

**FDA Regulation of Added Salt
Under the Food Additives Amendment of 1958**

Legal Framework and Options

Michael R. Taylor
Research Professor of Health Policy
School of Public Health and Health Services
The George Washington University

Presented at

Information Gathering Workshop
Committee on Strategies to Reduce Sodium Intake
Institute of Medicine

March 30, 2009

FDA Regulation of Added Salt Under the Food Additives Amendment of 1958

Legal Framework and Options

Michael R. Taylor¹

Purpose and Scope

This paper responds to a request from the IOM Committee on Strategies to Reduce Sodium Intake. Its purpose is to inform the Committee's deliberations by describing the legal framework governing the food industry's use and the Food and Drug Administration's regulation of added salt (sodium chloride) under the relevant provisions of FDA's governing statute. These include primarily the Food Additives Amendment of 1958 ("FAA") and, to a lesser extent, other food safety provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA").

This paper is by no means a complete primer on the complex topic of food additive and food safety regulation. Rather, it briefly outlines key features of the food safety legal framework as they apply to added salt and identifies some of the issues and options that arise in implementing that framework. This paper does not address education, voluntary initiatives and other public health activities FDA could pursue to reduce sodium intake as a complement to carrying out the agency's responsibilities under the food safety provisions of the law. Nor does the paper address FDA regulation of sodium labeling under the Nutrition Labeling and Education Act or other labeling provisions of the FDCA, except those related to ensuring the safety of added salt in food.

As requested, the paper provides background information and analysis only. It takes no position on the current legal status of salt in food and makes no recommendations regarding the Committee's report or FDA policy.

Key Conclusions

- Like any other substance intentionally added to food, the legal status of added salt is governed by the FAA and other provisions of the FDCA.
- The law imposes on the food industry a legal duty to use salt as an added food ingredient in a manner that complies with the requirements of the FAA and other relevant provisions of the FDCA.

¹ Mr. Taylor is a Research Professor at the George Washington University School of Public Health and Health Services. He has served at the Food and Drug Administration as Associate Chief Counsel for Foods and Deputy Commissioner for Policy.

- The law makes FDA responsible for implementing and enforcing the FAA to achieve the law’s food safety objective but accords FDA significant flexibility in how it carries out its responsibility, especially when new information arises about a long-marketed substance.

Key Elements of the Legal Framework

- Under the FAA, salt added to food by a manufacturer is a “food additive” except to the extent one or more particular uses are (1) “generally recognized as safe” (“GRAS”), based on today’s science, or (2) were affirmatively approved (“prior sanctioned”) by FDA or the Department of Agriculture prior to the 1958 enactment of the FAA.²
- The use of a food additive is unlawful unless its intended uses have been approved as safe by FDA in a food additive regulation.³
- The burden of proof on the safety of a food additive rests with the party seeking FDA approval, who must prove to a reasonable certainty that the particular proposed use of the substance is not harmful under its intended conditions of use.⁴
- The “reasonable certainty of no harm” safety standard sets a high standard for the safety of intentionally added food substances, while recognizing that safety cannot be proven with absolute scientific certainty; the operational meaning of the standard is grounded in long-established principles of chemical safety evaluation whose application in particular cases requires the exercise of scientific and public health policy judgment.⁵
- To be GRAS and thus excluded from the definition of “food additive,” the intended uses of a substance must satisfy the same “reasonable certainty of no harm” safety standard that is applicable to food additives, based on the same

² The term “food additive” is defined in 21 USC 321(s), in pertinent part, as follows:

The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include.... any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraphpursuant to this Act [enacted Sept. 6, 1958], the Poultry Products Inspection Actor the Meat Inspection Act

³ 21 USC 348 and 342(a)(2)(C), and 21 CFR Parts 170-179.

⁴ 21 CFR 170.6 (i).

⁵ 21 CFR Part 170, Subpart B (Food Additive Safety), and FDA/CFSAN, *Food and Color Additives Program* (<http://www.cfsan.fda.gov/~dms/opa-addi.html>).

quantity and quality of data (“scientific procedures”) required for FDA approval of a food additive, except that for substances used in food prior to 1958 the safety standard can be satisfied on the basis of such data or “experience based on common use in food.”⁶

- Whether based on “scientific procedures” or pre-1958 use in food, GRAS status requires not only a “reasonable certainty of no harm” but general agreement among qualified experts, based on generally available information, that the safety standard has been met.⁷
- For both food additives and GRAS substances, FDA has legal authority under the FAA to require labeling as needed to help ensure the safety of added substances, and any food packaged food can be deemed "misbranded" and thus unlawful "if its label fails to reveal factsmaterial with respect to consequences which may result from the use of the...[food]...under such conditions of use as are customary or usual."⁸
- In 1959, soon after passage of the FAA, FDA issued a list of substances it considered GRAS for various uses and whose use could thus continue without having to be approved as a food additive.⁹
- Beginning in the early 1970’s, FDA conducted a comprehensive safety review of the substances on its original GRAS list (the GRAS Review program); based on scientific reviews conducted by the Select Committee on GRAS Substances (SCOGS) under the auspices of FASEB,¹⁰ FDA affirmed the GRAS status of many substances, but also placed limits on the allowable uses and permitted levels of some GRAS substances.¹¹
- Inclusion in an FDA GRAS list is not required by the FAA for a substance to be GRAS and thus not a food additive; rather, food companies are free under the law to make their own “independent” determination that their use of an added substance is GRAS and use it on that basis, subject to the possibility that FDA will challenge that determination and declare the substance to be an unapproved food additive.
- In 1997, FDA established a GRAS notification program, which provided a voluntary mechanism for companies to alert FDA to their independent GRAS determinations and the basis for them; if FDA finds no basis to object to a

⁶ 21 USC 321(s) and 21 CFR 170.30.

⁷ 21 CFR 170.30.

⁸ See 21 USC 348 (c)(1)(A), 343 (a) and 321(n).

⁹ 21 CFR Part 182.

¹⁰ FDA/CFSAN/Office of Food Additive Safety, *Select Committee on GRAS Substances (SCOGS) Database Overview* (October 2006) (<http://www.cfsan.fda.gov/~dms/opascogs.html>).

¹¹ 21 CFR Part 184.

company's GRAS determination, it places the substance and its intended use on a list of substances that are subject to a GRAS notice.¹²

- FDA can revoke or modify the scope of a food additive approval or challenge the GRAS status of an added substance at any time based on new information or analysis that raises a significant question about safety, such that a “reasonable certainty of no harm” no longer exists; once such a question has been identified, the burden of proof shifts to the sponsor or user of the substance to prove safety; under the FAA, FDA is not required to prove harm in order to prohibit or restrict the use of a food additive or GRAS substance.

Background on the FAA and Salt

- When FDA issued its original GRAS list in 1959, the agency said that it is “impracticable” to list all GRAS substances, and it named salt, pepper, vinegar, baking powder and monosodium glutamate as examples of common food substances that it considered safe and thus presumably GRAS under the new FAA,¹³ though it did not include salt on the formal GRAS list.
- As part of the GRAS Review Program, FDA received in 1979 a SCOGS report on its safety review of sodium chloride, in which SCOGS concluded that: “The evidence on sodium chloride is insufficient to determine that the adverse effects reported are not deleterious to the public health when it is used at levels that are now current and in the manner now practiced.”¹⁴
- The conclusion on salt in the 1979 SCOGS report is of the type that, under the GRAS Review Program, would normally trigger FDA action to revise or revoke the GRAS status of a substance and, at a minimum, raised a serious question about the GRAS status of added salt in light of the “reasonable certainty of no harm safety” standard and the requirement that there be “general recognition” of safety to achieve and maintain GRAS status.
- In 1982, based on the SCOGS report and its own analysis of its regulatory options, FDA published a “Policy Notice” in which it called for reductions in the levels of added salt in processed food based on concerns about hypertension but concluded that it would not act “at this time” to revise the GRAS status of salt, relying instead on public education, voluntary industry efforts, and a new FDA effort to expand disclosure of sodium content on product labels.¹⁵

¹² FDA/CFSAN/Office of Food Additive Safety, *About the GRAS Notification Program* (August 2007)(<http://www.cfsan.fda.gov/~dms/gras-ov.html>).

¹³ 21 CFR Part 182.1(a).

¹⁴ SCOGS, *Sodium Chloride* (Rpt. No 102, 1979).

¹⁵ FDA, *GRAS Safety Review of Sodium Chloride; Policy Notice; Solicitation of Views*, 47 Fed. Reg. 26590 (June 18, 1982).

- In the 1982 notice, FDA said: “The agency wishes to emphasize that if there is no substantial reduction in the sodium content of processed foods and if information [sic] sodium labeling is not adopted after a reasonable period, FDA will consider additional regulatory actions, including proposing a change in salt’s GRAS status.”¹⁶
- In 2007, in response to a citizen petition filed by the Center for Science in the Public Interest, FDA convened a public hearing to receive comment on regulatory options for reducing sodium in food, including possible actions under the FAA.¹⁷
- If FDA were to conclude that current scientific evidence does not support the GRAS status of one or more current uses of salt in processed food, it would have flexibility to consider a range of regulatory options, as outlined in FDA’s 1982 FDA Policy Notice and 2007 Hearing Notice and discussed further below.

Discussion

It is important to understand that, in a case such as salt, implementing the FAA and other food safety provisions of the FDCA is not like flipping an on-off switch. It necessarily involves, as a prerequisite to FDA regulatory action, careful scientific review by FDA and can, as appropriate, include dialogue with the external scientific, industry and public interest communities both before and during any regulatory process to reduce sodium. In addition, FDA has significant flexibility under the law to devise a sensible regulatory strategy that is in accord with the FAA and gives practical consideration to the nature and extent of current salt uses.

The following are some features of the FAA legal and regulatory framework that both provide FDA flexibility in implementing the framework with respect to salt and add complexity to the analysis FDA would have to undertake should it conclude that the applicable law and science warrant consideration of change in salt’s regulatory status.

1. *The FAA is by design a mechanism for data generation.* By placing on sponsors and users of added substances the burden to prove safety, the FAA results in the generation of substantial safety-related information prior to approval of a substance as a food additive or use as a GRAS substance. Moreover, when a safety question arises about a marketed substance, the FAA can be and has been used to generate additional information to resolve the question and/or guide future FDA action.

For example, in 1980, FDA proposed to revoke its GRAS listing of caffeine as an added substance in soft drinks based on SCOG concerns about adverse

¹⁶ 47 Fed. Reg. at 26593 (col. 2).

¹⁷ FDA, *Salt and Sodium; Petition to Revise the Regulatory Status of Salt and Establish Food Labeling Requirements Regarding Salt and Sodium; Public Hearing; Request for Comments*, 72 Fed. Reg. 59973 (Oct. 23, 2007).

reproductive effects in certain rodent studies,¹⁸ and FDA proposed to list added caffeine as an “interim food additive”¹⁹ whose continued use was contingent on the industry conducting further studies addressing the safety question. The industry conducted studies that resolved the question to FDA’s satisfaction.

2. *Any action on salt under the FAA would involve rulemaking and a public deliberative process.* Given FDA’s longstanding acquiescence in the GRAS status of added salt, FDA action to alter or revoke its GRAS status would involve a rulemaking process that would include, at a minimum, public notice of proposed actions, an opportunity for public comment, and a reasoned FDA response to the public comments. Even prior to publishing a proposal, FDA could publish an advance notice of proposed rulemaking (ANPR) to outline its initial thinking and gather information on key issues; and, in the course of any rulemaking, FDA could at its discretion include whatever other public meetings, hearings, scientific consultations or other dialogue it thought appropriate to resolve the GRAS status of added salt and determine its regulatory and policy responses.
3. *FDA has broad discretion to determine effective dates and to phase in changes in salt’s regulatory status.* Within reason, FDA would have the discretion to determine the appropriate effective date for any measures under the FAA to reduce added salt in processed foods and to take into account feasibility and other constraints in crafting the implementation of any reductions, including possible phased-in reductions to acceptable levels.
4. *Any FDA proceeding on salt under the FAA would require the agency to address both scientific and regulatory policy questions.* In FDA’s implementation of the FAA, there is no bright line between scientific and regulatory policy questions. The central question, which is predominantly scientific, is whether the current levels and uses of added salt satisfy the “reasonable certainty of no harm” safety standard, based on today’s science. In addressing this question, FDA would be expected to take into account, among other sources of information and scientific findings “The Report of the Dietary Guidelines Advisory Committee on *Dietary Guidelines for Americans, 2005*,” which declared 2300 milligrams per day to be the appropriate upper limit on sodium intake in order to reduce the risk of high blood pressure.²⁰

One of the key questions with a major policy as well as scientific dimension is whether special labeling, whether aimed at the general population or high-risk subgroups, could contribute to a conclusion that certain uses meet the “reasonable certainty of no harm” safety standard that otherwise might not meet the standard.

¹⁸ FDA, *Caffeine; Deletion of GRAS Status, Proposed Declaration That No Prior Sanction Exists, and Use on an Interim Basis Pending Additional Study*, 45 Fed. Reg. 69817 (October 21, 1980).

¹⁹ See 21 CFR Part 181.

²⁰ See the HHS website at <http://www.health.gov/dietaryguidelines/dga2005/report/>.

5. *The possible existence of prior sanctions for salt complicates the analysis and may affect FDA's regulatory options.* In its 1982 Policy Notice on salt, FDA noted that a number of uses of salt in processed food had received FDA's approval prior to 1958, primarily in FDA standards of identity, and thus could be deemed to be "prior sanctioned" and excluded from food additive regulation on that basis.²¹ In considering the use of its food additive authority to reduce levels of sodium in food, FDA would have to resolve which uses are prior sanctioned and which are not.

Substances that are prior sanctioned remain subject to safety regulation by FDA,²² including limits on uses and use levels and labeling to help ensure safety and reveal "material consequences" of their use. For prior sanctioned substances, however, the burden rests on FDA to demonstrate that such regulation is needed to prevent possible harm.

6. *In implementing the FAA, FDA would have to consider salt's technical or functional effect in food.* Under the FAA, food additives and GRAS substances are generally required to have a demonstrated functional effect in food and to be used at a level that is not greater than necessary to achieve that effect. In any rulemaking to limit the level of added salt in processed food, FDA would have to solicit and analyze food industry information on the intended uses and technical effects of added salt.

Options

As made clear by FDA's 1982 Policy Notice, 2007 Hearing Notice and the preceding discussion, FDA could consider a range of regulatory options should it revisit the GRAS status of salt and conclude that certain uses or levels of use no longer meet the FAA's standard for GRAS status. Such a conclusion would begin the process of determining the ultimate regulatory outcome, not end it. That point is illustrated by the following array of regulatory pathways FDA could consider.

1. *Issue an interim food additive regulation to generate additional information* – In the 1980 caffeine case, the issuance of a proposal to revoke GRAS status and issue an interim food additive regulation stimulated research and the submission of information that helped resolve the safety issue. The interim food additive mechanism has not been used since 1980 and some question its legality. A proposal to simply revoke or limit the GRAS status of one or more uses of salt in processed food could, however, have the same data generating effect.
2. *Define the specific conditions under which salt is GRAS, including specific intended uses and use levels* – Other uses could be phased out or approval for them could be sought through the food additive approval process.

²¹ 1982 Policy Notice at note 15, above.

²² 21 USC 342(a)(1).

3. *Revoke salt's GRAS status for one or more uses or use levels* – FDA could issue, on its own initiative, a food additive regulation authorizing one or more uses (with or without stricter limits), require the submission of a food additive petition to justify continued use, or prohibit one or more uses.
4. *Require labeling aimed at reducing intake among at-risk populations* – Such labeling could range from more prominent quantity declarations to warnings about the specific risks associated with excess sodium intake, and it could be triggered, for example, by the addition via salt of some minimum percentage of the daily value of sodium to a serving of food.
5. *Couple use limitations, as a food additive or GRAS substance, with labeling to further reduce intake* – Such a dual approach could address sodium intake for both the general population and those at higher risk of hypertension.

Conclusion

The FAA is FDA's primary regulatory tool for mandating reductions in the levels of added salt in processed food, and FDA has complimentary legal authority to require labeling for food safety purposes. FDA's regulatory tools need not be implemented in isolation, however, but could be used in conjunction with public education, counseling by health care providers, incentives for technological innovation, and other interventions as part of an integrated public health strategy to reduce sodium intake.