
Docket No. AMS-TM-17-0050

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

**AGRICULTURAL MARKETING SERVICE
U.S. DEPARTMENT OF AGRICULTURE**

Concerning

**National Bioengineered Food Disclosure Standard;
Proposed Rule**

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 83 FED. REG. 19860 (MAY 4, 2018)

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**Re: National Bioengineered Food Disclosure Standard; Proposed Rule
Docket No. AMS-TM-17-0050, 83 Fed. Reg. 19860 (May 4, 2018)**

Dear Sir/Madam:

Washington Legal Foundation (WLF) is pleased to submit these comments in response to the Agricultural Marketing Service's (AMS) proposed rule that would establish a national mandatory bioengineered (BE) food disclosure standard.

WLF's comments focus on labeling requirements for highly refined foods and ingredients. We conclude that, in general, such foods do not meet the statutory definition of "bioengineered food" and thus are not subject to the labeling requirements. We further conclude that any effort by AMS to require such labeling would raise serious First Amendment concerns.

As the Proposed Rule recognizes, there is substantial evidence indicating that as a result of the refining process, many highly refined products derived from bioengineered food no longer contain (following the refining process) "genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques" and thus are not subject to the labeling requirements imposed under Subtitle E of the Agricultural Marketing Act (AMA). Any food disclosure rule that requires BE labeling of such products would therefore violate the terms of the AMA.

Any such rule would also violate the First Amendment rights of the food manufacturer and/or retailer because it would compel the manufacturer/retailer to utter speech that is neither factual nor uncontroversial. The First Amendment protects the right not to speak and applies to commercial and noncommercial speakers alike. Congress has defined BE food as limited to food that contains the requisite DNA material. If AMS has no evidence that a highly refined food actually contains such DNA material, the First Amendment prohibits AMS from compelling manufacturers or retailers to say that it does.

Those who support imposing a BE labeling requirement on highly refined products

produced from BE foods argue that “although a test may not detect the modified genetic material, it does not necessarily mean that there is no modified materials in the food.” 83 Fed. Reg. at 19863. But one could just as well argue that we should presume the existence of life on Mars because, after all, there is no reason to assume that no life exists on Mars simply because it has never been detected. If there is no evidence that the requisite DNA can be detected in a highly refined food, there is no statutory or constitutional basis for creating “a presumption that these products meet the definition of ‘bioengineering’ and are therefore BE foods.” *Id.*

The Proposed Rule takes no position regarding whether the AMA’s labeling requirements apply to highly refined food; it simply invites further comment on how the final standard should define “bioengineered food.” *Id.* But the Proposed Rule’s subsequent discussion of possible “Factors and Conditions” suggests that AMS may be leaning in the direction of: (1) requiring the labeling of all highly refined products derived from BE food; but then (2) recognizing, as a statutory “factor or condition” (that might exempt a product from labeling requirements) proof from a manufacturer that product testing has been unable to detect the presence of recombinant DNA. 83 Fed. Reg. at 19866-67. WLF urges AMS not to adopt this approach, which would be blatantly unconstitutional. This approach reverses the burden of proof appropriate to First Amendment analysis. If the federal government wishes to impinge on First Amendment rights by compelling manufacturers and retailers to place BE labels on their products, the law imposes on the government the burden of demonstrating the factual and uncontroversial nature of its mandated speech. If the government lacks a documented basis for concluding that highly refined food contains recombinant DNA, it lacks the authority to impose on manufacturers the burden of disproving the presence of recombinant DNA before they are “permitted” to refrain from conveying the government’s speech.

Once the national bioengineered food disclosure standard is in place (and if it survives a constitutional challenge), consumers will likely develop a reasonable expectation that food does not contain the requisite genetic material if it does not bear BE labeling. At that point, it would be reasonable for AMS to expect that manufacturers of highly refined products derived from BE food that does not bear BE labels to be able to substantiate that their products do not contain recombinant DNA. If AMS investigates and determines that the manufacturer lacks adequate substantiation, it can take appropriate enforcement action. What AMS may not do, however, is compel a manufacturer or retailer to speak involuntarily when AMS lacks evidence that the speech it seeks to compel is truthful.

I. Interests of WLF

WLF is a public interest law and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, a limited and accountable government, and the rule of law.

To that end, WLF litigates frequently in support of the speech rights of market participants, appearing in numerous federal courts in cases raising commercial speech issues. *See, e.g. IMS Health, Inc. v. Sorrell*, 564 U.S. 552 (2011); *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012). In particular, WLF has litigated regularly in opposition to government efforts to compel speech. *See, e.g., CTIA—The Wireless Ass’n v. City of Berkeley, pet. granted, judgment vacated, and remanded*, ___ U.S. ___, No. 17-976 (June 28, 2018); *Am. Beverage Ass’n v. City and Cnty. of San Francisco*, 871 F.3d 884 (9th Cir. 2017), *reh. en banc granted*, 880 F.3d 1019 (9th Cir. 2018); *Phillips v. Washington Legal Found.*, 524 U.S. 156 (1998).

WLF also regularly participates in federal administrative proceedings in support of expanded First Amendment rights. *See, e.g.*, FDA Docket No. FDA-2016-N-1149 (January 3, 2017) (response to FDA request for comments on manufacturer off-label communications); FDA Docket No. FDA-2008-D-0053 (May 15, 2014) (response to revised FDA Draft Guidance on distributing scientific and medical publications on off-label uses).

II. The 2016 Amendments to the AMA

In 2016, Congress amended the AMA, 7 U.S.C. § 1621 *et seq.*, by adding new Subtitles E and F. Subtitle E directs the Secretary of Agriculture to establish the National Bioengineered Food Disclosure Standard (NBFDS) for disclosing any BE food and any food that may be bioengineered. *See* 7 U.S.C. § 1639b(a)(1) (requiring the Secretary to establish a disclosure standard by July 29, 2018). Congress directed that the Secretary’s regulations “shall ... 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.” 7 U.S.C. § 1639b(b)(2)(C). The AMA as amended defines “bioengineering, with respect to a food,” as describing 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.” 7 U.S.C. § 1639(1). The amended act also preempts any state and local government’s genetic engineering labeling laws.

III. The Proposed Rule

The Secretary delegated to AMS the authority to create the NBFDS. The Proposed Rule, published by AMS in the Federal Register on May 4, 2018, would require the labeling of bioengineered food or food that contains a bioengineered ingredient. Rather than attempting to amplify the definition of “bioengineered food” set forth in the AMA, the Proposed Rule simply parrots that definition; it defines “bioengineered food” as “a food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.” *See* Proposed § 66.1. However, AMS stated that it welcomes comments regarding how to more precisely define the term.

In particular, AMS noted that earlier commenters strongly disagreed regarding whether highly refined foods and ingredients should fall within the definition of BE foods if they were produced using BE ingredients. AMS noted two widely disparate points of view:

Position 1: Highly refined products do not “contain genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.” The process of creating and manufacturing highly refined products removes genetic material, and there is no genetic material detected when the products are tested using common testing methods. Thus, highly refined products do not fall within the statutory definition of bioengineered food, and therefore do not require the disclosure.

Position 2: The definition of “bioengineering” includes all foods produced from bioengineering, such as highly refined products. Highly refined products contain modified genetic material before it is processed. Therefore, the resulting product could contain some trace amount of genetic material from the bioengineered food. There should be a presumption that highly refined products meet the statutory definition of “bioengineering” and are therefore bioengineered foods.

83 Fed. Reg. at 19862-63. The Proposed Rule took no position on this debate. It requested comments on these two different positions—in particular, comments on whether one position better accorded with the statutory definition.

The Proposed Rule did not propose the adoption of any “other factors and conditions under which a food is considered a bioengineered food,” as authorized by 7 U.S.C. § 1639b(b)(2)(C). It did however propose a regulation, Proposed § 66.200, that would permit any person to petition AMS to request the adoption of specified “other factors and conditions.” AMS suggested that one possible factor/condition might be the inability to detect recombinant DNA in highly refined products. 83 Fed. Reg. at 19866. AMS stated that, were it ultimately to adopt Position 2, later adoption of this factor/condition might permit manufacturers of highly refined products to avoid BE labeling requirements by demonstrating to AMS’s satisfaction that their products did not contain any recombinant DNA. *Id.* at 19866-87. In other words, the presumption would be that highly refined foods produced from BE ingredients are “bioengineered food,” and the regulated entities would be required to show to AMS’s satisfaction (to avoid a labeling requirement) that their highly refined products do not contain genetic material.

IV. First Amendment Background and Standard of Review

In order to demonstrate the serious First Amendment concerns raised by any effort by AMS to require BE labeling for a highly refined product in the absence of evidence

demonstrating that the product contains recombinant DNA, WLF briefly describes relevant First Amendment principles.

The First Amendment protects the freedom of speech as well as the freedom not to speak. *Wooley v. Maynard*, 430 U.S. 705, 713–15 (1977) (upholding right to refuse to display state motto, “Live Free or Die,” on automobile license plate). The right not to speak extends to businesses too, even when the compelled speech focuses explicitly on their commercial dealings. *See, e.g., United States v. United Foods, Inc.*, 533 U.S. 405, 410 (2001) (barring compelled support of mushroom advertising campaign to which the plaintiff objected based on its content); *Masterpiece Cakeshop, Ltd. v. Colorado Civil Rights Comm’n*, 138 S. Ct. 1719, 1745 (2018) (Thomas and Gorsuch, JJ., concurring in part and concurring in the judgment) (“The [lower court] also noted that [the involuntary speaker] is a ‘for-profit bakery’ that ‘charges its customers.’ ... But this Court has repeatedly rejected the notion that a speaker’s profit motive gives the government a freer hand in compelling speech.”) (citations omitted).

Although the Supreme Court has stated that commercial speech—that is, speech that does no more than propose a commercial transaction—is afforded a somewhat lower level of First Amendment protection than noncommercial speech, the Supreme Court has consistently held that commercial speech is nonetheless entitled to a substantial degree of constitutional protection. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 562–63 (1980). For example, in *Central Hudson*, the Court struck down a New York regulation that prohibited promotional advertising by an electrical utility company. *Id.* at 571–72. The Court established a four-prong test to review whether government regulation of commercial speech violates the First Amendment.¹ There, the Court found that the state had substantial governmental interests of (1) conserving energy, and (2) maintaining fair and efficient utility rates. *Id.* at 568–69. Additionally, it found that prohibiting promotional advertisements directly advanced the state’s governmental interests in energy conservation. *Id.* at 569. However, the Court determined that the speech regulation violated the First Amendment because its complete suppression of speech did not serve the state’s interest in a narrowly tailored manner. *Id.* at 571.

Some lower federal courts have mistakenly concluded that the First Amendment confers commercial entities with a lesser degree of protection from government-compelled speech than from government speech suppression. That conclusion is mistaken; the Supreme Court has repeatedly made clear—most recently in its decision last week in *NIFLA v. Becerra*, ___ U.S. ___, 2018 WL 3116336 (June 26, 2018)—that the First Amendment applies the same level of

¹ Under *Central Hudson*’s four-prong test, courts first consider whether the commercial speech is either inherently misleading or related to an unlawful activity. If not, the government may regulate the speech only upon a showing that: (2) the government has a substantial interest that it seeks to achieve; (3) the regulation directly advances the asserted interest; and (4) the regulation serves that interest in a narrowly tailored manner. *Central Hudson*, 447 U.S. at 566.

protection to both types of government speech regulation.

Those who seek to minimize constitutional protection against compelled commercial speech often point to the Supreme Court's decision in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985). But *Zauderer* was actually a largely successful First Amendment challenge to Ohio's efforts to impose significant restrictions on truthful attorney advertising. Applying *Central Hudson's* four-prong test, the Court struck down prohibitions on soliciting legal business through advertisements containing advice and/or information regarding specific legal problems and restrictions on the use of illustrations in attorney advertising. *Id.* at 639–49.

To be sure, the *Zauderer* Court did uphold Ohio's decision to discipline an attorney because he ran an advertisement that offered services on a "no cost" contingency-fee basis without simultaneously disclosing that clients could be liable for their opponents' litigation costs should they lose their case. *Id.* at 650–52. However, this was simply a special application of the *Central Hudson* test. Applying the *Central Hudson* four-prong test, the Court concluded that by imposing discipline on the attorney, Ohio was directly advancing its substantial interest in preventing consumer misunderstandings, and that requiring a company to include in its advertisement a government-mandated disclaimer designed to prevent consumer deception is preferable to prohibiting the advertisement altogether. *Id.* Thus, properly understood, *Zauderer* is applied as a means of directing governments to prefer disclaimer requirements as a more-narrowly-tailored alternative to outright speech bans when seeking to guard against consumer deception.

Zauderer's limited holding cannot be understood, as some lower federal courts have erroneously concluded, as stating that government *compulsion* of commercial speech deserves less First Amendment scrutiny than *restrictions* on commercial speech. Ohio was only compelling speech in the limited sense that it required attorneys wishing to advertise their services to include additional language "to dissipate the possibility of consumer confusion or deception." *Id.* at 651. *Zauderer* provides no support for the view that governments are permitted to require businesses to append virtually any "factual" speech to their advertisements/labeling that is reasonably related to the government's interest, and without regard to whether it is designed to dissipate the possibility of consumer deception. Application of the *Zauderer* standard is also limited to those instances in which the compelled government speech is both factual and uncontroversial. *Zauderer*, 471 U.S. at 651.

The limited scope of permissible government-mandated commercial speech was re-emphasized last week by the Supreme Court's *NIFLA* decision. The Court held that: (1) compelled speech must be designed "to remedy a harm that is potentially real, not purely hypothetical"; (2) it must "extend no more than reasonably is necessary"; and (3) the government bears "the burden to prove that the [compelled speech] is neither unjustified nor unduly burdensome." *NIFLA*, 2018 WL 3116336, at *14. *NIFLA* struck down California laws that compelled pregnancy crisis centers to notify women of California's free or low-cost services,

including abortion. In holding that California’s laws violated the pregnancy crisis centers’ First Amendment rights, the Court put tight limits on *Zauderer*. It affirmed that *Zauderer*’s “lower level of scrutiny” for compelled speech is limited to the mandatory “disclosure of purely factual and uncontroversial information about the terms under which services will be available.” *Id.* at *8 (citing *Zauderer*, 471 U.S. at 651). Because the speech compelled by California was not so limited, it could not withstand First Amendment scrutiny. *Ibid.*

V. *Zauderer* Does Not Apply to Bioengineered Food Labels

As the foregoing discussion makes clear, *Zauderer* is inapplicable to any effort by AMS to compel manufacturers and retailers to attach BE labeling to their highly refined products. The purpose of the proposed labeling requirement is to inform consumers of the food’s contents; it is not to prevent consumer deception. Unlike in *Zauderer*, consumers in this situation are not misled as to the contents of food products when it does not have a BE food label on it. Moreover, a BE food label on highly refined products most likely does not qualify as “factual” and certainly does not qualify as “uncontroversial” given on-going disputes regarding whether those products contain any recombinant DNA. The mere fact that there are strong views on both sides of the argument shows that the labeling of highly refined products as BE food is controversial speech. The purpose of the disclosure is to inform the public about the contents of the food, not to inform them of the farming practices used to produce the products. A BE food label on highly refined products does not achieve the purpose of informing the public about the food product’s contents.

Because *Zauderer* is inapplicable to a constitutional analysis of the Proposed Rule, any speech mandated by the Proposed Rule must pass constitutional muster under a review standard at least as stringent as the intermediate standard articulated in *Central Hudson*.² As explained below, any effort to compel BE labeling of highly refined foods would fail prongs two, three, and four of the *Central Hudson* test. AMS cannot demonstrate a substantial government interest in labeling, the compelled speech would not directly advance any such government interest, nor would it operate in a narrowly-tailored manner.

² To the extent that any rule adopted by AMS imposes *content-based* burdens on food manufacturers’ speech, those burdens should be subject to a heightened standard of review—even more stringent than the *Central Hudson* standard. *See, e.g., Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011). Indeed, *NIFLA* held that the compelled speech at issue in that case should be subject to *strict* scrutiny in light of the content-based nature of California’s speech requirements. *NIFLA*, 2018 WL 3116336 , at *7. However, there is no reason to address whether imposing BE labeling requirements on highly refined foods could pass heightened First Amendment scrutiny because it does not pass *Central Hudson*’s intermediate standard.

VI. The First Amendment Prohibits Compelled BE Labeling for Highly Refined Products for Which AMS Lacks Evidence of the Presence of Recombinant DNA

WLF does not address the constitutionality of BE labeling for highly refined products that, to AMS's knowledge, contains recombinant DNA. We address instead the situation posited by AMS in its Proposed Rule: highly refined products produced from BE foods *might* contain recombinant DNA even though its presence cannot be detected, and therefore (proponents of Position 2 contend) we should *presume* its presence and require labeling unless the manufacturer can demonstrate to the satisfaction of AMS that the products contain no recombinant DNA.

Any such Rule could not withstand *Central Hudson* scrutiny and would constitute a clear violation of the First Amendment. First, AMS could not identify a substantial government interest at stake. While there is a government interest in providing consumers with information about the ingredients of food they are purchasing, that interest is not at stake here if AMS does not know one way or the other whether the highly refined products actually contain recombinant DNA. Proponents of Position 2 presumably would argue that consumers have an interest in knowing that the highly refined products they are purchasing were produced from BE foods. But that alleged consumer interest has nothing to do with the ingredients of the product that the consumer is actually purchasing, if (as far as AMS knows) the ingredients of highly processed products are indistinguishable regardless of whether or not they were produced using BE foods.

No court has ever upheld compelled speech requirements based on alleged government interests of the sorts at issue here. For example, the Second Circuit has held that a government's interest of merely satisfying consumer curiosity is not a substantial government interest sufficient to justify compelled commercial speech. *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 73–74 (2d Cir. 1996). *Amestoy* struck down a Vermont law that required dairy manufacturers to label all dairy products produced from cows given a certain hormone to increase milk production. *Id.* The court reasoned that the hormone-derived products were identical to the dairy products from untreated cows, and that there were “no human safety or health concerns associated with [the hormone].” *Id.* Therefore, Vermont could not compel dairy manufacturers to label dairy products that came from cows treated with the hormone simply to satisfy consumer curiosity. *Id.* *Amestoy* demonstrates that the federal government lacks a substantial interest in mandating BE labeling for highly refined products in the absence of evidence that the ingredients of such products vary based on whether they were produced using BE foods.

Second, even if AMS could identify a substantial government interest, there is no evidence that BE labeling for highly refined products would substantially advance those interests. A BE label on highly refined products does nothing to provide consumers with accurate product-ingredient information if AMS is unable to carry its burden of demonstrating that the products actually contain recombinant DNA. Consumers would reasonably infer that a BE label suggests the product actually contains some vestiges of the BE foods from which it was produced. That

inference would be inaccurate in the absence of evidence that the product in question actually contains recombinant DNA. Adopting a presumption that such foods contain recombinant DNA and thereby should be subject to compelled-speech requirements is, as explained above, constitutionally impermissible. The burden of proof is on *AMS* to demonstrate that highly refined products contain recombinant DNA (and thus that compelled speech would directly serve its interest in providing consumers with accurate information), not on manufacturers to prove the opposite.

Lastly, the proposed labeling requirement does not serve the government's interest in a narrowly-tailored manner. If AMS desires to ensure that highly refined products that contain recombinant DNA are labeled, it could do so in a manner that would not impose burdens on manufacturers' First Amendment rights. AMS could impose regulation that requires manufacturers of highly refined products to keep records of their products and to conduct testing to ascertain whether their highly refined products contain relevant genetic material. If that testing satisfies the manufacturer that no such material is present, it would not be required to display BE labeling. This duty of substantiation is more narrowly-tailored than the sweeping regulation contemplated by Position 2. Under this alternative scenario, a labeling duty could arise only if AMS, while conducting audit procedures, determines that the manufacturer's testing is inadequate and/or that its products really do contain recombinant DNA.

VII. Conclusion

WLF appreciates the opportunity to submit these comments relating to AMS's Proposed Rule. For the reasons explained above, adoption of Position 2 outlined in the Proposed Rule would not only be inconsistent with the statutory definition of "bioengineered food," but it also would be inconsistent with First Amendment limitations on compelled government speech.

Sincerely,

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