

# Evaluation of Food Safety and its Regulations in Food Additives

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## Perspective

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## ABOUT THE STUDY

Food additives have become more common as the use of processed foods has increased since the nineteenth century. Many countries have laws that govern their use. For example, from the 1870s to the 1920s, boric acid was widely used as a food preservative, but it was banned after World War I due to its toxicity, as demonstrated in animal and human studies. It was used again during World War II due to the urgent need for cheap, readily available food preservatives, but it was finally banned in the 1950s. Such incidents sowed widespread scepticism about food additives, and an application of the precautionary principle led to the conclusion that only additives known to be safe should be used in foods.

## Food safety and its regulations

The Delaney clause, an amendment to the Federal Food, Drug, and Cosmetic Act of 1938, states that no carcinogenic substances may be used as food additives in the United States. However, after cyclamates were banned in the United States and the United Kingdom in 1969, saccharin, the only remaining legal artificial

sweetener at the time, was discovered to cause cancer in rats. Despite its violation of the Delaney clause, saccharin was retained in the United States due to widespread public outcry, which was partly communicated to Congress via postage-paid postcards included in the packaging of sweetened soft drinks. However, saccharin was discovered to be carcinogenic in rats in 2000 due to their unique urine chemistry. Food Standards Australia New Zealand published an official shoppers' guide in 2007 to address concerns about food additives and labeling. A new food additive can take ten years or more to be approved in the EU. This includes five years of safety testing, two years for evaluation by the European Food Safety Authority (EFSA), and another three years before the additive is approved for use in all European Union countries. Trading Standards officers (in the UK) protect the public from any illegal use or potentially dangerous misuse of food additives by performing random testing of food products.

There has been a lot of debate about the risks and benefits of food additives. Natural additives may be equally harmful or cause allergic reactions in some people. Safrole, for example, was used to flavor root beer until it was discovered to be carcinogenic. Because of the Delaney clause, it cannot be added to foods, despite the fact that it occurs naturally in sassafras and sweet basil.

**Hyperactivity:** Concerns have been expressed on occasion about a link between additives and hyperactivity, but "no clear evidence of ADHD was provided".

**Toxicity:** The EFSA proposed the tier approach to evaluating the potential toxicity of food additives in 2012. It is divided into four categories: toxic kinetics (absorption, distribution, metabolism, and excretion); genotoxicity; sub chronic (at least 90 data) and chronic toxicity and carcinogenicity; reproductive and developmental toxicity. Recent research has shown that certain food additives, such as carboxymethylcellulose, can cause microbes from the gastrointestinal tract to enter the protective mucus layer that lines the intestines. Preclinical research indicates that emulsifiers may disrupt the gut micro biome, cause or exacerbate inflammation, and increase intestinal permeability.

**Micronutrients:** Micronutrients, a subset of food additives, are added in food fortification processes to preserve nutrient value by providing vitamins and minerals to foods such as flour, cereal, margarine, and milk that would not normally retain such high levels. Air, bacteria, fungi, and yeast are added ingredients that contribute manufacturing and flavor qualities while also reducing spoilage.

### **Food additive approval in the United States**

A food additive is defined by the Food and Drug Administration (FDA) as "any substance whose intended use results or may reasonably be expected to result directly or indirectly in its becoming a component or otherwise affecting the characteristics of any food". A Food Additive Approval Petition (FAP) must be submitted to the FDA in order for a novel food additive to be approved in the United States. A FAP must define the identity of the ingredient, its proposed use in the food system, its technical effect, a method of analysis for the ingredient in foods, information on the manufacturing process, and full safety reports. The FDA evaluates the chemical composition of the ingredient, the quantities that would be typically consumed, acute and chronic health impacts, and other safety factors before approving a FAP. Prior to the additive's market approval, the FDA reviews the petition.