Thomson Reuters Law for the Layperson

A CONSUMER'S GUIDE TO FOOD REGULATION AND SAFETY

James T. O'Reilly

Legal Almanac Series

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A CONSUMER'S GUIDE TO FOOD REGULATION & SAFETY

by

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This Book is Dedicated to

Donald D. Black.

Last of the Frontiersmen,

With Great Affection and Respect

For His Life of Courage, Integrity,

And Selfless Sharing with Others.

PREFACE

The Broadway remake of Dickens' Oliver Twist features a dozen scrawny orphans singing, "Food! Glorious Food!" We love food; we eat it, think about it, plan for it, choose it, and admire it. But sometimes the people who deliver the food hurt us by their mistakes or oversight (or, rarely, their intention). And sometimes the people who have the food want to separate us from our money by claiming things about the food that just aren't true. In either instance, this book may be a help.

Consider this a kind of "cookbook," not of the joys of cooking food but the challenges of presenting safe, wholesome food in a truthful manner to an interested audience. Use this book for basic answers to questions of why certain things happen, how they can be resisted or punished, and who can provide you with the relief that you seek.

Of course, if you've suffered an unfortunate outcome related to food, seek medical help and try to avoid that problem in the future. If there was a serious harm done, find an experienced and competent attorney who concentrates his practice in the subject of the harm. If you and others were cheated by a fraudulent sales pitch for a food, one of the specialized class action lawyers who handles consumer cases may take on your claims. Just as a special occasion merits a specially talented chef's meal, so litigation involving food injury or fraud warrants the use of an experienced specialist who knows how to effectively represent your interests.

Best wishes, and Bon Appetit!

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Table of Contents

CHAPTER 1:
DEFINING KEY CONCEPTS IN FOOD

We begin with the basic terms that will be used throughout this book. "Food" is a solid, liquid, or other form of ingested material that is used for taste or nourishment. Basic definitions in common use in the food industry, like "safe food," are subjective terms that may not match the expectations of the consumer. To a consumer, a safe food would be pure with no contaminants. The industry definition allows low levels of contaminants and considers relative safety, taking into account the intended cooking and other methods of reducing risk, and judges safety as a relative factor within the comparative context of similar foods. Normally, the consumer expects food to be cheap and safe, tasty and not poisonous, attractive and not contaminated. At the consumer level, these expectations are usually met, and one often hears, "We have the safest food supply in the world."

The food producer—a farm or ranch operator "upstream" in the processing sequence for consumer food—is accustomed to seeing some very normal and predictable contaminants in every truckload of food, whether dirt on the potato or feces on the pigskin. That farmer or rancher or warehouse operator expects further cleaning and processing will occur in later stages, and that quality and safety will be enhanced. So food producers tend to be much more tolerant of contaminants than the average consumer of the finished food would be. By the time the food reaches the consumer's plate, it should be safe, and the systems should be in place to track its safety.

This book explores food "safety" broadly. We take the food consumer's viewpoint, and we recognize that some food producers will disagree. Overall, a greater consumer awareness of food safety regulation and its limitations helps everyone—from growers to diners. Safety is not automatic; and it is not without considerable costs built into the system.

On the food industry side, companies with the greatest marketplace strength receive the greatest consideration from Congress and regulatory agencies. The law's structures and incentives seem to accommodate and even reward the largest, most mechanized and most systematized growers and processors. A three hundred-acre carrot producer is less likely to have an impact on regulators than a wheat conglomerate with twenty-five grain elevators. Our nation's food supply and economic system is oriented to reward and incentivize the largest industrial food processors. The gap between the actual growers of food and those who eat the products of the land appears to be growing. The "Bibliography and Recommended Reading" later in this text lists a dozen books that adopt the viewpoint that there is a growing cultural shift that favors locally grown food. Unwritten, but equally true, is that cost subsidies and financial arrangements tend to disfavor the smaller, local grower. So readers should recognize from the outset that our concepts of food safety are no longer built upon comfortable familiarity with the grower or producer, but safety is measured on an industrial scale.

1. WHAT IS "SAFE"?

Safety can be defined as the absence of harm or injury. "Food safety" refers to the general desire of consumers and government agencies for an absence of avoidable human illness related to the ingestion or handling of food. For example, beef with high levels of maggots or lettuce with *Escherichia coli* (*E. coli*) are not deemed to be safe food. "Food security," a parallel but distinct term, means the protection of food from intentional tampering, poisoning, terrorism, or otherwise evil actions.

The safety of processing, manufacturing, and importing food is a centrally important issue throughout this book. Consumers don't want to eat bad food, and they don't want to worry about whether the food is safe and has been handled safely. Avoiding illness is important to the consumer and taxpayer. When companies fail to protect the food they sell to the public, the company and their managers may be punished in court and in the stock market; when regulators fail to avoid harms, they are replaced or de-funded.

Defining "safety" involves subjective perceptions. Safety is not the total absence of risk, but it is the quality of a product's condition that makes it reasonable to assume that no harm will be caused from ingesting the food. Congress has struggled with this balancing several times, and the "reasonable certainty of no harm" is the most recent compromise language. Parents want a reasonable certainty that the food they buy or cook will not cause harm to their children; and Congress seeks a similar goal in federal food safety legislation.

The increasing dissemination of scientific knowledge about viruses, bacterial particles, and tiny nano-sized contaminants has put a lot of scientific information into the public's hands, and some portion of that knowledge has aided the awareness of needs for protective activities. The FDA and state health inspectors use a series of tests to determine if a particular food is "safe" by counting the contaminants or doing lab testing of a sample of the food. Some bad material will usually be detectable, but how much is present? The "defect action level" concept is applied, meaning that a food can be contaminated to a small extent—e.g. twenty parts of flies in a pound of fresh butter—but cannot have more contaminants than FDA scientists believe would cause disease or other harms. If the contaminant quantity exceeds the "level," then the product is deemed to be "adulterated." It is the end condition of the food as eaten that matters; for example, properly cooked beef does not pass *E. coli* infections to humans.

2. HOW ARE CONTAMINANTS CONTROLLED?

Who is the nation's "food safety guru"? For meat, poultry, and eggs, the Food Safety Inspection Service of the U.S. Department of Agriculture (USDA) is the regulatory agency. For all other foods, the FDA and the state counterpart agencies that parallel the FDA are in charge of safety surveillance. The State Department of Agriculture or the State Department of Health train inspectors to visit food processing plants within the state on a regular basis to examine whether there is sufficient protection from harmful ingredients or illness-causing bacteria. They share data and findings with the FDA and often take parallel enforcement actions in holding back interstate and in-state shipments. The regulatory control of food safety is one part of the solution; corporate food processing companies need investor confidence and positive consumer loyalty, and that is another part of the incentives for safety. A minor but notable aspect of the safety incentive is the liability cost or bankruptcy that a company would face if its food caused injury, and if a jury agreed that damage awards should punish that firm's negligent conduct.

3. HOW ARE SAFETY STANDARDS CREATED?

Who decides what "safety" should look like? At the top of the "food chain" are congressional decisions on what should be regulated and in what ways. Congress can expressly require a specific set of ingredients and levels, as it once did for infant formula. This is the rare exception. Most of the laws Congress has adopted for food safety are delegations of power to administrative agency managers in the FDA and the USDA to use their discretionary power to protect the safety of foods.

Broader delegations and looser legislative language give more discretion to the agency managers and sets up the FDA or the USDA to make a decision about safety. A set of final, binding rules, established by processes that assure public awareness and comment, are the next level below the authority of legislation. These rules provide the agency's view of the most firm and enforceable standards of safety. Most participants in the food processing and distribution chain obey these binding rules, most of the time. Those who ignore the rules and are caught can be severely penalized.

The next level of standards (in terms of a hierarchy of enforcement ability) are "guidelines" or "policy statements" that indicate to food firms what the government agency expects, or explain how the government agency interprets the words Congress has used in statutes like the Meat Inspection Act or the Food Drug & Cosmetic Act. FDA guidance documents are not binding rules. While it is helpful to have some guidance to clarify uncertainties, FDA guidance documents are readily changeable, can be ignored if particular circumstances warrant, and often appear with disclaimers that limit the value of their protective intentions.

The lowest forms of directives are the letters written in particular cases in reply to questions from the industry. Is this action allowed? Will I be in trouble for doing this? Does your agency have a problem if I combine these two ingredients? Easy to obtain but hard to rely upon, these are the changeable statements of a busy bureaucracy that provide guidance in a particular case without having any longer-term weight in the world of regulation. Implicitly, they offer some assurance that the action can be taken or the measurement would be acceptable without criticism of that action by the regulators.

Not expressed to consumers, but publicly available in FDA internal manuals, are the "defect action levels," measurements at which quantitative points the FDA would start an enforcement action for adulteration, e.g. ten rodent hairs in powdered potato flakes. Food defects vary with types of foods and types of defects. These levels have been set and sometimes updated to reflect the findings that FDA staff makes during their actual hands-on inspections and lab tests of the food processing industry.

4. HOW DO REGULATORS BECOME INVOLVED AT THE VARIOUS STEPS OF THE PROCESS?

Government agencies act through regulation-writing, known as "rulemaking"; inspection and penalty assessment, known as "adjudication"; and prosecuting the worst offenders in court, known as "enforcement."

From the consumer's viewpoint, the slowest of these is rulemaking, and the one with the most impact is enforcement. Most of the administrative work is in adjudication of particular cases, with inspectors visiting plants and agency hearing officers imposing financial penalties or suspending licenses for inadequate compliance with food safety laws.

Consumer complaints about food issues typically go into the adjudication process. For example, an inspector will follow up a "glass in product" call or a quality complaint about a packaged food. Part of adjudication is the decision about whether a complaint is a rare occurrence, an aberration in a company whose reputation is stellar, or whether it is reason to shut down the company as a persistent safety violator. Remedies for specific cases vary: some will be forced to recall, some will be assessed fines, some will lose licenses, and some will be fully exonerated after the investigation clears the food firm of responsibility (e.g. for a tampering or intentional individual poisoning episode).

5. HOW ARE SPECIAL CATEGORIES OF FOOD REGULATED?

There are also special categories of food, recognized in specific federal laws, including dietary supplements, organic foods, and food additive ingredients. Each category has a special regulatory status, which is related to the desire of Congress to preserve certain products from further limitations. Congress carved out a special, less stringent rule for these product categories. The FDA and USDA treat these products in light of these special exceptions and statutory exclusions.

The largest category of food that has the intentionally weakest regulation, because of an excellent lobbying effort in 1994, is the category of "dietary supplements." This category is shielded from most of the FDA's controls, which apply to other categories of food. Dietary supplement makers have been able to avoid all of the FDA approval steps, and the controls that remain have been neutralized so as to be no real protection at all. Chapter 10 discusses this category in detail.

Another category of food that deserves special recognition is the so-called "organic" food products, which are intended to be grown or processed without the use of chemicals or biological pesticides. These products can be labeled "organic" because they comply with rules set by the U.S. Department of Agriculture, adapted from international standards. The rules prescribe the limited use of fertilizers, pesticides, and other chemicals as the crops are growing. Some controversy surrounds the USDA acceptance of some practices as being "organic." The price of organic food tends to be higher than that of conventional food, to make

up for the losses incurred by the organic farmer when his or her crop yield is reduced as a result of the limitations on fertilizers and pesticides. The perception of greater purity may be an illusion in some circumstances; but if consumers are willing to pay more for lower chemical exposure, then the marketplace will deliver what the consumer wishes, at a price.

Chemical products used in conjunction with food can be termed food ingredients, food additives, colors, or future "functional foods" undergoing development efforts. In the latter case, the company is attempting to demonstrate that their food product is different because of its unique attributes that enhance a consumer benefit. Chapter 5 discusses raw and organic ingredients and their legal issues.

6. WHAT STRATEGIES ARE UTILIZED?

American food law allows great flexibility to the food marketer, but that flexibility is tied to severe penalties if harm occurs to consumers from serious errors. "Sell at your own risk" approaches put the burden on food company executives to pay close attention to lists of safe ingredients and to avoid the ones on the lists that present problems. Preapproval is rarely used in food safety regulation, only the newest chemical additives are likely to receive detailed FDA scrutiny.

For meat products, a historic shift of approaches has occurred. The use in meat plants of a sophisticated planning and evaluation system called the Hazard Analysis of Critical Control Points (HACCP) increased in the last two decades to become the dominant theme in meat product safety, displacing generations of "hands-on" physical inspection of each carcass in each meat plant. By identifying where problems are most likely to arise, the focused effort of the HACCP safety program should reduce harm. Chapter 5 covers these issues.

7. SELLING FOOD

Food marketers tend to make excessive benefit assertions. Some creatively aggressive sales claims appear on the food labels; some marketers use advertising to assert their benefit claims. Back in 1938, Congress split jurisdiction over claims of food frauds between the Federal Trade Commission, the FDA, and the states. State attorneys general challenged a number of health benefit claims made for foods. In recent years, as a result of abuses in the system, Congress has designated the FDA to receive more appropriations for its enforcement roles, to make the FDA a more energized regulatory police agency against fraudulent claims in the food category. Chapter 3 addresses this area.

8. WHAT EFFECTS DO CONTAMINANT CHEMICALS HAVE IN FOODS?

The presence of insects and other predators on seeds, fruits, and vegetables has been a natural fact for millennia. Modern chemistry has the capacity to poison the predator and preserve the crop from destruction, sometimes by spraying a chemical and sometimes by breeding into the plant a natural protection through genetic engineering. The effect of the modern agricultural chemical "miracle" on foods has been cheaper, more readily available food that will last longer, mature later (after transcontinental air movement), or avoid problems that have led consumers to reject such food in the past. There is a trade-off for having more, better, and greener plant products—it is the human effects of pesticide residues. To the extent a new chemical pesticide has been tested and shown to have a potential human health consequence, its use can be limited by "tolerances," which are quantitative limits measured at harvest and after processing. Chapter 10 explores these in depth.

9. WHAT EFFECTS DO FOOD ALLERGIES HAVE ON POLICY?

Governments cannot change biology; some humans will have allergic responses to certain plant or animal aspects, such as a wheat gluten allergy. But governments can do more to require cautionary labels on products and to make people aware of the potential risks of ingesting food that has allergens present, whether in basic or in processed food. In the United States, after numerous state laws were enacted, a federal law on allergen warnings was adopted in 2004 and went into effect in 2006. Chapter 3 explores these issues.

As we enter the later chapters of this book, please keep these concepts in mind, as they are the shorthand versions of more complex topics. A guidance document on colors with contaminants is not infallible, but the context of its use against a food to punish the safety violator is built on the defined terms that we have discussed in this chapter.