

Standard Setting: Food Standards of Identity

Reading:

The Reg Map: Informal Rulemaking (TWEN, supplementary readings)

Federal Food, Drug, & Cosmetic Act §§401, 403, & 701 (TWEN, supplementary readings)

Hutt, Merrill, & Grossman, *Food and Drug Law*, pp. 162-163 (TWEN, supplementary readings)

Federal Security Administrator v. Quaker Oats Co. (TWEN, supplementary readings)

Hutt, Merrill, & Grossman, *Food and Drug Law*, pp. 165-180 (TWEN, supplementary readings)

Questions:

1. What purpose is served by mandating standards of identity for food? What are the strengths and weaknesses of this regulatory tool? How does it compare to labeling?

2. In *Quaker Oats Co. v. Federal Security Administrator*, did the agency exceed its statutory authority under the Food, Drug, & Cosmetic Act (FDCA) when it set standards of identity for farina and enriched farina?

3. Did the agency's treatment of vitamin D enrichment of farina constitute "a reasonable definition and standard of identity" under the FDCA?

4. In your opinion, did the agency's findings provide a proper foundation for its regulatory action? How much deference do you think the courts should have afforded to these findings?

5. Can you speculate as to the regulatory politics behind the rulemaking in *Columbia Cheese Co. v. McNutt*? Should this feature of regulation be relevant to judicial review?

6. Do you agree with the outcome of *Columbia Cheese*? Explain.

7. Do you agree with the provisions of the 1990 Nutrition Labeling and Education Act that excluded standards of identity from the FDCA §701(e) hearing requirements?

8. Do you think that the shift from a "recipe" approach to defining standards of identity for food to a more flexible allowing for any "safe and suitable" ingredients is an improvement in the FDA's efforts to regulate food ingredients and protect consumers?

9. What was the FDA's regulatory *justification* for liberalizing the standard of identity for ice cream? What were the politics of the reform? What were the politics of the opposition to the reform? How did the opponents of reform frame the issue differently from the proponents of reform? What was the FDA's regulatory justification for revoking the new standards? Would you favor liberalizing the standard of identity for ice cream?

Exercise:

The Potato Chip Institute (PCI), a trade association of potato chip manufacturers, petitioned the FDA to promulgate a definition and standard of identity for potato chips under §401 of the Food, Drug, and Cosmetic Act. In its petition, PCI argues that the standard ought to distinguish between “potato chips” made from potato slices and “potato snack foods” made from other forms of potato, such as potato flour. Following the filing of the petition, the FDA commissioner received a call from Congressman Charles (“Chip”) Smith of Cincinnati, the home of Procter & Gamble, which owns the Pringles brand. Smith insists that “Pringles are America’s #1 potato chip” and he is concerned that Procter & Gamble’s competitors are seeking FDA action that might damage the company’s position in the potato chip market. Smith also happens to chair the House Subcommittee on Food Safety and sit on the Appropriations Committee.

The Commissioner has called an informal meeting between representatives of the PCI, representatives of Procter & Gamble, staff members from Congressman Smith’s office, FDA policy experts, and attorneys from the FDA counsel’s office. The Commissioner seeks input on how best to proceed. Based on the role assigned to you, prepare for the meeting.