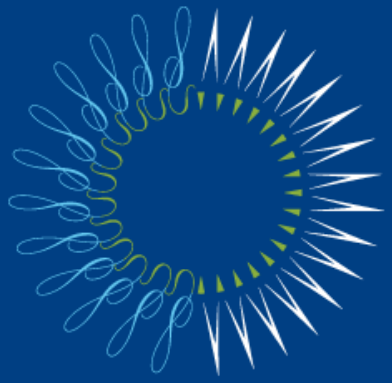

THE PEW CHARITABLE TRUSTS

Navigating the U.S. Food Additive Regulatory Program

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Pew Health Group

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Food Additives Project

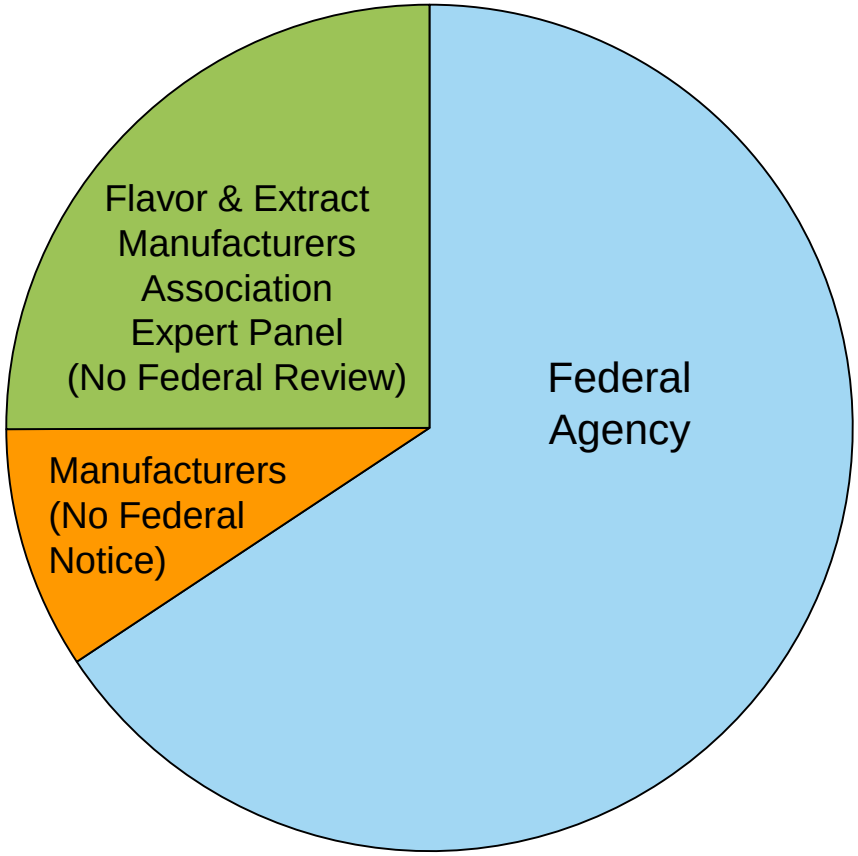
- Launched in 2010 to:
  - Conduct a comprehensive analysis of the existing regulatory program
  - Determine if the system works and whether chemicals added to food are safe as required by law
  - Develop policy recommendations to address any gaps
- Transparent process engages industry, academic, government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

Three ways chemicals are cleared for use in food

1. FDA issues a new or amended regulation
   - Used mostly before 1995
   - Includes public notice and comment
   - Less than 3% of FDA decisions from 2006 to 2010
2. 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 public notice or comment
3. A manufacturer or trade association decides a chemical’s use is “generally recognized as safe” or GRAS.
   - No public notice or comment
   - Notice to FDA is NOT required

Who makes safety decisions for chemicals added to human food?

- More than 10,000 chemicals allowed as of January 2011
- More than 3,000 (1/3 of total) were approved by trade association or manufacturers without FDA review
- Remaining two-thirds were cleared by a federal agency
  - EPA for pesticides
  - FDA for all other



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

Four Areas of Concern

- FDA unaware of a large number of GRAS substances and can't ensure safety decisions were properly made.
- Manufacturers not required to inform FDA of relevant health and safety studies or even name of chemical.
- FDA's expedited clearance approach occurs with little or no public engagement.
- FDA lacks the resources and information to identify and prevent potential health problems or set priorities for systematic reevaluation of past decisions.

To Learn More

Contact Tom Neltner, Project Director at tneltner@pewtrusts.org or 202-540-6475

or go to

www.pewtrusts.org/foodadditives