling on Highly Refined Foods.

The first step and lodestar in statutory interpretation is always the plain text of the statute. If the "express terms of a statute give us one answer," that answer does not buckle to "extratextual considerations." *Bostock v. Clayton Cnty.*, *Georgia*, 140 S. Ct. 1731, 1737 (2020). A court's job "isn't to write or revise legislative policy," but rather "to apply it faithfully." *Nieves v. Bartlett*, 139 S. Ct. 1715, 1730 (2019) (Gorsuch, J., concurring in part).

Adherence to text also safeguards the rule of law. Grafting onto statutes words that Congress has not written "deprives the citizenry of fair notice of what the law is." *Bostock*, 140 S. Ct. at 1828 (Kavanaugh, J., dissenting). Moreover, it "den[ies] the people the right to continue relying on the original meaning of the law they have counted on to settle their rights and obligations." *Id.* at 1738. Interpreting statutes in accordance with their plain meaning ensures that the law remains accessible and predictable to those who are obligated to follow it.

Here, there is simply no indication in the Disclosure Act that Congress intended for USDA to limit mandatory disclosure to GE foods with "detectable" GE material by any testing method, no matter how outdated.

To start, the statute defines "bioengineering" as food "that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques," full stop. 7 U.S.C. § 1639(1)(A) (emphases added). It includes no modifiers or exclusions for foods that contain "undetectable" genetic material that has been modified at some point during production. Maine v. Thiboutot, 448 U.S. 1, 14 (1980). It is a fundamental principle of statutory interpretation" that "absent provision[s]," such as "detectable" by unspecified testing methods, "cannot be supplied by the courts." Rotkiske v. Klemm, 140 S. Ct. 355, 360–361 (2019); see also Sale v. Haitian Ctrs. Council, Inc., 509 U.S. 155, 168 n.16 (1993) ("[W]e may not add terms or provisions where Congress has omitted them."). If Congress meant to create a disclosure scope under which only some GE foods require disclosure based on regulated entities' preferred testing methods for detection, it would have. "To

⁴ The Disclosure Act does include two express disclosure exemptions, for "food served in a restaurant or similar retail establishment," *id.* § 1639b(2)(G)(i), and for animals that "consumed feed produced from" a bioengineered source, *id.* § 1639b(b)(2)(A), illustrating that if Congress wanted to exempt highly refined foods, it would have.

supply omissions transcends the judicial function." *Nichols v. United States*, 578 U.S. 104, 110 (2016) (citing Iselin v. United States, 270 U.S. 245, 251 (1926)).

And undoubtedly, highly refined foods "contain" genetic material that "has been modified." Where a term is "neither defined in the statute nor a term of art, we are left to construe it 'in accordance with its ordinary or natural meaning.'" S.D. Warren Co. v. Me. Bd. of Env't Prot., 547 U.S. 370, 376 (2006) (quoting FDIC v. Meyer, 510 U.S. 471, 467 (1994)). Here the ordinary meaning of "contains" is simply "to have within," meaning USDA must disclose foods that have within them genetic material (i.e., DNA) that "has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques." 7 U.S.C. § 1639(1)(A) (emphasis added).

Take, for example, USDA's example of a carbonated soda containing corn syrup produced from GE corn. See 83 Fed. Reg. 65,830. USDA does not deny the corn syrup has genetic material that has been modified in it, nor could it, as it originated from GE corn. Rather, USDA exempts it simply because it "does not have detectable modified genetic material" in it after the refining process. 83 Fed. Reg. 65,830 (emphasis added). But again, nowhere did Congress specify detectability of modified genetic material in the final product; it unambiguously defined

⁵ Contain, Mirriam-Webster (2023); *see also Contain*, Cambridge Dictionary (2023) ("to have something inside or include something as a part").

"bioengineering" as foods that have or may have material that has been modified at some point in the production process, which USDA admits is the case with GE corn syrup, whether the product later went through a refinement process or not.

If the broad definition were not plain enough, in like manner Congress then further instructed USDA to require disclosure of "any bioengineered food and any food that may be bioengineered." 7 U.S.C. § 1639b(a)(1) (emphasis added); see A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 116 (2012) ("And joins a conjunctive list."). Here, too, Congress made plain the expansive scope of disclosure. "As this Court has 'repeatedly explained,' 'the word 'any' has an expansive meaning." Patel v. Garland, 142 S. Ct. 1614, 1622 (2022) (quoting Babb v. Wilkie, 140 S. Ct. 1168, 1173 n.2 (2020)). Even more so where "Congress did not add any language limiting the breadth of that word." United States v. Gonzales, 520 U.S. 1, 5 (1997). If a statute encompasses "any" of something, its directive is "comprehensive." SAS Inst., Inc. v. Iancu, 138 S. Ct. 1348, 1354 (2018). The statute thus requires disclosure of all foods that so much as may contain genetic material that has been modified at some point during production, not just some foods.

In sum, read together, 7 U.S.C. § 1639b(a)(1) and § 1639(1)(A) unambiguously mandate that USDA develop regulations for *both* food that "contains" genetic material that "has been modified" at some point and even food

that may "contain" genetic material that "has been modified." See Scalia & Garner at 168 (whole-text canon: "[T]he meaning of a statute is to be looked for, not in any single section, but in all the parts together and in their relation to the end in view.") (citation omitted).

The Act's text speaks for itself and should be decisive, *see Bostock*, 140 S. Ct. at 1737 (2020); however, the legislative history and regulatory history also squarely support highly refined foods' inclusion in the scope of disclosure. Congress knew full well most GE ingredients were highly refined and *repeatedly stated* that the Disclosure Act provides authority to USDA to cover refined sugars and other processed products. 162 Cong. Rec. S4783 (daily ed. July 6, 2016) (Disclosure Act "provides authority to the USDA to label refined sugars and other processed products."); 162 Cong. Rec. S4994 (daily ed. July 12, 2016) (The Act's scope "does not prohibit the labeling of highly refined products.").

If these statements were not enough, just weeks before the Act's passage, USDA's own General Counsel, Jeffrey Prieto, sent a letter to Congress assuring Congress it interpreted the Act as granting authority to include food products which contain "highly refined oils, sugars, or high fructose corn syrup that have been produced or developed from genetic modification techniques." 162 Cong. Rec. S4994 (daily ed. July 12, 2016). Sponsors of the bill then used this letter to explicitly

reassure other Congressional members that "this bill gives USDA broad authority to label GE products," including those referenced in USDA's July 1, 2016, letter, such as highly refined foods. 162 Cong. Rec. S4906, S4845 (daily ed. July 7, 2016); 162 Cong. Rec. S4994 (daily ed. July 12, 2016) (Senator Stabenow assuring Senator Leahy). Crucially, the statute's text did not change on this point between Prieto's letter and the Act' final passage, and Senator Stabenow, one of the Act's primary drafters, agreed with Prieto's views over a year *after* the Act's passage. *See* 3-ER-465-66. This letter would have been useless had Congress not sought to ensure that USDA included highly refined foods in the rules' scope.

And Congress's broad scope makes sense, considering the Disclosure Act's core purpose to replace individual state laws that *also required* highly refined foods to bear disclosure. After all, the purpose of the federal preemption doctrine is to prevent conflict between federal and state laws: "Congress enacts a law that imposes restrictions or confers rights on private actors; a state law confers rights or imposes restrictions that *conflict with the federal law*; and therefore the federal law takes precedence and the state law is preempted." *Murphy v. Nat'l Collegiate Athletic Ass'n*, 138 S. Ct. 1461, 1480 (2018). It would make little sense for Congress to preempt

⁶ 3-ER-601-609; see also 3-ER-552-53.

state labeling laws disclosing all GE foods with a federal law labeling less than a third of them.

B. The District Court Overlooked Numerous Statutory Interpretation Tools Before Deferring to USDA's *Post Hoc* Rationalization.

But the district court, for its part, *did not even mention* these critical Act provisions or legislative history. Instead, it deferred to USDA's new litigation position that exempting the entire class of highly refined foods from mandatory disclosure somehow counted as USDA setting the threshold for inadvertent presence of bioengineered material. 1-ER-22-23. This failure to interpret the pertinent provisions and legislative history constitutes reversible error for three reasons.

1. The District Court Erred in Endorsing USDA's Litigation Position.

First, *nowhere in USDA's rulemaking* did the agency even mention its authority to "determine the amounts of a bioengineered substance that may be present in a food, as appropriate, in order for the food to be a bioengineered food," 7 U.S.C. § 1639b(b)(2)(B), as support for its highly refined foods exemption. As such, the district court's reliance on this provision is erroneous. It is a cardinal rule of administrative law that "a court should decline to defer to a ... *post hoc* rationalizatio[n] advanced to defend past agency action against attack," *Kisor*, 139 S.

Ct. at 2417 (citations omitted), and that "an agency's action must be upheld, if at all, on the basis articulated by the agency itself" during rulemaking. Motor Vehicle Mfrs. Ass'n, 463 U.S. at 50; see also SEC v. Chenery Corp., 332 U.S. 194, 196 (1947) ("We may not supply a reasoned basis for the agency's action that the agency itself has not given."). This is because deficiencies in an agency's reasoning may not be rectified by providing reasoning which the agency itself has not articulated. See Motor Vehicle Mfrs., 463 U.S. at 43.

Moreover, even if USDA *had* supplied this statutory provision during rulemaking, its transposition to support USDA's decision required several significant logic-defying leaps, none of which the district court explained. Namely, the interpretation required the court to ignore the fact that USDA *did not* actually "determine [any] amounts," of bioengineered substance here. In fact, the exemption USDA made for highly refined foods has nothing to do with "amounts" of GE material in the food at all. Rather, the exemption is for all foods with *any amount* of GE material, that either went through a validated refining process or testing for GE material, using any test, of any sensitivity, that found GE material "undetectable." See 7 C.F.R. § 66.9.

This newfound reliance also required the district court to keep its head in the sand regarding the other key part of the provision: it is about determining these

amounts to *include* more foods in the scope of disclosure, not *exclude* them. Congress authorized USDA to set these amounts "in order for the food *to be* a bioengineered food," not for foods to *not be* bioengineered foods. 7 U.S.C. § 1639b(b)(2)(B).

The district court did not even note this inexplicable mismatch, let alone try to explain how exempting most foods somehow served as setting threshold amounts to *include* more foods in the scope of disclosure. It is unsurprising that USDA did not attempt to justify its sweeping exemption with this strained interpretation during rulemaking; the district court should not have attempted to do so either.

2. The District Court Overlooked the Disclosure Act's Unambiguous Requirement to Disclose Highly Refined Foods.

Second, the district court erred in failing to consider the key plain text of the Disclosure Act—the definition of "bioengineering"—before accepting USDA's interpretation. It is well established that, in interpreting a statute, the courts look not only to a particular clause but to the statute as a whole, and interpret it in light of its purpose. *Philbrook v. Glodgett*, 421 U.S. 707, 713 (1975); *Kokoszka v. Belford*, 417 U.S. 642, 650 (1974); *In re W. States Wholesale Nat. Gas Antitrust Litig.*, 715 F.3d 716, 731 (9th Cir. 2013) ("[S]tatutory provisions should not be read in isolation."); Scalia & Garner, at 168 (whole-text canon). The Supreme Court has repeatedly warned against undue reliance on a single word or phrase in interpreting a statute; instead, the statute as a whole must be considered. *Pilot Life Ins. Co. v. Dedeaux*, 481

U.S. 41, 51 (1987) ("On numerous occasions we have noted that '[i]n expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy."").

This is exactly what the lower court failed to do here. The starting point lies in the definition of "bioengineering," one of two provisions USDA heavily relied on during rulemaking in support of its highly refined exemption. This definition, enacted to ensure the rules cover highly refined foods, broadly defines "bioengineered food" as foods that contain or may contain genetic material (i.e., DNA) that "has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques." 7 U.S.C. § 1639(1)(A) (emphasis added); id. § 1639b(a)(1). This definition and mandate contain absolutely no indication that Congress intended to exclude the majority of GE ingredients from disclosure based on purported "detectability" in the final product. On the contrary, it specifically requires disclosure even of GE foods which regulated entities are uncertain about, id. § 1639b(a)(1) (requiring disclosure even of foods that "may be bioengineered"), and only provides authority for USDA to expand the scope of disclosure further, not limit it. Id. § 1639b(b)(2)(C) (granting USDA authority to determine "other factors and conditions under which a food is considered a bioengineered food.") (emphasis added).

Despite these key provisions, nowhere did the district court explain how it reached the conclusion that highly refined foods somehow do not "contain" or may not contain genetic material that has been modified at some point. Instead, the district court broke another cardinal rule of statutory interpretation: reading words into the statute that Congress did not include. See Scalia & Garner, at 93 ("Nothing is to be added to what the text states or reasonably implies."). Without explanation, and completely missing the required first step of statutory interpretation, the district court automatically deferred to USDA's interpretation that the scope of disclosure does not include "non-detectable" GE ingredients. 1-ER-22-23. Specifically, the district court reasoned that USDA's rules satisfy Congress's mandate to disclose foods that contain GE material because it requires disclosure of any food on USDA's List of Bioengineered Foods, unless a regulated entity provides records that it is not detectable. 1-ER-22.

This is not how statutory interpretation must be done. The APA's "unqualified command requires the court to determine legal questions—including questions about a regulation's meaning—by its own lights, not by those of political appointees or bureaucrats." *Kisor*, 139 S. Ct. at 2432 (Gorsuch, J. concurring). Courts should not even consider an agency's interpretation when the text is plain. Conn. *Nat'l Bank v. Germain*, 503 U.S. 249, 254 (1992) ("If the words of a statute are

unambiguous, this first step of the interpretive inquiry is our last."). Courts must instead inquire into the plain language of the text to ascertain the intent of Congress. *Lamie v. U.S. Tr.*, 540 U.S. 526, 534 (2004) ("[W]hen the statute's language is plain, the sole function of the courts—at least where the disposition required by the test is not absurd—is to enforce it according to its terms.") (citation omitted).

And to be sure, if Congress wanted to include a detectability requirement, it knows how to do so and would have. The Organic Foods Production Act, for example, requires any food product that contains "detectable" pesticides or non-organic residues or a prohibited natural substance to undergo investigation and potentially lose its organic label as a result, *see* 7 U.S.C. § 6511(c)(1): language that nowhere appears here.

Finally, even if the district court could properly append the "detectability" requirement onto the plain text, the district court also failed to explain how the rules are also supposed to cover foods that "may" contain "detectable" GE material. 7 U.S.C. § 1639b(a)(1). Its only mention of Congress's unambiguous requirement is parroting USDA's explanation that tests simply do not exist to detect foods that may contain GE ingredients. 1-ER-23. But again, Congress never included this requirement,

nor would Congress require a detectability test to determine if a product "may contain" GE ingredients: that simply does not make sense.

3. The District Court Failed to Give Effect to Legislative History and USDA's Interpretation of the Disclosure Act in Ascertaining Legislative Intent.

And finally, the district court also completely overlooked legislative history in its initial inquiry into the plain text. See, e.g., Altera Corp. & Subsidiaries v. Comm'r of Internal Revenue, 926 F.3d 1061, 1075 (9th Cir. 2019) (explaining that before deferring to any agency's interpretation, "[courts] examine the legislative history, the statutory structure, and 'other traditional aids of statutory interpretation' in order to ascertain congressional intent."). It failed to even mention—let alone give it the interpretative weight it should normally garner—legislative history and USDA's interpretation of the Disclosure Act, all of which supports Appellants. See supra at 30–31; see e.g., 162 Cong. Rec. S4783 (daily ed. July 6, 2016) (The Disclosure Act "provides authority to the USDA to label refined sugars and other processed products.").

In the same way, nor did the district court mention legislative history signaling Congressional intent to limit the financial burden on industry: a burden significantly *increased* by USDA's extra-statutory testing requirements. *See*, *e.g.*, *S*. REP. 114-403, 1, 6 (The Disclosure Act "is not intended to increase the costs of

food manufacturing or changes in distribution or handling."). Numerous titans of the food industry came out in favor of including all GE foods, not just to faithfully apply Congress's command, but because full disclosure would alleviate the costs of navigating potentially expensive, complex analytical testing methods, sample sizes, process variability, and evolving limits of detection to obtain proper documentation. 2-ER-162-63; 2-ER-220-21; 2-ER-278-79.

To give one example, Campbell's Soup Company described USDA's new antitextual position as "impractical to implement for the agency and industry" due to complex and costly analytical testing methods with differing degrees of efficacy. 2-ER-162. Several other companies similarly anticipated substantial costs of analytical testing for highly refined material and difficulty in enforcement, 2-ER-220-21; 2-ER-278-79, and pointed to USDA's own economic analysis that concluded the exclusion of highly refined foods would not reduce the costs for industry. 2-ER-294-96. Nevertheless, USDA ignored these concerns in favor of its extra-statutory exemption.

Likewise, the district court failed to acknowledge legislative history revealing that Congress rejected a voluntary labeling law: a scheme USDA's rules largely resurrect. See, e.g., Cheneau v. Garland, 997 F.3d 916, 923–26 (9th Cir. 2021) (relying on legislative history to determine plain meaning of statutory text); *Heavenly Hana*

LLC v. Hotel Union & Hotel Indus. of Haw. Pension Plan, 891 F.3d 839, 845 (9th Cir. 2018) (finding that a statute's "purpose and legislative history provide[d] significant guidance as to congressional intent"). Prior to the Disclosure Act's passage, the House version, H.R. 1599, was rejected, which would have rendered all GE labels voluntary in stark contrast to the state laws they replace. But the practical effect here of USDA's unlawful narrowing is voluntary labels on, by some accounts, 75% of highly refined ingredients in foods on grocery shelves, creating the very inconsistency and confusion for consumers Congress sought to prevent.

And so too did the district court overlook the *regulatory* history regarding USDA's authority under 7 U.S.C. § 1639b(b)(2)(B) to set threshold amounts for the presence of bioengineered material. During rulemaking, USDA interpreted its authority under this provision as allowing threshold amounts for accidental cross-contamination, not for intentional GE ingredients. Specifically, USDA correlated its authority under 7 U.S.C. § 1639b(b)(2)(B) to its regulation under 7 C.F.R. § 66.5(c), which establishes a five percent threshold for "*inadvertent or technically unavoidable*" material above which a "food [is] considered a bioengineered food." 7 C.F.R. § 66.5(c) (emphasis added).

In fact, USDA specifically rejected a floated option in the proposed rule that would have allowed regulated entities to *intentionally* use GE ingredients up to the

threshold amount. See 83 Fed. Reg. at 65,850; see also id. at 65,824 ("AMS did not ... allow for the intentional use of a BE substance without requiring disclosure because the agency believes that allowing entities to avoid disclosing despite the intentional presence of BE substances in food does not provide consumers with the information they desire."). In other words, USDA knew all along this Act provision was tied to inadvertent, accidental GE contamination in foods—not intentional yet highly refined ingredients— explaining why the agency never cited this provision as support for its highly refined exemption during rulemaking. The lower court would have realized this too, had it analyzed this regulatory history.

C. The District Court Erred in Deferring to USDA.

Deference to USDA's view of the Disclosure Act's requirements would have only been appropriate if the statutory text were ambiguous and the interpretation reasonable. See Kisor, 139 S. Ct at 2415 (Only when the "legal toolkit is empty and the interpretative question still has no single right answer" can a court "wave the ambiguity flag" and defer to the agency.); see also id. at 2416 ("[A]s under Chevron, the agency's reading must fall within the bounds of reasonable interpretation. And let there be no mistake: That is a requirement an agency can fail.") (citation omitted). As explained, the statute is clear on the issue and that should have been the end of the matter. See supra pp. 26–32. But even if the Disclosure Act were ambiguous,

USDA's interpretation did not deserve the heavy deference afforded to it by the district court, for five reasons.⁷

First, USDA's explanation that GE foods fall outside of the "bioengineering" definition because they "do[] not contain modified genetic material if the genetic material is not detectable," 7 C.F.R. § 66.1, is contradicted both by its own assertions and the weight of evidence. USDA's own guidance on testing methods admits that highly refined foods nonetheless still "contain" GE material. Specifically, USDA's

⁷ More generally, the current Supreme Court has expressed growing skepticism towards Chevron, U.S.A., Incorporated v. Natural Resources Defense Council, 467 U.S. 837 (1984) and other applications of agency deference. See, e.g., Baldwin v. United States, 140 S. Ct. 690, 691, 206 L. Ed. 2d 231 (2020) (Thomas, J., dissenting from the denial of certiorari) ("Chevron is in serious tension with the Constitution, the APA, and over 100 years of judicial decisions."); Kisor, 139 S. Ct. at 2425 (Gorsuch, J., concurring) (stating that "[i]t should have been easy for the Court to say goodbye to [Auer deference]" and describing the decision affirming Auer deference as "more of a stay of execution than a pardon."); Buffington v. McDonough, 143 S. Ct. 14, 22, 214 L. Ed. 2d 206 (2022) (Gorsuch, J. dissenting from the denial of certiorari) (describing the Chevron doctrine as a "project" that "deserves a tombstone no one can miss."). In fact, on May 1, 2023, in Loper Bright Enterprises v. Raimondo, the Supreme Court granted certiorari on the question of whether the Supreme Court should formally overrule Chevron—or at least put new limits on—the Chevron doctrine. See Loper Bright Enters. v. Raimondo, 143 S. Ct. 2429 (2023).

⁸ In July 2020, USDA issued a guidance to assist manufacturers, *National Bioengineered Food Disclosure Standard*; Guidance on Testing Methods (July 7, 2020, https://www.ams.usda.gov/sites/default/files/media/NBFDS_testingMethodology.pdf, and a Frequently Asked Questions document to answer the public's questions about these processes. *See USDA*, *Frequently Asked Questions: Guidance to Ensure Acceptable Validation of a Refining Process* (July 2, 2020),

guidance concedes that "a future test may detect modified genetic material in a highly refined food or ingredient that current tests do not," essentially admitting that the foods contain GE material. See supra at 28 (defining "contains" as "to have within"). A house may contain mold, whether or not it is detected by the eyes of the homeowner. Thus, even if the scope were limited by "contain"—as discussed above, it is not, but rather includes "may contain" and other factors that USDA could set—what is "contained" is not synonymous with what is "detected" by a common test.

Second, the record belies USDA's assertion that "highly refined foods" will often fall outside of this definition because they "have undergone processes that removed genetic material such that it *cannot* be detected using common testing methods," 83 Fed. Reg. at 65,834 (emphasis added), and the district court's agreement. 1-ER-23 (agreeing detection is "impossible to obtain with existing technology."). Rather, numerous studies using updated, more sensitive versions of the "common" polymerase chain reaction (PCR) testing method USDA identifies in

https://www.ams.usda.gov/sites/default/files/media/NBFDS_FAQrefiningProcess Validation.pdf.

⁹ USDA, Frequently Asked Questions: Guidance to Ensure Acceptable Validation of a Refining Process, at 3 (July 2, 2020), https://www.ams.usda.gov/sites/default/files/media/NBFDS_FAQrefiningProcess Validation.pdf (emphasis added).

its guidance ¹⁰ can detect GE material in previously "undetectable" highly refined foods. ¹¹ For example, a frequently cited paper on the absence of DNA in soybean oil, 4-ER-846-50, was contradicted just two years later by the same research team when researchers detected GE material in soybean oil they previously could not detect. 4-ER-808-12. Many other scientists have also detected DNA in refined oils like soybean oils, 4-ER-796-802, and commercial sunflower and maize oils that previous tests could not detect. 4-ER-803-07. Sensitivity is continually increasing, and current tests *can* detect highly refined GE material. *See e.g.*, 3-ER-682-92; 4-ER-803-07.

USDA instead chose to rely on a handful of studies that failed to detect GE material in some highly refined foods. But if anything, these studies only underscore the arbitrary nature of USDA's detectability requirement: A wide testing sensitivity range exists, creating a major loophole for regulated entities, untethered from the

¹⁰ USDA, National Bioengineered Food Disclosure Standard; Guidance on Testing Methods, at 2-3 (July 7, 2020, https://www.ams.usda.gov/sites/default/files/media/NBFDS_testingMethodology.pdf.

¹¹ For example, while a limit of detection of 0.1 percent was once common, 3-ER-487-96, scientists recently developed a real-time PCR screening with a sensitivity over ten-fold greater: < 0.01 percent for several GE corn products. 4-ER-764-72. Current methods have limits of detection all the way down to 0.005 percent, or 20 times more sensitive than many PCR tests not long ago. 2-ER-301-09.

statutory text. Companies could, for example, evade disclosure by strategically cherry-picking different PCR-based detection methods until finding one that does not detect GE material. This creates an arbitrarily shifting standard in which one entity could use a more sensitive test on an ingredient and disclose, while another could use an older test on that same ingredient and avoid disclosure. Such a loophole under which the labeling of the majority of foods depends solely on the sensitivity of a testing method violates the Act's purpose of providing uniform, consistent information to consumers.

Third, USDA's explanation that if "genetic material is not detected, then it is not possible to conclude that the food product or ingredient contains modified genetic material," 83 Fed. Reg. at 65,834 (emphasis added), is contradicted by years of companies labeling highly refined foods in the United States and around the world. See, e.g., 3-ER-498 (Campbell Soup Company); 2-ER-244-46 (Coca Cola); 3-ER-499 (Danone); 2-ER-268-76 (Unilever). USDA knows this, as the rules also list tracing sources as a method to verify a product does not contain GE ingredients. 83 Fed. Reg. at 65,817 ("[R]egulated entities can demonstrate that modified genetic material is not detectable with records verifying that the food is sourced from a non-bioengineered crop or other food source."). It is nonsensical then for USDA to claim it "not possible" to use source records to confirm the presence of genetic

material that has been modified. Indeed, USDA even expressly *allows* regulated entities to trace sources and voluntarily label ingredients "derived from bioengineering" or "ingredient(s) derived from a bioengineered source." 7 C.F.R. § 66.116(b)(1). This is in fact what food companies have been doing for years to determine if highly refined foods contain GE ingredients and what many seek to continue doing to spare the costs of testing and avoid confusing consumers. 2-ER-162-63; 2-ER-220-21; 2-ER-278-79 (expressing concerns about testing requirements due to cost); 2-ER-245; 2-ER-249 (supporting labels on all GE foods to avoid consumer confusion).

Fourth, the district court erred in deferring to USDA's arbitrary and capricious assertion that it had "determine[d] the amounts" of intentionally added, but "undetectable," GE material for several reasons. 1-ER-23. Namely, there is the glaring fact that USDA *refused* to determine any amounts. USDA expressly declined commenters' requests to set a minimum amount of modified genetic material intentionally present at or below which ingredients are not subject to mandatory disclosure. ¹² And in its guidance to industry, USDA explicitly asserted it will not set

 $^{^{\}rm 12}$ USDA, Frequently Asked Questions: Guidance of Testing Methods, at 1 (July 7, 2020),

https://www.ams.usda.gov/sites/default/files/media/NBFDS_FAQtestingMethods.pdf.

a Limit of Detection for acceptable testing methods; instead, USDA advised industry that it "should use validated methods ... to detect the modified genetic material" and "should consider sensitivity, specificity, accuracy, robustness, probability of detection (POD), limit of detection (LOD), limit of quantification (LOQ)," not that it must. ¹³ An LOD would have set some kind of "amount" that a test would need to be capable of detecting to satisfy the rules. But USDA did not even do that.

Further, there is the fact that USDA never before interpreted 7 U.S.C. § 1639b(b)(2)(B) as allowing it to set a standard for *intentional* GE material. Instead, USDA has always interpreted 7 U.S.C. § 1639b(b)(2)(B) as allowing for inadvertent GE material or cross-contamination, asking for public comment on what threshold to set for "inadvertent or technically unavoidable" material above which a "food [is] considered a bioengineered food." 7 C.F.R. § 66.5(c). Having your organic or conventional corn unintentionally cross-pollinated by GE corn and thus having accidental GE material is very different than knowingly using GE corn and then highly processing it. As such, as explained *supra*, this argument the district court

¹³ USDA, National Bioengineered Food Disclosure Standard; Guidance on Testing Methods, at 2 (July 7, 2020,

https://www.ams.usda.gov/sites/default/files/media/NBFDS_testingMethodology.pdf (emphasis added).

relied on is an impermissible "post hoc rationalization" and per se cannot support the decision. See Kisor, 139 S. Ct. at 2417.

Fifth and finally, USDA's exemption ignores the very purpose behind the laws Congress preempted: a meaningful disclosure of the broader impacts of a product's production on farmers and the environment through GE crop systems. See, e.g., 3-ER-449; 4-ER-720; 2-ER-443. The record reveals that the GE labeling movement that shaped the Disclosure Act never focused on the detection of GE material in an end product: the entire purpose of the movement and Congress's Disclosure Act in response was to create a uniform federal label to inform consumer if foods are produced using pesticide-promoting, GE crop systems. See 4-ER-745-46; 4-ER-750; see also 4-ER-775; 4-ER-781-86; 4-ER-755-56 (describing impacts of GE crop systems on the environment); 4-ER-751-54; 4-ER-789 (describing an epidemic of resistant "superweeds" now covering at least 120 million acres of U.S. farmland). As a result, the context in which the Disclosure Act was passed, along with the hundreds of comments consumers submitted, supports disclosure based on process not product: a context wholly ignored by USDA. See 7 U.S.C. § 1639(1)(A) (bioengineering is defined as food "that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.") (emphasis added); see

Alexander v. Sandoval, 532 U.S. 275, 313 (2001) (Stevens, J. dissenting) ("Congress does not legislate in a vacuum.").

II. THE DISTRICT COURT ERRED IN CONCLUDING USDA LAWFULLY BANNED SIMILAR TERMS.

USDA's stated explanation for its decision to restrict terminology, adopted by the district court, also received undue deference. USDA claimed using the terms, "genetically engineered" and "genetically modified," to label foods with "genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques," 7 U.S.C. § 1639(1) (emphases added), could "muddy the scope of disclosure." 83 Fed. Reg. at 65,837. Further, USDA asserted that the brand-new terminology, bioengineered, was sufficient on its own because it will not confuse consumers. 83 Fed. Reg. at 65,852 ("[T]he language used by Congress in the amended Act clearly and accurately describes the technology and provides consumers with the information they desire.").

Both explanations run "counter to the evidence before the agency," *Greater Yellowstone Coal.*, *Inc.*, 665 F.3d at 1023, and cannot stand under the APA: USDA's interpretation that the Disclosure Act's text uses GE/GMO and bioengineered to refer to different categories of foods makes no sense, as Congress itself used these terms interchangeably. And even if it did, USDA's explanation for prohibiting GE

and GMO to satisfy its mandatory rules is flatly contradicted by record evidence and its own prior position on terminology.

First, USDA's assertion that using "genetically modified" to label foods that "contain[] genetic material that has been modified" inaccurately defines the scope of disclosure is incorrect. 7 U.S.C. § 1639(1) (emphases added). This very definition of "bioengineering" explains why: Congress could not have been plainer in its instruction to USDA to broadly disclose foods with "genetical material that has been modified" and foods that may have genetic material that has been modified. Congress even used the words "genetically modified" and "genetically engineered" elsewhere in the Act to clarify that they are interchangeable: These terms cover the same scope as "bioengineered." See 7 U.S.C. § 6524 ("[Organic] certification shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as 'not bioengineered', 'non-GMO', or another similar claim."); 7 U.S.C. § 1639c(c) (grouping together "not bioengineered', 'non-GMO', or any other similar claim"); id. § 1639i(b) (preempting state laws labeling foods and seeds as "genetically engineered ... which shall include such other similar terms as determined by the Secretary of Agriculture," such as "bioengineered").

And in the bigger picture, this interchangeable terminology makes sense, considering the Disclosure Act's stated purpose: to provide a national standard

replacing state laws labeling GE foods. The legislative history underscores that Congress plainly intended the Disclosure Act to do just that: label at the very least the *same scope of foods* state laws labeled with a national, uniform label bearing either "bioengineered" or GE/GMO terminology. In fact, most of the legislative history—completely overlooked by the district court—*overwhelmingly* uses the terminology, GE and GMO, over bioengineered to explain the Act's purpose and scope. ¹⁴

¹⁴ See, e.g., A National Framework for the Review and Labeling of Biotechnology in Food: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 114th Cong. (2015) (using the term "genetically modified" or "GMO" 84 times; "genetically engineered," "genetic engineering," or "GE food" 58 times; and "bioengineered" five times); see also id. at 2 (statement by Rep. Pitts) (explaining the disclosure is intended to apply to "[glenetically modified organisms, or GMOs ... [which] refers to ingredients sourced from crops that have been genetically engineered"); id. at 5 (statement by Rep. Butterfield) (rules meant to cover all "foods produced with genetically modified ingredients"); 162 Cong. Rec. H4934 (daily ed. July 14, 2016) (statement by Rep. Peterson) (Congress was considering a bill that "recognizes consumers' demand to know more about their food by directing USDA to create a national, mandatory genetically engineered food labeling program."); id. (using "genetically engineered," "GE," "genetic engineering," "GMO," and "genetically modified" 69 times and "bioengineered" or "bioengineering" only 53 times just days before passing the Disclosure Act); 162 Cong. Rec. H4830 (daily ed. July 13, 2016) (representatives using "GMO," and "genetically modified" fifteen times and "bioengineered" three times, excluding the letters introduced into the record which overwhelmingly use GE/GMO terminology); 162 Cong. Rec. S4873 (daily ed. July 7, 2016) (using "bioengineering and "bioengineered" 31 times, and "genetic engineering," "genetically engineered," "GE food," "genetically modified," and "GMO" 218 times, excluding quotes from commenters introduced into the record which only use the terms, GE and GMO).

Indeed, if "bioengineered" referred to some wholly other class of foods,

Congress would not have repeatedly listed together these terms in legislative history
and in the statute itself. Under the associated-words canon, "[w]ords grouped in a
list should be given related meanings." Scalia & Garner, at 195; see also United States

v. Williams, 553 U.S. 285, 294 (2008) ("[A] word is given more precise content by the
neighboring words with which it is associated."). Congress not only intentionally
crafted the definition of "bioengineering" to include any foods with genetic material
that has been modified, but it intentionally included the terms, GE and GMO, in lists
with bioengineered. And Congress intentionally anticipated for "similar terms" such
as these in the rules. See 7 U.S.C. § 1639(1).

Second, USDA's reasoning that allowing GE and GMO along with bioengineered could lead to inconsistencies is also arbitrary and capricious considering Congress *explicitly authorized* this. See 5 U.S.C.A. § 706 (Courts shall "hold unlawful and set aside agency action, findings, and conclusions found to be ... not in accordance with law."). The Disclosure Act allows USDA to include *both* the terminology "bioengineered" *and* "any similar term, as determined by the Secretary" in the rules. If Congress thought additional terms like GE and GMO would *confuse* consumers, it would have prohibited "similar terms" itself, as it has in other labeling contexts. See, e.g., 7 U.S.C. § 6519(c) (prohibiting similar terms to "organic" under

the Organic Foods Production Act). It did the opposite: It told USDA to use similar terms. The agency just decided it knew better.

In truth, the most meaningful inconsistency here comes from USDA's failure to require mandatory labels on up to 75% of GE ingredients. See supra at 15–16. This extra-statutory exemption for highly refined foods results in a significant number of GE foods bearing only voluntary labels, if at all, irrespective of whether they contain genetic material that has been modified at some point in production. And these voluntary labels, in turn, mislead consumers by suggesting that highly refined GE foods without voluntary labels contain no GE ingredients when, as described supra, they do. This inconsistency is what Congress sought to prevent, not different terminology to describe the same thing.

Third, the record sharply contradicts USDA's assertion that "bioengineered" covers a different scope from GE and GMO. For example, USDA's own subagency, the Food Safety and Inspection Service, uses the terms, bioengineered and GMO, interchangeably in its guidance for labeling claims under meat labeling laws. 3-ER-599-600. And USDA also uses GE in its GE plant regulation under the Plant Protection Act to describe the plants from which GE foods are produced. See 7 C.F.R. Part 340.1. Similarly, in the Food & Drug Administration (FDA)'s 2015 guidance, Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived

from Genetically Engineered Plants, the agency uses both "genetic engineering" and "bioengineering" to describe "modern biotechnology," 3-ER-667-81, and encourages the use of not just "not bioengineered," but also "not genetically engineered," and "not genetically modified through the use of modern biotechnology." 3-ER-672-73; 3-ER-670 (FDA stating the terms, bioengineering and genetic engineering, "are often used interchangeably by industry, federal agencies, international bodies, and other interested stakeholders."). The scope is, and has always been, the same.

Tellingly, even in this very rulemaking, USDA used "GMO" on its website until at least July of 2017 and submitted to the U.S. Patents and Trademark office at least one disclosure symbol that was "GMO" in a circle. 3-ER-562-63. In May 2017, USDA admitted it "could view" GMO as "similar" due to the "longstanding" use of GMO by the government and scientific community. 3-ER-566. USDA's about-face decision to nevertheless suddenly prohibit GE/GMO constitutes arbitrary and capricious agency action in violation of the APA. See Motor Vehicle Mfrs. Ass'n, 463 U.S. at 43.

Fourth and finally, USDA's single conclusory sentence stating that bioengineered alone "clearly and accurately describes the technology and provides consumers with the information they desire," 83 Fed. Reg. at 65,852, runs contrary to overwhelming record evidence. USDA knows that GE/GMO has served as the

prominent terminology used in policy, industry, 2-ER-255; 2-ER-235, administrative agencies, 3-ER-667-71; 3-ER-672; 3-ER-599-600, almost every other country with a GE labeling law, 2-ER-315-414, and even the state laws Congress sought to replace. E.g., 2-ER-310-14; 3-ER-601-09; 3-ER-554-57; 2-ER-186-88. The scientific community uses GE and GMO in the context of food, with the Committees of the National Academy of Sciences seldom or never using "bioengineered." 4-ER-813-45; 3-ER-616-666. Manufacturers, too, have only labeled foods using the terminology, GE and GMO, and many seek to continue. 2-ER-255-56; 2-ER-235.

It is unsurprising, then, that numerous record studies, research, and comments confirm the *opposite* of what USDA claims: consumers do not recognize the term, "bioengineered." For example, 2017-2018 research showed an average of over six hundred thousand internet searches for GMO, fewer than eighty thousand for "bioengineered," and *none* for "bioengineered food" or "BE food." 2-ER-297-300. And Campbell Soup Company determined after testing nine labels that consumers understand GMO, while terms like "bioengineered" confuse consumers. 3-ER-597-98. The vast majority of consumer comments agreed that GE and GMO plainly communicate the disclosure, while bioengineered misleads and confuses them. 2-ER-152-53; 3-ER-504-05; 3-ER-472; 2-ER-259-60.

What's more, USDA itself insisted consumers only recognize GE/GMO just one year before the Disclosure Act's passage. In USDA's Process Verified Program for verifying companies' claims on the absence of GE ingredients, USDA insisted that using GE and GMO was "the official approach and the policy approach of our Department as a whole." 3-ER-558. Indeed, USDA went so far as to assert any other terminology would violate the Plain Writing Act of 2010 and Executive Order 13563, which ensure public recognition of government terminology. See 3-ER-560 ("It is important to emphasize that agencies should communicate with the public in a way that is clear, simple, meaningful, and jargon-free. A lack of clarity may prevent people from becoming sufficiently aware of programs or services."). USDA described GMO as "permeat[ing] American culture," 3-ER-561, and "nearly universally utilized, understood and communicated by all American journalists, broadcasters, public officials, and throughout culture and the public at large." 3-ER-560-61. USDA's decision to nevertheless arrogate the authority for the terminology decision for itself due to its unsupported belief that the public will suddenly understand "bioengineered" alone constitutes arbitrary and capricious agency action in violation of the APA. See Motor Vehicle Mfrs. Ass'n, 463 U.S. at 43.

III. THE DISTRICT COURT IMPROPERLY REMANDED THE QR CODE DISCLOSURE OPTION WITHOUT VACATUR.

Vacatur is the default remedy for unlawful agency action. *Pollinator Stewardship*Council v. EPA, 806 F.3d 520, 532 (9th Cir. 2015); All. for the Wild Rockies v. USFS,

907 F.3d 1105, 1121–22 (9th Cir. 2018) ("Presumption of vacatur" unless

Defendants meet burden showing otherwise). As such, remand without vacatur is
only appropriate in "limited" circumstances, *Pollinator*, 806 F.3d at 532, and only
when the agency can show "equity demands" that outcome. *Id.* (citations omitted).

To evaluate if these limited circumstances are met, courts apply the test from *Allied–Signal*, *Incorporated v. United States Nuclear Regulatory Commission*, 988 F.2d 146, 150–

51 (D.C. Cir. 1993), assessing "the seriousness of the agency's errors" weighed
"against the disruptive consequences of an interim change that may itself be
changed." *E.g.*, *Pollinator*, 806 F.3d at 532.

On the first vacatur prong to be weighed, the district court acknowledged that allowing for standalone QR code disclosures was a "significant error." 1-ER-21. This makes sense, as the Disclosure Act's core purpose is to provide disclosure, and USDA concluded that "consumers would not have sufficient access to the bioengineering disclosure through only electronic or digital means under ordinary shopping conditions at this time." 83 Fed. Reg. at 65,828. Because of USDA's violation, the core purpose of the statute—meaningful transparency for consumers—

was vitiated. Products were on market shelves, supposedly now labeled, but in a manner that USDA itself admitted was wholly inadequate and inaccessible to many.

But the district court nevertheless failed to weigh the seriousness of USDA's errors, despite agreeing with Appellants that the errors were "significant." 1-ER-21. Instead, it moved immediately to the second half of the vacatur calculus, the possible disruptive consequences of vacatur during remand, and incorrectly concluded it was required to defer to USDA's litigation position regarding the impact on regulated entities. See 1-ER-21 (granting remand without vacatur solely because "[USDA] says that vacatur would disrupt consumer access to bioengineering disclosures" and "[USDA] says that vacatur would disrupt the food industry.") (emphases added).

This was erroneous. When reviewing a final agency action under the APA, any theoretical deference is only due to the agency's technical analyses and judgments in certain circumstances on the *merits*, but *not* to the appropriate remedy. See, e.g., Sierra Forest Legacy v. Sherman, 646 F.3d 1161 (9th Cir. 2011) (declining to defer on remedy). Where in some cases it might be appropriate to defer on the merits, ¹⁵ it makes no sense to defer to an agency when a court has already found the agency action unlawful in some way and unsupported by the record; the doctrine of

¹⁵ Though for all the reasons stated above, USDA should be entitled to no deference on the merits here either. *See supra* pp. 25–56.

agency deference, instead, stems from the development of an administrative record and time spent analyzing a given issue, which is, of course, not present when analyzing remedy in litigation for the first time without any such supporting evidentiary record.

Indeed, vacatur would be exceedingly rare if courts were *required* to defer to an agency's choice of remedy, because agencies inevitably maintain that their actions are not "serious errors," even when they have violated the core of their controlling statutes and claim, without evidence, that disruptive consequences will be great.

As with statutory interpretation, the district court simply failed to go through its own analysis of the seriousness of USDA's error as to QR code labeling, and then evaluate the evidence, if any, of disruptive consequences in the interim of remand. Far from receiving deference as to the disruptive consequences of vacatur, USDA, in fact, has the *burden* to show that this is one of those rare circumstances where the equities demand a result *other than* vacatur. *All. for the Wild Rockies*, 907 F.3d at 1121–22. Here, USDA abjectly failed to meet that burden: USDA offered no record (or extra-record) support of the alleged "disruptive consequences" to the food industry in changing their labels to on-package text or symbol disclosure in the interim between vacatur and any potential change to the rules on remand. In fact, numerous manufacturers were already opting for on-package text and symbols,

neither of which vacatur of the QR code alternative alone would have affected. See, e.g., 2-ER-254.

However, what the undisputed record evidence does reveal is ongoing harm, in the form of barriers to access, due to the district court's failure to vacate. The QR code study Congress commissioned to ensure access concluded that "key technological challenges"-such as lack of technical knowledge, lack of association of digital links with food information, and lack of infrastructure—"prevented nearly all participants from obtaining the information through electronic or digital disclosure methods." 3-ER-524 (emphasis added). It showed that consumers failed to associate QR codes with food information, id.; all stores lacked scanners for those without smart phones, 3-ER-527; 85 percent of consumers struggled with software apps required to access disclosures, 3-ER-524; the majority of small retailers did not provide in-store Wi-Fi, id.; and nearly one quarter of Americans lacked a smart phone. 3-ER-526. Essentially, it showed that access was nearly impossible for the majority of consumers.

With these numerous barriers, millions of consumers continue to struggle to access disclosures. This should have compelled the district court to vacate. The district court's decision to ignore this evidence and simply defer to USDA was erroneous.

CONCLUSION

The district court failed to do its own statutory interpretation and instead improperly deferred to USDA's unlawful interpretation that a statute enacted to label any GE food can only label less than a *third* of the GE ingredients on grocery store shelves. It deferred to USDA's interpretation that a statute enacted to label foods with "genetic material" that "has been modified" does not allow the terminology, "genetically modified" or "genetically engineered," that Congress used, that 64 other countries use, and that the state laws it preempted used. And it left in place the unlawful use of a QR code to "disclose" the presence of GE food—requiring smart phone and internet access—a method USDA itself found wholly inadequate, and leaves millions of consumers in the dark.

Left standing, the decision will continue to deny access to GE food disclosures, despite 90% of Americans demanding them and Congress mandating them on "any bioengineered food and any food that may be bioengineered." 7 U.S.C. § 1639b(a)(1) (emphases added). Affirming the district court's decision to nullify core provisions of the Disclosure Act without first looking to the plain text will result in ongoing confusion for consumers and loopholes for regulated entities. For all these reasons, Appellants respectfully request this Court reverse and remand

to the district court with instructions to remand to the agency to conduct further proceedings consistent with this Court's decision.

Respectfully submitted this 5th day of September, 2023.

/s/ Meredith Stevenson
Meredith Stevenson
George A. Kimbrell
Amy van Saun
CENTER FOR FOOD SAFETY
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
T: (415) 826-2770
mstevenson@centerforfoodsafety.org
gkimbrell@centerforfoodsafety.org
avsaun@centerforfoodsafety.org

Counsel for Plaintiffs-Appellants

ADDENDUM OF STATUTES, REGULATIONS, AND RULES TABLE OF CONTENTS

FEDERAL STATUTES	PAGE(S)
5 U.S.C. § 702	A03
5 U.S.C. § 706	A04
7 U.S.C. § 1639	A06
7 U.S.C. § 1639b	A07
7 U.S.C. § 1639c	A12
7 U.S.C. § 1639i	A13
7 U.S.C. § 6511	A14
7 U.S.C. § 6519	A16
7 U.S.C. § 6524	A21
28 U.S.C. § 1291	A22
28 U.S.C. § 1331	A23
28 U.S.C. § 1346	A24
28 U.S.C. § 2107	A26
FEDERAL REGULATIONS	
7 C.F.R § 66.1	A28
7 C.F.R § 66.5	A31
7 C.F.R § 66.9	A32
7 C.F.R § 66.100	A34
7 C.F.R § 66.102	A36

7 C.F.R § 66.106	A38
7 C.F.R § 66.108	A40
7 C.F.R § 66.166	A42
7 C.F.R § 340.1	A45
FEDERAL RULES	
Fed. R. App. P. 4	A48

United States Code Annotated
Title 5. Government Organization and Employees (Refs & Annos)
Part I. The Agencies Generally
Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C.A. § 702

§ 702. Right of review

Currentness

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. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: *Provided*, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 392; Pub.L. 94-574, § 1, Oct. 21, 1976, 90 Stat. 2721.)

Notes of Decisions (1410)

5 U.S.C.A. § 702, 5 USCA § 702

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

KeyCite Yellow Flag - Negative Treatment

Unconstitutional or PreemptedLimitation Recognized by Krafsur v. Davenport, 6th Cir.(Tenn.), Dec. 04, 2013

KeyCite Yellow Flag - Negative TreatmentProposed Legislation

United States Code Annotated

Title 5. Government Organization and Employees (Refs & Annos)

Part I. The Agencies Generally

Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

- (1) compel agency action unlawfully withheld or unreasonably delayed; and
- (2) hold unlawful and set aside agency action, findings, and conclusions found to be--
 - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
 - **(B)** contrary to constitutional right, power, privilege, or immunity;
 - (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
 - **(D)** without observance of procedure required by law;
 - (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
 - (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

CREDIT(S)

A04

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

Notes of Decisions (5438)

5 U.S.C.A. § 706, 5 USCA § 706

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated

Title 7. Agriculture (Refs & Annos)

Chapter 38. Distribution and Marketing of Agricultural Products (Refs & Annos)

Subchapter V. National Bioengineered Food Disclosure Standard

7 U.S.C.A. § 1639

§ 1639. Definitions

Effective: July 29, 2016 Currentness

In this subchapter:

(1) Bioengineering

The term "bioengineering", and any similar term, as determined by the Secretary, with respect to a food, refers to a food-

- (A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and
- (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.

(2) Food

The term "food" means a food (as defined in section 321 of Title 21) that is intended for human consumption.

(3) Secretary

The term "Secretary" means the Secretary of Agriculture.

CREDIT(S)

(Aug. 14, 1946, c. 966, Title II, § 291, as added Pub.L. 114-216, § 1, July 29, 2016, 130 Stat. 834.)

Notes of Decisions (1)

7 U.S.C.A. § 1639, 7 USCA § 1639

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated

Title 7. Agriculture (Refs & Annos)

Chapter 38. Distribution and Marketing of Agricultural Products (Refs & Annos)

Subchapter V. National Bioengineered Food Disclosure Standard

7 U.S.C.A. § 1639b

§ 1639b. Establishment of national bioengineered food disclosure standard

Effective: July 29, 2016 Currentness

(a) Establishment of mandatory standard

Not later than 2 years after July 29, 2016, the Secretary shall--

- (1) establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered; and
- (2) establish such requirements and procedures as the Secretary determines necessary to carry out the standard.

(b) Regulations

(1) In general

A food may bear a disclosure that the food is bioengineered only in accordance with regulations promulgated by the Secretary in accordance with this subchapter.

(2) Requirements

A regulation promulgated by the Secretary in carrying out this subchapter shall--

- (A) prohibit a food derived from an animal to be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance;
- **(B)** determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food;
- (C) establish a process for requesting and granting a determination by the Secretary regarding other factors and conditions under which a food is considered a bioengineered food;

- **(D)** in accordance with subsection (d), require that the form of a food disclosure under this section be a text, symbol, or electronic or digital link, but excluding Internet website Uniform Resource Locators not embedded in the link, with the disclosure option to be selected by the food manufacturer;
- (E) provide alternative reasonable disclosure options for food contained in small or very small packages;
- (F) in the case of small food manufacturers, provide--
 - (i) an implementation date that is not earlier than 1 year after the implementation date for regulations promulgated in accordance with this section; and
 - (ii) on-package disclosure options, in addition to those available under subparagraph (D), to be selected by the small food manufacturer, that consist of--
 - (I) a telephone number accompanied by appropriate language to indicate that the phone number provides access to additional information; and
 - (II) an Internet website maintained by the small food manufacturer in a manner consistent with subsection (d), as appropriate; and
- (G) exclude--
 - (i) food served in a restaurant or similar retail food establishment; and
 - (ii) very small food manufacturers.

(3) Safety

For the purpose of regulations promulgated and food disclosures made pursuant to paragraph (2), a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering.

(c) Study of electronic or digital link disclosure

(1) In general

Not later than 1 year after July 29, 2016, the Secretary shall conduct a study to identify potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods.

(2) Public comments

In conducting the study under paragraph (1), the Secretary shall solicit and consider comments from the public.

(3) Factors

The study conducted under paragraph (1) shall consider whether consumer access to the bioengineering disclosure through electronic or digital disclosure methods under this subchapter would be affected by the following factors:

- (A) The availability of wireless Internet or cellular networks.
- **(B)** The availability of landline telephones in stores.
- (C) Challenges facing small retailers and rural retailers.
- (D) The efforts that retailers and other entities have taken to address potential technology and infrastructure challenges.
- (E) The costs and benefits of installing in retail stores electronic or digital link scanners or other evolving technology that provide bioengineering disclosure information.

(4) Additional disclosure options

If the Secretary determines in the study conducted under paragraph (1) that consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods, the Secretary, after consultation with food retailers and manufacturers, shall provide additional and comparable options to access the bioengineering disclosure.

(d) Disclosure

In promulgating regulations under this section, the Secretary shall ensure that--

- (1) on-package language accompanies--
 - (A) the electronic or digital link disclosure, indicating that the electronic or digital link will provide access to an Internet website or other landing page by stating only "Scan here for more food information", or equivalent language that only reflects technological changes; or
 - **(B)** any telephone number disclosure, indicating that the telephone number will provide access to additional information by stating only "Call for more food information.";

- (2) the electronic or digital link will provide access to the bioengineering disclosure located, in a consistent and conspicuous manner, on the first product information page that appears for the product on a mobile device, Internet website, or other landing page, which shall exclude marketing and promotional information;
- (3)(A) the electronic or digital link disclosure may not collect, analyze, or sell any personally identifiable information about consumers or the devices of consumers; but
- **(B)** if information described in subparagraph (A) must be collected to carry out the purposes of this subchapter, that information shall be deleted immediately and not used for any other purpose;
- (4) the electronic or digital link disclosure also includes a telephone number that provides access to the bioengineering disclosure; and
- (5) the electronic or digital link disclosure is of sufficient size to be easily and effectively scanned or read by a digital device.

(e) State food labeling standards

Notwithstanding section 1639i of this title, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using bioengineering for a food that is the subject of the national bioengineered food disclosure standard under this section that is not identical to the mandatory disclosure requirement under that standard.

(f) Consistency with certain laws

The Secretary shall consider establishing consistency between--

- (1) the national bioengineered food disclosure standard established under this section; and
- (2) the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.) and any rules or regulations implementing that Act.

(g) Enforcement

(1) Prohibited act

It shall be a prohibited act for a person to knowingly fail to make a disclosure as required under this section.

(2) Recordkeeping

Each person subject to the mandatory disclosure requirement under this section shall maintain, and make available to the Secretary, on request, such records as the Secretary determines to be customary or reasonable in the food industry, by regulation, to establish compliance with this section.

(3) Examination and audit

(A) In general

The Secretary may conduct an examination, audit, or similar activity with respect to any records required under paragraph (2).

(B) Notice and hearing

A person subject to an examination, audit, or similar activity under subparagraph (A) shall be provided notice and opportunity for a hearing on the results of any examination, audit, or similar activity.

(C) Audit results

After the notice and opportunity for a hearing under subparagraph (B), the Secretary shall make public the summary of any examination, audit, or similar activity under subparagraph (A).

(4) Recall authority

The Secretary shall have no authority to recall any food subject to this subchapter on the basis of whether the food bears a disclosure that the food is bioengineered.

CREDIT(S)

(Aug. 14, 1946, c. 966, Title II, § 293, as added Pub.L. 114-216, § 1, July 29, 2016, 130 Stat. 835.)

Notes of Decisions (5)

7 U.S.C.A. § 1639b, 7 USCA § 1639b

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated

Title 7. Agriculture (Refs & Annos)

Chapter 38. Distribution and Marketing of Agricultural Products (Refs & Annos)

Subchapter V. National Bioengineered Food Disclosure Standard

7 U.S.C.A. § 1639c

§ 1639c. Savings provisions

Effective: July 29, 2016 Currentness

(a) Trade

This subchapter shall be applied in a manner consistent with United States obligations under international agreements.

(b) Other authorities

Nothing in this subchapter--

- (1) affects the authority of the Secretary of Health and Human Services or creates any rights or obligations for any person under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or
- (2) affects the authority of the Secretary of the Treasury or creates any rights or obligations for any person under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.).

(c) Other

A food may not be considered to be "not bioengineered", "non-GMO", or any other similar claim describing the absence of bioengineering in the food solely because the food is not required to bear a disclosure that the food is bioengineered under this subchapter.

CREDIT(S)

(Aug. 14, 1946, c. 966, Title II, § 294, as added Pub.L. 114-216, § 1, July 29, 2016, 130 Stat. 838.)

7 U.S.C.A. § 1639c, 7 USCA § 1639c

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated

Title 7. Agriculture (Refs & Annos)

Chapter 38. Distribution and Marketing of Agricultural Products (Refs & Annos)

Subchapter VI. Labeling of Certain Food

7 U.S.C.A. § 1639i

§ 1639i. Federal preemption

Effective: July 29, 2016 Currentness

(a) Definition of food

In this subchapter, the term "food" has the meaning given the term in section 321 of Title 21.

(b) Federal preemption

No State or a political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered (which shall include such other similar terms as determined by the Secretary of Agriculture) or was developed or produced using genetic engineering, including any requirement for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering.

CREDIT(S)

(Aug. 14, 1946, c. 966, Title II, § 295, as added Pub.L. 114-216, § 1, July 29, 2016, 130 Stat. 838.)

Notes of Decisions (3)

7 U.S.C.A. § 1639i, 7 USCA § 1639i

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

 $\ensuremath{\mathbb{C}}$ 2023 Thomson Reuters. No claim to original U.S. Government Works.

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 94. Organic Certification (Refs & Annos)

7 U.S.C.A. § 6511

§ 6511. Additional guidelines

Effective: February 7, 2014

Currentness

(a) In general

The Secretary, the applicable governing State official, and the certifying agent shall utilize a system of residue testing to test products sold or labeled as organically produced under this chapter to assist in the enforcement of this chapter.

(b) Preharvest testing

The Secretary, the applicable governing State official, or the certifying agent may require preharvest tissue testing of any crop grown on soil suspected of harboring contaminants.

(c) Compliance review

(1) Inspection

If the Secretary, the applicable governing State official, or the certifying agent determines that an agricultural product sold or labeled as organically produced under this chapter contains any detectable pesticide or other non-organic residue or prohibited natural substance the Secretary, the applicable governing State official, or the certifying agent shall conduct an investigation to determine if the organic certification program has been violated, and may require the producer or handler of such product to prove that any prohibited substance was not applied to such product.

(2) Removal of organic label

If, as determined by the Secretary, the applicable governing State official, or the certifying agent, the investigation conducted under paragraph (1) indicates that the residue is--

- (A) the result of intentional application of a prohibited substance; or
- **(B)** present at levels that are greater than unavoidable residual environmental contamination as prescribed by the Secretary or the applicable governing State official in consultation with the appropriate environmental regulatory agencies;

such agricultural product shall not be sold or labeled as organically produced under this chapter.

A14

CREDIT(S)

(Pub.L. 101-624, Title XXI, § 2112, Nov. 28, 1990, 104 Stat. 3942; Pub.L. 102-237, Title X, § 1001(4), Dec. 13, 1991, 105 Stat. 1893; Pub.L. 113-79, Title X, § 10005(a), Feb. 7, 2014, 128 Stat. 944.)

7 U.S.C.A. § 6511, 7 USCA § 6511

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 94. Organic Certification (Refs & Annos)

7 U.S.C.A. § 6519

§ 6519. Recordkeeping, investigations, and enforcement

Effective: December 20, 2018
Currentness

(a) Recordkeeping

(1) In general

Except as otherwise provided in this chapter, each person who sells, labels, or represents any agricultural product as having been produced or handled using organic methods shall make available to the Secretary or the applicable governing State official, on request by the Secretary or official, all records associated with the agricultural product.

(2) Certified operations

Each producer that operates a certified organic farm or certified organic handling operation under this chapter shall maintain, for a period of not less than 5 years, all records concerning the production or handling of any agricultural product sold or labeled as organically produced under this chapter, including--

- (A) a detailed history of substances applied to fields or agricultural products;
- (B) the name and address of each person who applied such a substance; and
- **(C)** the date, rate, and method of application of each such substance.

(3) Certifying agents

(A) Maintenance of records

A certifying agent shall maintain all records concerning the activities of the certifying agent under this chapter for a period of not less than 10 years.

(B) Access for Secretary

A certifying agent shall provide to the Secretary and the applicable governing State official (or a representative) access to all records concerning the activities of the certifying agent under this chapter.

(C) Transference of records

If a private person that was certified under this chapter is dissolved or loses accreditation, all records and copies of records concerning the activities of the person under this chapter shall be--

- (i) transferred to the Secretary; and
- (ii) made available to the applicable governing State official.

(4) Unlawful act

It shall be unlawful and a violation of this chapter for any person covered by this chapter to fail or refuse to provide accurate information (including a delay in the timely delivery of such information) required by the Secretary under this chapter.

(5) Confidentiality

Except as provided in section 6506(a)(9) of this title, or as otherwise directed by the Secretary or the Attorney General for enforcement purposes, no officer, employee, or agent of the United States shall make available to the public any information, statistic, or document obtained from, or made available by, any person under this chapter, other than in a manner that ensures that confidentiality is preserved regarding--

- (A) the identity of all relevant persons (including parties to a contract); and
- **(B)** proprietary business information.

(b) Investigations

(1) In general

The Secretary may take such investigative actions as the Secretary considers to be necessary-

- (A) to verify the accuracy of any information reported or made available under this chapter; and
- **(B)** to determine whether a person covered by this chapter has committed a violation of any provision of this chapter, including an order or regulation promulgated by the Secretary pursuant to this chapter.

(2) Specific investigative powers

In carrying out this chapter, the Secretary may
(A) administer oaths and affirmations;
(B) subpoena witnesses;
(C) compel attendance of witnesses;
(D) take evidence; and
(E) require the production of any records required to be maintained under this chapter that are relevant to an investigation.
(3) Information sharing during active investigation
In carrying out this chapter, all parties to an active investigation (including certifying agents, State organic certification programs, and the national organic program) shall share confidential business information with Federal Government officers and employees involved in the investigation as necessary to fully investigate and enforce potential violations of this chapter.
(c) Violations of chapter
(1) Misuse of label
Any person who knowingly sells or labels a product as organic, except in accordance with this chapter, shall be subject to a civil penalty of not more than \$10,000.
(2) False statement
Any person who makes a false statement under this chapter to the Secretary, a governing State official, or a certifying agent shall be punished in accordance with section 1001 of Title 18.
(3) Ineligibility
(A) In general

Except as provided in subparagraph (C), any person that carries out an activity described in subparagraph (B), after notice and an opportunity to be heard, shall not be eligible, for the 5-year period beginning on the date of the occurrence, to receive a certification under this chapter with respect to any farm or handling operation in which the person has an interest.

(B) Description of activities

An activity referred to in subparagraph (A) is--

- (i) making a false statement;
- (ii) attempting to have a label indicating that an agricultural product is organically produced affixed to an agricultural product that a person knows, or should have reason to know, to have been produced or handled in a manner that is not in accordance with this chapter; or
- (iii) otherwise violating the purposes of the applicable organic certification program, as determined by the Secretary.

(C) Waiver

Notwithstanding subparagraph (A), the Secretary may modify or waive a period of ineligibility under this paragraph if the Secretary determines that the modification or waiver is in the best interests of the applicable organic certification program established under this chapter.

(4) Reporting of violations

A certifying agent shall immediately report any violation of this chapter to the Secretary or the applicable governing State official.

(5) Violations by certifying agent

A certifying agent that is a private person that violates the provisions of this chapter or falsely or negligently certifies any farming or handling operation that does not meet the terms and conditions of the applicable organic certification program as an organic operation, as determined by the Secretary or the applicable governing State official shall, after notice and an opportunity to be heard--

- (A) lose accreditation as a certifying agent under this chapter; and
- **(B)** be ineligible to be accredited as a certifying agent under this chapter for a period of not less than 3 years, beginning on the date of the determination.

(6) Effect on other law

Nothing in this chapter alters--

- (A) the authority of the Secretary concerning meat, poultry and egg products under--
 - (i) the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);
 - (ii) the Poultry Products Inspection Act (21 U.S.C. 451 et seq.); or

A19

- (iii) the Egg Products Inspection Act (21 U.S.C. 1031 et seq.);
- **(B)** the authority of the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or
- (C) the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

CREDIT(S)

(Pub.L. 101-624, Title XXI, § 2120, Nov. 28, 1990, 104 Stat. 3949; Pub.L. 102-237, Title X, § 1001(8), Dec. 13, 1991, 105 Stat. 1893; Pub.L. 113-79, Title X, § 10005(c), Feb. 7, 2014, 128 Stat. 944; Pub.L. 115-334, Title X, § 10104(g), Dec. 20, 2018, 132 Stat. 4901.)

Notes of Decisions (2)

7 U.S.C.A. § 6519, 7 USCA § 6519

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 94. Organic Certification (Refs & Annos)

7 U.S.C.A. § 6524

§ 6524. Organically produced food

Effective: July 29, 2016 Currentness

In the case of a food certified under the national organic program established under the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.), the certification shall be considered sufficient to make a claim regarding the absence of bioengineering in the food, such as "not bioengineered", "non-GMO", or another similar claim.

CREDIT(S)

(Pub.L. 114-216, § 2, July 29, 2016, 130 Stat. 838.)

7 U.S.C.A. § 6524, 7 USCA § 6524

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document



KeyCite Yellow Flag - Negative Treatment

Proposed Legislation

United States Code Annotated

Title 28. Judiciary and Judicial Procedure (Refs & Annos)
Part IV. Jurisdiction and Venue (Refs & Annos)
Chapter 83. Courts of Appeals (Refs & Annos)

28 U.S.C.A. § 1291

§ 1291. Final decisions of district courts

Currentness

The courts of appeals (other than the United States Court of Appeals for the Federal Circuit) shall have jurisdiction of appeals from all final decisions of the district courts of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, and the District Court of the Virgin Islands, except where a direct review may be had in the Supreme Court. The jurisdiction of the United States Court of Appeals for the Federal Circuit shall be limited to the jurisdiction described in sections 1292(c) and (d) and 1295 of this title.

CREDIT(S)

(June 25, 1948, c. 646, 62 Stat. 929; Oct. 31, 1951, c. 655, § 48, 65 Stat. 726; Pub.L. 85-508, § 12(e), July 7, 1958, 72 Stat. 348; Pub.L. 97-164, Title I, § 124, Apr. 2, 1982, 96 Stat. 36.)

Notes of Decisions (3592)

28 U.S.C.A. § 1291, 28 USCA § 1291

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated

Title 28. Judiciary and Judicial Procedure (Refs & Annos)

Part IV. Jurisdiction and Venue (Refs & Annos)

Chapter 85. District Courts; Jurisdiction (Refs & Annos)

28 U.S.C.A. § 1331

§ 1331. Federal question

Currentness

The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.

CREDIT(S)

(June 25, 1948, c. 646, 62 Stat. 930; Pub.L. 85-554, § 1, July 25, 1958, 72 Stat. 415; Pub.L. 94-574, § 2, Oct. 21, 1976, 90 Stat. 2721; Pub.L. 96-486, § 2(a), Dec. 1, 1980, 94 Stat. 2369.)

Notes of Decisions (3247)

28 U.S.C.A. § 1331, 28 USCA § 1331

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

KeyCite Yellow Flag - Negative Treatment

Unconstitutional or PreemptedLimitation Recognized by United States v. Jonas, 5th Cir. (Tex.), Aug. 14, 2020

KeyCite Yellow Flag - Negative TreatmentProposed Legislation

United States Code Annotated

Title 28. Judiciary and Judicial Procedure (Refs & Annos) Part IV. Jurisdiction and Venue (Refs & Annos)

Chapter 85. District Courts; Jurisdiction (Refs & Annos)

28 U.S.C.A. § 1346

§ 1346. United States as defendant

Effective: March 7, 2013 Currentness

- (a) The district courts shall have original jurisdiction, concurrent with the United States Court of Federal Claims, of:
 - (1) Any civil action against the United States for the recovery of any internal-revenue tax alleged to have been erroneously or illegally assessed or collected, or any penalty claimed to have been collected without authority or any sum alleged to have been excessive or in any manner wrongfully collected under the internal-revenue laws;
 - (2) Any other civil action or claim against the United States, not exceeding \$10,000 in amount, founded either upon the Constitution, or any Act of Congress, or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort, except that the district courts shall not have jurisdiction of any civil action or claim against the United States founded upon any express or implied contract with the United States or for liquidated or unliquidated damages in cases not sounding in tort which are subject to sections 7104(b)(1) and 7107(a)(1) of title 41. For the purpose of this paragraph, an express or implied contract with the Army and Air Force Exchange Service, Navy Exchanges, Marine Corps Exchanges, Coast Guard Exchanges, or Exchange Councils of the National Aeronautics and Space Administration shall be considered an express or implied contract with the United States.
- (b)(1) Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone and the District Court of the Virgin Islands, shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.
- (2) No person convicted of a felony who is incarcerated while awaiting sentencing or while serving a sentence may bring a civil action against the United States or an agency, officer, or employee of the Government, for mental or emotional injury suffered while in custody without a prior showing of physical injury or the commission of a sexual act (as defined in section 2246 of title 18).

- (c) The jurisdiction conferred by this section includes jurisdiction of any set-off, counterclaim, or other claim or demand whatever on the part of the United States against any plaintiff commencing an action under this section.
- (d) The district courts shall not have jurisdiction under this section of any civil action or claim for a pension.
- (e) The district courts shall have original jurisdiction of any civil action against the United States provided in section 6226, 6228(a), 7426, or 7428 (in the case of the United States district court for the District of Columbia) or section 7429 of the Internal Revenue Code of 1986.
- **(f)** The district courts shall have exclusive original jurisdiction of civil actions under section 2409a to quiet title to an estate or interest in real property in which an interest is claimed by the United States.
- (g) Subject to the provisions of chapter 179, the district courts of the United States shall have exclusive jurisdiction over any civil action commenced under section 453(2) of title 3, by a covered employee under chapter 5 of such title.

CREDIT(S)

(June 25, 1948, c. 646, 62 Stat. 933; Apr. 25, 1949, c. 92, § 2(a), 63 Stat. 62; May 24, 1949, c. 139, § 80(a), (b), 63 Stat. 101; Oct. 31, 1951, c. 655, § 50(b), 65 Stat. 727; July 30, 1954, c. 648, § 1, 68 Stat. 589; Pub.L. 85-508, § 12(e), July 7, 1958, 72 Stat. 348; Pub.L. 88-519, Aug. 30, 1964, 78 Stat. 699; Pub.L. 89-719, Title II, § 202(a), Nov. 2, 1966, 80 Stat. 1148; Pub.L. 91-350, § 1(a), July 23, 1970, 84 Stat. 449; Pub.L. 92-562, § 1, Oct. 25, 1972, 86 Stat. 1176; Pub.L. 94-455, Title XII, § 1204(c)(1), Title XIII, § 1306(b)(7), Oct. 4, 1976, 90 Stat. 1697, 1719; Pub.L. 95-563, § 14(a), Nov. 1, 1978, 92 Stat. 2389; Pub.L. 97-164, Title I, § 129, Apr. 2, 1982, 96 Stat. 39; Pub.L. 97-248, Title IV, § 402(c)(17), Sept. 3, 1982, 96 Stat. 669; Pub.L. 99-514, § 2, Oct. 22, 1986, 100 Stat. 2095; Pub.L. 102-572, Title IX, § 902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub.L. 104-134, Title I, § 101[(a)][Title VIII, § 806], Apr. 26, 1996, 110 Stat. 1321, 1321-75; renumbered Title I, Pub.L. 104-140, § 1(a), May 2, 1996, 110 Stat. 1327; amended Pub.L. 104-331, § 3(b)(1), Oct. 26, 1996, 110 Stat. 4069; Pub.L. 111-350, § 5(g)(6), Jan. 4, 2011, 124 Stat. 3848; Pub.L. 113-4, Title XI, § 1101(b), Mar. 7, 2013, 127 Stat. 134.)

Notes of Decisions (4200)

28 U.S.C.A. § 1346, 28 USCA § 1346

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 28. Judiciary and Judicial Procedure (Refs & Annos)
Part V. Procedure
Chapter 133. Review--Miscellaneous Provisions

28 U.S.C.A. § 2107

§ 2107. Time for appeal to court of appeals

Effective: December 1, 2011
Currentness

- (a) Except as otherwise provided in this section, no appeal shall bring any judgment, order or decree in an action, suit or proceeding of a civil nature before a court of appeals for review unless notice of appeal is filed, within thirty days after the entry of such judgment, order or decree.
- (b) In any such action, suit, or proceeding, the time as to all parties shall be 60 days from such entry if one of the parties is-
 - (1) the United States;
 - (2) a United States agency;
 - (3) a United States officer or employee sued in an official capacity; or
 - (4) a current or former United States officer or employee sued in an individual capacity for an act or omission occurring in connection with duties performed on behalf of the United States, including all instances in which the United States represents that officer or employee when the judgment, order, or decree is entered or files the appeal for that officer or employee.
- (c) The district court may, upon motion filed not later than 30 days after the expiration of the time otherwise set for bringing appeal, extend the time for appeal upon a showing of excusable neglect or good cause. In addition, if the district court finds-
 - (1) that a party entitled to notice of the entry of a judgment or order did not receive such notice from the clerk or any party within 21 days of its entry, and
 - (2) that no party would be prejudiced,

the district court may, upon motion filed within 180 days after entry of the judgment or order or within 14 days after receipt of such notice, whichever is earlier, reopen the time for appeal for a period of 14 days from the date of entry of the order reopening the time for appeal.

(d) This section shall not apply to bankruptcy matters or other proceedings under Title 11.

CREDIT(S)

(June 25, 1948, c. 646, 62 Stat. 963; May 24, 1949, c. 139, §§ 107, 108, 63 Stat. 104; Pub.L. 95-598, Title II, § 248, Nov. 6, 1978, 92 Stat. 2672; Pub.L. 102-198, § 12, Dec. 9, 1991, 105 Stat. 1627; Pub.L. 111-16, § 6(3), May 7, 2009, 123 Stat. 1608; Pub.L. 112-62, § 3, Nov. 29, 2011, 125 Stat. 757.)

Notes of Decisions (219)

28 U.S.C.A. § 2107, 28 USCA § 2107

Current through P.L.118-13. Some statute sections may be more current, see credits for details.

End of Document

Code of Federal Regulations

Title 7. Agriculture

Subtitle B. Regulations of the Department of Agriculture

Chapter I. Agricultural Marketing Service (Standards, Inspections, Marketing Practices)

Subchapter C. Requirements and Standards Under the Agricultural Marketing Act of 1946 and the Egg Products Inspection Act (Refs & Annos)

Part 66. National Bioengineered Food Disclosure Standard (Refs & Annos)

Subpart A. General Provisions

7 C.F.R. § 66.1

§ 66.1 Definitions.

Effective: February 19, 2019
Currentness

Act means the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.), as amended to include Subtitle E—National Bioengineered Food Disclosure Standard and Subtitle F—Labeling of Certain Food.

Administrator means the Administrator of the Agricultural Marketing Service, United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

AMS means the Agricultural Marketing Service of the United States Department of Agriculture.

Bioengineered food means—

- (1) Subject to the factors, conditions, and limitations in paragraph (2) of this definition:
- (i) A food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature; provided that
- (ii) Such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9.
- (2) A food that meets one of the following factors and conditions is not a bioengineered food.
- (i) An incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food, as described in 21 CFR 101.100(a)(3).
- (ii) [Reserved]

Bioengineered substance means substance that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

Compliance date means—

- (1) Mandatory compliance date. Entities responsible for bioengineered food disclosure must comply with the requirements of this part by January 1, 2022.
- (2) Updates to the List of Bioengineered Foods. When AMS updates the List of Bioengineered Foods pursuant to § 66.7, entities responsible for bioengineered food disclosures must comply with the updates no later than 18 months after the effective date of the update.

Food means a food (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that is intended for human consumption.

Food manufacturer means an entity that manufactures, processes, or packs human food and labels the food or food product for U.S. retail sale.

Importer means the importer of record, as determined by U.S. Customs and Border Protection (19 U.S.C. 1484(a)(2)(B)), who engages in the importation of food or food products labeled for retail sale into the United States.

Information panel means that part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g. irregular shape with one usable surface).

Label means a display of written, printed, or graphic matter upon the immediate container or outside wrapper of any retail package or article that is easily legible on or through the outside container or wrapper.

Labeling means all labels and other written, printed, or graphic matter:

- (1) Upon any article or any of its containers or wrappers; or
- (2) Accompanying such article.

List of Bioengineered Foods means a list, maintained and updated by AMS and provided in § 66.6, of foods for which bioengineered versions have been developed.

Marketing and promotional information means any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs that are distributed, broadcast, or made available to assist in the sale or promotion of a product.

Predominance means an ingredient's position in the ingredient list on a product's label. Predominant ingredients are those most abundant by weight in the product, as required under 21 CFR 101.4(a)(1).

Principal display panel means that part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

Processed food means any food other than a raw agricultural commodity, and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

Raw agricultural commodity means any agricultural commodity in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

Case: 22-16770, 09/05/2023, ID: 12786932, DktEntry: 18, Page 103 of 144

Regulated entity means the food manufacturer, importer, or retailer that is responsible for making bioengineered food disclosures under § 66.100(a).

Secretary means the United States Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

Similar retail food establishment means a cafeteria, lunch room, food stand, food truck, transportation carrier (such as a train or airplane), saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises.

Small food manufacturer means any food manufacturer with annual receipts of at least \$2,500,000, but less than \$10,000,000.

Small package means food packages that have a total surface area of less than 40 square inches.

Very small food manufacturer means any food manufacturer with annual receipts of less than \$2,500,000.

Very small package means food packages that have a total surface area of less than 12 square inches.

SOURCE: 83 FR 65871, Dec. 21, 2018; 85 FR 19379, April 7, 2020, unless otherwise noted.

AUTHORITY: 7 U.S.C. 1621 et seq.

Notes of Decisions (1)

Current through Aug. 28, 2023, 88 FR 59438. Some sections may be more current. See credits for details.

Footnotes

Includes matters within the responsibility of the Federal Grain Inspection Service.

End of Document

Code of Federal Regulations

Title 7. Agriculture

Subtitle B. Regulations of the Department of Agriculture

Chapter I. Agricultural Marketing Service (Standards, Inspections, Marketing Practices)

Subchapter C. Requirements and Standards Under the Agricultural Marketing Act of 1946 and the Egg Products Inspection Act (Refs & Annos)

Part 66. National Bioengineered Food Disclosure Standard (Refs & Annos)

Subpart A. General Provisions

7 C.F.R. § 66.5

§ 66.5 Exemptions.

Effective: February 19, 2019
Currentness

This part shall not apply to the food and entities described in this section.

- (a) Food served in a restaurant or similar retail food establishment.
- (b) Very small food manufacturers.
- (c) A food in which no ingredient intentionally contains a bioengineered (BE) substance, with an allowance for inadvertent or technically unavoidable BE presence of up to five percent (5%) for each ingredient.
- (d) A food derived from an animal shall not be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance.
- (e) Food certified under the National Organic Program.

SOURCE: 83 FR 65871, Dec. 21, 2018; 85 FR 19379, April 7, 2020, unless otherwise noted.

AUTHORITY: 7 U.S.C. 1621 et seq.

Current through Aug. 28, 2023, 88 FR 59438. Some sections may be more current. See credits for details.

Footnotes

Includes matters within the responsibility of the Federal Grain Inspection Service.

End of Document

Code of Federal Regulations

Title 7. Agriculture

Subtitle B. Regulations of the Department of Agriculture

Chapter I. Agricultural Marketing Service (Standards, Inspections, Marketing Practices)

Subchapter C. Requirements and Standards Under the Agricultural Marketing Act of 1946 and the Egg Products Inspection Act (Refs & Annos)

Part 66. National Bioengineered Food Disclosure Standard (Refs & Annos)

Subpart A. General Provisions

7 C.F.R. § 66.9

§ 66.9 Detectability.

Effective: February 19, 2019
Currentness

- (a) Recordkeeping requirements. Modified genetic material is not detectable if, pursuant to the recordkeeping requirements of § 66.302, the entity responsible for making a BE food disclosure maintains:
 - (1) Records to verify that the food is sourced from a non-bioengineered crop or source; or
 - (2) Records to verify that the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable; or
 - (3) Certificates of analysis or other records of testing appropriate to the specific food that confirm the absence of modified genetic material.
- (b) Validated refining process.
 - (1) Analytical testing that meets the standards described in paragraph (c) of this section must be used to validate that a refining process renders modified genetic material in a food undetectable.
 - (2) Once a refining process has been so validated, additional testing is not necessary to confirm the absence of detectable modified genetic material in food subsequently refined through that process, provided that no significant changes are made to the validated process and provided that records are maintained to demonstrate that the refining process has been validated and that the validated refining process is followed.
- (c) Standards of performance for detectability testing. Analytical testing for purposes of detecting the presence of modified genetic material in refined foods pursuant to paragraph (a) of this section shall meet the following standard:
 - (1) Laboratory quality assurance must ensure the validity and reliability of test results;

A32

- (2) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;
- (3) The demonstration of testing validity must ensure consistent accurate analytical performance; and
- (4) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

SOURCE: 83 FR 65871, Dec. 21, 2018; 85 FR 19379, April 7, 2020, unless otherwise noted.

AUTHORITY: 7 U.S.C. 1621 et seq.

Current through Aug. 28, 2023, 88 FR 59438. Some sections may be more current. See credits for details.

Footnotes

Includes matters within the responsibility of the Federal Grain Inspection Service.

End of Document

KeyCite Red Flag - Severe Negative Treatment

Unconstitutional or PreemptedHeld Invalid Natural Grocers v. Vilsack, N.D.Cal., Sep. 13, 2022

Code of Federal Regulations

Title 7. Agriculture

Subtitle B. Regulations of the Department of Agriculture

Chapter I. Agricultural Marketing Service (Standards, Inspections, Marketing Practices)

Subchapter C. Requirements and Standards Under the Agricultural Marketing Act of 1946 and the Egg Products Inspection Act (Refs & Annos)

Part 66. National Bioengineered Food Disclosure Standard (Refs & Annos)

Subpart B. Bioengineered Food Disclosure

7 C.F.R. § 66.100

§ 66.100 General.

Effective: February 19, 2019
Currentness

- (a) Responsibility for disclosure.
 - (1) For a food that is packaged prior to receipt by a retailer, the food manufacturer or importer is responsible for ensuring that the food label bears a bioengineered food disclosure in accordance with this part.
 - (2) If a retailer packages a food or sells a food in bulk, that retailer is responsible for ensuring that the food bears a bioengineered food disclosure in accordance with this part.
- (b) Type of disclosure. If a food must bear a bioengineered food disclosure under this part, the disclosure must be in one of the forms described in this paragraph (b), except as provided in §§ 66.110 and 66.112.
 - (1) A text disclosure in accordance with § 66.102.
 - (2) A symbol disclosure in accordance with § 66.104.
 - (3) An electronic or digital link disclosure in accordance with § 66.106.
 - (4) A text message disclosure in accordance with § 66.108.
- (c) Appearance of disclosure. The required disclosure must be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the consumer under ordinary shopping conditions.

- (d) Placement of the disclosure. Except as provided in § 66.114 for bulk food, the disclosure must be placed on the label in one of the manners described in this paragraph (d).
 - (1) The disclosure is placed in the information panel directly adjacent to the statement identifying the name and location of the handler, distributor, packer, manufacturer, importer, or any statement disclosing similar information.
 - (2) The disclosure is placed in the principal display panel.
 - (3) The disclosure is placed in an alternate panel likely to be seen by a consumer under ordinary shopping conditions if there is insufficient space to place the disclosure on the information panel or the principal display panel.
- (e) Uniform Resource Locator (URL). Except for disclosures made by small manufacturers and for disclosures on very small packages, a bioengineered food disclosure may not include an internet website URL that is not embedded in an electronic or digital link.

SOURCE: 83 FR 65871, Dec. 21, 2018; 85 FR 19379, April 7, 2020, unless otherwise noted.

AUTHORITY: 7 U.S.C. 1621 et seq.

Notes of Decisions (6)

Current through Aug. 28, 2023, 88 FR 59438. Some sections may be more current. See credits for details.

Footnotes

Includes matters within the responsibility of the Federal Grain Inspection Service.

End of Document

Code of Federal Regulations

Title 7. Agriculture

Subtitle B. Regulations of the Department of Agriculture

Chapter I. Agricultural Marketing Service (Standards, Inspections, Marketing Practices)

Subchapter C. Requirements and Standards Under the Agricultural Marketing Act of 1946 and the Egg Products Inspection Act (Refs & Annos)

Part 66. National Bioengineered Food Disclosure Standard (Refs & Annos)

Subpart B. Bioengineered Food Disclosure

7 C.F.R. § 66.102

§ 66.102 Text disclosure.

Effective: February 19, 2019
Currentness

A text disclosure must bear the text as described in this section. A text disclosure may use a plural form if applicable, e.g. if a food product includes more than one bioengineered food, then "bioengineered foods" or "bioengineered food ingredients" may be used.

- (a) Bioengineered foods. If a food (including any ingredient produced from such food) is on the List of Bioengineered Foods, and records maintained by a regulated entity demonstrate that the food is bioengineered, the text disclosure must be one of the following, as applicable:
 - (1) "Bioengineered food" for bioengineered food that is a raw agricultural commodity or processed food that contains only bioengineered food ingredients; or
 - (2) "Contains a bioengineered food ingredient" for multi-ingredient food that is not described in paragraph (a)(1) of this section but contains one or more bioengineered food ingredients.
- (b) Predominant language in U.S. Food subject to disclosure that is distributed solely in a U.S. territory may be labeled with statements equivalent to those required in this part, using the predominant language used in that territory.

SOURCE: 83 FR 65871, Dec. 21, 2018; 85 FR 19379, April 7, 2020, unless otherwise noted.

AUTHORITY: 7 U.S.C. 1621 et seq.

Current through Aug. 28, 2023, 88 FR 59438. Some sections may be more current. See credits for details.

Footnotes

A36

Includes matters within the responsibility of the Federal Grain Inspection Service.

End of Document

© 2023 Thomson Reuters. No claim to original U.S. Government Works.

KeyCite Yellow Flag - Negative Treatment

Unconstitutional or Preempted Validity Called into Doubt by Natural Grocers v. Vilsack, N.D.Cal., Sep. 13, 2022

Code of Federal Regulations

Title 7. Agriculture

Subtitle B. Regulations of the Department of Agriculture

Chapter I. Agricultural Marketing Service (Standards, Inspections, Marketing Practices)

Subchapter C. Requirements and Standards Under the Agricultural Marketing Act of 1946 and the Egg Products Inspection Act (Refs & Annos)

Part 66. National Bioengineered Food Disclosure Standard (Refs & Annos)

Subpart B. Bioengineered Food Disclosure

7 C.F.R. § 66.106

§ 66.106 Electronic or digital link disclosure.

Effective: February 19, 2019
Currentness

<For statutory provision affecting validity of the text message disclosure option, see: 7 USCA § 1639b(c)(4).>

If a required bioengineered food disclosure is made through an electronic or digital link printed on the label, the disclosure must comply with the requirements described in this section.

- (a) Accompanying statement.
 - (1) An electronic or digital disclosure must be accompanied by, and be placed directly above or below, this statement: "Scan here for more food information" or equivalent language that only reflects technological changes (e.g., "Scan anywhere on package for more food information" or "Scan icon for more food information").
 - (2) The electronic or digital disclosure must also be accompanied by a telephone number that will provide the bioengineered food disclosure to the consumer, regardless of the time of day. The telephone number instructions must be in close proximity to the digital link and the accompanying statement described in paragraph (a)(1) of this section, must indicate that calling the telephone number will provide more food information, and must be accompanied by the statement "Call [1–000–000–0000] for more food information."
- (b) Product information page. When the electronic or digital link is accessed, the link must go directly to the product information page for display on the electronic or digital device. The product information page must comply with the requirements described in this paragraph (b).
 - (1) The product information page must be the first screen to appear on an electronic or digital device after the link is accessed as directed.

- (2) The product information page must include a bioengineered food disclosure that is consistent with § 66.102 or § 66.104.
- (3) The product information page must exclude marketing and promotional information.
- (4) The electronic or digital link disclosure may not collect, analyze, or sell any personally identifiable information about consumers or the devices of consumers; however, if this information must be collected to carry out the purposes of this part, the information must be deleted immediately and not used for any other purpose.

SOURCE: 83 FR 65871, Dec. 21, 2018; 85 FR 19379, April 7, 2020, unless otherwise noted.

AUTHORITY: 7 U.S.C. 1621 et seq.

Current through Aug. 28, 2023, 88 FR 59438. Some sections may be more current. See credits for details.

Footnotes

Includes matters within the responsibility of the Federal Grain Inspection Service.

End of Document

© 2023 Thomson Reuters. No claim to original U.S. Government Works.

KeyCite Red Flag - Severe Negative Treatment

Unconstitutional or PreemptedHeld Invalid Natural Grocers v. Vilsack, N.D.Cal., Sep. 13, 2022

Code of Federal Regulations

Title 7. Agriculture

Subtitle B. Regulations of the Department of Agriculture

Chapter I. Agricultural Marketing Service (Standards, Inspections, Marketing Practices)

Subchapter C. Requirements and Standards Under the Agricultural Marketing Act of 1946 and the Egg Products Inspection Act (Refs & Annos)

Part 66. National Bioengineered Food Disclosure Standard (Refs & Annos)

Subpart B. Bioengineered Food Disclosure

7 C.F.R. § 66.108

§ 66.108 Text message disclosure.

Effective: February 19, 2019
Currentness

<For statutory provision affecting validity of the text message disclosure option, see: 7 USCA § 1639b(c)(4).>

The regulated entity must not charge a person any fee to access the bioengineered food information through text message and must comply with the requirements described in this section.

- (a) The label must include this statement "Text [command word] to [number] for bioengineered food information." The number must be a number, including a short code, that sends an immediate response to the consumer's mobile device.
- (b) The response must be a one-time response and the only information in the response must be the appropriate bioengineered food disclosure described in § 66.102 or § 66.116.
- (c) The response must exclude marketing and promotional information.
- (d) A regulated entity that selects the text message option must comply with the requirements of this paragraph (d).
 - (1) The regulated entity must not collect, analyze, or sell any personally identifiable information about consumers or the devices of consumers.
 - (2) The regulated entity must not use any information related to the text message option for any marketing purposes.
 - (3) If any information must be collected to carry out the purposes of this part, the information must be deleted as soon as possible and not be used for any other purpose.

SOURCE: 83 FR 65871, Dec. 21, 2018; 85 FR 19379, April 7, 2020, unless otherwise noted.

AUTHORITY: 7 U.S.C. 1621 et seq.

Current through Aug. 28, 2023, 88 FR 59438. Some sections may be more current. See credits for details.

Footnotes

Includes matters within the responsibility of the Federal Grain Inspection Service.

End of Document

© 2023 Thomson Reuters. No claim to original U.S. Government Works.

Code of Federal Regulations

Title 7. Agriculture

Subtitle B. Regulations of the Department of Agriculture

Chapter I. Agricultural Marketing Service (Standards, Inspections, Marketing Practices)

Subchapter C. Requirements and Standards Under the Agricultural Marketing Act of 1946 and the Egg Products Inspection Act (Refs & Annos)

Part 66. National Bioengineered Food Disclosure Standard (Refs & Annos)

Subpart B. Bioengineered Food Disclosure

7 C.F.R. § 66.116

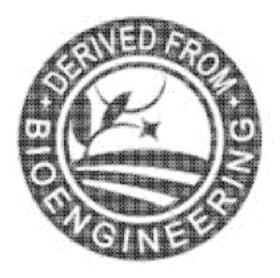
§ 66.116 Voluntary disclosure.

Effective: February 19, 2019
Currentness

- (a) Disclosure of bioengineered food by exempt entities. If a food on the List of Bioengineered Foods is subject to disclosure, a very small food manufacturer, restaurant, or similar retail food establishment may voluntarily provide that disclosure. The disclosure must be in one or more of the forms described in this paragraph (a).
 - (1) A text disclosure, in accordance with § 66.102.
 - (2) A symbol disclosure, in accordance with § 66.104.
 - (3) An electronic or digital link disclosure, in accordance with § 66.106.
 - (4) A text message disclosure, in accordance with § 66.108.
 - (5) Appropriate small manufacturer and small and very small package disclosure options, in accordance with §§ 66.110 and 66.112.
- (b) Disclosure of foods derived from bioengineering. For foods or food ingredients that do not meet paragraph (1) of the definition of bioengineered food in § 66.1, that do not qualify as a factor or condition under paragraph (2) of the definition of bioengineered food in § 66.1, that are not exempt from disclosure under § 66.5, and that are derived from a food on the List of Bioengineered Foods, regulated entities may disclose such foods with one of the disclosures described in this paragraph (b).
 - (1) A text disclosure with the following statement: "derived from bioengineering" or "ingredient(s) derived from a bioengineered source." The word "ingredient(s)" may be replaced with the name of the specific crop(s) or food ingredient(s).
 - (2) A symbol disclosure using the following symbol:

A42

Figure 1 to § 66.116



- (3) An electronic or digital link disclosure, in accordance with § 66.106, provided that the disclosure is the text described in paragraph (b)(1) of this section or the symbol in Figure 1 to this section.
- (4) A text message disclosure, in accordance with § 66.108, provided that the response is the text described in paragraph (b)(1) of this section or the symbol in Figure 1 to this section.
- (5) Appropriate small manufacturer and small and very small package disclosure options, in accordance with §§ 66.110 and 66.112, provided that the disclosure is the text described in paragraph (b)(1) of this section or the symbol in Figure 1 to this section.
- (c) Appearance of disclosure. The disclosure should be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the consumer under ordinary shopping conditions.
- (d) Recordkeeping. Reasonable and customary records should be maintained to verify disclosures made under this section, in accordance with § 66.302.

SOURCE: 83 FR 65871, Dec. 21, 2018; 85 FR 19379, April 7, 2020, unless otherwise noted.

AUTHORITY: 7 U.S.C. 1621 et seq.

Current through Aug. 28, 2023, 88 FR 59438. Some sections may be more current. See credits for details.

Footnotes

Includes matters within the responsibility of the Federal Grain Inspection Service.

End of Document

© 2023 Thomson Reuters. No claim to original U.S. Government Works.

Code of Federal Regulations

Title 7. Agriculture

Subtitle B. Regulations of the Department of Agriculture

Chapter III. Animal and Plant Health Inspection Service, Department of Agriculture

Part 340. Movement of Organisms Modified or Produced Through Genetic Engineering (Refs & Annos)

7 C.F.R. § 340.1

§ 340.1 Applicability of this part.

Effective: August 17, 2020 Currentness

- (a) The regulations in this part apply to those organisms described in § 340.2, but not to any organism that is exempt from this part under paragraph (b), (c), or (d) of this section.
- (b) The regulations in this part do not apply to plants that have been modified such that they contain either a single modification of a type listed in paragraphs (b)(1) through (3) of this section, or additional modifications as determined by the Administrator, and described in paragraph (b)(4) of this section.
 - (1) The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or
 - (2) The genetic modification is a targeted single base pair substitution; or
 - (3) The genetic modification introduces a gene known to occur in the plant's gene pool, or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.
 - (4) The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be Agency-initiated, and follow the process in paragraph (b)(4)(i) of this section, or in response to a request made in accordance with paragraph (b)(4)(ii) of this section.
 - (i) APHIS—initiated proposals for exemptions. APHIS will publish a notice in the Federal Register of the proposal by the Administrator to exempt plants with additional modifications. The notice will make available any supporting documentation, and will request public comment. After reviewing the comments, APHIS will publish a subsequent notice in the Federal Register announcing its final determination.
 - (ii) Other parties' requests for exemptions. Any person may request that the Administrator exempt plants developed with additional modifications that could be achieved through conventional breeding. To submit a request, the person must provide, in writing, information supporting the modification(s). Supporting information must include the following:

- (A) A description of the modification(s);
- (B) The factual grounds demonstrating that the proposed modification(s) could be achieved through conventional plant breeding;
- (C) Copies of scientific literature, unpublished studies, or other data that support the request; and
- (D) Any information known to the requestor that would be unfavorable to the request.
- (iii) Timeframe for Agency review of requests for additional exemptions. After APHIS receives all information required under paragraph (b)(4)(ii) of this section, APHIS will complete its review of the request and render a determination within 12 months, except in circumstances that could not reasonably have been anticipated.
- (iv) Denial of requests. If APHIS disagrees with the conclusions of the request or determines that there is insufficient evidence that the modification could be achieved through conventional breeding methods, APHIS will deny the request and notify the requestor in writing regarding this denial.
- (v) Agreement with requests. If APHIS initially determines that the modification could be achieved through conventional breeding methods, APHIS will publish a notice in the Federal Register and request public comments in accordance with the process set forth in paragraph (b)(4)(i) of this section. After reviewing the comments, APHIS will publish a subsequent notice in the Federal Register announcing its final determination.
- (vi) website posting. A list specifying the additional modifications will be posted on the APHIS website at https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.
- (c) The regulations in this part do not apply to a plant with:
 - (1) A plant-trait-mechanism of action combination that has previously undergone an analysis by APHIS in accordance with § 340.4 and has been determined by APHIS not to be regulated under this part, or
 - (2) A plant-trait-mechanism of action combination found in a plant that APHIS determined to be deregulated in response to a petition submitted prior to October 1, 2021, pursuant to § 340.6 as that section was set forth prior to August 17, 2020. All plants determined by APHIS to be deregulated pursuant to § 340.6 as that section was set forth prior to August 17, 2020 will retain their nonregulated status under these regulations.
- (d) The regulations in this part do not apply to plants determined by APHIS not to require regulation under this part pursuant to the "Am I Regulated" process. All plants determined by APHIS not to require regulation under this part pursuant to the "Am I Regulated" process will retain their nonregulated status under these regulations.

(e) Developers may request confirmation from APHIS that a plant is not within the scope of this part. APHIS will provide a written response (confirmation letter) within 120 days of receiving a sufficiently detailed confirmation request, except in circumstances that could not reasonably have been anticipated.

(Approved by the Office of Management and Budget under control number 0579–0471)

SOURCE: 85 FR 29832, May 18, 2020, unless otherwise noted.

AUTHORITY: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Current through Aug. 28, 2023, 88 FR 59438. Some sections may be more current. See credits for details.

End of Document

© 2023 Thomson Reuters. No claim to original U.S. Government Works.

United States Code Annotated
Federal Rules of Appellate Procedure (Refs & Annos)
Title II. Appeal from a Judgment or Order of a District Court

Federal Rules of Appellate Procedure Rule 4, 28 U.S.C.A.

Rule 4. Appeal as of Right--When Taken

Currentness

- (a) Appeal in a Civil Case.
 - (1) Time for Filing a Notice of Appeal.
 - (A) In a civil case, except as provided in Rules 4(a)(1)(B), 4(a)(4), and 4(c), the notice of appeal required by Rule 3 must be filed with the district clerk within 30 days after entry of the judgment or order appealed from.
 - **(B)** The notice of appeal may be filed by any party within 60 days after entry of the judgment or order appealed from if one of the parties is:
 - (i) the United States;
 - (ii) a United States agency;
 - (iii) a United States officer or employee sued in an official capacity; or
 - (iv) a current or former United States officer or employee sued in an individual capacity for an act or omission occurring in connection with duties performed on the United States' behalf--including all instances in which the United States represents that person when the judgment or order is entered or files the appeal for that person.
 - **(C)** An appeal from an order granting or denying an application for a writ of error coram nobis is an appeal in a civil case for purposes of Rule 4(a).
 - (2) Filing Before Entry of Judgment. A notice of appeal filed after the court announces a decision or order--but before the entry of the judgment or order--is treated as filed on the date of and after the entry.
 - (3) Multiple Appeals. If one party timely files a notice of appeal, any other party may file a notice of appeal within 14 days after the date when the first notice was filed, or within the time otherwise prescribed by this Rule 4(a), whichever period ends later.

(4) Effect of a Motion on a Notice of Appeal.

- (A) If a party files in the district court any of the following motions under the Federal Rules of Civil Procedure--and does so within the time allowed by those rules--the time to file an appeal runs for all parties from the entry of the order disposing of the last such remaining motion:
 - (i) for judgment under Rule 50(b);
 - (ii) to amend or make additional factual findings under Rule 52(b), whether or not granting the motion would alter the judgment;
 - (iii) for attorney's fees under Rule 54 if the district court extends the time to appeal under Rule 58;
 - (iv) to alter or amend the judgment under Rule 59;
 - (v) for a new trial under Rule 59; or
- <[Text of subsection (a)(4)(A)(vi) effective until December 1, 2023, absent contrary Congressional action.]>
 - (vi) for relief under Rule 60 if the motion is filed no later than 28 days after the judgment is entered.
- <[Text of subsection (a)(4)(A)(vi) effective December 1, 2023, absent contrary Congressional action.]>
 - (vi) for relief under Rule 60 if the motion is filed within the time allowed for filing a motion under Rule 59.
- **(B)(i)** If a party files a notice of appeal after the court announces or enters a judgment--but before it disposes of any motion listed in Rule 4(a)(4)(A)--the notice becomes effective to appeal a judgment or order, in whole or in part, when the order disposing of the last such remaining motion is entered.
- (ii) A party intending to challenge an order disposing of any motion listed in Rule 4(a)(4)(A), or a judgment's alteration or amendment upon such a motion, must file a notice of appeal, or an amended notice of appeal—in compliance with Rule 3(c)—within the time prescribed by this Rule measured from the entry of the order disposing of the last such remaining motion.
- (iii) No additional fee is required to file an amended notice.
- (5) Motion for Extension of Time.
 - (A) The district court may extend the time to file a notice of appeal if:

A49

- (i) a party so moves no later than 30 days after the time prescribed by this Rule 4(a) expires; and
- (ii) regardless of whether its motion is filed before or during the 30 days after the time prescribed by this Rule 4(a) expires, that party shows excusable neglect or good cause.
- **(B)** A motion filed before the expiration of the time prescribed in Rule 4(a)(1) or (3) may be ex parte unless the court requires otherwise. If the motion is filed after the expiration of the prescribed time, notice must be given to the other parties in accordance with local rules.
- (C) No extension under this Rule 4(a)(5) may exceed 30 days after the prescribed time or 14 days after the date when the order granting the motion is entered, whichever is later.
- **(6) Reopening the Time to File an Appeal.** The district court may reopen the time to file an appeal for a period of 14 days after the date when its order to reopen is entered, but only if all the following conditions are satisfied:
 - (A) the court finds that the moving party did not receive notice under Federal Rule of Civil Procedure 77(d) of the entry of the judgment or order sought to be appealed within 21 days after entry;
 - **(B)** the motion is filed within 180 days after the judgment or order is entered or within 14 days after the moving party receives notice under Federal Rule of Civil Procedure 77(d) of the entry, whichever is earlier; and
 - (C) the court finds that no party would be prejudiced.

(7) Entry Defined.

- (A) A judgment or order is entered for purposes of this Rule 4(a):
 - (i) if Federal Rule of Civil Procedure 58(a) does not require a separate document, when the judgment or order is entered in the civil docket under Federal Rule of Civil Procedure 79(a); or
 - (ii) if Federal Rule of Civil Procedure 58(a) requires a separate document, when the judgment or order is entered in the civil docket under Federal Rule of Civil Procedure 79(a) and when the earlier of these events occurs:
 - the judgment or order is set forth on a separate document, or
 - 150 days have run from entry of the judgment or order in the civil docket under Federal Rule of Civil Procedure 79(a).
- **(B)** A failure to set forth a judgment or order on a separate document when required by Federal Rule of Civil Procedure 58(a) does not affect the validity of an appeal from that judgment or order.

(b)	Ap	peal	in	a	Criminal	Case.
------------	----	------	----	---	----------	-------

(1) Time for Filing a Notice of Appeal.

- (A) In a criminal case, a defendant's notice of appeal must be filed in the district court within 14 days after the later of:
 - (i) the entry of either the judgment or the order being appealed; or
 - (ii) the filing of the government's notice of appeal.
- **(B)** When the government is entitled to appeal, its notice of appeal must be filed in the district court within 30 days after the later of:
 - (i) the entry of the judgment or order being appealed; or
 - (ii) the filing of a notice of appeal by any defendant.
- **(2) Filing Before Entry of Judgment.** A notice of appeal filed after the court announces a decision, sentence, or order--but before the entry of the judgment or order--is treated as filed on the date of and after the entry.

(3) Effect of a Motion on a Notice of Appeal.

- (A) If a defendant timely makes any of the following motions under the Federal Rules of Criminal Procedure, the notice of appeal from a judgment of conviction must be filed within 14 days after the entry of the order disposing of the last such remaining motion, or within 14 days after the entry of the judgment of conviction, whichever period ends later. This provision applies to a timely motion:
 - (i) for judgment of acquittal under Rule 29;
 - (ii) for a new trial under Rule 33, but if based on newly discovered evidence, only if the motion is made no later than 14 days after the entry of the judgment; or
 - (iii) for arrest of judgment under Rule 34.
- **(B)** A notice of appeal filed after the court announces a decision, sentence, or order--but before it disposes of any of the motions referred to in Rule 4(b)(3)(A)--becomes effective upon the later of the following:

- (i) the entry of the order disposing of the last such remaining motion; or
- (ii) the entry of the judgment of conviction.
- (C) A valid notice of appeal is effective--without amendment--to appeal from an order disposing of any of the motions referred to in Rule 4(b)(3)(A).
- (4) Motion for Extension of Time. Upon a finding of excusable neglect or good cause, the district court may--before or after the time has expired, with or without motion and notice--extend the time to file a notice of appeal for a period not to exceed 30 days from the expiration of the time otherwise prescribed by this Rule 4(b).
- (5) Jurisdiction. The filing of a notice of appeal under this Rule 4(b) does not divest a district court of jurisdiction to correct a sentence under Federal Rule of Criminal Procedure 35(a), nor does the filing of a motion under 35(a) affect the validity of a notice of appeal filed before entry of the order disposing of the motion. The filing of a motion under Federal Rule of Criminal Procedure 35(a) does not suspend the time for filing a notice of appeal from a judgment of conviction.
- (6) Entry Defined. A judgment or order is entered for purposes of this Rule 4(b) when it is entered on the criminal docket.
- (c) Appeal by an Inmate Confined in an Institution.
 - (1) If an institution has a system designed for legal mail, an inmate confined there must use that system to receive the benefit of this Rule 4(c)(1). If an inmate files a notice of appeal in either a civil or a criminal case, the notice is timely if it is deposited in the institution's internal mail system on or before the last day for filing and:
 - (A) it is accompanied by:
 - (i) a declaration in compliance with 28 U.S.C. § 1746--or a notarized statement--setting out the date of deposit and stating that first-class postage is being prepaid; or
 - (ii) evidence (such as a postmark or date stamp) showing that the notice was so deposited and that postage was prepaid; or
 - **(B)** the court of appeals exercises its discretion to permit the later filing of a declaration or notarized statement that satisfies Rule 4(c)(1)(A)(i).
 - (2) If an inmate files the first notice of appeal in a civil case under this Rule 4(c), the 14-day period provided in Rule 4(a)(3) for another party to file a notice of appeal runs from the date when the district court dockets the first notice.

- (3) When a defendant in a criminal case files a notice of appeal under this Rule 4(c), the 30-day period for the government to file its notice of appeal runs from the entry of the judgment or order appealed from or from the district court's docketing of the defendant's notice of appeal, whichever is later.
- (d) Mistaken Filing in the Court of Appeals. If a notice of appeal in either a civil or a criminal case is mistakenly filed in the court of appeals, the clerk of that court must note on the notice the date when it was received and send it to the district clerk. The notice is then considered filed in the district court on the date so noted.

CREDIT(S)

(As amended Apr. 30, 1979, eff. Aug. 1, 1979; Nov. 18, 1988, Pub.L. 100-690, Title VII, § 7111, 102 Stat. 4419; Apr. 30, 1991, eff. Dec. 1, 1991; Apr. 22, 1993, eff. Dec. 1, 1993; Apr. 27, 1995, eff. Dec. 1, 1995; Apr. 24, 1998, eff. Dec. 1, 1998; Apr. 29, 2002, eff. Dec. 1, 2002; Apr. 25, 2005, eff. Dec. 1, 2005; Mar. 26, 2009, eff. Dec. 1, 2009; Apr. 28, 2010, eff. Dec. 1, 2010; Apr. 26, 2011, eff. Dec. 1, 2011; Apr. 28, 2016, eff. Dec. 1, 2016; Apr. 27, 2017, eff. Dec. 1, 2017; Apr. 24, 2023, eff. Dec. 1, 2023, absent contrary Congressional action.)

ADVISORY COMMITTEE NOTES 1967 Adoption

Subdivision (a). This subdivision is derived from FRCP 73(a) [rule 73(a), Federal Rules of Civil Procedure, this title] without any change of substance. The requirement that a request for an extension of time for filing the notice of appeal made after expiration of the time be made by motion and on notice codifies the result reached under the present provisions of FRCP 73(a) and 6(b) [rules 73(a) and 6(b), Federal Rules of Civil Procedure]. *North Umberland Mining Co. v. Standard Accident Ins. Co.*, 193 F.2d 951 (9th Cir., 1952); *Cohen v. Plateau Natural Gas Co.*, 303 F.2d 273 (10th Cir., 1962); *Plant Economy, Inc. v. Mirror Insulation Co.*, 308 F.2d 275 (3d Cir., 1962).

Since this subdivision governs appeals in all civil cases, it supersedes the provisions of § 25 of the Bankruptcy Act (11 U.S.C. § 48). Except in cases to which the United States or an officer or agency thereof is a party, the change is a minor one, since a successful litigant in a bankruptcy proceeding may, under § 25, oblige an aggrieved party to appeal within 30 days after entry of judgment—the time fixed by this subdivision in cases involving private parties only—by serving him with notice of entry on the day thereof, and by the terms of § 25 and aggrieved party must in any event appeal within 40 days after entry of judgment. No reason appears why the time for appeal in bankruptcy should not be the same as that in civil cases generally. Furthermore, § 25 is a potential trap for the uninitiated. The time for appeal which it provides is not applicable to all appeals which may fairly be termed appeals in bankruptcy. Section 25 governs only those cause referred to in § 24 as "proceedings in bankruptcy" and "controversies arising in proceedings in bankruptcy." *Lowenstein v. Reikes*, 54 F.2d 481 (2d Cir., 1931), cert. den., 285 U.S. 539, 52 S.Ct. 311, 76 L.Ed. 932 (1932). The distinction between such cases and other cases which arise out of bankruptcy is often difficult to determine. See 2 Moore's Collier on Bankruptcy ¶24.12 through ¶24.36 (1962). As a result it is not always clear whether an appeal is governed by § 25 or by FRCP 73(a) [rule 73(a), Federal Rules of Civil Procedure, this title], which is applicable to such appeals in bankruptcy as are not governed by § 25.

In view of the unification of the civil and admiralty procedure accomplished by the amendments of the Federal Rules of Civil Procedure effective July 1, 1966, this subdivision governs appeals in those civil actions which involve admiralty or maritime claims and which prior to that date were known as suits in admiralty.

The only other change possibly effected by this subdivision is in the time for appeal from a decision of a district court on a petition for impeachment of an award of a board of arbitration under the Act of May 20, 1926, c. 347, § 9 (44 Stat. 585), 45 U.S.C. § 159. The act provides that a notice of appeal from such a decision shall be filed within 10 days of the decision. This

singular provision was apparently repealed by the enactment in 1948 of 28 U.S.C. § 2107, which fixed 30 days from the date of entry of judgment as the time for appeal in all actions a civil nature except actions in admiralty or bankruptcy matters or those in which the United States is a party. But it was not expressly repealed, and its status is in doubt. See 7 Moore's Federal Practice ¶73.09[2] (1966). The doubt should be resolved, and no reason appears why appeals in such cases should not be taken within the time provided for civil cases generally.

Subdivision (b). This subdivision is derived from FRCrP 37(a)(2) [rule 37(a)(2), Federal Rules of Criminal Procedure] without change of substance.

1979 Amendment

Subdivision (a)(1). The words "(including a civil action which involves an admiralty or maritime claim and a proceeding in bankruptcy or a controversy arising therein)," which appear in the present rule are struck out as unnecessary and perhaps misleading in suggesting that there may be other categories that are not either civil or criminal within the meaning of Rule 4(a) and (b).

The phrases "within 30 days of such entry" and "within 60 days of such entry" have been changed to read "after" instead of "or." The change is for clarity only, since the word "of" in the present rule appears to be used to mean "after." Since the proposed amended rule deals directly with the premature filing of a notice of appeal, it was thought useful to emphasize the fact that except as provided, the period during which a notice of appeal may be filed is the 30 days, or 60 days as the case may be, following the entry of the judgment or order appealed from. See Notes to Rule 4(a)(2) and (4), below.

Subdivision (a)(2). The proposed amendment to Rule 4(a)(2) would extend to civil cases the provisions of Rule 4(b), dealing with criminal cases, designed to avoid the loss of the right to appeal by filing the notice of appeal prematurely. Despite the absence of such a provision in Rule 4(a) the courts of appeals quite generally have held premature appeals effective. See, e.g., *Matter of Grand Jury Empanelled Jan. 21, 1975*, 541 F.2d 373 (3d Cir. 1976); *Hodge v. Hodge*, 507 F.2d 87 (3d Cir. 1976); *Song Jook Suh v. Rosenberg*, 437 F.2d 1098 (9th Cir. 1971); *Ruby v. Secretary of the Navy*, 365 F.2d 385 (9th Cir. 1966); *Firchau v. Diamond Nat'l Corp.*, 345 F.2d 269 (9th Cir. 1965).

The proposed amended rule would recognize this practice but make an exception in cases in which a post trial motion has destroyed the finality of the judgment. See Note to Rule 4(a)(4) below.

Subdivision (a)(4). The proposed amendment would make it clear that after the filing of the specified post trial motions, a notice of appeal should await disposition of the motion. Since the proposed amendments to Rules 3, 10, and 12 contemplate that immediately upon the filing of the notice of appeal the fees will be paid and the case docketed in the court of appeals, and the steps toward its disposition set in motion, it would be undesirable to proceed with the appeal while the district court has before it a motion the granting of which would vacate or alter the judgment appealed from. See, e.g., *Keith v. Newcourt*, 530 F.2d 826 (8th Cir. 1976). Under the present rule, since docketing may not take place until the record is transmitted, premature filing is much less likely to involve waste effort. See, e.g. *Stockes v. Peyton's Inc.*, 508 F.2d 1287 (5th Cir. 1975). Further, since a notice of appeal filed before the disposition of a post trial motion, even if it were treated as valid for purposes of jurisdiction, would not embrace objections to the denial of the motion, it is obviously preferable to postpone the notice of appeal until after the motion is disposed of.

The present rule, since it provides for the "termination" of the "running" of the appeal time, is ambiguous in its application to a notice of appeal filed prior to a post trial motion filed within the 10 day limit. The amendment would make it clear that in such circumstances the appellant should not proceed with the appeal during pendency of the motion but should file a new notice of appeal after the motion is disposed of.

Subdivision (a)(5). Under the present rule it is provided that upon a showing of excusable neglect the district court at any time may extend the time for the filing of a notice of appeal for a period not to exceed 30 days from the expiration of the time otherwise prescribed by the rule, but that if the application is made after the original time has run, the order may be made only on motion with such notice as the court deems appropriate.

A literal reading of this provision would require that the extension be ordered and the notice of appeal filed within the 30 day period, but despite the surface clarity of the rule, it has produced considerable confusion. See the discussion by Judge Friendly in In re Orbitek, 520 F.2d 358 (2d Cir. 1975). The proposed amendment would make it clear that a motion to extend the time must be filed no later than 30 days after the expiration of the original appeal time, and that if the motion is timely filed the district court may act upon the motion at a later date, and may extend the time not in excess of 10 days measured from the date on which the order granting the motion is entered.

Under the present rule there is a possible implication that prior to the time the initial appeal time has run, the district court may extend the time on the basis of an informal application. The amendment would require that the application must be made by motion, though the motion may be made *ex parte*. After the expiration of the initial time a motion for the extension of the time must be made in compliance with the F.R.C.P. [Federal Rules of Civil Procedure] and local rules of the district court. See Note to proposed amended Rule 1, *supra*. And see Rules 6(d), 7(b) of the F.R.C.P. [rules 6(d) and 7(b), Federal Rules of Civil Procedure].

The proposed amended rule expands to some extent the standard for the grant of an extension of time. The present rule requires a "showing of excusable neglect." While this was an appropriate standard in cases in which the motion is made after the time for filing the notice of appeal has run, and remains so, it has never fit exactly the situation in which the appellant seeks an extension before the expiration of the initial time. In such a case "good cause," which is the standard that is applied in the granting of other extensions of time under Rule 26(b) seems to be more appropriate.

Subdivision (a)(6). The proposed amendment would call attention to the requirement of Rule 58 of the F.R.C.P. [Federal Rules of Civil Procedure] that the judgment constitute a separate document. See *United States v. Indrelunas*, 411 U.S. 216 (1973). When a notice of appeal is filed, the clerk should ascertain whether any judgment designated therein has been entered in compliance with Rules 58 and 79(a) and if not, so advise all parties and the district judge. While the requirement of Rule 58 is not jurisdictional, (see *Bankers Trust Co. v. Mallis*, 431 U.S. 928 (1977)), compliance is important since the time for the filing of a notice of appeal by other parties is measured by the time at which the judgment is properly entered.

1991 Amendment

The amendment provides a limited opportunity for relief in circumstances where the notice of entry of a judgment or order, required to be mailed by the clerk of the district court pursuant to Rule 77(d) of the Federal Rules of Civil Procedure, is either not received by a party or is received so late as to impair the opportunity to file a timely notice of appeal. The amendment adds a new subdivision (6) allowing a district court to reopen for a brief period the time for appeal upon a finding that notice of entry of a judgment or order was not received from the clerk or a party within 21 days of its entry and that no party would be prejudiced. By "prejudice" the Committee means some adverse consequence other than the cost of having to oppose the appeal and encounter the risk of reversal, consequences that are present in every appeal. Prejudice might arise, for example, if the appellee had taken some action in reliance on the expiration of the normal time period for filing a notice of appeal.

Reopening may be ordered only upon a motion filed within 180 days of the entry of a judgment or order or within 7 days of receipt of notice of such entry, whichever is earlier. This provision establishes an outer time limit of 180 days for a party who fails to receive timely notice of entry of a judgment to seek additional time to appeal and enables any winning party to shorten the 180-day period by sending (and establishing proof of receipt of) its own notice of entry of a judgment, as authorized by Fed.R.Civ.P. 77(d). Winning parties are encouraged to send their own notice in order to lessen the chance that a judge will accept a claim of non-receipt in the face of evidence that notices were sent by both the clerk and the winning party. Receipt of

a winning party's notice will shorten only the time for reopening the time for appeal under this subdivision, leaving the normal time periods for appeal unaffected.

If the motion is granted, the district court may reopen the time for filing a notice of appeal only for a period of 14 days from the date of entry of the order reopening the time for appeal.

Transmittal Note: Upon transmittal of this rule to Congress, the Advisory Committee recommends that the attention of Congress be called to the fact that language in the fourth paragraph of 28 U.S.C. § 2107 might appropriately be revised in light of this proposed rule.

1993 Amendment

Note to Paragraph (a)(1). The amendment is intended to alert readers to the fact that paragraph (a)(4) extends the time for filing an appeal when certain posttrial motions are filed. The Committee hopes that awareness of the provisions of paragraph (a)(4) will prevent the filing of a notice of appeal when a posttrial tolling motion is pending.

Note to Paragraph (a)(2). The amendment treats a notice of appeal filed after the announcement of a decision or order, but before its formal entry, as if the notice had been filed after entry. The amendment deletes the language that made paragraph (a) (2) inapplicable to a notice of appeal filed after announcement of the disposition of a posttrial motion enumerated in paragraph (a)(4) but before the entry of the order, see *Acosta v. Louisiana Dep't of Health & Human Resources*, 478 U.S. 251 (1986) (per curiam); *Alerte v. McGinnis*, 898 F.2d 69 (7th Cir.1990). Because the amendment of paragraph (a)(4) recognizes all notices of appeal filed after announcement or entry of judgment--even those that are filed while the posttrial motions enumerated in paragraph (a)(4) are pending--the amendment of this paragraph is consistent with the amendment of paragraph (a)(4).

Note to Paragraph (a)(3). The amendment is technical in nature; no substantive change is intended.

Note to Paragraph (a)(4). The 1979 amendment of this paragraph created a trap for an unsuspecting litigant who files a notice of appeal before a posttrial motion, or while a posttrial motion is pending. The 1979 amendment requires a party to file a new notice of appeal after the motion's disposition. Unless a new notice is filed, the court of appeals lacks jurisdiction to hear the appeal. *Griggs v. Provident Consumer Discount Co.*, 459 U.S. 56 (1982). Many litigants, especially pro se litigants, fail to file the second notice of appeal, and several courts have expressed dissatisfaction with the rule. See, e.g., *Averhart v. Arrendondo*, 773 F.2d 919 (7th Cir.1985); *Harcon Barge Co. v. D & G Boat Rentals, Inc.*, 746 F.2d 278 (5th Cir.1984), cert. denied, 479 U.S. 930 (1986).

The amendment provides that a notice of appeal filed before the disposition of a specified posttrial motion will become effective upon disposition of the motion. A notice filed before the filing of one of the specified motions or after the filing of a motion but before disposition of the motion is, in effect, suspended until the motion is disposed of, whereupon, the previously filed notice effectively places jurisdiction in the court of appeals.

Because a notice of appeal will ripen into an effective appeal upon disposition of a posttrial motion, in some instances there will be an appeal from a judgment that has been altered substantially because the motion was granted in whole or in part. Many such appeals will be dismissed for want of prosecution when the appellant fails to meet the briefing schedule. But, the appellee may also move to strike the appeal. When responding to such a motion, the appellant would have an opportunity to state that, even though some relief sought in a posttrial motion was granted, the appellant still plans to pursue the appeal. Because the appellant's response would provide the appellee with sufficient notice of the appellant's intentions, the Committee does not believe that an additional notice of appeal is needed.

The amendment provides that a notice of appeal filed before the disposition of a posttrial tolling motion is sufficient to bring the underlying case, as well as any orders specified in the original notice, to the court of appeals. If the judgment is altered upon

disposition of a posttrial motion, however, and if a party wishes to appeal from the disposition of the motion, the party must amend the notice to so indicate. When a party files an amended notice, no additional fees are required because the notice is an amendment of the original and not a new notice of appeal.

Paragraph (a)(4) is also amended to include, among motions that extend the time for filing a notice of appeal, a Rule 60 motion that is served within 10 days after entry of judgment. This eliminates the difficulty of determining whether a posttrial motion made within 10 days after entry of a judgment is a Rule 59(e) motion, which tolls the time for filing an appeal, or a Rule 60 motion, which historically has not tolled the time. The amendment comports with the practice in several circuits of treating all motions to alter or amend judgments that are made within 10 days after entry of judgment as Rule 59(e) motions for purposes of Rule 4(a)(4). See, e.g., *Finch v. City of Vernon*, 845 F.2d 256 (11th Cir.1988); *Rados v. Celotex Corp.*, 809 F.2d 170 (2d Cir.1986); *Skagerberg v. Oklahoma*, 797 F.2d 881 (10th Cir.1986). To conform to a recent Supreme Court decision, however--*Budinich v. Becton Dickinson and Co.*, 486 U.S. 196 (1988)--the amendment excludes motions for attorney's fees from the class of motions that extend the filing time unless a district court, acting under Rule 58, enters an order extending the time for appeal. This amendment is to be read in conjunction with the amendment of Fed.R.Civ.P. 58.

Note to subdivision (b). The amendment grammatically restructures the portion of this subdivision that lists the types of motions that toll the time for filing an appeal. This restructuring is intended to make the rule easier to read. No substantive change is intended other than to add a motion for judgment of acquittal under Criminal Rule 29 to the list of tolling motions. Such a motion is the equivalent of a Fed.R.Civ.P. 50(b) motion for judgment notwithstanding the verdict, which tolls the running of time for an appeal in a civil case.

The proposed amendment also eliminates an ambiguity from the third sentence of this subdivision. Prior to this amendment, the third sentence provided that if one of the specified motions was filed, the time for filing an appeal would run from the entry of an order denying the motion. That sentence, like the parallel provision in Rule 4(a)(4), was intended to toll the running of time for appeal if one of the posttrial motions is timely filed. In a criminal case, however, the time for filing the motions runs not from entry of judgment (as it does in civil cases), but from the verdict or finding of guilt. Thus, in a criminal case, a posttrial motion may be disposed of more than 10 days before sentence is imposed, i.e. before the entry of judgment. *United States v. Hashagen*, 816 F.2d 899, 902 n. 5 (3d Cir.1987). To make it clear that a notice of appeal need not be filed before entry of judgment, the amendment states that an appeal may be taken within 10 days after the entry of an order disposing of the motion, or within 10 days after the entry of judgment, whichever is later. The amendment also changes the language in the third sentence providing that an appeal may be taken within 10 days after the entry of an order *denying* the motion; the amendment says instead that an appeal may be taken within 10 days after the entry of an order *disposing* of the last such motion outstanding. (Emphasis added) The change recognizes that there may be multiple posttrial motions filed and that, although one or more motions may be granted in whole or in part, a defendant may still wish to pursue an appeal.

The amendment also states that a notice of appeal filed before the disposition of any of the posttrial tolling motions becomes effective upon disposition of the motions. In most circuits this language simply restates the current practice. See *United States v. Cortes*, 895 F.2d 1245 (9th Cir.), cert. denied, 495 U.S. 939 (1990). Two circuits, however, have questioned that practice in light of the language of the rule, see *United States v. Gargano*, 826 F.2d 610 (7th Cir.1987), and *United States v. Jones*, 669 F.2d 559 (8th Cir.1982), and the Committee wishes to clarify the rule. The amendment is consistent with the proposed amendment of Rule 4(a)(4).

Subdivision (b) is further amended in light of new Fed.R.Crim.P. 35(c), which authorizes a sentencing court to correct any arithmetical, technical, or other clear errors in sentencing within 7 days after imposing the sentence. The Committee believes that a sentencing court should be able to act under Criminal Rule 35(c) even if a notice of appeal has already been filed; and that a notice of appeal should not be affected by the filing of a Rule 35(c) motion or by correction of a sentence under Rule 35(c).

Note to subdivision (c). In *Houston v. Lack*, 487 U.S. 266 (1988), the Supreme Court held that a *pro se* prisoner's notice of appeal is "filed" at the moment of delivery to prison authorities for forwarding to the district court. The amendment reflects that decision. The language of the amendment is similar to that in Supreme Court Rule 29.2.

Permitting an inmate to file a notice of appeal by depositing it in an institutional mail system requires adjustment of the rules governing the filing of cross-appeals. In a civil case, the time for filing a cross-appeal ordinarily runs from the date when the first notice of appeal is filed. If an inmate's notice of appeal is filed by depositing it in an institution's mail system, it is possible that the notice of appeal will not arrive in the district court until several days after the "filing" date and perhaps even after the time for filing a cross-appeal has expired. To avoid that problem, subdivision (c) provides that in a civil case when an institutionalized person files a notice of appeal by depositing it in the institution's mail system, the time for filing a cross-appeal runs from the district court's receipt of the notice. The amendment makes a parallel change regarding the time for the government to appeal in a criminal case.

1995 Amendment

Subdivision (a). Fed.R.Civ.P. 50, 52, and 59 were previously inconsistent with respect to whether certain postjudgment motions had to be filed or merely served no later than 10 days after entry of judgment. As a consequence Rule 4(a)(4) spoke of making or serving such motions rather than filing them. Civil Rules 50, 52, and 59, are being revised to require filing before the end of the 10-day period. As a consequence, this rule is being amended to provide that 'filing' must occur within the 10 day period in order to affect the finality of the judgment and extend the period for filing a notice of appeal.

The Civil Rules require the filing of postjudgment motions 'no later than 10 days after entry of judgment'--rather than 'within' 10 days--to include postjudgment motions that are filed before actual entry of the judgment by the clerk. This rule is amended, therefore, to use the same terminology.

The rule is further amended to clarify the fact that a party who wants to obtain review of an alteration or amendment of a judgment must file a notice of appeal or amend a previously filed notice to indicate intent to appeal from the altered judgment.

1998 Amendments

The language and organization of the rule are amended to make the rule more easily understood. In addition to changes made to improve the understanding the Advisory Committee has changed language to make style and terminology consistent throughout the appellate rules. These changes are intended to be stylistic only; in this rule, however, substantive changes are made in paragraphs (a)(6) and (b)(4), and in subdivision (c).

Subdivision (a), paragraph (1). Although the Advisory Committee does not intend to make any substantive changes in this paragraph, cross-references to Rules 4(a)(1)(B) and (4)(c) have been added to subparagraph (a)(1)(A).

Subdivision (a), paragraph (4). Item (iv) in subparagraph (A) of Rule 4(a)(4) provides that filing a motion for relief under Fed.R.Civ.P. 60 will extend the time for filing a notice of appeal if the Rule 60 motion is filed no later than 10 days after judgment is entered. Again, the Advisory Committee does not intend to make any substantive change in this paragraph. But because Fed.R.Civ.P. 6(a) and Fed.R.App.P. 26(a) have different methods for computing time, one might be uncertain whether the 10-day period referred to in Rule 4(a)(4) is computed using Civil Rule 6(a) or Appellate Rule 26(a). Because the Rule 60 motion is filed in the district court, and because Fed.R.App.P. 1(a)(2) says that when the appellate rules provide for filing a motion in the district court, "the procedure must comply with the practice of the district court," the rule provides that the 10-day period is computed using Fed.R.Civ.P. 6(a)

Subdivision (a), paragraph (6). Paragraph (6) permits a district court to reopen the time for appeal if a party has not received notice of the entry of judgment and no party would be prejudiced by the reopening. Before reopening the time for appeal, the

existing rule requires the district court to find that the moving party was entitled to notice of the entry of judgment and did not receive it "from the clerk or any party within 21 days of its entry." The Advisory Committee makes a substantive change. The finding must be that the movant did not receive notice "from the district court or any party within 21 days after entry." This change broadens the type of notice that can preclude reopening the time for appeal. The existing rule provides that only notice from a party or from the clerk bars reopening. The new language precludes reopening if the movant has received notice from "the court."

Subdivision (b). Two substantive changes are made in what will be paragraph (b)(4). The current rule permits an extension of time to file a notice of appeal if there is a "showing of excusable neglect." First, the rule is amended to permit a court to extend the time for "good cause" as well as for excusable neglect. Rule 4(a) permits extensions for both reasons in civil cases and the Advisory Committee believes that "good cause" should be sufficient in criminal cases as well. The amendment does not limit extensions for good cause to instances in which the motion for extension of time is filed before the original time has expired. The rule gives the district court discretion to grant extensions for good cause whenever the court believes it appropriate to do so provided that the extended period does not exceed 30 days after the expiration of the time otherwise prescribed by Rule 4(b). Second, paragraph (b)(4) is amended to require only a "finding" of excusable neglect or good cause and not a "showing" of them. Because the rule authorizes the court to provide an extension without a motion, a "showing" is obviously not required; a "finding" is sufficient.

Subdivision (c). Substantive amendments are made in this subdivision. The current rule provides that if an inmate confined in an institution files a notice of appeal by depositing it in the institution's internal mail system, the notice is timely filed if deposited on or before the last day for filing. Some institutions have special internal mail systems for handling legal mail; such systems often record the date of deposit of mail by an inmate, the date of delivery of mail to an inmate, etc. The Advisory Committee amends the rule to require an inmate to use the system designed for legal mail, if there is one, in order to receive the benefit of this subdivision.

When an inmate uses the filing method authorized by subdivision (c), the current rule provides that the time for other parties to appeal begins to run from the date the district court "receives" the inmate's notice of appeal. The rule is amended so that the time for other parties begins to run when the district court "dockets" the inmates appeal. A court may "receive" a paper when its mail is delivered to it even if the mail is not processed for a day or two, making the date of receipt uncertain. "Docketing" is an easily identified event. The change eliminates uncertainty. Paragraph (c)(3) is further amended to make it clear that the time for the government to file its appeal runs from the later of the entry of the judgment or order appealed from or the district court's docketing of a defendant's notice filed under this paragraph (c).

2002 Amendments

Subdivision (a)(1)(C). The federal courts of appeals have reached conflicting conclusions about whether an appeal from an order granting or denying an application for a writ of error *coram nobis* is governed by the time limitations of Rule 4(a) (which apply in civil cases) or by the time limitations of Rule 4(b) (which apply in criminal cases). *Compare United States v. Craig*, 907 F.2d 653, 655-57, *amended* 919 F.2d 57 (7th Cir. 1990); *United States v. Cooper*, 876 F.2d 1192, 1193-94 (5th Cir. 1989); and *United States v. Keogh*, 391 F.2d 138, 140 (2d Cir. 1968) (applying the time limitations of Rule 4(a)); *with Yasui v. United States*, 772 F.2d 1496, 1498-99 (9th Cir. 1985); and *United States v. Mills*, 430 F.2d 526, 527-28 (8th Cir. 1970) (applying the time limitations of Rule 4(b)). A new part (C) has been added to Rule 4(a)(1) to resolve this conflict by providing that the time limitations of Rule 4(a) will apply.

Subsequent to the enactment of Fed. R. Civ. P. 60(b) and 28 U.S.C. § 2255, the Supreme Court has recognized the continued availability of a writ of error *coram nobis* in at least one narrow circumstance. In 1954, the Court permitted a litigant who had been convicted of a crime, served his full sentence, and been released from prison, but who was continuing to suffer a legal disability on account of the conviction, to seek a writ of error *coram nobis* to set aside the conviction. *United States v. Morgan*, 346 U.S. 502 (1954). As the Court recognized, in the *Morgan* situation an application for a writ of error *coram nobis* "is of the

same general character as [a motion] under 28 U.S.C. § 2255." *Id.* at 506 n.4. Thus, it seems appropriate that the time limitations of Rule 4(a), which apply when a district court grants or denies relief under 28 U.S.C. § 2255, should also apply when a district court grants or denies a writ of error *coram nobis*. In addition, the strong public interest in the speedy resolution of criminal appeals that is reflected in the shortened deadlines of Rule 4(b) is not present in the *Morgan* situation, as the party seeking the writ of error *coram nobis* has already served his or her full sentence.

Notwithstanding *Morgan*, it is not clear whether the Supreme Court continues to believe that the writ of error *coram nobis* is available in federal court. In civil cases, the writ has been expressly abolished by Fed. R. Civ. P. 60(b). In criminal cases, the Supreme Court has recently stated that it has become "difficult to conceive of a situation" in which the writ "would be necessary or appropriate." *Carlisle v. United States*, 517 U.S. 416, 429 (1996) (quoting *United States v. Smith*, 331 U.S. 469, 475 n.4 (1947)). The amendment to Rule 4(a)(1) is not intended to express any view on this issue; rather, it is merely meant to specify time limitations for appeals.

Rule 4(a)(1)(C) applies only to motions that are in substance, and not merely in form, applications for writs of error *coram nobis*. Litigants may bring and label as applications for a writ of error *coram nobis* what are in reality motions for a new trial under Fed. R. Crim. P. 33 or motions for correction or reduction of a sentence under Fed. R. Crim. P. 35. In such cases, the time limitations of Rule 4(b), and not those of Rule 4(a), should be enforced.

Changes Made After Publication and Comments No changes were made to the text of the proposed amendment or to the Committee Note.

Subdivision (a)(4)(A)(vi). Rule 4(a)(4)(A)(vi) has been amended to remove a parenthetical that directed that the 10-day deadline be "computed using Federal Rule of Civil Procedure 6(a)." That parenthetical has become superfluous because Rule 26(a)(2) has been amended to require that all deadlines under 11 days be calculated as they are under Fed. R. Civ. P. 6(a).

Changes Made After Publication and Comments No changes were made to the text of the proposed amendment or to the Committee Note.

Subdivision (a)(5)(A)(ii). Rule 4(a)(5)(A) permits the district court to extend the time to file a notice of appeal if two conditions are met. First, the party seeking the extension must file its motion no later than 30 days after the expiration of the time originally prescribed by Rule 4(a). Second, the party seeking the extension must show either excusable neglect or good cause. The text of Rule 4(a)(5)(A) does not distinguish between motions filed prior to the expiration of the original deadline and those filed after the expiration of the original deadline. Regardless of whether the motion is filed before or during the 30 days after the original deadline expires, the district court may grant an extension if a party shows either excusable neglect or good cause.

Despite the text of Rule 4(a)(5)(A), most of the courts of appeals have held that the good cause standard applies only to motions brought prior to the expiration of the original deadline and that the excusable neglect standard applies only to motions brought during the 30 days following the expiration of the original deadline. *See Pontarelli v. Stone*, 930 F.2d 104, 109-10 (1st Cir. 1991) (collecting cases from the Second, Fifth, Sixth, Seventh, Eighth, Ninth, and Eleventh Circuits). These courts have relied heavily upon the Advisory Committee Note to the 1979 amendment to Rule 4(a)(5). But the Advisory Committee Note refers to a draft of the 1979 amendment that was ultimately rejected. The rejected draft directed that the good cause standard apply only to motions filed prior to the expiration of the original deadline. Rule 4(a)(5), as actually amended, did not. *See* 16A CHARLES ALAN WRIGHT, ET AL., FEDERAL PRACTICE AND PROCEDURE § 3950.3, at 148-49 (2d ed. 1996).

The failure of the courts of appeals to apply Rule 4(a)(5)(A) as written has also created tension between that rule and Rule 4(b) (4). As amended in 1998, Rule 4(b)(4) permits the district court to extend the time for filing a notice of appeal in a *criminal* case for an additional 30 days upon a finding of excusable neglect or good cause. Both Rule 4(b)(4) and the Advisory Committee Note to the 1998 amendment make it clear that an extension can be granted for either excusable neglect or good cause, regardless of whether a motion for an extension is filed before or during the 30 days following the expiration of the original deadline.

Rule 4(a)(5)(A)(ii) has been amended to correct this misunderstanding and to bring the rule in harmony in this respect with Rule 4(b)(4). A motion for an extension filed prior to the expiration of the original deadline may be granted if the movant shows either excusable neglect or good cause. Likewise, a motion for an extension filed during the 30 days following the expiration of the original deadline may be granted if the movant shows either excusable neglect or good cause.

The good cause and excusable neglect standards have "different domains." *Lorenzen v. Employees Retirement Plan*, 896 F.2d 228, 232 (7th Cir. 1990). They are not interchangeable, and one is not inclusive of the other. The excusable neglect standard applies in situations in which there is fault; in such situations, the need for an extension is usually occasioned by something within the control of the movant. The good cause standard applies in situations in which there is no fault--excusable or otherwise. In such situations, the need for an extension is usually occasioned by something that is not within the control of the movant.

Thus, the good cause standard can apply to motions brought during the 30 days following the expiration of the original deadline. If, for example, the Postal Service fails to deliver a notice of appeal, a movant might have good cause to seek a post-expiration extension. It may be unfair to make such a movant prove that its "neglect" was excusable, given that the movant may not have been neglectful at all. Similarly, the excusable neglect standard can apply to motions brought prior to the expiration of the original deadline. For example, a movant may bring a pre-expiration motion for an extension of time when an error committed by the movant makes it unlikely that the movant will be able to meet the original deadline.

Changes Made After Publication and Comments No changes were made to the text of the proposed amendment. The stylistic changes to the Committee Note suggested by Judge Newman were adopted. In addition, two paragraphs were added at the end of the Committee Note to clarify the difference between the good cause and excusable neglect standards.

Subdivision (a)(7). Several circuit splits have arisen out of uncertainties about how Rule 4(a)(7)'s definition of when a judgment or order is "entered" interacts with the requirement in Fed. R. Civ. P. 58 that, to be "effective," a judgment must be set forth on a separate document. Rule 4(a)(7) and Fed. R. Civ. P. 58 have been amended to resolve those splits.

1. The first circuit split addressed by the amendments to Rule 4(a)(7) and Fed. R. Civ. P. 58 concerns the extent to which orders that dispose of post-judgment motions must be set forth on separate documents. Under Rule 4(a)(4)(A), the filing of certain post-judgment motions tolls the time to appeal the underlying judgment until the "entry" of the order disposing of the last such remaining motion. Courts have disagreed about whether such an order must be set forth on a separate document before it is treated as "entered." This disagreement reflects a broader dispute among courts about whether Rule 4(a)(7) independently imposes a separate document requirement (a requirement that is distinct from the separate document requirement that is imposed by the Federal Rules of Civil Procedure ("FRCP")) or whether Rule 4(a)(7) instead incorporates the separate document requirement as it exists in the FRCP. Further complicating the matter, courts in the former "camp" disagree among themselves about the scope of the separate document requirement imposed by the FRCP.

Rule 4(a)(7) has been amended to make clear that it simply incorporates the separate document requirement as it exists in Fed. R. Civ. P. 58. If Fed. R. Civ. P. 58 does not require that a judgment or order be set forth on a separate document, then neither does Rule 4(a)(7); the judgment or order will be deemed entered for purposes of Rule 4(a) when it is entered in the civil docket. If Fed. R. Civ. P. 58 requires that a judgment or order be set forth on a separate document, then so does Rule 4(a)(7); the judgment or order will not be deemed entered for purposes of Rule 4(a) until it is so set forth and entered in the civil docket (with one important exception, described below).

In conjunction with the amendment to Rule 4(a)(7), Fed. R. Civ. P. 58 has been amended to provide that orders disposing of the postjudgment motions listed in new Fed. R. Civ. P. 58(a)(1) (which postjudgment motions include, but are not limited to, the post-judgment motions that can toll the time to appeal under Rule 4(a)(4)(A)) do not have to be set forth on separate documents.

See Fed. R. Civ. P. 58(a)(1). Thus, such orders are entered for purposes of Rule 4(a) when they are entered in the civil docket pursuant to Fed. R. Civ. P. 79(a). See Rule 4(a)(7)(A)(1).

2. The second circuit split addressed by the amendments to Rule 4(a)(7) and Fed. R. Civ. P. 58 concerns the following question: When a judgment or order is required to be set forth on a separate document under Fed. R. Civ. P. 58 but is not, does the time to appeal the judgment or order--or the time to bring post-judgment motions, such as a motion for a new trial under Fed. R. Civ. P. 59--ever begin to run? According to every circuit except the First Circuit, the answer is "no." The First Circuit alone holds that parties will be deemed to have waived their right to have a judgment or order entered on a separate document three months after the judgment or order is entered in the civil docket. See Fiore v. Washington County Community Mental Health Ctr., 960 F.2d 229, 236 (1st Cir. 1992) (en banc). Other circuits have rejected this cap as contrary to the relevant rules. See, e.g., United States v. Haynes, 158 F.3d 1327, 1331 (D.C. Cir. 1998); Hammack v. Baroid Corp., 142 F.3d 266, 269-70 (5th Cir. 1998); Rubin v. Schottenstein, Zox & Dunn, 110 F.3d 1247, 1253 n.4 (6th Cir. 1997), vacated on other grounds, 143 F.3d 263 (6th Cir. 1998) (en banc). However, no court has questioned the wisdom of imposing such a cap as a matter of policy.

Both Rule 4(a)(7)(A) and Fed. R. Civ. P. 58 have been amended to impose such a cap. Under the amendments, a judgment or order is generally treated as entered when it is entered in the civil docket pursuant to Fed. R. Civ. P. 79(a). There is one exception: When Fed. R. Civ. P. 58(a)(1) requires the judgment or order to be set forth on a separate document, that judgment or order is not treated as entered until it is set forth on a separate document (in addition to being entered in the civil docket) or until the expiration of 150 days after its entry in the civil docket, whichever occurs first. This cap will ensure that parties will not be given forever to appeal (or to bring a postjudgment motion) when a court fails to set forth a judgment or order on a separate document in violation of Fed. R. Civ. P. 58(a)(1).

3. The third circuit split--this split addressed only by the amendment to Rule 4(a)(7)--concerns whether the appellant may waive the separate document requirement over the objection of the appellee. In *Bankers Trust Co. v. Mallis*, 435 U.S. 381, 387 (1978) (per curiam), the Supreme Court held that the "parties to an appeal may waive the separate-judgment requirement of Rule 58." Specifically, the Supreme Court held that when a district court enters an order and "clearly evidence[s] its intent that the ... order ... represent[s] the final decision in the case," the order is a "final decision" for purposes of 28 U.S.C. § 1291, even if the order has not been set forth on a separate document for purposes of Fed. R. Civ. P. 58. *Id.* Thus, the parties can choose to appeal without waiting for the order to be set forth on a separate document.

Courts have disagreed about whether the consent of all parties is necessary to waive the separate document requirement. Some circuits permit appellees to object to attempted *Mallis* waivers and to force appellants to return to the trial court, request that judgment be set forth on a separate document, and appeal a second time. *See, e.g., Selletti v. Carey*, 173 F.3d 104, 109-10 (2d Cir. 1999); *Williams v. Borg*, 139 F.3d 737, 739-40 (9th Cir. 1998); *Silver Star Enters., Inc. v. M/V Saramacca*, 19 F.3d 1008, 1013 (5th Cir. 1994). Other courts disagree and permit *Mallis* waivers even if the appellee objects. *See, e.g., Haynes*, 158 F.3d at 1331; *Miller v. Artistic Cleaners*, 153 F.3d 781, 783-84 (7th Cir. 1998); *Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996, 1006 n.8 (3d Cir. 1994).

New Rule 4(a)(7)(B) is intended both to codify the Supreme Court's holding in *Mallis* and to make clear that the decision whether to waive the requirement that the judgment or order be set forth on a separate document is the appellant's alone. It is, after all, the appellant who needs a clear signal as to when the time to file a notice of appeal has begun to run. If the appellant chooses to bring an appeal without waiting for the judgment or order to be set forth on a separate document, then there is no reason why the appellee should be able to object. All that would result from honoring the appellee's objection would be delay.

4. The final circuit split addressed by the amendment to Rule 4(a)(7) concerns the question whether an appellant who chooses to waive the separate document requirement must appeal within 30 days (60 days if the government is a party) from the entry in the civil docket of the judgment or order that should have been set forth on a separate document but was not. In *Townsend v. Lucas*, 745 F.2d 933 (5th Cir. 1984), the district court dismissed a 28 U.S.C. § 2254 action on May 6, 1983, but failed to set forth the judgment on a separate document. The plaintiff appealed on January 10, 1984. The Fifth Circuit dismissed the appeal,

reasoning that, if the plaintiff waived the separate document requirement, then his appeal would be from the May 6 order, and if his appeal was from the May 6 order, then it was untimely under Rule 4(a)(1). The Fifth Circuit stressed that the plaintiff could return to the district court, move that the judgment be set forth on a separate document, and appeal from that judgment within 30 days. *Id.* at 934. Several other cases have embraced the *Townsend* approach. *See, e.g., Armstrong v. Ahitow*, 36 F.3d 574, 575 (7th Cir. 1994) (per curiam); *Hughes v. Halifax County Sch. Bd.*, 823 F.2d 832, 835-36 (4th Cir. 1987); *Harris v. McCarthy*, 790 F.2d 753, 756 n.1 (9th Cir. 1986).

Those cases are in the distinct minority. There are numerous cases in which courts have heard appeals that were not filed within 30 days (60 days if the government was a party) from the judgment or order that should have been set forth on a separate document but was not. *See, e.g., Haynes,* 158 F.3d at 1330-31; *Clough v. Rush,* 959 F.2d 182, 186 (10th Cir. 1992); *McCalden v. California Library Ass'n,* 955 F.2d 1214, 1218-19 (9th Cir. 1990). In the view of these courts, the remand in *Townsend* was "precisely the purposeless spinning of wheels abjured by the Court in the [*Mallis*] case." 15B CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 3915, at 259 n.8 (3d ed. 1992).

The Committee agrees with the majority of courts that have rejected the *Townsend* approach. In drafting new Rule 4(a)(7)(B), the Committee has been careful to avoid phrases such as "otherwise timely appeal" that might imply an endorsement of *Townsend*.

Changes Made After Publication and Comments No changes were made to the text of proposed Rule 4(a)(7)(B) or to the third or fourth numbered sections of the Committee Note, except that, in several places, references to a judgment being "entered" on a separate document were changed to references to a judgment being "set forth" on a separate document. This was to maintain stylistic consistency. The appellate rules and the civil rules consistently refer to "entering" judgments on the civil docket and to "setting forth" judgments on separate documents.

Two major changes were made to the text of proposed Rule 4(a)(7)(A)--one substantive and one stylistic. The substantive change was to increase the "cap" from 60 days to 150 days. The Appellate Rules Committee and the Civil Rules Committee had to balance two concerns that are implicated whenever a court fails to enter its final decision on a separate document. On the one hand, potential appellants need a clear signal that the time to appeal has begun to run, so that they do not unknowingly forfeit their rights. On the other hand, the time to appeal cannot be allowed to run forever. A party who receives no notice whatsoever of a judgment has only 180 days to move to reopen the time to appeal from that judgment. See Rule 4(a)(6)(A). It hardly seems fair to give a party who does receive notice of a judgment an unlimited amount of time to appeal, merely because that judgment was not set forth on a separate piece of paper. Potential appellees and the judicial system need some limit on the time within which appeals can be brought.

The 150-day cap properly balances these two concerns. When an order is not set forth on a separate document, what signals litigants that the order is final and appealable is a lack of further activity from the court. A 60-day period of inactivity is not sufficiently rare to signal to litigants that the court has entered its last order. By contrast, 150 days of inactivity is much less common and thus more clearly signals to litigants that the court is done with their case.

The major stylistic change to Rule 4(a)(7) requires some explanation. In the published draft, proposed Rule 4(a)(7)(A) provided that "[a] judgment or order is entered for purposes of this Rule 4(a) when it is entered for purposes of Rule 58(b) of the Federal Rules of Civil Procedure." In other words, Rule 4(a)(7)(A) told readers to look to FRCP 58(b) to ascertain when a judgment is entered for purposes of starting the running of the time to appeal. Sending appellate lawyers to the civil rules to discover when time began to run for purposes of the appellate rules was itself somewhat awkward, but it was made more confusing by the fact that, when readers went to proposed FRCP 58(b), they found this introductory clause: "Judgment is entered for purposes of Rules 50, 52, 54(d)(2)(B), 59, 60, and 62 when...."

This introductory clause was confusing for both appellate lawyers and trial lawyers. It was confusing for appellate lawyers because Rule 4(a)(7) informed them that FRCP 58(b) would tell them when the time begins to run for purposes of the *appellate* rules, but when they got to FRCP 58(b) they found a rule that, by its terms, dictated only when the time begins to run for

purposes of certain *civil* rules. The introductory clause was confusing for trial lawyers because FRCP 58(b) described when judgment is entered for some purposes under the civil rules, but then was completely silent about when judgment is entered for other purposes.

To avoid this confusion, the Civil Rules Committee, on the recommendation of the Appellate Rules Committee, changed the introductory clause in FRCP 58(b) to read simply: "Judgment is entered for purposes of *these Rules* when...." In addition, Rule 4(a)(7)(A) was redrafted so that the triggering events for the running of the time to appeal (entry in the civil docket, and being set forth on a separate document or passage of 150 days) were incorporated directly into Rule 4(a)(7), rather than indirectly through a reference to FRCP 58(b). This eliminates the need for appellate lawyers to examine Rule 58(b) and any chance that Rule 58(b)'s introductory clause (even as modified) might confuse them.

We do not believe that republication of Rule 4(a)(7) or FRCP 58 is necessary. In *substance*, rewritten Rule 4(a)(7)(A) and FRCP 58(b) operate identically to the published versions, except that the 60-day cap has been replaced with a 150-day cap--a change that was suggested by some of the commentators and that makes the cap more forgiving.

Subdivision (b)(5). Federal Rule of Criminal Procedure 35(a) permits a district court, acting within 7 days after the imposition of sentence, to correct an erroneous sentence in a criminal case. Some courts have held that the filing of a motion for correction of a sentence suspends the time for filing a notice of appeal from the judgment of conviction. *See, e.g., United States v. Carmouche*, 138 F.3d 1014, 1016 (5th Cir. 1998) (per curiam); *United States v. Morillo*, 8 F.3d 864, 869 (1st Cir. 1993). Those courts establish conflicting timetables for appealing a judgment of conviction after the filing of a motion to correct a sentence. In the First Circuit, the time to appeal is suspended only for the period provided by Fed. R. Crim. P. 35(a) for the district court to correct a sentence; the time to appeal begins to run again once 7 days have passed after sentencing, even if the motion is still pending. By contrast, in the Fifth Circuit, the time to appeal does not begin to run again until the district court actually issues an order disposing of the motion.

Rule 4(b)(5) has been amended to eliminate the inconsistency concerning the effect of a motion to correct a sentence on the time for filing a notice of appeal. The amended rule makes clear that the time to appeal continues to run, even if a motion to correct a sentence is filed. The amendment is consistent with Rule 4(b)(3)(A), which lists the motions that toll the time to appeal, and notably omits any mention of a Fed. R. Crim. P. 35(a) motion. The amendment also should promote certainty and minimize the likelihood of confusion concerning the time to appeal a judgment of conviction.

If a district court corrects a sentence pursuant to Fed. R. Crim. P. 35(a), the time for filing a notice of appeal of the corrected sentence under Rule 4(b)(1) would begin to run when the court enters a new judgment reflecting the corrected sentence.

Changes Made After Publication and Comments The reference to Federal Rule of Criminal Procedure 35(c) was changed to Rule 35(a) to reflect the pending amendment of Rule 35. The proposed amendment to Criminal Rule 35, if approved, will take effect at the same time that the proposed amendment to Appellate Rule 4 will take effect, if approved.

2005 Amendments

Rule 4(a)(6) has permitted a district court to reopen the time to appeal a judgment or order upon finding that four conditions were satisfied. First, the district court had to find that the appellant did not receive notice of the entry of the judgment or order from the district court or any party within 21 days after the judgment or order was entered. Second, the district court had to find that the appellant moved to reopen the time to appeal within 7 days after the appellant received notice of the entry of the judgment or order. Third, the district court had to find that the appellant moved to reopen the time to appeal within 180 days after the judgment or order was entered. Finally, the district court had to find that no party would be prejudiced by the reopening of the time to appeal.

Rule 4(a)(6) has been amended to specify more clearly what type of "notice" of the entry of a judgment or order precludes a party from later moving to reopen the time to appeal. In addition, Rule 4(a)(6) has been amended to address confusion about what type of "notice" triggers the 7-day period to bring a motion to reopen. Finally, Rule 4(a)(6) has been reorganized to set forth more logically the conditions that must be met before a district court may reopen the time to appeal.

Subdivision (a)(6)(A). Former subdivision (a)(6)(B) has been redesignated as subdivision (a)(6)(A), and one substantive change has been made. As amended, the subdivision will preclude a party from moving to reopen the time to appeal a judgment or order only if the party receives (within 21 days) formal notice of the entry of that judgment or order under Civil Rule 77(d). No other type of notice will preclude a party.

The reasons for this change take some explanation. Prior to 1998, former subdivision (a)(6)(B) permitted a district court to reopen the time to appeal if it found "that a party entitled to notice of the entry of a judgment or order did not receive such notice from the clerk or any party within 21 days of its entry." The rule was clear that the "notice" to which it referred was the notice required under Civil Rule 77(d), which must be served by the clerk pursuant to Civil Rule 5(b) and may also be served by a party pursuant to that same rule. In other words, prior to 1998, former subdivision (a)(6)(B) was clear that, if a party did not receive formal notice of the entry of a judgment or order under Civil Rule 77(d), that party could later move to reopen the time to appeal (assuming that the other requirements of subdivision (a)(6) were met).

In 1998, former subdivision (a)(6)(B) was amended to change the description of the type of notice that would preclude a party from moving to reopen. As a result of the amendment, former subdivision (a)(6)(B) no longer referred to the failure of the moving party to receive "such notice"—that is, the notice required by Civil Rule 77(d)—but instead referred to the failure of the moving party to receive "the notice." And former subdivision (a)(6)(B) no longer referred to the failure of the moving party to receive notice from "the clerk or any party," both of whom are explicitly mentioned in Civil Rule 77(d). Rather, former subdivision (a)(6)(B) referred to the failure of the moving party to receive notice from "the district court or any party."

The 1998 amendment meant, then, that the type of notice that precluded a party from moving to reopen the time to appeal was no longer limited to Civil Rule 77(d) notice. Under the 1998 amendment, *some* type of notice, in addition to Civil Rule 77(d) notice, precluded a party. But the text of the amended rule did not make clear what type of notice qualified. This was an invitation for litigation, confusion, and possible circuit splits.

To avoid such problems, former subdivision (a)(6)(B)--new subdivision (a)(6)(A)--has been amended to restore its pre-1998 simplicity. Under new subdivision (a)(6)(A), if the court finds that the moving party was not notified under Civil Rule 77(d) of the entry of the judgment or order that the party seeks to appeal within 21 days after that judgment or order was entered, then the court is authorized to reopen the time to appeal (if all of the other requirements of subdivision (a)(6) are met). Because Civil Rule 77(d) requires that notice of the entry of a judgment or order be formally served under Civil Rule 5(b), any notice that is not so served will not operate to preclude the reopening of the time to appeal under new subdivision (a)(6)(A).

Subdivision (a)(6)(B). Former subdivision (a)(6)(A) required a party to move to reopen the time to appeal "within 7 days after the moving party receives notice of the entry [of the judgment or order sought to be appealed]." Former subdivision (a)(6)(A) has been redesignated as subdivision (a)(6)(B), and one important substantive change has been made: The subdivision now makes clear that only formal notice of the entry of a judgment or order under Civil Rule 77(d) will trigger the 7-day period to move to reopen the time to appeal.

The circuits have been split over what type of "notice" is sufficient to trigger the 7-day period. The majority of circuits that addressed the question held that only *written* notice was sufficient, although nothing in the text of the rule suggested such a limitation. *See, e.g., Bass v. United States Dep't of Agric.*, 211 F.3d 959, 963 (5th Cir. 2000). By contrast, the Ninth Circuit held that while former subdivision (a)(6)(A) did not require written notice, "the quality of the communication [had to] rise to the functional equivalent of written notice." *Nguyen v. Southwest Leasing & Rental, Inc.*, 282 F.3d 1061, 1066 (9th Cir. 2002). Other circuits suggested in dicta that former subdivision (a)(6)(A) required only "actual notice," which, presumably, could have

included oral notice that was not "the functional equivalent of written notice." See, e.g., Lowry v. McDonnell Douglas Corp., 211 F.3d 457, 464 (8th Cir. 2000). And still other circuits read into former subdivision (a)(6)(A) restrictions that appeared only in former subdivision (a)(6)(B) (such as the requirement that notice be received "from the district court or any party," see Benavides v. Bureau of Prisons, 79 F.3d 1211, 1214 (D.C. Cir. 1996)) or that appeared in neither former subdivision (a)(6)(A) nor former subdivision (a)(6)(B) (such as the requirement that notice be served in the manner prescribed by Civil Rule 5, see Ryan v. First Unum Life Ins. Co., 174 F.3d 302, 304-05 (2d Cir. 1999)).

Former subdivision (a)(6)(A)--new subdivision (a)(6)(B)--has been amended to resolve this circuit split by providing that only formal notice of the entry of a judgment or order under Civil Rule 77(d) will trigger the 7-day period. Using Civil Rule 77(d) notice as the trigger has two advantages: First, because Civil Rule 77(d) is clear and familiar, circuit splits are unlikely to develop over its meaning. Second, because Civil Rule 77(d) notice must be served under Civil Rule 5(b), establishing whether and when such notice was provided should generally not be difficult.

Using Civil Rule 77(d) notice to trigger the 7-day period will not unduly delay appellate proceedings. Rule 4(a)(6) applies to only a small number of cases--cases in which a party was not notified of a judgment or order by either the clerk or another party within 21 days after entry. Even with respect to those cases, an appeal cannot be brought more than 180 days after entry, no matter what the circumstances. In addition, Civil Rule 77(d) permits parties to serve notice of the entry of a judgment or order. The winning party can prevent Rule 4(a)(6) from even coming into play simply by serving notice of entry within 21 days. Failing that, the winning party can always trigger the 7-day deadline to move to reopen by serving belated notice.

2009 Amendments

Subdivision (a)(4)(A)(vi). Subdivision (a)(4) provides that certain timely post-trial motions extend the time for filing an appeal. Lawyers sometimes move under Civil Rule 60 for relief that is still available under another rule such as Civil Rule 59. Subdivision (a)(4)(A)(vi) provides for such eventualities by extending the time for filing an appeal so long as the Rule 60 motion is filed within a limited time. Formerly, the time limit under subdivision (a)(4)(A)(vi) was 10 days, reflecting the 10-day limits for making motions under Civil Rules 50(b), 52(b), and 59. Subdivision (a)(4)(A)(vi) now contains a 28-day limit to match the revisions to the time limits in the Civil Rules.

Subdivision (a)(4)(B)(ii). Subdivision (a)(4)(B)(ii) is amended to address problems that stemmed from the adoption-during the 1998 restyling project--of language referring to "a judgment altered or amended upon" a post-trial motion.

Prior to the restyling, subdivision (a)(4) instructed that "[a]ppellate review of an order disposing of any of [the post-trial motions listed in subdivision (a)(4)] requires the party, in compliance with Appellate Rule 3(c), to amend a previously filed notice of appeal. A party intending to challenge an alteration or amendment of the judgment shall file a notice, or amended notice, of appeal within the time prescribed by this Rule 4 measured from the entry of the order disposing of the last such motion outstanding." After the restyling, subdivision (a)(4)(B)(ii) provided: "A party intending to challenge an order disposing of any motion listed in Rule 4(a)(4)(A), or a judgment altered or amended upon such a motion, must file a notice of appeal, or an amended notice of appeal--in compliance with Rule 3(c)--within the time prescribed by this Rule measured from the entry of the order disposing of the last such remaining motion."

One court has explained that the 1998 amendment introduced ambiguity into the Rule: "The new formulation could be read to expand the obligation to file an amended notice to circumstances where the ruling on the post-trial motion alters the prior judgment in an insignificant manner or in a manner favorable to the appellant, even though the appeal is not directed against the alteration of the judgment." *Sorensen v. City of New York*, 413 F.3d 292, 296 n.2 (2d Cir. 2005). The current amendment removes that ambiguous reference to "a judgment altered or amended upon" a post-trial motion, and refers instead to "a judgment's alteration or amendment" upon such a motion. Thus, subdivision (a)(4)(B)(ii) requires a new or amended notice of appeal when an appellant wishes to challenge an order disposing of a motion listed in Rule 4(a)(4)(A) or a judgment's alteration or amendment upon such a motion.

Subdivision (a)(5)(C). The time set in the former rule at 10 days has been revised to 14 days. See the Note to Rule 26.

Subdivision (a)(6)(B). The time set in the former rule at 7 days has been revised to 14 days. Under the time-computation approach set by former Rule 26(a), "7 days" always meant at least 9 days and could mean as many as 11 or even 13 days. Under current Rule 26(a), intermediate weekends and holidays are counted. Changing the period from 7 to 14 days offsets the change in computation approach. See the Note to Rule 26.

Subdivisions (b)(1)(A) and (b)(3)(A). The times set in the former rule at 10 days have been revised to 14 days. See the Note to Rule 26.

2010 Amendments

Subdivision (a)(7). Subdivision (a)(7) is amended to reflect the renumbering of Civil Rule 58 as part of the 2007 restyling of the Civil Rules. References to Civil Rule "58(a)(1)" are revised to refer to Civil Rule "58(a)." No substantive change is intended.

2011 Amendments

Subdivision (a)(1)(B). Rule 4(a)(1)(B) has been amended to make clear that the 60-day appeal period applies in cases in which an officer or employee of the United States is sued in an individual capacity for acts or omissions occurring in connection with duties performed on behalf of the United States. (A concurrent amendment to Rule 40(a)(1) makes clear that the 45-day period to file a petition for panel rehearing also applies in such cases.)

The amendment to Rule 4(a)(1)(B) is consistent with a 2000 amendment to Civil Rule 12(a)(3), which specified an extended 60-day period to respond to complaints when "[a] United States officer or employee [is] sued in an individual capacity for an act or omission occurring in connection with duties performed on the United States' behalf." The Committee Note to the 2000 amendment explained: "Time is needed for the United States to determine whether to provide representation to the defendant officer or employee. If the United States provides representation, the need for an extended answer period is the same as in actions against the United States, a United States agency, or a United States officer sued in an official capacity." The same reasons justify providing additional time to the Solicitor General to decide whether to file an appeal.

However, because of the greater need for clarity of application when appeal rights are at stake, the amendment to Rule 4(a) (1)(B), and the corresponding legislative amendment to 28 U.S.C. § 2107 that is simultaneously proposed, include safe harbor provisions that parties can readily apply and rely upon. Under new subdivision 4(a)(1)(B)(iv), a case automatically qualifies for the 60-day appeal period if (1) a legal officer of the United States has appeared in the case, in an official capacity, as counsel for the current or former officer or employee and has not withdrawn the appearance at the time of the entry of the judgment or order appealed from or (2) a legal officer of the United States appears on the notice of appeal as counsel, in an official capacity, for the current or former officer or employee. There will be cases that do not fall within either safe harbor but that qualify for the longer appeal period. An example would be a case in which a federal employee is sued in an individual capacity for an act occurring in connection with federal duties and the United States does not represent the employee either when the judgment is entered or when the appeal is filed but the United States pays for private counsel for the employee.

2016 Amendments

A clarifying amendment is made to subdivision (a)(4). Former Rule 4(a)(4) provided that "[i]f a party timely files in the district court" certain post-judgment motions, "the time to file an appeal runs for all parties from the entry of the order disposing of the last such remaining motion." Responding to a circuit split concerning the meaning of "timely" in this provision, the amendment adopts the majority approach and rejects the approach taken in *National Ecological Foundation v. Alexander*, 496 F.3d 466 (6th Cir. 2007). A motion made after the time allowed by the Civil Rules will not qualify as a motion that, under Rule 4(a)(4)

(A), re-starts the appeal time--and that fact is not altered by, for example, a court order that sets a due date that is later than permitted by the Civil Rules, another party's consent or failure to object to the motion's lateness, or the court's disposition of the motion without explicit reliance on untimeliness.

Rule 4(c)(1) is revised to streamline and clarify the operation of the inmate-filing rule.

The Rule requires the inmate to show timely deposit and prepayment of postage. The Rule is amended to specify that a notice is timely if it is accompanied by a declaration or notarized statement stating the date the notice was deposited in the institution's mail system and attesting to the prepayment of first-class postage. The declaration must state that first-class postage "is being prepaid," not (as directed by the former Rule) that first-class postage "has been prepaid." This change reflects the fact that inmates may need to rely upon the institution to affix postage after the inmate has deposited the document in the institution's mail system. New Form 7 in the Appendix of Forms sets out a suggested form of the declaration.

The amended rule also provides that a notice is timely without a declaration or notarized statement if other evidence accompanying the notice shows that the notice was deposited on or before the due date and that postage was prepaid. If the notice is not accompanied by evidence that establishes timely deposit and prepayment of postage, then the court of appeals has discretion to accept a declaration or notarized statement at a later date. The Rule uses the phrase "exercises its discretion to permit"--rather than simply "permits"--to help ensure that pro se inmate litigants are aware that a court will not necessarily forgive a failure to provide the declaration initially.

2017 Amendments

Subdivision (a)(4)(B)(iii). This technical amendment restores the former subdivision (a)(4)(B)(iii) that was inadvertently deleted in 2009.

<[Effective December 1, 2023, absent contrary Congressional action.]>

2023 Amendments

The amendment is designed to make Rule 4 operate smoothly with Emergency Civil Rule 6(b)(2) if that emergency Civil Rule is ever in effect, while not making any change to the operation of Rule 4 at any other time. It does this by replacing the phrase "no later than 28 days after the judgment is entered" in Rule 4(a)(4)(A)(vi) with the phrase "within the time allowed for filing a motion under Rule 59."

Certain post-judgment motions--for example, a renewed motion for judgment as a matter of law under Civil Rule 50(b) and a motion for a new trial under Civil Rule 59--may be made in the district court shortly after judgment is entered. Recognizing that it makes sense to await the district court's decision on these motions before pursuing an appeal, Rule 4(a)(4)(A) resets the time to appeal from the judgment so that it does not run until entry of an order disposing of the last such motion.

Rule 4 gives this resetting effect only to motions that are filed within the time allowed by the Civil Rules. For most of these motions, the Civil Rules require that the motion be filed within 28 days of the judgment. See Civil Rules 50(b) and (d), 52(b), 59(b), (d), and (e). The time requirements for a Civil Rule 60(b) motion, however, are notably different. It must be filed "within a reasonable time," and for certain Civil Rule 60(b) motions, no more than a year after judgment. For this reason, Rule 4 does not give resetting effect to all Civil Rule 60(b) motions that are filed within the time allowed by the Civil Rules, but only to those Civil Rule 60(b) motions that are filed within 28 days of the entry of judgment. That is why most of the motions listed in Rule 4(a)(4)(A) are governed simply by the general requirement that they be filed within the time allowed by the Civil Rules, but Rule 4(a)(4)(A)(vi) adds the requirement that a Civil Rule 60(b) motion has resetting effect only if "filed no later than 28 days after the judgment is entered."

Significantly, Civil Rule 6(b)(2) prohibits the district court from extending the time to act under Rules 50(b) and (d), 52(b), 59(b), (d), and (e), and 60(b). That means that when Rule 4 requires that a motion be filed within the time allowed by the Civil Rules, the time allowed by those Rules for motions under Rules 50(b) and (d), 52(b), 59(b), (d), and (e) will be 28 days—matching the 28-day requirement in Rule 4(a)(4)(A)(vi) applicable to Rule 60(b) motions.

However, Emergency Civil Rule 6(b)(2)--which would be operative only if the Judicial Conference of the United States were to declare a Civil Rules emergency under Civil Rule 87--authorizes district courts to grant extensions that they are otherwise prohibited from granting. If that emergency Civil Rule is in effect, district courts may grant extensions to file motions under Civil Rules 50(b) and (d), 52(b), 59(b), (d), and (e), and 60(b). For all these motions except Civil Rule 60(b) motions, Rule 4 works seamlessly. Rule 4 requires only that those motions be filed "within the time allowed by" the Civil Rules, and a motion filed within a properly granted extension is filed "within the time allowed by" those rules. An emergency Civil Rule is no less a Civil Rule simply because it is operative only in a Civil Rules emergency.

Without amendment, Rule 4 would not work seamlessly with the Emergency Civil Rule for Rule 60(b) motions because the 28-day requirement in Rule 4(a)(4)(A)(vi) would not correspond to the extended time to file other resetting motions. For this reason, the amendment replaces the phrase "if the motion is filed no later than 28 days after the judgment is entered" with the phrase "within the time allowed for filing a motion under Rule 59."

At all times that no Civil Rules emergency has been declared, the amended Rule 4 functions exactly as it did prior to the amendment. A Civil Rule 60(b) motion has resetting effect only if it is filed within the time allowed for filing a motion under Civil Rule 59--which is 28 days.

When a Civil Rules emergency has been declared, however, if a district court grants an extension of time to file a Civil Rule 59 motion and a party files a Civil Rule 60(b) motion, that Civil Rule 60(b) motion has resetting effect so long as it is filed within the extended time set for filing a Civil Rule 59 motion. The Civil Rule 60(b) motion has this resetting effect even if no Civil Rule 59 motion is filed.

Notes of Decisions (2115)

Footnotes

A redraft of Rule 4(a)(7) was faxed to members of the Appellate Rules Committee two weeks after our meeting in New Orleans. The Committee consented to the redraft without objection.

F. R. A. P. Rule 4, 28 U.S.C.A., FRAP Rule 4 Including Amendments Received Through 8-1-23

End of Document

© 2023 Thomson Reuters. No claim to original U.S. Government Works.

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form08instructions.pdf 9th Cir. Case Number(s) I am the attorney or self-represented party. This brief contains words, including words manually counted in any visual images, and excluding the items exempted by FRAP 32(f). The brief's type size and typeface comply with FRAP 32(a)(5) and (6). I certify that this brief (select only one): (•) complies with the word limit of Cir. R. 32-1. is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1. is an amicus brief and complies with the word limit of FRAP 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3). is for a death penalty case and complies with the word limit of Cir. R. 32-4. complies with the longer length limit permitted by Cir. R. 32-2(b) because (select only one): it is a joint brief submitted by separately represented parties. a party or parties are filing a single brief in response to multiple briefs. a party or parties are filing a single brief in response to a longer joint brief. complies with the length limit designated by court order dated is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a). 9/5/2023 s/Meredith Stevenson Signature Date (use "s/[typed name]" to sign electronically-filed documents)

Feedback or questions about this form? Email us at <u>forms@ca9.uscourts.gov</u>

Form 8

Rev. 12/01/22

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Form 15. Certificate of Service for Electronic Filing

Instructions for this form: http://www.ca9.uscourts.gov/forms/form15instructions.pdf

9th Cir. Case Number(s) 22-16770
I hereby certify that I electronically filed the foregoing/attached document(s) or this date with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the Appellate Electronic Filing system.
Service on Case Participants Who Are Registered for Electronic Filing:
I certify that I served the foregoing/attached document(s) via email to all registered case participants on this date because it is a sealed filing or is submitted as an original petition or other original proceeding and therefore cannot be served via the Appellate Electronic Filing system.
Service on Case Participants Who Are <u>NOT</u> Registered for Electronic Filing:
I certify that I served the foregoing/attached document(s) on this date by hand delivery, mail, third party commercial carrier for delivery within 3 calendar days, or, having obtained prior consent, by email to the following unregistered case participants (list each name and mailing/email address):
Description of Document(s) (required for all documents):
Natural Grocers, et al. Plaintiffs-Appellants' Opening Brief
Simulations of Many 1ith Standard Date San 5, 2022
Signature s/Meredith Stevenson Date Sep 5, 2023 (use "s/[typed name]" to sign electronically-filed documents)
Feedback or questions about this form? Email us at forms@ca9.uscourts.gov

Form 15 Rev. 12/01/2018