How do new substances enter the US food supply?

A manufacturer that wants to **add a new substance** to food has several possible paths to market. Here are the processes to establish the substance as "safe" and legal to be used in foods.

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**Secret GRAS**

- Manufacturer makes **its own determination** that the substance is "generally recognized as safe"  
- FDA is never notified of new substance being used and **never reviews any safety information**  
- Manufacturer uses substance in product **without formal FDA approval**

**Voluntary GRAS notice**

- Manufacturer submits **voluntary notice** to FDA that the substance is "generally recognized as safe"; FDA reviews notice; no opportunity for comments from the public  
- After reviewing the notice for safety of the substance, FDA sends "No Questions" letter* to manufacturer

**FDA pre-market approval** (CSPI-preferred pathway)

- Manufacturer submits **pre-market petition** to FDA  
  - FDA conducts safety assessment  
  - Members of the public have the opportunity to comment  
  - If FDA has unresolved safety questions/concerns, then FDA rejects the petition** or manufacturer withdraws the petition or GRAS notice

- FDA formally approves new food substance

- Manufacturers can use the "secret GRAS" pathway of the GRAS loophole to use the substance in the food product anyway

- Manufacturer **does not use substance** (CSPI-preferred outcome in the event of petition or notice rejection)

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**Food manufacturers should not decide in secret that the substances they put in our foods are safe. CSPI calls on the FDA and Congress to close the GRAS loophole.**

For more information on CSPI's additives advocacy work, visit [https://www.cspinet.org/highlight/food-additives](https://www.cspinet.org/highlight/food-additives)

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*A "No Questions" letter is not considered an approval by FDA.  
**"FDA rejects the petition" is only applicable to the FDA pre-market approval pathway.*