



FDA Regulation of Added Salt Under the Food Additives Amendment: Legal Framework and Options

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My Charge

- n Lay out FDA's legal framework for reducing added salt under the FAA
- n Identify implementation issues and options
- n Indicate range of FDA's flexibility
- n **NOT to address other tools**
- n **NOT to make recommendations**



Key Points

- n The FAA and related safety provisions are the governing law for direct control of salt levels
 - n Define industry's duty regarding the safety of added salt
 - n Establish the safety standards FDA is to apply
- n The 1979 SCOGS review and current Dietary Guidelines raise a serious question about salt's GRAS status under the FAA and thus the legality of at least some current uses of added sodium
- n FDA has ample legal authority and flexibility under the FAA to address the safety of salt and devise a deliberate sodium reduction strategy



Definition of Food Additive

An intentionally added substance like salt is a “**food additive**” requiring formal FDA approval, *unless* it is –

- n Generally Recognized as Safe (**GRAS**) based on today’s science,
- or
- n Affirmatively approved (**prior sanctioned**) by FDA or USDA prior to the 1958 enactment of the FAA



Food Additive Requirements

- n Pre-market approval by FDA for each intended use
- n Burden of proof on the sponsor to demonstrate safety to FDA's satisfaction
- n Safety standard is "reasonable certainty of no harm"
- n Significant safety question is basis for withdrawing approval



GRAS Requirements

- n Pre-market approval NOT required, BUT
 - n SAME “reasonable certainty of no harm” safety standard
 - n PLUS general recognition of safety among experts
 - n AND legal duty on food companies not to use substance unless GRAS, approved as a food additive, or prior sanctioned
- n Significant safety question is basis for loss or revision of GRAS status



Prior Sanctioned Substances

- n Premarket approval NOT required
- n Subject to “may render injurious” safety standard
- n Burden on FDA to demonstrate some possibility of harm
- n Some uses of salt likely are prior sanctioned



Status of Salt Under the FAA

- n Treated as GRAS in 1959
- n Included in GRAS Review Program
- n SCOGS report concluded in 1979:

Evidence on sodium chloride is insufficient to determine that the adverse effects reported are not deleterious to public health when used at levels now current and in manner now practiced .

- n FDA responded with sodium reduction strategy in 1982 but deferred action on GRAS status
- n Dietary Guidance upper limit of 2300mg is relevant



FDA Flexibility Under the FAA

In implementing the FAA, FDA has flexibility to

- n Use FAA burden of proof to generate data
- n Build a public deliberative process into rulemaking
- n Exercise scientific and public health policy judgment
- n Reduce level of use rather than prohibit use
- n Reduce some but not all uses
- n Use labeling tools as a complement to or in lieu of use restrictions
- n Exercise broad discretion on effective dates and phasing in of changes



Conclusion

- n The FDA provides ample legal authority to reduce levels of added sodium, as warranted by the science
- n The GRAS status of added salt is an important unresolved issue
- n FDA has flexibility in how it addresses the legal status of salt and devises a public health-oriented sodium reduction strategy

