No. 09-2762

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

IN RE AURORA DAIRY CORP.
ORGANIC MILK MARKETING AND
SALES PRACTICES LITIGATION

On Appeal from the United States District Court
for the Eastern District of Missouri,
Case No. 4:08-md-01907-ERW,
The Honorable E. Richard Webber

BRIEF OF *AMICUS CURIAE* THE ORGANIC TRADE ASSOCIATION IN SUPPORT OF AFFIRMANCE AND THE DEFENDANTS-APPELLEES

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November 13, 2009

FEDERAL RULE OF APPELLATE PROCEDURE 26.1 AND CIRCUIT RULE 26.1A DISCLOSURE STATEMENT

The undersigned, counsel for *Amicus Curiae* the Organic Trade Association, hereby furnishes the following information in accordance with Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1A:

The Organic Trade Association is an industry trade association. It has no parent corporation, and no publicly-held corporation owns 10 percent or more of its stock.

/s/ Charles H.P. Vance

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INTEREST OF *AMICUS CURIAE*

Amicus, the Organic Trade Association ("OTA"), is an international association whose members include organic farmers, traders, processors, manufacturers, and retailers. OTA is the oldest and largest organic advocacy group in North America, and has more than 1500 members. OTA's core purpose is to promote and protect truthful trade in organic products. OTA advocates for and protects existing organic standards, the rights of consumers to receive accurate information regarding organic products, and assists in developing and refining organic standards for emerging product areas. OTA also takes positions on legislation that may affect organic agriculture and products, and represents the interests of organic farmers, consumers, and businesses before federal and state regulators, elected officials, and international bodies.

OTA has appeared previously as *amicus* and as a party in federal litigation that implicates the interests of its members. OTA will present additional, relevant argument in support of the judgment of the District Court. OTA will provide a perspective that is currently not before the court because OTA is the only entity that represents the interests of all sectors of the organic community—including farmers, consumers, and businesses—and that is able to present a perspective untied to the more narrow interests that govern the parties' arguments.

This *amicus* brief is filed with the consent of Defendants-Appellees Aurora

Dairy Corporation, Quality Assurance International, and the Organic Retail Defendants, and with the consent of co-lead counsel for all Plaintiffs-Appellants.

SUMMARY OF ARGUMENT

This first impression case provides the court an opportunity to develop and clarify the preemptive impact of the Organic Foods Production Act ("OFPA")[1] and the implementing regulations under the National Organic Program ("NOP")[2] on state law claims seeking to override decisions by the expert federal agency assigned to administer the federal regulatory program.

As Plaintiffs' arguments on appeal demonstrate, the District Court's statement that "[i]rrespective of whether Defendant Aurora was meeting the organic standards established under the OFPA and NOP, Defendant Aurora was a certified operation, and was fully entitled under the OFPA and NOP to label, market and sell its products as organic"[3] is subject to misunderstanding and facile mischaracterization.[4] Plaintiffs erroneously claim that the District Court's decision stands for the sweeping proposition that *initial certification* under the NOP

[1] 7 U.S.C. §§ 6501-6523.

[2] 7 C.F.R. pt. 205.

[3] *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, 2009 WL 1576928 at *6 (E.D. Mo. 2009) ("*District Court decision*").

[4] *See, e.g., Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 2009 WL 3460808 at *9 (7th Cir. 2009) (noting common problem of litigants misconstruing judicial shorthand statements).

"immunized" the defendant dairy from scrutiny and liability under state consumer protection laws. *See Appellants' Brief in Chief* at 34-35 ("*App. BIC*"). No party, and certainly not *Amicus*, contends that initial federal certification is a complete bar to scrutiny of a certified entity's compliance with its obligation to deploy organic marketing claims consistent with its organic credential.[5]

Plaintiffs' argument misconstrues the District Court decision, a proper reading of which accords with USDA's rules. USDA has the duty and the exclusive authority to (i) *initially* decide whether an applicant for certification has successfully demonstrated that "all procedures and activities of the applicant's operation are in compliance" with federal protocols, 7 C.F.R. § 205.403(c)(1) (Granting Certification), and (ii) continually assess whether "the certified operation is complying with the Act and the regulations," *id.* § 205.406 (Continuation of Certification).

Preemption of the state law claims in this case is thus based on the overall continuum of scrutiny under the relevant statutory and regulatory provisions and not simply, as Plaintiffs believe, on the initial organic certification. Congress's

[5] *Amicus* believes that state consumer law cases can be maintained solely when the allegation of falseness or misrepresentation is that the party claimed it was a certified entity when it was not, in fact, certified under federal law. This case does not involve such an allegation and thus was properly dismissed. *See, e.g.*, *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 939 (8th Cir. 2005) (noting that federal agency expertise is not needed when question is simply answered by reference to publicly available documentation under Lanham Act).

purpose and objective of assuring consumers adequate availability of truthfully and consistently labeled organic products via a comprehensive national regulatory system left no gap to be filled by state tort law and would be significantly undermined by unchecked second-guessing of USDA's certification decisions under the laws of the 50 states.

Accordingly, OTA believes that the District Court's decision was correctly decided and that this appeal provides an important opportunity to recognize the unique role of federal certification as the exclusive basis for use of USDA's organic seal (and for "organic" product labeling generally). OTA therefore urges the issuance of a clarifying opinion to provide guidance to lower courts that will undoubtedly confront this question again.

ARGUMENT

I. ORGANIC PRODUCTS ARE UNIQUELY REGULATED BY THE FEDERAL GOVERNMENT TO BALANCE CONSUMER AND BUSINESS INTERESTS AND THE DISTRICT COURT RULING OBSERVED AND MAINTAINED THAT BALANCE

A. Congress Set National Organic Production Standards, Eliminated All Existing State And Private Organic Requirements, And Created Exclusive Authority In USDA To Assess Initial And Ongoing Compliance With The Federal Standards

Nearly 40 years ago, organic agricultural products began a long journey

from small organic farm stands to the supermarket shelves of Main Street.[6] The organic food industry began its federally regulated life as a unique partnership between farmers, consumers, and environmental advocates. *See* S. Rep. No. 101-357, at 291 (1990), *reprinted in* 1990 U.S.C.C.A.N. 4656, 4945 (noting support of the "organic industry, as well as consumer and environmental advocacy organizations"). The partnership focused on a shared interest in managing the entire food production system from the farm to the final retail product, and managing farmland in harmony with natural processes. *See id.* at 4946 (explaining that "[o]rganic food is food produced using sustainable production methods that rely primarily on natural materials" and that "[t]his legislation covers *all* food products from their inception through final processing" (emphasis added)).

When the sales of organic products expanded, and moved out of the local farmers markets and into stores, it was based on disparate private definitions of organic practices and private certifications that proclaimed the seller of an organic product adhered to a particular set of identifiable standards. *See id.* at 4943 ("Farmers and processors have no choice but to produce and label their products according to conflicting standards."). These efforts were supplemented later by

[6] *See, e.g.*, National Organic Program, Final Rule, 65 Fed. Reg. 80,548, 80,664 (Dec. 21, 2000) (explaining in Appendix to Preamble that "[t]he first organization to offer third-party certification, California Certified Organic Farmers, was formed in the early 1970's, and the first State regulations and laws on organic labeling were also passed in the 1970's") ("Final Rule").

action in some states to define key terms in a manner consistent with America's larger market economy. *See id.* ("Twenty-two states now regulate organic food but no two State laws are alike.").

By the late 1980s there were conflicting state and private standards for organic farm management and a patchwork of certification schemes. As interstate commerce in these products increased, and the availability of organic products expanded beyond single agricultural commodities like carrots and potatoes and began to include multi-ingredient products, three needs became apparent. First, on-the-ground farm management protocols needed to be harmonized to assure that consistent practices led to consistent product labeling. *See id.* at 4946 ("This legislation establishes a USDA 'organically produced' label—a USDA seal of approval for organic products."). Second, the various private and state certification programs needed a framework in which they could recognize each other's certifications, so that ingredients produced under different programs could be mixed together to make new products without conflict or diminished organic integrity. Third, the methods and capability of the certification agents to ensure consistent and meaningful oversight of organic operations had to be evaluated against federal licensing criteria. *See id.* at 4947 ("In order to become a certifying agent, an entity or individual must apply to the USDA and become accredited to serve in that role.").

In 1990, Congress answered the call and passed the OFPA, which directed the Secretary of Agriculture to create two programs. NOP was created to facilitate interstate commerce by stabilizing the transactional environment for organic farmers and food processors and to assure organic consumers that they were purchasing truthfully labeled products, and a federal "accreditation" program was established to license the certification services that were providing quality assurance oversight to the burgeoning industry. *See* 7 U.S.C. § 6514. Congress expressly invalidated all existing state laws regulating organic standards and all private certification programs and labeling regimes[7] and authorized a single organic "certification" regime and USDA organic seal for operations meeting the minimum requirements set in the OFPA. *See id.* §§ 6503 & 6505(a)(2).

The OFPA's core purpose was to "facilitate interstate commerce" and "assure consumers" by "establish[ing] national standards governing the marketing of certain agricultural products as organically produced products." *Id.* § 6501. Inconsistent organic certification standards and labeling regimes were a primary

[7] Congress expressly and completely preempted all *existing* state organic standards and labeling regimes. *See* 7 U.S.C. § 6505(a)(1). Congress did leave the door open for a state to partner with the federal government and establish "additional guidelines" through a state organic certification program, *id.* § 6506(d), provided that the "governing State official" submits the plan to USDA for review and approval, *id.* § 6507. *See also* Final Rule, 65 Fed. Reg. at 80,682 ("States also are preempted under…the OFPA…from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.").

Congressional concern. *See, e.g.*, S. Rep. No. 101-357, *reprinted in* 1990 U.S.C.C.A.N. at 4946 ("This legislation establishes a USDA 'organically produced' label—a USDA seal of approval for organic products. After September, 1992 no other label will be allowed…") & 4949 ("The Committee, however, is most concerned that State action not disrupt interstate commerce."); *see also Harvey v. Veneman*, 396 F.3d 28, 36 (1st Cir. 2005) (recognizing the NOP as a "comprehensive labeling and certification scheme").

B. Organic Certification Is Based On The Verification Of Production And Processing Methods—It Is Not A Statement Of Product Identity

Unlike most preemption cases, which involve tension between the federal approval of a particular product or its label on the one hand and the advertising of that product on the other, organic certification does not refer to the qualities of any particular product.[8] "The Secretary shall establish an organic certification program for producers and handlers of agricultural products *that have been produced using organic methods as provided for in this chapter*." 7 U.S.C. § 6503(a) (emphasis added). Congress itself recognized the unique nature of the organic program it was creating, noting that "much of this title breaks new ground for the Federal government and will require the development of a unique regulatory scheme." S.

[8] *See, e.g., Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1005 (2008) (noting that statute requires FDA approval for particular medical device); *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009) (noting that statute requires FDA approval for particular drug).

Rep. No. 101-357, *reprinted in* 1990 U.S.C.C.A.N. at 4947. Unlike other food regulatory programs, "[t]he 'organically produced' label authorized under this bill…pertains to the production methods used to produce the food rather than to the content of the food." *Id.* at 4946. In short, "organically produced food is food produced using certain defined materials and production methods." *Id.* at 4947.

USDA referred to this approach as "process verification," and echoed Congress by saying that "the national organic standards… are based on the method of production, not the content of the product." Final Rule, 65 Fed. Reg. at 80,631; *see also id*. at 80,567 ("USDA has consistently stated that certification is a process claim, not a product claim…"). USDA noted the functional difference between a product claim and a claim based on process verification by explaining that "[o]rganic products cannot be distinguished from conventionally produced products by sight inspection, and consumers rely on verification methods such as certification to ensure that organic claims are true." *Id.* at 80,668. Moreover, "[t]he national organic standards…address the methods, practices, and substances used in producing and handling crops, livestock, and processed agricultural products. The requirements apply to the way the product is created, not to measurable properties of the product itself."[9]

[9] *See* USDA, *Organic Production and Handling Standards, available at* http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3004445&acct=nopgeninfo (last visited Nov. 11, 2009).

C. The Authorization To Use USDA's Organic Seal Is Based On A Comprehensive Assessment That Is Uniquely Within The Expertise Of USDA And Its Accredited Certifying Agents, Not A Grading Of A Final Agricultural Product

The unique nature of the federal organic regulatory program has significant implications for this case. First, an organic certification is the result of a comprehensive initial and ongoing review process regarding the production and processing protocols used by the certified operation. *See* 7 C.F.R. §§ 205.403(c)(1) (Granting Certification) & 205.406 (Continuation of Certification); *see also* S. Rep. No. 101-357, *reprinted in* 1990 U.S.C.C.A.N. at 4948 ("Certification is the process of inspecting farming and handling operations to make certain that the requirements set forth under this title for organic production have been met."). Under this approach, USDA is charged with assessing a great number of on-the-ground factors, few (if any) of which conclusively answer the question of whether an operation is capable of implementing the federal management protocols that underpin its entitlement to receive federal certification and authorization to use the USDA seal.[10] All organic operations are run according

[10] For example, the following NOP definitions demonstrate that NOP certification presents a complex series of questions that can be answered only by an expert federal agency. They also demonstrate, in a summary fashion, that organic certification involves many factors that USDA's agents must separately evaluate and weigh. *See* 7 C.F.R. § 205.2 (Definitions) (emphasis added).

Practice standard. "The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard includes a series

to specialized and technical "practice standards" set forth in that operation's comprehensive "organic system plan." *See* 7 U.S.C. §§ 6513 (setting forth components of an operation's Organic System Plan ("OSP")) & 6506(a)(2) (setting forth general requirements, one of which is that each NOP participant develops an OSP). The OSP is site-specific and highly individualized; not only are no two exactly alike, but no single factor or set of factors governs evaluation of every operation. *See* S. Rep. No. 101-357, *reprinted in* 1990 U.S.C.C.A.N. at 4946 ("Organically grown food is produced using farming and handling systems that include site-specific farm plans."). For example, the particular crop rotation followed and the selection of seed varieties to best suit the local soil and growing conditions are common decisions that are unique to each operation, and the certifying agent is given discretion to assess them. *See* Final Rule, 65 Fed. Reg. at 80,569 ("[t]he crop rotation component of an organic system plan must be

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of allowed and prohibited actions, materials, and conditions to establish a minimum level performance for planning, conducting, and maintaining a function, such as livestock health care or facility pest management, essential to an organic operation."

Organic production. "A production system that is managed in accordance with the Act and regulations in this part to respond to *site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity*."

Organic system plan. "A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part."

considered within the context of site-specific environmental conditions including climate, hydrology, soil conditions, and the crops being produced."); *id.* at 80,559 ("The site-specific nature of organic production and handling necessitates that certifying agents have the authority to determine whether specific information is needed to carry out their function.").

Second, based on the approach taken by Congress and USDA, a consumer product bearing USDA's organic seal or one of USDA's approved marketing claims is not a widget that can be measured with a set of calipers. Thus, unlike typical fruit and vegetable grading standards that establish designations based on product standards of identity—for example, Grade A or No. 1—the "organic" product designation is not primarily a statement about the final product itself.[11]

The unique character of the federal certification regime described above—one focusing on the "process" by which a product is produced and handled rather than any particular characteristic of the product itself—means that there is no distinction between the entitlement to affix the organic seal (or make an "organic"

[11] Unlike "organic" products, a great many products are indeed regulated according to easily verified characteristics. *See, e.g.*, USDA, *Quality Standards*, *available at* http://www.ams.usda.gov/AMSv1.0/standards (last visited Nov. 11, 2009) ("USDA quality standards are based on measurable attributes…[and there are]…more than 312 fruit, vegetable, and specialty product standards."); 7 C.F.R § 28.1 ("[T]he classification of any cotton shall be determined…by the length of staple, and fiber property measurements such as micronaire."); *Lion Raisins, Inc. v. USDA*, 636 F. Supp. 2d 1081, 1083 (E.D. Cal. 2009) ("USDA inspectors assess the quality of raisins in various categories such as weight, color, and size.").

marketing claim) and the product to which it is affixed. *See, e.g., Schering-Plough*, 2009 WL 3460808 at *5 ("We can also set aside any argument that the defendants' drugs are misbranded because they are labeled prescription drugs—they *are* prescription drugs, so their labels *have* to say that….").

Complaints brought under state consumer laws designed to ensure that "products" are fairly represented to consumers under the federal organic regime require only that a court consider whether the party affixing the "organic" label was appropriately credentialed, which the District Court here did. *See District Court decision* at *7; *see also, e.g., Alpharma*, 411 F.3d at 939 (noting that federal agency expertise is not needed to decide if product is "approved" by federal agency under Lanham Act). If a claimant wishes to contest whether the party affixing the "organic" label was at all times in actual compliance with its credential, the issue is solely for the expert federal agency to determine. *See* 7 C.F.R. §§ 205.403(c)(1) (providing for on-site inspections to verify information) & 205.406 (establishing continuing responsibilities relating to maintenance of certification).

It is this continuum of federal oversight that underpins the integrity of organic certifications and product claims, and that supports the District Court's holding that allowing state tort cases would significantly interfere with Congress's objectives and purposes. Once certified, the federal approval "continues in effect" unless the certification is surrendered or "suspended or revoked by the certifying

agent…." 7 C.F.R. § 205.404(c).

D. The "Organic" Labeling Claim Is A Statement Of The Percentage Of Organic Content In The Product And Is Subject To Pre-Market Approval By An Accredited Federal Certifying Agent And Cannot Be Challenged Using State Tort Laws

Plaintiffs mistakenly believe that no explicit pre-market approval is required for labels under the NOP. This is incorrect. USDA recognizes four distinct marketing terms under its organic labeling regime. *See* 7 C.F.R. § 205.301; *see also Mass. Indep. Certification, Inc. v. Johanns*, 486 F. Supp. 2d 105, 110-11 (D. Mass. 2007) ("The USDA regulations also contain detailed standards for certification, pursuant to which a producer or handler may label its products according to a four-tiered scheme as '100% organic,' 'organic,' 'made with organic [ingredients]' or 'organic [ingredients],' depending on the percentage of organic contents.").

To be authorized to enter the stream of interstate commerce, each product sold by a certified organic entity must demonstrate to which of the four categories the product belongs, and an "organic" claim means not less than 95% organic content. *See* 7 C.F.R. § 205.301(b). The percentage of organic content for each product sold in the United States "*must be*…*verified* by the certifying agent of the handler." *Id.* § 205.302(c). A product is marketed as "organic" because the federal certifying agent has determined, as an exercise of premarket review and approval, that the product formulation does in fact meet the particular labeling

category's content requirements. *See, e.g.*, *Schering-Plough*, 2009 WL 3460808 at *5 (products approved under federal standard are not misbranded). Thus, the products at issue in this case did (and do) receive the pre-market approval that Plaintiffs claim is missing. *See District Court decision* at *7; *see also Int'l Dairy Foods Ass'n v. Boggs*, 2009 WL 937045 at *15 (S.D. Ohio 2009) ("Subpart D of the NOP specifically regulates labels, labeling and marketing information for use of the term 'organic' on labels. 7 C.F.R. §§ 205.300-205.311."). It can fairly be said that such products enter interstate commerce "only by federal permission, subject to federal inspection, in the hands of federally certified personnel and under an intricate system of federal commands." *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 634 (1973) (quoting *Nw. Airlines v. Minnesota*, 322 U.S. 292, 303 (1944) (Jackson, J., concurring)). Nothing in the OFPA suggests Congress intended that businesses acting in reliance on decisions made exclusively by federal actors would be subject to liability for their mandatory compliance therewith.[12] *See, e.g.*, *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir. 1993)

[12] One additional point bears consideration. Unlike the situation in *Wyeth v. Levine*—where preemption was rejected in part because private party control over the warning label was the "central premise" of federal compliance and was subject to an ongoing duty to amend, 129 S. Ct. at 1197-98—the phrases "100% organic," "organic," and "made with organic ingredients" are wholly owned and controlled by the federal government. *See* 7 C.F.R § 205.300-305. No certified entity may use these phrases without pre-approval from a federal agent. *See id.* § 205.302(c). To permit state tort liability for alleged "advertising" deficiencies based on the *agency's* words would impart liability for decisions taken by federal actors, and be

("[M]anufacturers will not be held liable [in breach of warranty claims] for packaging and labeling *imposed* by the FDA." (emphasis added)).

II. CONSUMERS SHOULD PRESENT ALLEGATIONS OF MISLABELED ORGANIC PRODUCTS TO USDA FOR REVIEW; ALLOWING STATE TORT CLAIMS NEVER PRESENTED TO USDA WOULD UNDERMINE THE UNIQUE FEDERAL ORGANIC CERTIFICATION, ACCREDITATION, AND LABELING APPROACH TAKEN BY CONGRESS

Useful to the preemption analysis here is (i) that Congress declined to create a private right of action to enforce the OFPA or its implementing regulations but created significant federal penalties that consumers may request be imposed; (ii) that Congress created an exclusive federal procedure for challenging USDA's certification decisions, compliance decisions, and its disposition of consumer complaints regarding substandard labeling and marketing; and (iii) the key role that certified ingredients play in downstream products. *See* 7 C.F.R. § 205.501(a)(13) (requiring certifying agents to accept decisions of other certifying agents). This

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predicated on words and phrases that are not within the discretionary control of the certified entity. This fact alone should preclude such liability. The unique "process verification" approach and the wholly controlled labeling regime, when taken together, are so unlike other product and label "approvals" that unique treatment is required. Of course, such treatment is authorized by the Supreme Court's repeated emphasis on examination of the specific nature of the federal statute and regulations at issue to discern congressional intent with regard to preemption matters. *See DOJ v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 765 (1989); *City of New York v. FCC*, 486 U.S. 57, 63 (1988) (intent determined by statute and any agency regulations enacted under the statute). As the District Court correctly determined, to permit liability here, "[T]he Court would have to invalidate the regulatory scheme established under the OFPA and NOP." *District Court decision*, 2009 WL 1576928 at *7.

court should not allow an end run around federal expertise and federal review mechanisms via state tort law, at least in part because attacks on a single, validly-certified organic supplier could have significant ripple effects on other uses of that supplier's products. "An assessment of the scope of a pre-emption provision must give effect to a 'reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law.'" *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 592 (2002) (Stevens, J., concurring in part, concurring in the judgment in part, and dissenting in part) (quoting *Medtronic Inc. v. Lohr*, 518 U.S. 470, 486 (1996)); *see also Brown v. Hotel & Rest. Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491, 503 (1984) ("If the state law regulates conduct that is actually protected by federal law, however, pre-emption follows not as a matter of protecting primary jurisdiction, but as a matter of substantive right.").

A. Congress Declined To Create A Private Right Of Action To Enforce The OFPA And NOP, But Authorized USDA To Accept Complaints From Consumers

The OFPA "itself does not provide for the right to bring suit as a Federal cause of action, and we could not grant it through this regulation." Final Rule, 65 Fed. Reg. at 80,556. Instead, the Act authorizes a statutory civil penalty of $10,000 per violation and the potential referral for criminal prosecution for the making of false statements. *See* 7 U.S.C. § 6519. "Only USDA may bring an

action under 7 U.S.C. 6519." Final Rule, 65 Fed. Reg. at 80,627. Plainly, a state tort claim imposing a financial penalty on a certified organic entity would achieve indirectly what the USDA has directly foreclosed. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 455 (2005) (Breyer, J., concurring) ("[T]he federal agency charged with administering the statute is often better able than are courts to determine the extent to which state liability rules mirror or distort federal requirements.").

The NOP and OFPA "preempt State statutes and regulations related to organic agriculture," and USDA has exclusive "authority to take action against misuse of the term 'organic.'"[13] Final Rule, 65 Fed. Reg. at 80,682, 80,582. Indeed, the "NOP is ultimately responsible for the oversight and enforcement of the program, including oversight of exempt and excluded operations and cases of fraudulent or misleading labeling. We expect, however, that States would want to monitor for false claims or misleading labeling under these regulations and would *forward any complaints to the NOP*." *Id.* at 80,557 (emphasis added). USDA is

[13] The Bureau of Alcohol, Tobacco, and Firearms has similarly concluded that the OFPA's purpose is to establish national standards and that USDA is vested with exclusive enforcement authority over the type of compositional and labeling claims made in this case. *See* Organic Claims in Labeling and Advertising of Alcohol Beverages, Temporary Rule, 67 Fed. Reg. 62,856 (Oct. 8, 2002) (codified at 27 C.F.R. pts. 4, 5, 7 & 13). In an April 2006 rulemaking, USDA reiterated that on "October 21, 2002, the NOP regulations became fully implemented by USDA as the uniform standard of production and handling for organic agricultural products in the United States." National Organic Program, Notice of Proposed Rulemaking, 71 Fed. Reg. 24,820, 24,820 (Apr. 27, 2006).

responsible for all enforcement activities, including those against businesses that are not certified. By contrast, citizens and states lack the authorization to seek judicial enforcement of the OFPA, and the tort claims in this case are nothing but an attempt to enforce claims that federal organic standards were not observed. The requested injunctive relief is even farther afield, as not even USDA may directly interfere with interstate commerce regarding purportedly mislabeled products. *See id.* at 80,627 ("[T]he Act does not authorize USDA to stop the sale of [a] product….Citizens have no authority under the NOP to stop the sale of a product.").

But consumers may seek government intervention regarding any product marketed in the U.S. bearing an organic claim:

> Anyone may file a complaint.…alleging violation of the Act or these regulations. Certifying agents, SOP's governing State officials, and USDA will receive, review, and investigate complaints alleging violations of the Act or these regulations….*Citizens have no authority under the NOP to investigate complaints alleging violation of the Act or these regulations.…Only USDA may bring an action under 7 U.S.C. 6519*.

Id. (emphasis added). USDA has reasonably interpreted Congressional intent to prohibit private causes of action, thereby allowing only USDA to enforce the terms of the statute and regulations, though consumers *do have standing* to trigger this federal enforcement machinery by filing complaints with the agency. *See id.*

B. Consumers Have Standing To Challenge The Resolution Of Their Complaints Administratively, May Seek Federal Judicial Review, And Have Access To An Adequate Remedy

Congress mandated that USDA operate an "expedited administrative appeals procedure" that allows appeal of *any final action* taken under the federal program by USDA or its organic certifying agents operating under the federal umbrella. *See* 7 U.S.C. § 6520 (authorizing standing for "any person" to seek relief); *see also id.* § 6506(a)(3) (requiring appeal procedures for "producers and handlers"); *Schering-Plough*, 2009 WL 3460808 at *5 ("We can set aside the letters from subordinate officials of the FDA; the letters are not final agency action binding on the district court, as there has been no final agency action, let alone action that has been or could be judicially reviewed.").

Congress fashioned the broadest possible standing provision, bringing within the zone of interest not just participants in the agency's certification program but any person that is "adversely affect[ed]" by the challenged administrative decision or who believes that the decision "is inconsistent" with the OFPA or NOP. 7 U.S.C. § 6520; *see also Mass. Indep. Certification*, 486 F. Supp. 2d at 118 (construing NOP's standing provision and concluding that a certifying agent has standing); *Harvey*, 396 F.3d at 34 (holding organic consumer had Article III standing to challenge USDA organic regulations).

Congress created an exclusive *federal judicial* remedy authorizing a person aggrieved by a "final decision" of USDA to seek review of that decision in federal district court. 7 U.S.C. § 6520(b). Thus, not only is there a statutorily-created administrative review procedure, but a federal district court is also authorized (upon exhaustion of administrative remedies) to provide a remedy to individuals who can demonstrate that the challenged decision was inconsistent with the OFPA.

C. Plaintiffs Should Be Required To Present Their Federal Compliance Allegations In The First Instance To USDA Under The Unique Regulatory Scheme Enacted By The OFPA That Relies On "Process Verification" And Mandatory Labeling Phrases Because These Are Not The Kind Of Factual Questions That Are Well Suited To Judicial Review In The First Instance

It is clear in this case that Plaintiffs themselves did not pursue any administrative remedy or ruling on the merits from USDA. Typically, the issue of administrative exhaustion is acceptably raised on appeal because it deprives the court of subject matter jurisdiction.[14] *Amicus* believes that because Congress

[14] "Lack of subject-matter jurisdiction, unlike many other objections to the jurisdiction of a particular court, cannot be waived. It may be raised at any time by a party to an action, or by the court *sua sponte*." *Bueford v. Resolution Trust Corp.*, 991 F.2d 481, 485 (8th Cir. 1993) (rejecting argument that jurisdictional requirement of administrative exhaustion could be waived by explicit or implicit party consent). *See also Thomas v. Basham*, 931 F.2d 521, 522-23 (8th Cir. 1991) ("[E]very federal appellate court has a special obligation to consider its own jurisdiction."); *Lemonds v. St. Louis County*, 222 F.3d 488, 492 (8th Cir. 2000) (explaining that jurisdictional issues may be addressed for the first time on appeal); *Ark. Blue Cross & Blue Shield v. Little Rock Cardiology Clinic, P.A.*, 551 F.3d 812, 816 (8th Cir. 2009) (asserting that "[t]he burden of establishing that a cause of action lies within the limited jurisdiction of the federal courts is on the party

delegated the exclusive enforcement authority to USDA and declined to create a private right of action, this court should consider the exhaustion argument on appeal.[15]

Plaintiffs argue that marketing products with "organic" claims requires (i) that initial organic certification be awarded by the federal government and (ii) ongoing and absolute compliance with federal organic production and processing protocols. This suggests that mere disagreement with USDA's compliance decision suffices by itself to raise a question of fact that cannot be resolved on a motion to dismiss. *See App. BIC* at 35.

However, Plaintiffs ignore that proper preemption analysis involves resolution of the following antecedent questions: where did Congress place the responsibility for making the determinations at issue, and were those determinations made in a particular case in accordance with the designated

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asserting jurisdiction," and that "a court may not assume 'hypothetical jurisdiction' to decide 'contested questions of law when its jurisdiction is in doubt'" (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 101 (1998))).

[15] This issue was raised before, but was not decided by, the District Court. A federal appellate court may affirm a lower court's judgment on any basis supported by the record. *See, e.g.*, *Richmond v. Higgins*, 435 F.3d 825, 828 (8th Cir. 2006) ("Although the district court did not address [the defendant's] alternative grounds for summary judgment, this court may affirm on any basis supported by the record."); *Woods v. DaimlerChrysler Corp.*, 409 F.3d 984, 990 (8th Cir. 2005) (same); *Brown v. St. Louis Police Dep't*, 691 F.2d 393, 396 (8th Cir. 1982) (explaining that an appeals court may affirm on any ground supported by the record "even if the issue was not pleaded, tried, or otherwise referred to in the proceedings below").

allocation of responsibility.[16] Review of the relevant statutory and regulatory provisions inescapably demonstrates Congressional intent to grant the federal government the exclusive right to render *both* the initial certification decision as well as ongoing compliance decisions to most effectively assure that products placed in interstate commerce are truthfully represented.

Amicus is aware that USDA cannot award money damages to plaintiffs, and that it is arguable that no exhaustion requirement exists for such claims. However, as this court noted in *Harris v. P.A.M. Transport, Inc.*, resolution of an issue in a case involving money damages may require an agency ruling in the first instance where the gravamen of the case turns on a question that Congress entrusted to an expert agency and where a framework for review is available. 339 F.3d 635, 638 (8th Cir. 2003) ("Congress has delegated to the Secretary of Transportation the authority to prescribe driver qualifications.").

Here, the majority of consumers benefit from a stable transactional environment for organic products. If the agency—which by force of law can be said to have rejected any claim that the products in question are substandard under its rules since it has at all times authorized their designation as organic—is not

[16] In the OFPA, Congress created a single path to federal court for individuals "adversely" affected by a USDA decision or who believe that such a decision was "inconsistent with" the controlling principles of the OFPA or the NOP. *See* 7 U.S.C. § 6520. At no time did any of the Plaintiffs or the original administrative complainant actually seek to exercise the right of review expressly granted to them under the OFPA.

given a chance to decide the matter in the first instance, it leaves the court to evaluate the very questions Congress entrusted to the agency's expertise and destabilizes the entire marketplace. As this court said in *Harris*, "'[e]xhaustion' applies where a claim is cognizable in the first instance by an administrative agency alone." *Id.* (citing *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63 (1956)). The unique nature of organic regulation suggests that any alleged breach of these highly-specific federal standards is best presented to the agency for resolution. *See id.* ("DOT is charged with and is much better equipped to handle resolution of disputes over a driver's medical qualifications and can do so far more expertly and efficiently than a reviewing court. Thus, we hold that failure to exhaust the remedies available under 49 C.F.R. § 391.47 requires dismissal of this action, precluding Harris from obtaining review of his ADA claim in this court.").

CONCLUSION

For all of the above reasons, the judgment of the District Court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,069 words as calculated by my word processing program (Microsoft Word 2003), excluding the parts of the brief specifically exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii). This brief also complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared with a proportionally spaced typeface using Microsoft Word 2003 in Times New Roman font size 14. Further, the undersigned certifies that in conformity with 8th Circuit Local Rule 28A(d), the diskette has been scanned for viruses and is virus-free.

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November 13, 2009

CERTIFICATE OF SERVICE

I, the undersigned attorney, hereby certify that on November 13, 2009, I caused two hard copies and one electronic copy of the foregoing Brief of *Amicus Curiae* the Organic Trade Association in Support of Affirmance and the Defendants-Appellees to be served via U.S. mail, postage prepaid, on each of the following:

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