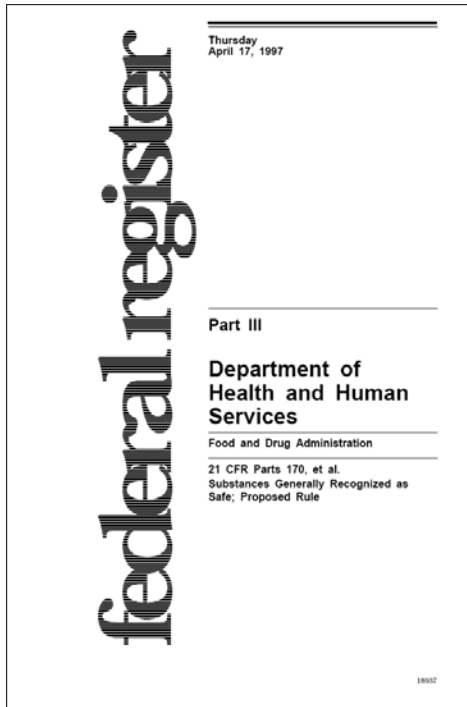# Statutory Definition of "Food Additive"
(FD&C Act Section 201(s))

"…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…to be safe under the conditions of its intended use…"

The GRAS Provision

- GRAS is:
  - **Embedded** in the FD&C Act
    - Sections 201(s) and 409
    - Preserves FDA's pre- and post-market authority
  - a practical approach to allocating resources using scientific judgment

- GRAS is not:
  - an inherent quality of a substance
  - a lesser safety standard

Evolution of FDA's GRAS Program

Thursday
April 17, 1997

federal register

Part III

Department of
Health and Human
Services

Food and Drug Administration

21 CFR Parts 170, et al.
Substances Generally Recognized as
Safe; Proposed Rule

1959-61: "The GRAS List"

1960's: Opinion Letters

1969-72: Comprehensive Review

1972: GRAS Affirmation Petitions

1997: GRAS Notification Proposal

62 FR 18938, April 17, 1997

FDA Response to GAO Recommendations

1	Require companies to provide FDA with basic information	The public expectation would be for FDA to validate determinations reported; basic information would not be sufficient.
2	Address conflicts of interest (issue guidance)	FDA is considering issuing such guidance; it would be non-binding.
3	Conduct random audits (issue documentation guidance)	For a self-determination, FDA has a limited basis on which to audit; the preamble of the 1997 proposed GRAS rule provides extensive information about documenting GRAS notices.
4	Finalize the 1997 GRAS proposed rule	FDA agrees with finalizing the proposed rule; FDA reopened the comment period and is working to finalize the rule.
5	Reconsider safety over time (develop criteria)	FDA agrees that post-market oversight, guided by criteria, would help better ensure food safety; however, FDA is restrained by resources and needed authorities.
6	Ensure the safety of engineered nanomaterials	FDA has issued draft guidance on nanotechnology and its strategy will continue to evolve; GRAS criteria would be hard to meet.