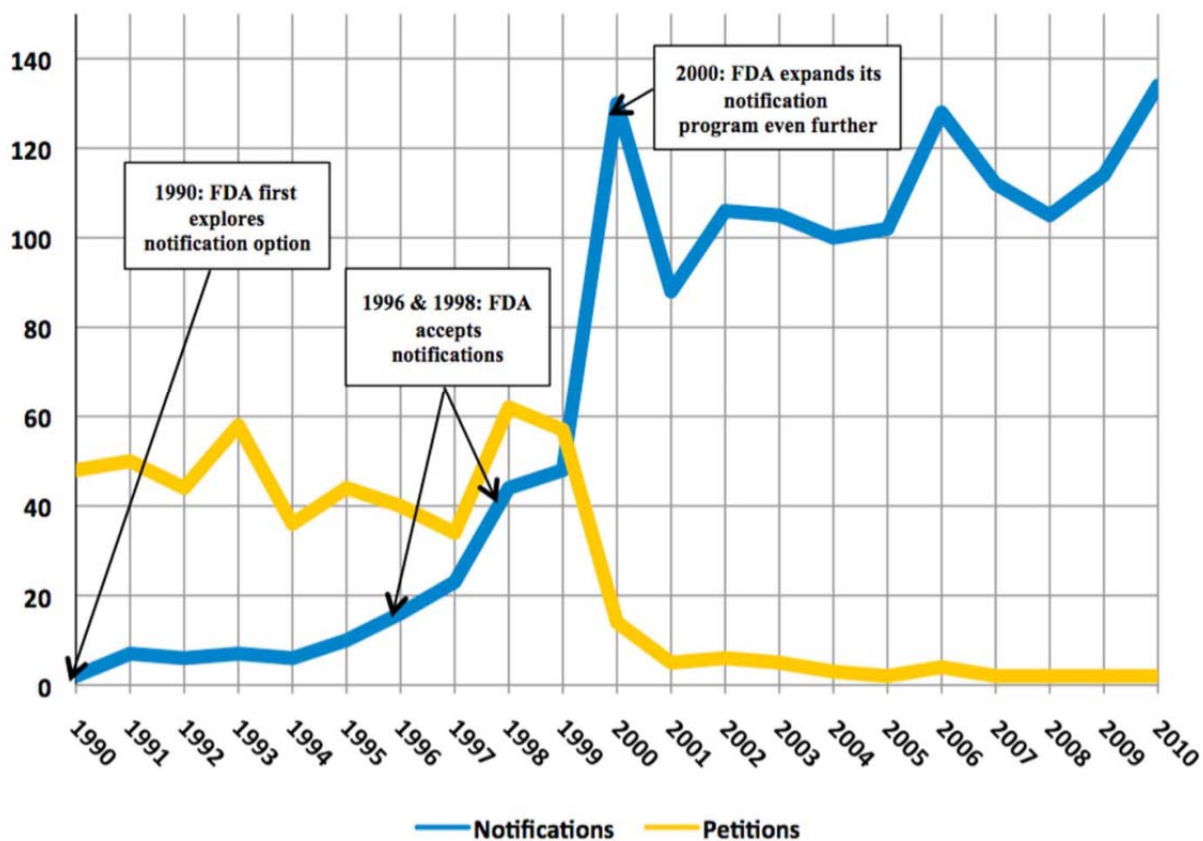


Chemical Additives... Five Facts

- 1) 10,000 chemicals allowed to be added to food
- 2) 3,000 of these have never been reviewed by FDA
- 3) 1,000 of these are completely unknown to FDA
- 4) > 90% of the 10,000 are food additives or “generally recognized as safe” (GRAS) substances
- 5) Most of the new chemicals are approved by companies who then may notify FDA...

Figure 2 - Filings Submitted to FDA 1990-2010



“The Loophole that Swallowed the Law”

- In 1958, Congress:
 - Required food additives to go through petition and rulemaking to allow them in food;
 - Created the GRAS exemption for common food ingredients; and
 - Under FDA’s interpretation, allowed manufacturers to determine a chemical’s use was GRAS without notifying FDA.
 - The exemption has expanded over the decades so, today, most new chemicals pass through the loophole.
 - **FDA reviews only those voluntarily submitted to the agency**
-

U.S. Government Accountability Office’s 2010 report

GAO’s Findings:

- “FDA’s oversight process does not help ensure the safety of all new GRAS determinations.”
- “FDA is not systematically ensuring the continued safety of current GRAS substances.”
- “FDA’s approach to regulating nanotechnology allows engineered nanomaterials to enter the food supply as GRAS substances without FDA’s knowledge.”

GAO’s Recommendations: FDA should develop a strategy to:

1. Conduct reconsiderations of the safety of GRAS substances in a more systematic manner.
2. Finalize the rule that governs the voluntary notification program.
3. Monitor the appropriateness of companies’ GRAS determinations.
4. Minimize the potential for conflicts of interest in companies’ determinations.
5. Require any company that conducts a GRAS determination to provide FDA with basic information.
6. Help ensure the safety of engineered nanomaterials that companies market as GRAS substances without the agency’s knowledge (*Note: FDA issued draft guidance in 2012*).