



FDA Authority to Regulate On-Farm Activity

-name redacted-

Legislative Attorney

August 14, 2008

Congressional Research Service

7-....

www.crs.gov

RS22939

Summary

Recent concerns regarding fresh produce contaminated with *E. coli* or *Salmonella* have brought attention to the Food and Drug Administration (FDA)'s regulatory authority. Some advocates have requested new FDA food safety regulations, including rules that would regulate activity on farms. One question is whether the FDA has the authority to regulate on-farm activities. H.R. 1108 and S. 625, which would authorize the FDA to regulate tobacco products, would limit the FDA's authority to regulate activities on certain tobacco farms. However, it appears that the FDA has the authority to regulate at least some on-farm activities related to other food products under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. In 2004, the FDA issued a proposed rule governing safety procedures for shell eggs, which would be its first comprehensive on-farm regulation. Legislative proposals, including H.R. 912, H.R. 3624, H.R. 5620, H.R. 5904, H.R. 6581, S. 2077, and S. 3385, also address the FDA's role on farms.

Contents

Background	1
Statutory Language	1
Analysis.....	2
FDA’s Regulatory Activity	5

Contacts

Author Contact Information	5
Acknowledgment	5

Background

Although the U.S. Department of Agriculture is responsible for ensuring the safety of meat, poultry, and certain egg products, the FDA is the federal agency primarily responsible for ensuring the safety of all other food.¹ In recent years, incidents of contaminated spinach, jalapeño and Serrano peppers, and other produce have brought attention to the FDA's role in maintaining a safe food supply.² In general, the FDA has responded to recent contamination incidents with guidance documents and other informal measures rather than by proposing new regulations.³ For example, in 2006, it responded to an E. coli contamination with a series of alerts, an investigation, and an agreement by certain growers' and shippers' associations to implement voluntary safety measures.⁴

In response to recent produce contamination incidents, some advocacy groups have argued that new regulations, rather than guidance documents, are necessary to prevent contamination.⁵ Some new regulations proposed by the advocacy groups include rules that affect on-farm operations. For example, one advocacy group has requested regulations that would prohibit use of raw manure on produce and require growers to utilize potable water for cleaning.⁶ These proposals raise an obvious threshold question: Does the FDA have statutory authority to regulate on-farm activity?

Statutory Language

Congress authorized the FDA to promulgate regulations relating to food safety through two federal statutes: the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act (PHSA).⁷ Examining relevant language from both statutes is important for determining the intended scope of the FDA's regulatory authority.

The FFDCA prohibits “the adulteration or misbranding of any food.”⁸ It likewise prohibits introduction of adulterated or misbranded food into the streams of commerce.⁹ Four categories of foods considered “adulterated” under the statute are especially relevant to on-farm activities.

¹ For more information about the FDA and other agencies' roles in ensuring food safety, see CRS Report RL32746, *Fruits, Vegetables, and Other Specialty Crops: A Primer on Government Programs*, by (name redacted).

² See, e.g., Marian Burros, *Who's Watching What We Eat?*, N.Y. Times, May 16, 2007, at F1.

³ Although it has no official policy against notice-and-comment rulemaking, the FDA has shown a preference for guidance documents over regulations in recent years. For example, the FDA Commissioner has stated that voluntary guidance has certain advantages over regulations, including the “flexibility to update science” and a less “cumbersome” nature. *Id.*

⁴ For more information about responses to the 2006 E. coli contamination, see CRS Report RL33722, *Food Safety: Federal and State Response to the Spinach E. coli Outbreak*, by (name redacted).

⁵ See, e.g., Center for Science in the Public Interest, Citizen Petition 6 (2006) (“The most important benefit of a mandatory regulatory program is that it would assure that all growers and processors implement good agricultural practices. While many of the best growers [comply with the FDA's guidance documents], compliance is clearly not universal”), http://www.cspinet.org/new/pdf/fda_produce_petition.pdf.

⁶ *Id.* at 2-3.

⁷ Federal Food, Drug and Cosmetic Act of 1938, as amended, 21 U.S.C. §§ 301 *et. seq.*; Public Health Service Act of 1944, as amended, 42 U.S.C. §§ 201 *et seq.*

⁸ 21 U.S.C. § 331(b) (2007).

⁹ 21 U.S.C. § 331(a).

These categories are (1) food bearing or containing “added” substances that may “render [the food] injurious to health”; (2) food bearing or containing substances that are not “added” but that are of such a quantity that they “ordinarily render [the food] injurious to health”; (3) food bearing or containing “unsafe ... pesticide chemical residues”; and (4) food that has been “prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.”¹⁰ The FFDCFA authorizes the FDA “to promulgate regulations for the efficient enforcement” of these and other prohibitions contained within the statute.¹¹

The PHSFA authorizes the FDA to “make and enforce such regulations as ... are necessary to prevent the introduction, transmission, or spread of communicable diseases... from one state ... into any other state.”¹² To enforce such regulations, the statute authorizes the FDA to “provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, or other measures.”¹³

Analysis

The FDA appears to have authority under the FFDCFA and the PHSFA to regulate at least some on-farm activities. A preliminary question when interpreting any statute is whether the statute’s language provides explicit guidance. Neither the FFDCFA nor the PHSFA expressly authorizes the FDA to regulate farm operations,¹⁴ nor does either statute expressly limit the FDA’s on-farm regulatory authority.¹⁵ However, both statutes explicitly provide the FDA with rulemaking authority over areas that could be interpreted as covering on-farm activities, especially through the specific provisions enumerated above. The specific FFDCFA provisions discussed above all apply generally to “food,”¹⁶ without specifying the location of the food. In addition, these adulterated-food provisions describe characteristics that could first develop on farms. For example, “foods bearing ... unsafe pesticide[s]” might have first been exposed to pesticides in farm fields; “foods bearing ... added substances” or harmful substances of such a quantity that they “ordinarily render [the food] injurious to health” might have acquired such substances on farms; and foods might be “held in insanitary conditions” on farms, perhaps soon after they were harvested.¹⁷ Similarly, the PHSFA explicitly authorizes the FDA to promulgate rules to prevent the “introduction ... of communicable diseases,”¹⁸ a provision that could be interpreted as including,

¹⁰ 21 U.S.C. § 342(a)(1); 21 U.S.C. § 342(a)(2)(A); 21 U.S.C. § 342(a)(2)(B); 21 U.S.C. § 342(a)(4).

¹¹ 42 U.S.C. § 371(a).

¹² 42 U.S.C. § 264(a).

¹³ *Id.*

¹⁴ Statutory silence does not necessarily indicate lack of authorization for a given activity. For more information, see CRS Report 97-589, *Statutory Interpretation: General Principles and Recent Trends*, by Yule Kim.

¹⁵ Versions of a bill that would amend the FFDCFA to authorize the FDA to regulate tobacco products were recently introduced in the House (H.R. 1108) and Senate (S. 625). Both versions would expressly limit the FDA’s on-farm regulatory authority vis-a-vis tobacco, specifically by prohibiting the FDA from “enter[ing] onto a farm owned by a producer of tobacco leaf without the written consent of such producer,” unless the producer either was also a tobacco manufacturer or was “controlled by a tobacco manufacturer.” Section 901(c)(2), S. 625, as reported; Section 901(c)(2), H.R. 1108, as reported.

¹⁶ Under the FFDCFA, “food” means 1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” 21 U.S.C. § 321(f).

¹⁷ See 42 U.S.C. § 342(a).

¹⁸ 42 U.S.C. § 264(a) (emphasis added). Under the statute, lists of specified “communicable diseases” are determined by executive orders. 42 U.S.C. § 264(b).

for example, preventing harmful bacteria from developing on growing crops or during harvesting. Thus, it appears that FFDCA and PHSa provisions could be interpreted as extending the FDA's regulatory authority to the regulation of farm activities. The remaining question is whether Congress intended such an interpretation.

It would be possible to interpret the FDA's regulatory authority narrowly under these provisions, as limited to the promulgation of regulations that affect food only after it has left farms. As support for this narrow reading, one might assert that because the FFDCA and the PHSa aim to prevent the movement of adulterated food through streams of commerce and to prevent the *spread* of disease, respectively, it makes sense to construe the provisions narrowly, as extending only to food that has actually left farms; or in other words, as extending only to food that is actually in the stream of commerce such that it is capable of spreading disease or causing other harm.¹⁹

However, courts have interpreted the FFDCA and the PHSa broadly rather than narrowly, especially when broad interpretations of the statutes effectuate prevention of public harm. The Supreme Court has stated that “regard” for Congress’ purpose of keeping “adulterated foods ... out of the channels of commerce” should “infuse construction” of the FFDCA.²⁰ The Court has also held that as “remedial legislation,” the FFDCA should be “given a liberal construction consistent with the Act’s overriding purpose to protect the public health.”²¹ Federal circuit courts have similarly interpreted the FFDCA and the PHSa broadly to effectuate protection of the public.²²

Together with broad constructions of the whole statutes, courts have applied broad interpretations to the specific FFDCA and PHSa provisions relevant to on-farm regulations. For example, interpreting the “prepared, packed, or held under insanitary conditions” provision, a federal circuit court rejected the assertion that “insanitary conditions” include only conditions in processing facilities.²³ Instead, the court held that the provision, and therefore the FDA’s regulatory authority, extends to “conditions” already present on the food at the time it reaches a

¹⁹ Regardless of the interpretation of agency authority, note that Congress likely has the power, under the Commerce Clause, to regulate activity on individual farms, even if the regulations affect food that never enters the stream of interstate commerce. The Supreme Court has upheld Congress’s power to regulate marijuana grown for at-home consumption. The Court held that Congress has broad authority to regulate even wholly intrastate activities, as long as they “substantially affect” interstate commerce. *Gonzalez v. Raich*, 545 U.S. 1, 16-17 (2005) (analogizing to *Wickard v. Filburn*, 317 U.S. 111 (1942), which upheld federal regulation of wheat intended for consumption on farms where it was grown).

²⁰ *62 Cases, More or Less, Each Containing Six Jars of Jam v. U.S.*, 340 U.S. 593, 596 (1951) (quoting *U.S. v. U.S. v. Dotterweich*, 320 U.S. 277, 280 (1943)).

²¹ *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

²² *See, e.g., Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1039 (10th Cir. 2006) (“[The FFDCA] should not be read too restrictively but in manner consistent with the statute’s overriding purpose to protect public health.”); *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 246 (2nd Cir. 1977) (invalidating the FDA’s time-temperature-salinity regulation as applied to whitefish because the FDA failed to follow proper rulemaking procedures but upholding the FDA’s authority to promulgate such a regulation: “when agency rule-making serves the purposes of the statute, courts should refuse to adopt a narrow construction of the enabling legislation which would undercut the agency’s authority to promulgate such rules.”)

²³ *Nova Scotia*, 568 F.2d at 245-46.

processing facility.²⁴ Likewise, a federal circuit court construed the term “added” in the added-substance provision broadly to include all substances “attributable to the acts of man.”²⁵

Courts have also recognized the FDA’s “broad authority” to implement FFDC provisions.²⁶ In addition, the Supreme Court has generally treated agency decisions deferentially. The Court has held that if statutory language is ambiguous, agency interpretations of a statute’s provisions should be upheld as long as they are based on a “permissible construction of the statute.”²⁷ The FFDC and PHSA provisions discussed above appear to be ambiguous such that a court would defer to the FDA’s interpretation. In response to a challenge to the FDA’s authority to regulate tobacco, the Court found that Congress had “directly spoken to the question at issue,” because it had specifically rejected amendments that would have explicitly granted the FDA jurisdiction over tobacco and had later enacted tobacco-specific statutes granting authority over tobacco to other agencies such as the Federal Trade Commission.²⁸ In contrast, Congress did not consider any amendment regarding FDA jurisdiction over farm operations; nor did it later enact any specific legislation addressing the question. Therefore, a court would likely defer to the FDA’s interpretation of its authority to regulate on-farm activities.

Finally, it is telling in assessing the FDA’s authority that independent agency reports, the FDA itself, and other sources have assumed that the FDA has the authority to regulate on-farm activities. For example, a U.S. Government Accountability Office report assumed that the FDA has authority over on-farm activities relating to the production of pizza and eggs.²⁹ In addition, when it issued a proposed regulation regarding shell eggs, the FDA affirmatively asserted its authority under both the FFDC and the PHSA to regulate on-farm activities.³⁰ During the late 1990s, the Clinton Administration likewise asserted that the FDA “has jurisdiction where food is produced.”³¹ Various law review articles state similar conclusions.³²

Thus, it appears likely that a court would find the FDA to have statutory authority to promulgate rules regulating at least some on-farm activities. The number of regulations and the speed at which the FDA could promulgate them pursuant to this authority may be subjected to practical

²⁴ *Id.* at 246.

²⁵ *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157, 160-62 (5th Cir. 1980) (holding that mercury found in the ocean is an “added” substance in fish, where mercury was present in the ocean partly as a result of human actions).

²⁶ *See, e.g., Nutraceutical Corp.*, 459 F.3d at 1035.

²⁷ *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-44 (1984). Note, however, that in recent cases, the Court appears to have narrowed this so-called “Chevron deference,” holding that it applies only if the agency interpretation is the result of a formal process such as notice and comment proceedings. *See Christensen v. Harris County*, 529 U.S. 576 (2000); *United States v. Mead Corp.*, 533 U.S. 218 (2001).

²⁸ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160-61 (2000).

²⁹ GAO Report 04-588T, *Federal Food Safety and Security System: Fundamental Restructuring Is Needed to Address Fragmentation and Overlap* (March 30, 2004).

³⁰ Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, 69 Fed. Reg. 56823, 56842-45 (proposed September 22, 2004).

³¹ *See Overlap and Duplication in the Federal Food Safety System: Hearing Before the Subcomm. on Oversight of Govt. Mgmt., Restructuring, and the District of Columbia of the S. Comm. on Governmental Affairs*, 106th Cong. 3 (1999) (written statement on behalf of the President’s Council on Food Safety), <http://www.fda.gov/ola/1999/foodsafety.html>.

³² *See, e.g., Sandra B. Eskin, Putting All Your Eggs in One Basket: Egg Safety and the Case for a Single Food-Safety Agency*, 59 Food & Drug L.J. 441, 443 (2004) (“FDA ... is responsible for eggs while they are on the farm” (citing the FFDC and the PHSA)).

impediments, such as procedural requirements for notice-and-comment rulemaking under the Administrative Procedure Act and judicial review.³³

FDA's Regulatory Activity

The FDA has promulgated numerous regulations under the FFDCA and the PHS Act that indirectly affect farm operations. For example, it mandates that milk sold into interstate commerce for direct human consumption must be pasteurized.³⁴ In 2004, the FDA issued a proposed rule that would have directly regulated farm operations, which some called the FDA's "first comprehensive on-farm regulation."³⁵ Specifically, the proposed rule would mandate various on-farm procedures in an effort to prevent *Salmonella* Enteritidis.³⁶ The proposed rule would require growers to implement certain cleaning, refrigeration, and other "on-farm prevention measures."³⁷ In 2005, the FDA extended the comment period for the proposed rule.³⁸ The FDA has indicated its intent to promulgate a final version of the rule.³⁹ Thus, although FDA appears to presume that it has the authority to regulate at least some on-farm activities, the FDA has not necessarily exercised this authority to its fullest potential.

Author Contact Information

(name redacted)
Legislative Attorney
[redacted]@crs.loc.gov, 7-....

Acknowledgment

This report was originally written by (name redacted), Law Clerk.

³³ 5 U.S.C. §§ 553, 701. See *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 410 (1971) (holding that a regulation is "subject to judicial review except where there is a statutory prohibition on review or where 'agency action is committed to agency discretion by law'" (quoting 5 U.S.C. § 701)).

³⁴ 21 C.F.R. §1240.61 (2007).

³⁵ Gerald F. Masoudi, *Developments in Food and Drug Law*, 60 Food & Drug L.J. 107, 109 (2005).

³⁶ Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, 69 Fed. Reg. 56823 (proposed September 22, 2004).

³⁷ *Id.*

³⁸ 70 Fed. Reg. 24490-91 (May 10, 2005).

³⁹ U.S. Dept. of Health and Human Services, the FDA, *Prevention of Salmonella Enteritidis in Shell Eggs*, Unified Agenda of Federal Regulatory and Deregulatory Actions, Reg. Identification No. 0910-AC14, <http://www.reginfo.gov/public/do/eAgendaViewRule?ruleID=284739>.

EveryCRSReport.com

The Congressional Research Service (CRS) is a federal legislative branch agency, housed inside the Library of Congress, charged with providing the United States Congress non-partisan advice on issues that may come before Congress.

EveryCRSReport.com republishes CRS reports that are available to all Congressional staff. The reports are not classified, and Members of Congress routinely make individual reports available to the public.

Prior to our republication, we redacted names, phone numbers and email addresses of analysts who produced the reports. We also added this page to the report. We have not intentionally made any other changes to any report published on EveryCRSReport.com.

CRS reports, as a work of the United States government, are not subject to copyright protection in the United States. Any CRS report may be reproduced and distributed in its entirety without permission from CRS. However, as a CRS report may include copyrighted images or material from a third party, you may need to obtain permission of the copyright holder if you wish to copy or otherwise use copyrighted material.

Information in a CRS report should not be relied upon for purposes other than public understanding of information that has been provided by CRS to members of Congress in connection with CRS' institutional role.

EveryCRSReport.com is not a government website and is not affiliated with CRS. We do not claim copyright on any CRS report we have republished.