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Navigating the U.S. Food Additive Regulatory Program

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PEW

Food Additives Project

- Launched in 2010 to:
  - Conduct a comprehensive analysis of the existing regulatory program
  - Determine if the system works and whether chemicals added to food are safe as required by law
  - Develop policy recommendations to address any gaps or problems
- Transparent process engages industry, academic, government and public interest stakeholders
- Project staff convene workshops and publish articles, primarily in peer-reviewed journals

Laws impacting chemicals added to food

- Federal Food Drug and Cosmetic Act of 1938
- Food Additives Amendment of 1958
- Also:
  - Color Additives Amendment of 1960
  - Drug Amendments of 1962
  - Animal Drug Amendments of 1968
  - Federal Insecticide, Fungicide, and Rodenticide Act (1972)
  - Saccharin Study and Labeling Act (1977)
  - Infant Formula Act of 1980
  - Dietary Supplement Health and Education Act of 1994
  - Food Quality Protection Act of 1996
  - FDA Modernization Act of 1997
  - FDA Food Safety Modernization Act (2011)

What is food?

Includes:

- Human food
- Pet food
- Animal feed
- Substances migrating to food from food contact articles (a.k.a. food contact substances or FCSs)

Intended use is critical to defining
legal responsibilities under the FFDCA

Categories of chemicals added to food

Category	Definition: *Chemicals whose intended use:*
Food additives	may reasonably be expected to result in them becoming a component or otherwise affecting the characteristics of any food and that do not fit into any of the six categories listed below
"Generally recognized as safe" (GRAS) substances	is generally recognized among experts qualified by scientific training and experience to evaluate the safety as having been adequately shown be safe
Prior-sanctioned substances	was approved prior to 9/6/58
Color additives	imparts color to food unless intended to be used solely for other purposes
Pesticide chemicals or residues	includes prevention, destruction, or repulsion, of any pest used in or on a raw agricultural commodity or in some situations, when applied to food contact surfaces
Animal drugs	is to diagnose, cure, mitigate, treat, or prevent disease in animals
Dietary supplement ingredients	is in non-conventional food or is not as a sole item of a meal

Three ways new chemicals are cleared for use in food

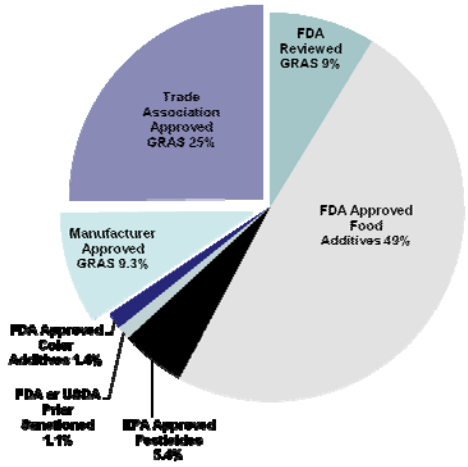
- FDA issues a new or amended regulation
  - Universal before 1995
  - Less than 3% of FDA decisions from 2006 to 2010
- FDA issues a "no objection" letter in response to a manufacturer's request for review of a chemical
  - More than 97% of FDA decisions from 2006 to 2010
  - No advance notice or opportunity for public comment
- A manufacturer or trade association decides a chemical's use is "generally recognized as safe" or GRAS.
- Notice to FDA is NOT required
- Public notice NOT required

Estimated number of substances currently allowed in human food

Category[c]	Final Evaluator	No. of substances
Food additives	FDA	5,292
"Generally recognized as safe" (GRAS) substances		4,646
	Manufacturer	1,000[a]
	Trade association[b]	2,702
	FDA	944
Prior-sanctioned substances	FDA or USDA	120
Color additives	FDA	148
Pesticide chemicals or residues	EPA	581
OVERALL TOTAL		10,787

[a] This is an educated estimate since manufacturers choosing to make a self-determination of safety rarely advertise their decision
[b] Flavors and extracts only
[c] Dietary supplements and animal drugs are excluded from these counts because they are not a part of conventional human food

Contribution of substances currently allowed in human food to estimated 10,000



What is constitutes 'safe' for each category?

Category	Must be reasonably certain of no harm	Must not induce cancer in animals or humans
Food additives	Yes	Yes
"Generally recognized as safe" (GRAS) substances	Yes	Yes
Color additives	Yes with convincing evidence	Yes for human / Limited for animal feed
Prior-sanctioned substances	No	No
Pesticide chemicals or residues	Yes	No
Drugs in animal feed	Generally yes	Limited
Dietary supplement ingredients	No	No

- Good Manufacturing Practices (GMP)
  - Ensure purity
  - Use no more than is needed

Who decides and who knows about the decision before it's made?

Category	Must federal agency make or review safety decision?	Does public have opportunity to comment before decision made?
Food additives	Yes (FDA)	Yes except for FCSs covered by a notification to FDA
"Generally recognized as safe" (GRAS) substances	No	No
Color additives	Yes (FDA)	Yes
Prior-sanctioned substances	Yes (FDA or USDA)	No
Pesticide chemicals or residues	Yes (EPA)	Yes
Drugs in animal feed	Yes (FDA)	Yes
Dietary supplement ingredients	Only if first used after 1994 (FDA)	No

Food manufacturers' post-market responsibilities

Category	Comply with safety standard	Verify compliance [a]	Report new research on hazards	Report adverse health reactions?
Food additives	Yes	Confirm use is approved	No	Yes, if death or serious
GRAS Substances	Yes	"	No	"
Prior-sanctioned substances	Yes	"	No	"
Color additives	Yes	"	No	"
Pesticide chemicals or residues	Yes	Conduct hazard analysis	Yes	Yes
Drugs in animal feed	Yes	"	No	Yes
Dietary supplement ingredients	Yes	"	No	Yes, if serious adverse event

[a] Only applies at food facilities. Not applicable for food contact substances

Food additives v. industrial chemicals

Food Additives Amendment of 1958

- Safe = Reasonable certainty use is not harmful
- Premarket clearance or approval **unless GRAS**
- Use or production not regularly reported
- New health and safety studies not required to be reported
- No mandated periodic reassessment

Toxic Substances Control Act of 1976

- Presents or will present an unreasonable risk
- Premarket notification if not on master list
- Use and production reported every 4 years (§ 8(d))
- Substantial risk reporting (§ 8(e)) and EPA call-in (§ 8(d))

Also FIFRA requires review of pesticides every 15 years

Based on:

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To Learn More

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