



Pennsylvania  
Association for  
Sustainable Agriculture

104 North Street  
PO Box 419  
Millheim, PA 16854  
(814) 349-9856  
Fax (814) 349-9840  
www.pasafarming.org

To: Pennsylvania Independent Regulatory Review Commission (IRRC)

From: Brian Snyder  
Executive Director  
Pennsylvania Association for Sustainable Agriculture (PASA)

Date: October 7, 2010

Re: PA Department of Agriculture Final Regulation #2-160 (IRRC #2777): "Milk Sanitation"

Dear Commissioners,

My name is Brian Snyder, and I represent the nearly 6,000 members of the Pennsylvania Association for Sustainable Agriculture. With regard to the matter before you today, I presume you have read our formal comments, and I will therefore not repeat them at this time.

I will, however, implore you to decide this matter in consideration not only of the farmers who are in attendance, but those who are not. Dairy farming is well known to be among the most challenging enterprises any farmer can pursue, particularly in terms of the time required, on a regular schedule, usually twice per day, 365 days per year. It is in fact very difficult for any active dairy farmer to participate in meetings of this nature, or to represent him or herself in such proceedings.

You should also take note that very many of the dairy farmers affected by the proposed regulations – the "regulated community" as you call them – represent a minority population that does not have easy access to highly technological forms of communication. That is in fact one of the main reasons we are asking you to send these regulations back to the Department of Agriculture, asking them to conduct a more thorough and just process, in order to bring you a more workable document in the future. Even though our organization made numerous appeals to the Department to include all the farmers they regulate in the process of writing these regulations, that goal was never effectively responded to or achieved.

We also ask you to pay particular attention, not only to the way in which the Department failed to communicate to these farmers, but how they chose to communicate about them and their work in some of the answers to your queries, and those offered by the public in this process. We found some of their answers to be naïve at best, but misleading and even demeaning if taken literally. I feel it would dishonor the farmers affected by these regulations if you approve this document under those circumstances.

Finally, we also draw your attention to, and have provided you with copies of a landmark decision returned just last week by the United States Court of Appeals, Sixth Circuit (Ohio) that found credible evidence of compositional differences between milk produced with and without the use of the artificial growth hormone known as Recombinant Bovine Somatotropin, or rbST. Furthermore, the court's finding was that such compositional differences often constitute lower quality milk coming from cows treated with this drug, including a possible increase in cancer risk to citizens who consume dairy products. We raise this issue because some of the comments made to the commission following the first draft of regulations involved the possibility of treating rbST as an adulterant, to be declared on product labels in the public's best interest. The Department's response was basically to deny compositional differences, in declining to require such labels. We feel this matter deserves closer examination by the Department in light of the Circuit Court's recent instructions, and that this constitutes another good reason to reject the draft "final" regulations at this time.

Thank you very much for this opportunity to address the commission on this important matter.



RECOMMENDED FOR FULL-TEXT PUBLICATION  
Pursuant to Sixth Circuit Rule 206

File Name: 10a0322p.06

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

INTERNATIONAL DAIRY FOODS ASSOCIATION  
(09-3515); ORGANIC TRADE ASSOCIATION  
(09-3526),

*Plaintiffs-Appellants,*

v.

ROBERT J. BOGGS, in his official capacity as  
Ohio Director of Agriculture,

*Defendant-Appellee.*

Nos. 09-3515/3526

Appeal from the United States District Court  
for the Southern District of Ohio at Columbus.  
Nos. 08-00628; 08-00629—James L. Graham, District Judge.

Argued: June 10, 2010

Decided and Filed: September 30, 2010

Before: GILMAN and WHITE, Circuit Judges; THAPAR, District Judge.\*

**COUNSEL**

**ARGUED:** Charles M. English, Jr., OBER, KALER, GRIMES & SHRIVER, Washington, D.C., Randall J. Sunshine, LINER GRODE STEIN YANKELEVITZ SUNSHINE REGENSTREIF & TAYLOR LLP, Los Angeles, California, for Appellants. David M. Lieberman, OFFICE OF THE OHIO ATTORNEY GENERAL, Columbus, Ohio, for Appellee. **ON BRIEF:** Charles M. English, Jr., Wendy Yoviene, OBER, KALER, GRIMES & SHRIVER, Washington, D.C., Randall J. Sunshine, LINER GRODE STEIN YANKELEVITZ SUNSHINE REGENSTREIF & TAYLOR LLP, Los Angeles, California, for Appellants. David M. Lieberman, Benjamin C. Mizer, Stephen P. Carney, William J. Cole, James Patterson, OFFICE OF THE OHIO ATTORNEY GENERAL, Columbus, Ohio, for Appellee. Gregory R. Flax, BAKER & HOSTETLER

\*The Honorable Amul R. Thapar, United States District Judge for the Eastern District of Kentucky, sitting by designation.

LLP, Columbus, Ohio, Paige Tomaselli, THE CENTER FOR FOOD SAFETY, San Francisco, California, for Amici Curiae.

---

**OPINION**

---

RONALD LEE GILMAN, Circuit Judge. In response to a number of dairy processors advertising their nonuse of artificial hormones in the production of milk, the Ohio Department of Agriculture (ODA) adopted a regulation designed to curb the allegedly misleading labeling of dairy products. The regulation prohibits dairy processors from making claims about the absence of artificial hormones in their milk products (composition claims), and it also requires them to include a disclaimer when making such claims about their production processes. Two separate dairy-processor trade organizations filed suit, asserting that the regulation violates their First Amendment rights and the dormant Commerce Clause.

The district court granted summary judgment in favor of the state of Ohio on all but one of these claims. Based on this ruling, the court also denied the dairy processors' motion for a preliminary injunction. The processors then filed an interlocutory appeal with regard to both orders. For the following reasons, we **REVERSE** the judgment of the district court to the extent that it upheld the regulation's prophylactic ban on composition claims and its prohibition on the use of an asterisk for required disclosures to accompany production claims, **AFFIRM** the remainder of the judgment, and **REMAND** the case to the district court for further proceedings consistent with this opinion.

**I. BACKGROUND**

**A. Factual history**

This case concerns the labeling of milk products to reflect the nonuse of artificial hormones by members of two dairy-processor trade organizations, the International Dairy Foods Association (IDFA) and the Organic Trade Association (OTA). The IDFA

is a trade organization whose collective membership consists of an estimated 85 percent of the milk, cultured-products, cheese, and frozen-desserts producers in the United States. In contrast, OTA's members span the entire organic industry, including dairy production. Several OTA members are certified organic dairy processors that must comply with the Organic Foods Production Act (OFPA), 7 U.S.C. § 6501 et seq., which forbids the use of antibiotics, artificial hormones, and pesticides in food production. (The IDFA and the OTA are hereinafter collectively referred to as "the Processors.")

At issue in this case is a genetically engineered hormone called recombinant bovine somatotropin (rbST), also known as recombinant bovine growth hormone (rbGH). The substance is given to lactating cows to increase their milk production. As used, rbST combines with the naturally occurring bovine somatotropin (bST) to increase dairy cows' milk production by up to 10 percent over cows not given the artificial hormone.

In 1993, the Food and Drug Administration (FDA) approved the use of rbST in cows, concluding that the artificial hormone "is safe and effective for dairy cows, that milk from rbST-treated cows is safe for human consumption, and that production and use of the product do not have a significant impact on the environment." Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279, 6279-80 (Feb. 10, 1994); *see also* 58 Fed. Reg. 59946 (Nov. 12, 1993) (approving the use of rbST). The agency further "found that there was no significant difference between milk from treated and untreated cows." *Id.* at 6280. Recognizing that some food companies might wish to inform consumers that they do not use milk from cows receiving rbST, the FDA determined that such companies could voluntarily label their products as such, provided that "any statements made are truthful and not misleading." *Id.*

In response to requests from several states for further guidance on this issue, the FDA in 1994 published an Interim Guidance regarding the labeling of milk and milk products from cows not treated with rbST. The Guidance addressed two types of claims: (1) "composition claims," which refer to the final composition of the milk or milk

product (e.g., “rbST free”), and (2) “production claims,” which refer to the manner in which the product is produced (e.g., “from cows not treated with rbST”). With regard to composition claims, the FDA strongly discouraged their use. It concluded that the term “bST-free” would be false under any circumstances, given that bST is naturally present in milk. 59 Fed. Reg. at 6280. The FDA next addressed the claim “rbST free,” noting that it was “concerned that the term . . . may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced.” *Id.*

Instead, the agency encouraged dairy processors to use production claims such as “from cows not treated with rbST.” But it cautioned that even these claims have “the potential to be misunderstood by consumers” because they “may imply that milk from untreated cows is safer or of higher quality than milk from treated cows,” an implication that would be “false and misleading.” *Id.* The FDA therefore suggested that processors place production claims “in a proper context,” such as by pairing a production claim with the statement that “[n]o significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows,” or “by conveying the firm’s reasons (other than safety or quality) for choosing not to use milk from cows treated with rbST.” *Id.*

Bowing to “the traditional role of the States in overseeing milk production,” the FDA clarified that its Guidance was a nonbinding document intended to give states assistance in formulating their own labeling laws. *Id.* The FDA also recommended that states require food companies to maintain records substantiating their claims and to make those records available for inspection. *Id.*

In the 14 years since the FDA issued its Guidance, consumer demand for dairy products made with milk from non-rbST-treated cows has increased. Many dairy processors, including those belonging to both the IDFA and the OTA, no longer accept milk from dairy farmers that comes from cows treated with rbST. Some IDFA processors, for example, have entered into agreements with milk suppliers to ensure that the milk received is from untreated cows, and the processors label their products to

reflect this fact. And OTA members who label their products as “organic” are specifically precluded by the OFPA from using milk from cows treated with rbST or any other artificial hormone.

Several of these Processors advertised their nonuse of rbST on dairy products that they sold in Ohio. In response, Ohio Governor Ted Strickland issued an executive order in February 2008 that directed the ODA to “define what constitutes false and misleading labels on milk and milk products.” Ohio Governor Executive Order 2008-03S (Feb. 7, 2008). He further ordered the agency to require dairy producers claiming that they do not use rbST to submit supporting documentation and to create labels containing representations consistent with the FDA’s rbST findings.

The ODA then issued a proposed Rule restricting the types of claims that dairy processors could make about milk and milk products. To gauge public support for these labeling restrictions, the ODA solicited comments about the proposed Rule and held two public hearings. Less than 70 of the 2,700 emails and letters sent to the ODA during this time period were in favor of the proposed Rule, according to estimates made by the Processors.

ODA Director Robert Boggs nevertheless adopted the Rule in May 2008. In relevant part, the final Rule states that

(A) Pursuant to sections 917.05 and 3715.60 of the Revised Code, dairy products will be deemed to be misbranded if they contain a statement which is false or misleading.

(B) A dairy label which contains a production claim that “this milk is from cows not supplemented with rbST” (or a substantially equivalent claim) may be considered misleading on the basis of such language, unless:

(1) The labeling entity has verified that the claim is accurate, and proper documents, including, but not limited to, producer signed affidavits, farm weight tickets and plant audit trails, to support the claim, are made readily available to ODA for inspection; and

(2) The label contains, in the same label panel, in exactly the same font, style, case, and color and at least half the

size (but no smaller than seven point font) as the foregoing representation, the following contiguous additional statement (or a substantially equivalent statement): "The FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows."

(C) Making claims regarding the composition of milk with respect to hormones, such as "No Hormones", "Hormone Free", "rbST Free", "rbGH Free", "No Artificial Hormones" and "bST Free", is false and misleading. ODA will not permit such statements on any dairy product labels.

(D) Statements may be considered to be false or misleading if they indicate the absence of a compound not permitted by the United States [F]ood and [D]rug [A]dministration to be present in any dairy product, including, but not limited to antibiotics or pesticides. Except as otherwise provided in this rule, accurate production claims will not be deemed false or misleading.

Ohio Admin. Code § 901:11-8-01.

## **B. Procedural history**

Shortly after the final adoption of the Rule, the IDFA and the OTA filed separate lawsuits in the district court, challenging the Rule as unconstitutional. The two cases were later consolidated by the district court. According to the Processors, Ohio's labeling Rule infringes on their First Amendment rights, violates the dormant Commerce Clause, is unconstitutionally vague, and is preempted by the OFPA. The IDFA also asserted an equal protection claim in its complaint.

The Processors sought a preliminary injunction, after which both sides moved for summary judgment on all issues except the IDFA's equal protection claim. Addressing all three motions in one order, the district court granted summary judgment in favor of the State on the Processors' Commerce Clause, void-for-vagueness, and preemption claims. Regarding the Processors' First Amendment claim, the court granted summary judgment in favor of the State on the issue of the Rule's prohibition of composition claims. But it granted the State only partial summary judgment as to the Rule's restrictions on production claims in light of an undeveloped factual record on the



issue of whether the Rule's requirements were unduly burdensome as applied to small containers. The court found that, in light of these rulings, the Processors had not shown that they were likely to prevail on the merits of their claims and therefore denied their motion for a preliminary injunction. This interlocutory appeal of the district court's preliminary injunction and summary judgment orders followed. The Processors contest the district court's ruling only as it pertains to their First Amendment and Commerce Clause claims.

## II. ANALYSIS

### A. Standards of review

We review de novo a district court's grant of summary judgment. *ACLU of Ky. v. Grayson County*, 591 F.3d 837, 843 (6th Cir. 2010). Summary judgment is proper where no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c)(2). In considering a motion for summary judgment, the district court must draw all reasonable inferences in favor of the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The central issue is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986).

By contrast, the decision of whether to grant a motion for a preliminary injunction is "left to the sound discretion of the district court." *Deja Vu of Cincinnati, L.L.C. v. Union Twp. Bd. of Trs.*, 411 F.3d 777, 782 (6th Cir. 2005). "A district court, in deciding whether to grant an injunction, abuses its discretion when it applies the incorrect legal standard, misapplies the correct legal standard, or relies upon clearly erroneous findings of fact." *Id.* (citation and internal quotation marks omitted). The following factors are to be considered by a district court in deciding whether to grant a preliminary injunction:

- (1) whether the plaintiff has established a substantial likelihood or probability of success on the merits;
- (2) whether there is a threat of irreparable harm to the plaintiff;
- (3) whether issuance of the injunction

would cause substantial harm to others; and (4) whether the public interest would be served by granting injunctive relief.

*Nightclubs, Inc. v. City of Paducah*, 202 F.3d 884, 888 (6th Cir. 2000), *overruled on other grounds by 729, Inc. v. Kenton County Fiscal Court*, 515 F.3d 485 (6th Cir. 2008).

Like the parties, the district court focused exclusively on the first of these four factors—whether the Processors are likely to succeed on the merits of their claims—and relied on its summary judgment ruling to conclude that the Processors were not entitled to injunctive relief. The key issue on appeal is thus whether the district court erred in its adverse rulings on the Processors' (1) First Amendment challenge to the Rule's prophylactic ban on composition claims, (2) First Amendment challenge to the Rule's disclosure requirement for production claims, and (3) dormant Commerce Clause challenge to the Rule. We address each claim in turn below.

**B. First Amendment challenge to the ban on composition claims**

The Processors contend that the Ohio rule violates the First Amendment by placing a prophylactic ban on composition claims such as “rbST free,” “antibiotic-free,” and “pesticide-free.” Both sides agree that the composition claims at issue constitute commercial speech and are thus afforded less extensive protection under the First Amendment than noncommercial speech. *See Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 637 (1985) (making the commercial-noncommercial distinction in the context of restrictions on attorney advertising). Under the commercial-speech framework, “[t]ruthful advertising related to lawful activities is entitled to the protections of the First Amendment,” *In re R.M.J.*, 455 U.S. 191, 203 (1982), but the government is “free to prevent the dissemination of commercial speech that is false, deceptive, or misleading,” *Zauderer*, 471 U.S. at 638.

Prophylactic bans on commercial speech are evaluated under a four-part analysis first set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). Pursuant to that analysis, a court first determines whether the speech concerns unlawful activity or is misleading. *Id.* at 566. If a court finds in the

affirmative on either prong, the speech is not entitled to First Amendment protection, and the analysis ends. *Id.* But if the court finds that the speech is entitled to First Amendment protection, it then makes three additional inquiries: (1) whether the asserted governmental interest is substantial, (2) whether the regulation directly advances that interest, and (3) whether the regulation is more extensive than necessary to serve the asserted interest. *Id.*

***1. Whether the Processors' composition claims are inherently misleading***

The district court in the present case concluded that the composition claims were misleading and therefore not entitled to any First Amendment protection. "Misleading advertising may be prohibited entirely," including where the speech is "inherently likely to deceive or where the record indicates that a particular form or method of advertising has in fact been deceptive." *In re R.M.J.*, 455 U.S. at 202-03. Where speech is only potentially misleading, however, the *Central Hudson* framework applies. *Id.* at 203. Under these circumstances, "the preferred remedy is more disclosure, rather than less." *Bates v. State Bar of Ariz.*, 433 U.S. 350, 374-75 (1977) (striking down a ban on price advertising for "routine" legal services in part because "it seems peculiar to deny the consumer, on the ground that the information is incomplete, at least some of the relevant information needed to reach an informed decision").

The district court held that the composition claims were inherently misleading because "they imply a compositional difference between those products that are produced with rb[ST] and those that are not," in contravention of the FDA's finding that there is no measurable compositional difference between the two. This conclusion is belied by the record, however, which shows that, contrary to the district court's assertion, a compositional difference does exist between milk from untreated cows and conventional milk ("conventional milk," as used throughout this opinion, refers to milk from cows treated with rbST). As detailed by the amici parties seeking to strike down the Rule, the use of rbST in milk production has been shown to elevate the levels of insulin-like growth factor 1 (IGF-1), a naturally-occurring hormone that in high levels is linked to several types of cancers, among other things. The amici also point to certain

studies indicating that rbST use induces an unnatural period of milk production during a cow's "negative energy phase." According to these studies, milk produced during this stage is considered to be low quality due to its increased fat content and its decreased level of proteins. The amici further note that milk from treated cows contains higher somatic cell counts, which makes the milk turn sour more quickly and is another indicator of poor milk quality. This evidence precludes us from agreeing with the district court's conclusion that there is no compositional difference between the two types of milk.

In addition, and more salient to the regulation of composition claims like "rbST free," the failure to discover rbST in conventional milk is not necessarily because the artificial hormone is absent in such milk, but rather because scientists have been unable to perfect a *test* to detect it. As recognized by the State's brief in the district court, "given existing technology, it is currently impossible to test milk to determine whether the hormones present are natural hormones or recombinant hormones (such as rbST)." The State further conceded this point at oral argument, acknowledging that conventional milk "could" contain rbST, but that no test has been able to verify if this is in fact the case. This uncertainty is also implicit in the FDA's 1994 Guidance. There, the agency stated that "there [i]s no *significant* difference between milk from treated and untreated cows" because "[t]here is currently no way to differentiate analytically between naturally occurring bST and [r]bST in milk." 59 Fed. Reg. 6279, 6280 (emphasis added). The FDA thus appears to have left room for the fact that *some* compositional difference between the two types of milk may exist, leaving open the possibility that one day a method might exist to detect whether rbST is in fact present in conventional milk.

Taken collectively, this evidence points to two distinct types of milk. On the one hand is milk from cows never given rbST, which in turn cannot produce milk that has rbST as a matter of fact. The composition claim "rbST free" is therefore demonstrably true as applied to this milk. On the other hand, milk from cows treated with rbST might contain the artificial hormone, although there is currently no way to determine whether that is the case. But even if rbST is not present in conventional milk, there is still

evidence that it contains increased levels of IGF-1 and might be compositionally of a lesser quality.

A compositional difference thus exists between the two types of milk, although the extent of this difference—namely whether conventional milk does in fact contain rbST—is still very much an open question. As such, the composition claim “rbST free” at best informs consumers of a meaningful distinction between conventional and other types of milk and at worst potentially misleads them into believing that a compositionally distinct milk adversely affects their health. Under these circumstances, we conclude that composition claims like “rbST free” are not inherently misleading. We must therefore apply the remaining three *Central Hudson* factors to assess the constitutionality of the Rule’s prophylactic ban on the composition claims “rbST free” and “artificial hormone free.”

As a separate matter, the Processors challenge on appeal the Rule’s ban of composition claims related to antibiotics and pesticides. The State responds that antibiotics and pesticides are “largely detectable in milk” and that “all milk is routinely tested for antibiotics, and the presence of any antibiotic in any amount renders the milk unacceptable for consumption.” It added that cost considerations prevent the routine testing of every batch of milk. The State, however, did not present any evidence with regard to testing procedures used to detect antibiotics and pesticides.

Evidence of this testing might well influence our determination as to whether the claims “antibiotic free” and “pesticide free” are inherently misleading. If the State’s testing can detect these substances and prevent any amount of them from being present in conventional milk, then such claims would be inherently misleading because they falsely imply that conventional milk contains antibiotics and pesticides when in fact the State tests to ensure that it does not. But there is no evidence in the record to verify the State’s contention. In light of this insufficiently developed factual record, the State has not shown that it is entitled to summary judgment on this challenge. We therefore remand the issue for further proceedings.

**2. *The remaining Central Hudson factors***

Having determined that the composition claim “rbST free” is not inherently misleading, we must review the State’s ban on such claims under the final three *Central Hudson* factors: (1) whether the State’s asserted interest is substantial, (2) whether the regulation directly advances that interest, and (3) whether the regulation is no more extensive than necessary to serve the asserted interest. *See Central Hudson*, 447 U.S. at 566. All three of these factors must be met in order for the Rule to be upheld. *See id.*

Turning to the first factor, we note that the Rule’s purported purpose is to prevent the use of “false or misleading” labeling. *See Ohio Admin. Code § 901:11-8-01(A)*. The Processors concede that this interest is substantial. But because the Rule is aimed at preventing consumer deception, the State bears the burden to “demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.” *Ibanez v. Fla. Dep’t of Bus. & Prof’l Regulation, Bd. of Accountancy*, 512 U.S. 136, 146 (1994) (citation omitted). In *Ibanez*, the Supreme Court declared unconstitutional the Florida Board of Accountancy’s censuring of an attorney for referring to her designation as a Certified Public Accountant and as a Certified Financial Planner in her advertising materials and other communications with the public. The Court’s ruling stemmed from “the failure of the Board to point to any harm that is potentially real, not purely hypothetical” and the “complete absence of any evidence of deception.” *Id.* at 145-46 (citation omitted).

In the present case, the record of deception is weak at best. The only evidence that the State points to is the FDA’s Interim Guidance and consumer comments that it received in response to the proposed Rule. But the Guidance provides little support in this regard. The FDA suggests in the Guidance that the claim “rbST free” “*may imply a compositional difference*” between the two types of milk, 59 Fed. Reg. 6279, 6280 (emphasis added), but this statement does not establish that such a claim is necessarily misleading in every context. Furthermore, the FDA cited no evidence or studies in the Guidance to support its concerns regarding consumer confusion. The Guidance therefore does not constitute “evidence of deception” as required under *Ibanez*.

Also unhelpful are the consumer comments that the ODA received after issuing the proposed Rule. The State received approximately 2,700 comments, of which the Processors estimate that only 70 were in support of the Rule. We agree with the State that some of these comments demonstrate consumer confusion regarding the use of rbST in milk production. One commenter, for example, asserted that she needed “to know that the milk I drink has no added hormones,” thereby indicating that she believed rbST to be present in conventional milk. But few if any of these commenters indicated that their confusion stemmed from the product labels. The commenter quoted above, for instance, was informed about rbST and milk production from conversations with her oncologist, not from reading the labels. Although there is not a “complete absence of deception” as there was in *Ibanez*, the proof falls far short of establishing that Ohio consumers have been misled by dairy-product labeling.

We need not address this issue further, however, because we conclude that the Rule does not directly advance the State’s interest and is more extensive than necessary to serve that interest. These last two steps of the *Central Hudson* test are complementary. They involve “asking whether the speech restriction is not more extensive than necessary to serve the interests that support it.” *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 556 (2001) (citation omitted). Accordingly, there must be a “reasonable fit between the legislature’s ends and the means chosen to accomplish those ends, a means narrowly tailored to achieve the desired objective.” *Id.* (citation, ellipsis, and internal quotation marks omitted). “[I]f there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech, that is certainly a relevant consideration in determining whether the ‘fit’ between ends and means is reasonable.” *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 n.13 (1993).

We agree with the Processors that the potential consumer confusion created by the composition claim “rbST free” could be alleviated by accompanying the claim with a disclaimer informing consumers that rbST has yet to be detected in conventional milk. Examples of possible disclaimers include a statement regarding the lack of evidence that

conventional milk contains rbST, or even the disclaimer already required by the Rule to accompany production claims: “The FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows.”

The district court rejected the use of a disclaimer to cure any confusion caused by the claim “rbST free,” reasoning that “such a statement would only serve to confuse a consumer.” In the district court’s view, “the label would contain contradictory information—it would say a product is ‘free’ of rbST, but at the same time state that there is no rbST in other products, which defeats the purpose of making the claim in the first place.” But this conclusion rests on the assumption that conventional milk has conclusively been shown to be free of rbST, when in fact that possibility remains an open question. The claim “rbST free,” when used in conjunction with an appropriate disclaimer, could assure consumers that the substance is definitively not in milk so labeled while also advising them that it has yet to be detected in conventional milk. There thus exists a method by which the potential difference between the two types of milk can be presented without also being deceptive. *See In re R.M.J.*, 455 U.S. 191, 203 (1982) (“[T]he States may not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive.”).

For these reasons, we conclude that the Rule’s prophylactic ban of composition claims such as “rbST free” is more extensive than necessary to serve the State’s interest in preventing consumer deception. This provision of the Rule therefore cannot withstand scrutiny under *Central Hudson*.

**C. First Amendment challenge to the disclosure requirement for production claims**

In addition to composition claims, the Ohio Rule regulates the use of production claims such as “this milk is from cows not supplemented with rbST.” When using these claims, processors must include a disclosure on the label stating that “[t]he FDA has determined that no significant difference has been shown between milk derived from



rbST-supplemented and non-rbST-supplemented cows.” Ohio Admin. Code § 901:11-8-01(B)(2). This disclosure must be on the same label panel, “in exactly the same font, style, case, and color and at least half the size (but no smaller than seven point font)” as the production claim. *Id.*

The district court granted the State partial summary judgment on this issue. First, the court held that the disclosure requirement is subject to a reasonableness standard rather than intermediate scrutiny under the *Central Hudson* test. The court then found that the claim “this milk is from cows not supplemented with rbST” implies that processors using rbST have an inferior or unsafe product, and that the State has an interest in preventing the dissemination of this potentially misleading information. Although the court rejected the Processors’ argument that the cost of ensuring that their labels comply with the Rule makes the Rule unduly burdensome, it found that there was a factual dispute as to whether the Rule’s formatting requirements were unduly burdensome to the extent that the Processors might not be able to include the required disclosure on small containers. The court therefore denied the State summary judgment on this latter issue.

**1. *Proper standard for evaluating disclosure requirements***

As an initial matter, the Processors argue that the district court failed to employ the appropriate standard of review for evaluating disclosure requirements. The court relied on *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985), where the Supreme Court articulated a more lenient standard than the *Central Hudson* test to use when disclosure requirements, as opposed to outright prohibitions on speech, are at issue. In *Zauderer*, the Supreme Court explained that, “because disclosure requirements trench much more narrowly on an advertiser’s interests than do flat prohibitions on speech, warnings or disclaimers might be appropriately required in order to dissipate the possibility of consumer confusion or deception.” *Id.* at 651 (alterations, citation, and ellipsis omitted). It therefore held that disclosure requirements do not violate an advertiser’s First Amendment rights where the requirements “are reasonably related to the State’s interest in preventing deception of

consumers.” *Id.* Such requirements, however, cannot be “unjustified or unduly burdensome.” *Id.*

The Supreme Court recently clarified the standard of review to apply to disclosure requirements in *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324 (2010). That case involved challenges to recent revisions of the Bankruptcy Code, including provisions that require certain professionals providing debt-relief assistance to disclose in their advertisements that their help was related to bankruptcy relief and to identify themselves as debt-relief agencies. *Id.* at 1330. The Court observed that the relevant provisions targeted marketing claims that were inherently deceptive because they promised “debt relief without any reference to the possibility of filing for bankruptcy, which has inherent costs.” *Id.* at 1340. Given this, and the fact that the regulation required a disclosure rather than imposing a prohibition on speech, the Court upheld the constitutionality of the provisions under *Zauderer*. *Id.*

*Milavetz* thus established that *Zauderer* applies where a disclosure requirement targets speech that is *inherently* misleading. We conclude that *Zauderer* also controls our analysis where, as here, the speech at issue is *potentially* misleading. Several reasons support this conclusion. First, in *Milavetz*, the Court did not explicitly limit its application of *Zauderer* to inherently misleading speech, instead stating that a relaxed standard of review applies to disclosure requirements regulating “*misleading* commercial speech.” *Id.* at 1339 (emphasis in original). *But see id.* (Thomas, J., concurring) (“[A] disclosure requirement passes constitutional muster only to the extent that it is aimed at advertisements that, by their nature, [are inherently likely to deceive or have in fact been deceptive].”).

In addition, as the Court recognized in *Milavetz*, the impetus behind the formation of the *Zauderer* standard was the fact that “First Amendment protection for commercial speech is justified in large part by the information’s value to consumers.” *Id.* The speech rights of advertisers, in contrast, are of less value; specifically, their “constitutionally protected interest in *not* providing the required factual information is ‘minimal.’” *Id.* (citing *Zauderer*, 471 U.S. at 651). This justification for the

*Zauderer* standard thus fits regulations that require a disclosure, regardless of whether the speech being targeted is inherently or potentially misleading. Because the Ohio Rule regulates production claims by requiring them to be accompanied by a disclosure, *Zauderer* controls our review.

Our sister circuits have similarly recognized this rationale for employing the *Zauderer* standard. The Court of Appeals for the Second Circuit, for example, has held that “there are material differences between purely factual and uncontroversial disclosure requirements and outright prohibitions on speech.” *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 113 (2d Cir. 2001) (citing *Zauderer*) (brackets and internal quotation marks omitted). Such differential treatment is due to the fact that the “mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests.” *Id.* at 114; *see also United States v. Wenger*, 427 F.3d 840, 849 (10th Cir. 2005) (observing that advertisers’ “constitutionally protected interest in not providing any particular factual information in [their] advertising is minimal” (quoting *Zauderer*)).

In arguing to the contrary, the Processors rely on two decisions from the Eleventh Circuit Court of Appeals in which that court applied the *Central Hudson* factors to disclosure requirements. One of these is *Borgner v. Brooks*, 284 F.3d 1204, 1210-13 (11th Cir. 2002), which applied the *Central Hudson* test to a statute requiring dentists to include disclaimers when advertising a specialty practice not recognized by the Florida Board of Dentistry and/or membership in an organization affiliated with such a specialty. The other is *Mason v. Florida Bar*, 208 F.3d 952, 954-55 (11th Cir. 2000), where the court analyzed a Florida Bar disclosure requirement for “self laudatory” statements under the *Central Hudson* framework. But in neither case did the Eleventh Circuit explain its decision to employ the *Central Hudson* test instead of *Zauderer*. Moreover, the *Borgner* decision acknowledged that “[c]ourts have been more tolerant of regulations mandating disclosure requirements than they have been of regulations that

impose a total ban on commercial speech.” *Borgner*, 284 F.3d at 1214. We therefore find these two cases unpersuasive in determining the proper standard of review.

In sum, we conclude that the Rule’s disclosure requirement is reasonably related to the State’s interest in preventing consumers from being deceived by production claims. Like composition claims, production claims such as “this milk is from cows not supplemented with rbST” are potentially misleading because they imply that conventional milk is inferior or unsafe in some way. But neither the FDA nor any study has conclusively shown that to be the case. Furthermore, unlike its regulation of composition claims, the Rule does not prohibit the use of production claims. It instead requires only the disclosure of accompanying information. We therefore conclude that the less-burdensome analytical framework from *Zauderer* should apply.

## **2. *Evaluation of the disclosure requirement under Zauderer***

Under *Zauderer*, the Rule’s disclosure requirement for production claims must be “reasonably related to the State’s interest in preventing deception of consumers” and cannot be “unjustified or unduly burdensome.” *Zauderer*, 471 U.S. at 651. The district court concluded that the Rule was in compliance with the *Zauderer* standard because the production claim that “this milk is from cows not supplemented with rbST,” despite its accuracy, nevertheless “implies that those processors that do use rbST have an inferior or unsafe product or that it is compositionally different.” Ohio’s Rule, the court continued, “strikes the right balance between preventing misleading information and providing enough information for consumers to make an informed choice.”

The Processors first contend that the State failed to show that their production claims are misleading. But the State’s burden of providing such evidence is more relaxed where disclosure requirements are at issue (as opposed to a ban on commercial speech) and “the possibility of deception is . . . self-evident.” *See Zauderer*, 471 U.S. at 652 (holding that, to justify the state’s imposition of a disclosure requirement for attorney advertising, the state need not “conduct a survey of the public before it may determine that the advertisement had a tendency to mislead” (alterations, citation, and ellipsis omitted)).

The Supreme Court rejected a similar argument made by those challenging the revised Bankruptcy Code in *Milavetz*, noting *Zauderer*'s holding that a survey of the public was unnecessary. *Milavetz*, 130 S. Ct. at 1340. It instead determined that “[e]vidence in the congressional record demonstrating a pattern of [misleading] advertisements . . . is adequate to establish that the likelihood of deception in this case is hardly a speculative one.” *Id.* (citation and internal quotation marks omitted). Although the FDA’s Interim Guidance and the consumer comments relied on by the State constitute weak evidence of deception, they at least demonstrate that the risk of deception in this case is not speculative. At a minimum, the Guidance supports the conclusion that production claims can be misleading and the comments show that there is general confusion among some Ohio consumers regarding what substances are (or are not) in the milk they purchase. The district court accordingly did not err in concluding that the Rule’s disclosure requirement is reasonably related to thwarting that risk.

Notwithstanding our conclusion that the Rule’s disclosure requirement is reasonably related to the State’s interest in preventing consumer deception, we find there to be no rational basis between this concern and the “contiguous” requirement of such a disclosure. The Rule stipulates that disclosures must be “in the same label panel, in exactly the same font, style, case, and color and at least half the size (but no smaller than seven point font)” as the production claim. Ohio Admin. Code § 901:11-8-01(B)(2). A disclosure also must be contiguous to the production claim. The font, style, case, and color requirements for the disclosure’s text have a self-evident rational basis. As Director Boggs testified in his deposition, these provisions are in place to prevent marketers from rendering the disclosure “unreadable” by using a miniscule font or “washing the color out.” These provisions thus prevent label designers from hiding the disclosure by manipulating the text.

In contrast, we find no rational basis in the record for the Rule’s contiguity requirement. The Processors specifically take issue with this provision, noting that it prevents them from linking the production claim to the disclosure through the use of an asterisk. Director Boggs testified in his deposition that the ODA decided against the use

of an asterisk based on his “anecdotal experience” of talking to consumers in grocery stores. According to Director Boggs, these consumers informed him that “oftentimes it’s hard to understand labels, especially when the print is so small.” But these observations reveal nothing about whether the use of an asterisk to link information was effective in conveying a disclosure to consumers. Nor did Director Boggs point to any other basis for his belief. He instead asserted, without any supporting evidence, that he had “been aware of [asterisks being a problem in conveying information] for a long time.”

In light of the paucity of evidence supporting the Rule’s contiguity requirement, we conclude that it has no demonstrable connection to ensuring that consumers are not misled. We therefore hold that it lacks a rational basis. *See Nat’l Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001) (“The [First] Amendment is satisfied . . . by a rational connection between the purpose of a commercial disclosure requirement and the means employed to realize that purpose.”).

Finally, the Processors challenge the Rule’s disclosure requirement as being unduly burdensome. They contend that it hinders their ability to convey their message regarding rbST as well as their ability to operate in interstate commerce. But the Processors’ concerns regarding the ability to convey their message stem largely from the Rule’s prohibition on asterisks, a concern that we have dealt with above. And they have not pointed to any evidence that the Rule’s font, size, and color requirements impair their ability to communicate effectively.

Any alleged burden that the Rule imposes on the Processors’ ability to participate in interstate commerce has similarly been alleviated. The Processors argue that the Rule’s requirements are sufficiently distinct from those of other states so as to necessitate Ohio-specific labels and to cause disruption of the nationwide distribution of dairy products. Without the prophylactic ban on composition claims and the prohibition on asterisk use, however, the Rule will be largely indistinguishable from similar regulations in other states. *See, e.g., Alaska Stat. § 17.20.013(a)* (requiring production claims to be accompanied by the disclaimer “No significant difference has

been shown between milk derived from rBST treated and non-rBST treated cows”); Vt. Stat. Ann. tit. 6, § 2762(3) (requiring production claims to be followed by a disclaimer such as “[T]he U.S. Food and Drug Administration has not found a significant difference to exist between milk derived from rbST-treated and non-rbST-treated cows”). The Processors’ concerns regarding the allegedly more demanding scope of Ohio’s regulation, including the extra costs of compliance, have thus been effectively addressed by our rulings above.

#### **D. Dormant Commerce Clause**

As a final challenge to the Rule, the Processors claim that it violates the dormant Commerce Clause. The Constitution grants Congress power “[t]o regulate Commerce with foreign Nations, and among the several States.” U.S. Const. art. I, § 8, cl. 3. “Although the Commerce Clause is by its text an affirmative grant of power to Congress to regulate interstate and foreign commerce, the Clause has long been recognized as a self-executing limitation on the power of the States to enact laws imposing substantial burdens on such commerce.” *S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 87 (1984). In this “dormant” form, the Commerce Clause limits the power of states “to erect barriers against interstate trade.” *Lewis v. BT Inv. Managers, Inc.*, 447 U.S. 27, 35 (1980).

##### ***1. Standard for evaluating dormant Commerce Clause challenges***

The parties initially dispute whether the district court used the proper standard to evaluate the Processors’ Commerce Clause claims. Such claims are traditionally evaluated using a two-tiered analysis. The first inquiry requires a court to determine whether “a state statute directly regulates or discriminates against interstate commerce, or [whether] its effect is to favor in-state economic interests over out-of-state interests.” *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986). If a state statute does either, it is “generally struck down . . . without further inquiry.” *Id.*; see also *Dep’t of Revenue of Ky. v. Davis*, 553 U.S. 328, 338 (2008) (holding that a discriminatory state law is “virtually *per se* invalid” and “will survive only if it advances a legitimate local purpose that cannot be adequately served by reasonable

nondiscriminatory alternatives” (citation and internal quotation marks omitted)). But if the “statute has only indirect effects on interstate commerce and regulates evenhandedly,” *Brown-Forman*, 476 U.S. at 579, a court then moves on to the second inquiry, which requires the application of the balancing test set forth in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). That test upholds a state regulation unless the burden it imposes upon interstate commerce is “clearly excessive in relation to the putative local benefits.” *Id.* at 142.

The first inquiry under *Brown-Forman* focuses on whether a regulation has a direct effect or only an incidental effect on interstate commerce. But “[w]hat counts as a ‘direct’ burden on interstate commerce has long been a matter of difficulty for courts, and, presumably due to its questionable value as an analytical device, the ‘direct/incidental’ distinction has fallen out of use in dormant commerce clause analysis.” *Tenn. Scrap Recyclers Ass’n v. Bredesen*, 556 F.3d 442, 448-49 (6th Cir. 2009). This court in *Tennessee Scrap* thus reformulated the dormant Commerce Clause analysis as follows:

The first prong targets the core concern of the dormant commerce clause, protectionism—that is, differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter. Protectionist laws are generally struck down without further inquiry, because absent an extraordinary showing the burden they impose on interstate commerce will always outweigh their local benefits. However, if the Court determines that the law is not protectionist, it goes on to analyze the law under the deferential *Pike* balancing test.

*Id.* at 449 (citations and internal quotation marks omitted).

In addition to regulations that are protectionist, the Supreme Court has recognized a second category of regulation that is also virtually per se invalid under the dormant Commerce Clause: a regulation that has the practical effect of controlling commerce that occurs entirely outside of the state in question. The Commerce Clause “precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders, whether or not the commerce has effects within the State.” *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (citation omitted) (striking down as



unconstitutional a New York liquor price-affirmation statute that caused distillers to adjust their pricing in other states). A state, in other words, cannot “project its legislation” into another state, *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935), such as by forcing “an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another,” *Healy*, 491 U.S. at 337. Most critical to this inquiry is the issue of “whether the practical effect of the regulation is to control conduct beyond the boundaries of the State.” *Id.* at 336. Like a regulation that favors in-state economic interests at the expense of out-of-state interests, a state’s regulation that controls extraterritorial conduct is per se invalid. See *KT & G Corp. v. Att’y Gen. of Okla.*, 535 F.3d 1114, 1143 (10th Cir. 2008) (“[A] statute will be invalid *per se* if it has the practical effect of extraterritorial control of commerce occurring entirely outside the boundaries of the state in question.” (citation omitted)).

The district court in the present case addressed the Processors’ extraterritorial arguments in the latter half of its analysis under *Tennessee Scrap*, where it employed the *Pike* test. According to the Processors, the court erred by failing to recognize that the Rule is per se invalid if it has the practical effect of controlling commerce outside of Ohio. In response, the State defends the court’s analysis as correct in light of *Tennessee Scrap*.

But the plaintiffs in *Tennessee Scrap* did not argue that the regulation at issue in that case had any extraterritorial effects. *Tenn. Scrap*, 556 F.3d at 448. Moreover, recent cases from other circuits have expressly held that a state regulation that governs extraterritorially is a per se violation of the Commerce Clause. The Eighth Circuit Court of Appeals, for example, has held that

[a] statute may violate the dormant Commerce Clause in one of three ways: (1) the statute clearly discriminates against interstate commerce in favor of in-state commerce; (2) it imposes a burden on interstate commerce that outweighs any benefits received; or (3) it has the practical effect of extraterritorial control of interstate commerce.

*Grand River Enters. Six Nations, Ltd. v. Beebe*, 574 F.3d 929, 942 (8th Cir. 2009) (citations omitted).

At least three other circuits have expressed their Commerce Clause jurisprudence in a similar three-part fashion. See *Selevan v. N.Y. Thruway Auth.*, 584 F.3d 82, 90 (2d Cir. 2009); *KT & G Corp.*, 535 F.3d at 1143; *Cloverland-Green Spring Dairies, Inc. v. Pa. Milk Mktg. Bd.*, 462 F.3d 249, 261-63 (3d Cir. 2006). And five more circuits recognize the extraterritorial-effects inquiry as being distinct from the *Pike* balancing test. See *Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 665 (7th Cir. 2010) (“But another class of nondiscriminatory local regulations is invalidated without a balancing of local benefit against out-of-state burden, and that is where states actually attempt to regulate activities in other states.”); *Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc.*, 492 F.3d 484, 489 (4th Cir. 2007) (“The principle that state laws may not generally operate extraterritorially is one of constitutional magnitude.”); *Alliance of Auto. Mfrs. v. Gwadosky*, 430 F.3d 30, 35 (1st Cir. 2005) (“A state statute that purports to regulate commerce occurring wholly beyond the boundaries of the enacting state outstrips the limits of the enacting state’s constitutional authority and, therefore, is *per se* invalid.”); *Bainbridge v. Turner*, 311 F.3d 1104, 1112 (11th Cir. 2002) (holding that “laws that directly regulate commerce occurring in other states are invalid”); *Gerling Global Reinsurance Corp. of Am. v. Low*, 240 F.3d 739, 746 (9th Cir. 2001) (“The Commerce Clause seeks to prevent extraterritorial economic ‘effects’ . . .”).

To be sure, “the critical consideration” in any dormant Commerce Clause analysis “is the overall effect of the statute on both local and interstate activity.” *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986) (remarking that “there is no clear line separating the category of state regulation that is virtually *per se* invalid under the Commerce Clause, and the category subject to the *Pike v. Bruce Church* balancing approach”). Nevertheless, a state regulation is “virtually *per se* invalid” if it is *either* extraterritorial *or* discriminatory in effect. When it is neither, then the *Pike* balancing test controls. *Id.*

2. *Whether the Rule governs extraterritorially*

Our first consideration is therefore whether the Ohio Rule has any extraterritorial effect. As discussed above, “a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State’s authority.” *Healy*, 491 U.S. at 336.

The Supreme Court has struck down state regulations due to their extraterritorial effects in the context of price-affirmation statutes. In *Brown-Forman*, for example, the Court analyzed a New York law that required liquor distillers selling to wholesalers in the state to affirm that the prices charged were not higher than the lowest price at which the same product was sold in any other state during the month covered by the affirmation. Certain distillers offered “promotional allowances” to wholesalers purchasing their products, but were not allowed to do so in New York. The state further determined that promotional allowances offered to wholesalers in other states effectively lowered the prices charged in those states, a view that was not shared by other states with affirmation laws. These distillers were therefore faced with the choice of either reducing their New York prices, in violation of the affirmation laws in other states, or discontinuing their promotional programs in the other states. *Brown-Forman*, 476 U.S. at 576, 579-82.

The Supreme Court struck down New York’s affirmation law. As a result of the statute, the Court observed, distillers who had posted prices in New York were unable to change their prices elsewhere during the relevant month. The statute therefore had the effect of “[f]orcing a merchant to seek regulatory approval in one State before undertaking a transaction in another.” *Id.* at 582. Although New York was free to regulate the price of liquor within its own borders, it could not “project its legislation into other States by regulating the price to be paid for liquor in those States.” *Id.* at 582-83 (brackets, citation, and internal quotation marks omitted).

The Supreme Court struck down a somewhat different affirmation law in *Healy*. There, a Connecticut statute required out-of-state beer shippers to affirm that their posted prices for products sold to in-state wholesalers were no higher, at the moment of posting,

than prices charged in all neighboring states. The Court reasoned that the statute effectively required “out-of-state shippers to forgo the implementation of competitive-pricing schemes in out-of-state markets because those pricing decisions are imported by statute into the Connecticut market regardless of local competitive conditions.” *Healy*, 491 U.S. at 339. By having “the undeniable effect of controlling commercial activity occurring wholly outside the boundary of the State,” the Court concluded that the statute violated the Commerce Clause. *Id.* at 337.

Ohio’s Rule, by contrast, does not affect interstate commerce in the same manner as the statutes at issue in *Brown-Forman* and *Healy*. The Processors argue that, due to the complex national distribution channels through which milk products are delivered and the costs associated with changing their labels, the Rule in effect forces them to create a nationwide label in accordance with Ohio’s requirements. But unlike the price-affirmation statutes, which directly tied their pricing requirements to the prices charged by the distillers in other states, the Ohio Rule’s labeling requirements have no direct effect on the Processors’ out-of-state labeling conduct. That is to say, how the Processors label their products in Ohio has no bearing on how they are required to label their products in other states (or vice versa). Nor does compliance with the Ohio Rule raise the possibility that the Processors would be in violation of the regulations of another state—the key problem with the New York statute in *Brown-Forman*. The Rule accordingly does not purport to “regulate conduct occurring wholly outside the state.” *See Brown-Forman*, 476 U.S. at 582 (alteration and citation omitted).

In addition to *Brown-Forman* and *Healy*, the Processors rely on *Southern Pacific Co. v. Arizona*, 325 U.S. 761 (1945), in support of their extraterritorial argument. The Supreme Court in that case struck down an Arizona statute that restricted the maximum number of railroad cars comprising a train in that state to 14 for passenger trains and 70 for freight trains. *Id.* at 763. Because most trains in the country exceeded those number of cars, train operators were forced to break up their trains prior to entering Arizona and reassemble them upon leaving the state. Observing that the Arizona statute essentially governed the flow of train traffic from Los Angeles, California to El Paso, Texas, the

Court held that “[t]he practical effect of such regulation is to control train operations beyond the boundaries of the state exacting it.” *Id.* at 775. National uniformity in the regulation of railroads, the Court pointed out, was “practically indispensable to the operation of an efficient and economical national railway system.” *Id.* at 771.

Unlike the Arizona statute, the Ohio Rule in the present case does not impede or control the flow of milk products across the country. The Rule therefore does not create a “serious impediment to the free flow of commerce.” *See id.* at 775. Moreover, the need for regulation “prescribed by a single body having a nation-wide authority [was] apparent” in *Southern Pacific, id.*, whereas in the present case the FDA explicitly acknowledged the power of the states to regulate the labeling of products from cows not treated with rbST. *See* Interim Guidance, 59 Fed. Reg. 6279, 6280 (“Given the traditional role of the States in overseeing milk production, the agency intends to rely primarily on the enforcement activities of the interested States . . .”). *Southern Pacific* is therefore distinguishable on this basis. We accordingly reject the Processors’ argument that the Rule governs extraterritorially and is per se invalid as a result.

### 3. *Whether the Rule is protectionist*

In addition to a consideration of the Rule’s alleged extraterritorial effects, we must assess whether it is protectionist; that is, whether the Rule results in “differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter.” *Tenn. Scrap Recyclers Ass’n v. Bredesen*, 556 F.3d 442, 449 (6th Cir. 2009) (citation omitted). “A [state regulation] can discriminate against out-of-state interests in three different ways: (a) facially, (b) purposefully, or (c) in practical effect.” *E. Ky. Res. v. Fiscal Court of Magoffin County*, 127 F.3d 532, 540 (6th Cir. 1997). The Processors have not alleged that the Rule is facially discriminatory, so we need address only the latter two types of discrimination.

In general, the purpose of a regulation can be ascertained from its language. *Id.* at 542. Here, the Rule’s purpose is to prevent the “false or misleading” labeling of dairy products. Ohio Admin. Code § 901:11-8-01(A). Nothing about this purpose indicates

that Ohio is attempting to protect its local economic interests or burden out-of-state actors.

The Processors argue, however, that other evidence indicates the presence of a discriminatory purpose. They allege that traditional Ohio dairy farmers and Monsanto, which is headquartered in Missouri, “were the driving force behind the proposals.” According to the Processors, traditional Ohio dairy farmers and Monsanto pushed through the enactment of the Rule in order to derail other Ohio dairy processors in their effort to use milk only from cows not given rbST. A number of out-of-state processors, who had already committed to not using milk from cows treated with rbST, were also stripped of any competitive advantage they had developed from advertising their nonuse of such milk in Ohio.

But the Processors’ discriminatory-purpose argument is undermined by their own evidence. They assert that traditional Ohio dairy farmers and Monsanto lobbied for the Rule in an effort to prevent other *Ohio* dairy processors from converting to products made with milk from cows not treated with rbST. Their argument therefore does not support the conclusion that the Rule is aimed at favoring Ohio economic actors at the expense of out-of-state interests.

The Processors next contend that the Rule has a discriminatory effect. “[T]here are two complementary components to a claim that a statute has a discriminatory effect on interstate commerce: the claimant must show both how local economic actors are favored by the legislation, and how out-of-state actors are burdened by the legislation.” *E. Ky. Res.*, 127 F.3d at 543.

The case of *Hunt v. Washington State Apple Advertising Commission*, 432 U.S. 333 (1977), is illustrative of this point. In *Hunt*, a North Carolina regulation prohibited the importation into the state of closed containers of apples bearing another state’s grading or classification system. Washington state apple growers, who were subject to strict grading requirements under their own state’s law, were therefore unable to sell apples in North Carolina using their labels. Although the regulation was not facially discriminatory and did not have a discriminatory purpose, the Supreme Court held that

it nevertheless burdened Washington growers by preventing them from advertising their grading system and by essentially requiring them to downgrade their product. *Id.* at 352. This in turn benefitted North Carolina growers, whose apples were not of as high a quality as those from Washington. *Id.*

In the present case, the Processors argue that the Rule favors those Ohio dairy farmers who wish to continue treating their cows with rbST, and harms out-of-state farmers and processors who have committed to discontinuing the use of the hormone. But the Rule burdens Ohio dairy farmers and processors who do not use rbST in their production of milk products to the same extent as it burdens out-of-state farmers and processors not using rbST. Conversely, the Rule favors out-of-state farmers and processors who *do* use rbST in the same way that it favors Ohio farmers and processors who use rbST. The point is made all the more clear by the fact that an out-of-state processor whose production includes the use of rbST benefits from the Rule more than an Ohio processor who uses milk from cows not treated with rbST.

As the district court noted, the Processors' "argument is more akin to stating that the law discriminates against dairy producers that do not use rbST as opposed to dairy producers that do use rbST." The problem with the Processors' argument is that it is of no help in meeting their burden of demonstrating how Ohio economic actors are favored by the Rule at the expense of out-of-state actors. Both Ohio and out-of-state processors are in effect either benefitted or burdened equally. Accordingly, we conclude that the Processors' claim that the Rule is protectionist and thus per se invalid is without merit.

#### **4. *Weighing the Rule's burdens and benefits***

Because the Rule does not have an impermissible extraterritorial effect and is not protectionist, we must weigh its burdens and benefits in accordance with the *Pike* test. See *Tenn. Scrap Recyclers Ass'n v. Bredesen*, 556 F.3d 442, 449 (6th Cir. 2009). That test requires us to uphold the Rule "unless the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

Applying *Pike* to the present case results in our finding that the alleged burdens on interstate commerce are not excessive in relation to the putative local benefits. The Processors' primary complaint is that Ohio's absolute prohibitions, formatting restrictions, and cumbersome requirements are different from those in other states, and the economic realities will require them to either stop selling in Ohio or conform their national labels to Ohio's requirements. But these burdens have largely been alleviated by our conclusion that the more restrictive provisions of the Rule are invalid under the First Amendment.

Moreover, Ohio has a reasonable basis to believe that the Rule's intended benefit—consumer protection—is significant. “[T]he supervision of the readying of foodstuffs for market has always been deemed a matter of peculiarly local concern,” and states “have always possessed a legitimate interest in the protection of their people against fraud and deception in the sale of food products.” *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 144 (1963) (brackets, citation, and internal quotation marks omitted). Because there is a rational basis to believe that the Rule's benefit outweighs any burden that it imposes, the Rule is constitutional under *Pike*.

### III. CONCLUSION

For all of the reasons set forth above, we **REVERSE** the judgment of the district court to the extent that it upheld the Ohio Rule's prophylactic ban on composition claims and its prohibition on the use of an asterisk for required disclosures to accompany production claims, **AFFIRM** the remainder of the judgment, and **REMAND** the case to the district court for further proceedings consistent with this opinion.