2

WHAT IS FOOD?

2.1 INTRODUCTION TO THE FOOD, DRUG, AND COSMETIC ACT

The Federal Food, Drug, and Cosmetic (FD&C) Act[1] regulates more products that Americans use in their daily activities than any other federal statute. Most foods are regulated under the FD&C Act, as well as pharmaceuticals, medical devices, and cosmetics.

The regulation of these products and food share many similarities; however, the requirements applying to food differ significantly from those for drugs. Accordingly, the law's classification of a product as a food or drug can determine how rigorously the product is regulated—or whether the product is even legal. Thus, the statute's definitions of these products deserve close attention.

After you complete this chapter, you will have an understanding of

- what makes an article subject to the FD&C Act;
- what makes an article a food, a drug, or a product outside the scope of the FD&C Act; and
- the central role of intended use.

[1] 21 U.S.C. Sec. 321 *et seq.*

2.1.1 Definitions

* * * * *

SEC. 201. [321][2] For the purposes of this Act—

. . . .

(f) The term "**food**" means (1) *articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any other such article.*

(g) (1) The term "**drug**" means

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or

[2] Statutory citations used in this material generally are to the FD&C Act statutory sections. The citation within the brackets is the U.S.C. number. The United States Code (U.S.C.) is organized into subject matter titles with numbering that is unique from the section numbering in the statutes. For example, section 201 of the Food, Drug, and Cosmetic Act is codified as 21 U.S.C. § 321. Thus, this section is cited as "FD&C Act Sec. 201. [321]."

Food Regulation: Law, Science, Policy, and Practice, Second Edition. Neal D. Fortin.

dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement. . . .

(h) The term "**device**" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(i) The term "**cosmetic**" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

. . . .

(s) The term "**food additive**" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this . . . or

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

. . . .

(ff) The term "**dietary supplement**"—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A) (i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title;

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does—

(A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include—

(i) an article that is approved as a new drug under section 355 of this title, certified as

an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

Except for purposes of paragraph (g), a dietary supplement shall be deemed to be a food within the meaning of this chapter.

* * * * *

2.1.2 FDA's Jurisdiction and the Definition of Food

The scope of FDA's authority over food derives in large measure from the definition of "food" in the FD&C Act. Therefore, the definition bears importance in determining the reach and limits of the FDA's jurisdiction and authority.

The statutory definition of "food" in the FD&C Act section 321(f) is a term of art that is broader than the commonsense definition of food. This creates pitfalls for the unwary. For instance, the definition of "food" includes chewing gum and food additives. Moreover, "food additives" include substances that are not food ingredients but otherwise affect the characteristics of a food.[3]

To a large extent, the use of a product will determine the regulatory category into which it will fall. The manufacturer's representations and the intended use also play an important part in determining the classification. A manufacturer may occasionally benefit from changing its representations so that their product falls into a different category. For example, a laxative gum can escape the definition of food by being represented unequivocally as a drug product.

NOTES AND QUESTIONS

2.1. The broad definition of "food" under the FD&C Act provides a broad scope of authority to the FDA. As worded, does this broad scope overlap with the U.S. Department of Agriculture (USDA) FSIS's authority?

[3] *See* 21 U.S.C. § 321(s).

2.1.3 Specific Food Classifications

Meat, Poultry, and Eggs The USDA is responsible for meat, poultry, and processed eggs; however, which agency has jurisdiction over these foods is complex and sometimes uncertain. All foods are subject to the FD&C Act—meats are exempt from the FD&C Act provisions, but only to the extent that the Federal Meat Inspection Act (FMIA) applies.[4]

FDA generally has jurisdiction over live meat animals intended for food, but USDA has authority regarding the illegal transportation of diseased animals in commerce.[5] USDA has exclusive jurisdiction over the slaughter and processing of meat animals. However, food additives are under the jurisdiction of the FDA; therefore, the USDA and FDA have joint jurisdiction over food additives in meat and poultry.

FDA has the main regulatory authority over the transport of food, but USDA has some jurisdiction over the illegal transport of meat in commerce.[6] FDA has exclusive jurisdiction over retail establishments (when in federal jurisdiction). Nonetheless, USDA may still regulate USDA-labeled packages that are found in retail establishments, but USDA lacks authority over the retail establishments directly.

In addition to the statutory demarcations of jurisdiction, the agencies also divide responsibility based on Memoranda of Understandings (MOUs).[7] For multi-ingredient products that contain meat, the percentage of meat determines whether the product is subject to USDA jurisdiction. For example, a product containing 3% or less raw meat falls under FDA jurisdiction.

Water The Safe Drinking Water Act[8] places the responsibility for the safety and purity of drinking water on the EPA. However, the FDA retains the authority over bottled drinking water. Differences between these two standards sometimes create consternation for the agencies, the bottled water industry, and municipal water agencies.

In addition, water, when used as a food ingredient, is a food, and thus is subject to all the same requirements of the FD&C Act as any other food ingredient. Similarly, for ice added as an ingredient, the FDA has jurisdiction over packaged ice as a food.

2.2 WHAT MAKES AN ARTICLE A FOOD OR A DRUG?

The *Nutrilab* starch blockers case below highlights the importance of the definitions in determining how a product

[4] 21 U.S.C. § 392(b).

[5] *See, e.g.*, 21 U.S.C. § 644 (regarding transporting in commerce dead, dying, disabled, or diseased animals.)

[6] *See, e.g.*, 21 U.S.C. § 610(c) (regarding transportation in commerce of without complying with inspection and marking provisions).

[7] For a summary of these MOUs, *see* FDA, INVESTIGATIONS OPERATIONS MANUAL (2012), Subchapter 3.2, Federal Agency Interaction.

[8] 88 Stat. 1660 (1974).

will be regulated. Nutrilab claimed their starch blockers were a food because the product was derived from beans. The court, however, found that starch blockers were a drug under the FD&C Act because the "tablets and pills at issue were not consumed primarily for taste, aroma, or nutritive value" . . . but "they are taken for their ability to block the digestion of food and aid in weight loss." Foods are normally digested, but starch blockers blocked the digestion, which shows intent to affect the structure or function of the body. Starch blockers were, therefore, deemed to be drugs under Section 321(g)(1)(C) of the FD&C Act.

* * * * *

Nutrilab, Inc. v. Schweiker

713 F.2d 335 (1983)

Judges: CUMMINGS, Chief Judge; POSNER, Circuit Judge; and FAIRCHILD, Senior Circuit Judge
Opinion: CUMMINGS

Plaintiffs manufacture and market a product known as "starch blockers" which "block" the human body's digestion of starch as an aid in controlling weight. . . . The only issue on appeal is whether starch blockers are foods or drugs under the Federal Food, Drug, and Cosmetic Act. Starch blocker tablets and capsules consist of a protein which is extracted from a certain type of raw kidney bean. That particular protein functions as an alpha-amylase inhibitor; alpha-amylase is an enzyme produced by the body which is utilized in digesting starch. When starch blockers are ingested during a meal, the protein acts to prevent the alpha-amylase enzyme from acting, thus allowing the undigested starch to pass through the body and avoiding the calories that would be realized from its digestion.

Kidney beans, from which alpha-amylase inhibitor is derived, are dangerous if eaten raw. By August 1982, FDA had received seventy-five reports of adverse effects on people who had taken starch blockers, including complaints of gastro-intestinal distress such as bloating, nausea, abdominal pain, constipation and vomiting. Because plaintiffs consider starch blockers to be food, no testing as required to obtain FDA approval as a new drug has taken place. If starch blockers were drugs, the manufacturers would be required to file a new drug application pursuant to 21 U.S.C. § 355 and remove the product from the marketplace until approved as a drug by the FDA.

The statutory scheme under the Food, Drug, and Cosmetic Act is a complicated one. Section 321(g)(1) provides that the term "drug" means. . . .

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.

The term "food" as defined in Section 321(f) means

(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

Section 321(g)(1)(C) was added to the statute in 1938 to expand the definition of "drug." The amendment was necessary because certain articles intended by manufacturers to be used as drugs did not fit within the "disease" requirement of Section 321(g)(1)(B). Obesity in particular was not considered a disease. Thus "anti-fat remedies" marketed with claims of "slenderizing effects" had escaped regulation under the prior definition. The purpose of part C in Section 321(g)(1) supra was "to make possible the regulation of a great many products that have been found on the market that cannot be alleged to be treatments for diseased conditions."

It is well established that the definitions of food and drug are normally not mutually exclusive; an article that happens to be a food but is intended for use in the treatment of disease fits squarely within the drug definition in part B of Section 321(g)(1) and may be regulated as such. Under part C of the statutory drug definition, however, "articles (other than food)" are expressly excluded from the drug definition (as are devices) in Section 321(g)(1). In order to decide if starch blockers are drugs under Section 321(g)(1)(C), therefore, we must decide if they are foods within the meaning of the part C "other than food" parenthetical exception to Section 321(g)(1)(C). And in order to decide the meaning of "food" in that parenthetical exception, we must first decide the meaning of "food" in Section 321(f).

Congress defined "food" in Section 321(f) as "articles used as food." This definition is not too helpful, but it does emphasize that "food" is to be defined in terms of its function as food, rather than in terms of its source, biochemical composition, or ingestibility. Plaintiffs' argument that starch blockers are food because they are derived from food—kidney beans—is not convincing; if Congress intended food to mean articles derived from food it would have so specified. Indeed some articles that are derived from food are indisputably not food, such as caffeine and penicillin. In addition, all articles that are classed biochemically as proteins cannot be food either, because for example insulin, botulism toxin, human hair, and influenza virus are proteins that are clearly not food.

Plaintiffs argue that 21 U.S.C. § 343(j) specifying labeling requirements for food for special dietary uses indicates that Congress intended products offered for weight conditions to come within the statutory definition of "food." Plaintiffs misinterpret that statutory Section. It does not define food but merely requires that if a product is a food and purports to be for special dietary uses, its label must contain certain information to avoid being misbranded. If all products intended to affect underweight or overweight conditions were per se foods, no diet product could be regulated as a drug under Section 321(g)(1)(C), a result clearly contrary to

the intent of Congress that "anti-fat remedies" and "slenderizers" qualify as drugs under that Section.

If defining food in terms of its source or defining it in terms of its biochemical composition is clearly wrong, defining food as articles intended by the manufacturer to be used as food is problematic. When Congress meant to define a drug in terms of its intended use, it explicitly incorporated that element into its statutory definition. For example, Section 321(g)(1)(B) defines drugs as articles "intended for use" in, among other things, the treatment of disease; Section 321(g)(1)(C) defines drugs as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." . . . Further, a manufacturer cannot avoid the reach of the FDA by claiming that a product which looks like food and smells like food is not food because it was not intended for consumption. . . . In *United States v. Technical Egg Prods., Inc.*, the defendant argued that the eggs at issue were not adulterated food under the Act because they were not intended to be eaten. The court held that there was a danger of their being diverted to food use and rejected defendant's argument.

Although it is easy to reject the proffered food definitions, it is difficult to arrive at a satisfactory one. In the absence of clear-cut Congressional guidance, it is best to rely on statutory language and common sense. The statute evidently uses the word "food" in two different ways. The statutory definition of "food" in Section 321(f) is a term of art, and is clearly intended to be broader than the common-sense definition of food, because the statutory definition of "food" also includes chewing gum and food additives. Food additives can be any substance the intended use of which results or may reasonably result in its becoming a component or otherwise affecting the characteristics of any food. Paper food-packaging when containing polychlorinated biphenyls (PCBs), for example, is an adulterated food because the PCBs may migrate from the package to the food and thereby become a component of it. Yet the statutory definition of "food" also includes in Section 321(f)(1) the common-sense definition of food. When the statute defines "food" as "articles used for food," it means that the statutory definition of "food" includes articles used by people in the ordinary way most people use food—primarily for taste, aroma, or nutritive value. To hold as did the district court that articles used as food are articles used solely for taste, aroma or nutritive value is unduly restrictive since some products such as coffee or prune juice are undoubtedly food but may be consumed on occasion for reasons other than taste, aroma, or nutritive value. . . .

This double use of the word "food" in Section 321(f) makes it difficult to interpret the parenthetical "other than food" exclusion in the Section 321(g)(1)(C) drug definition. As shown by that exclusion, Congress obviously meant a drug to be something "other than food," but was it referring to "food" as a term of art in the statutory sense or to foods in their ordinary meaning? Because all such foods are "intended to affect the structure or any function of the body of man or other animals" and would thus come within the part C drug definition, presumably Congress meant to exclude common-sense foods. Fortunately, it is not necessary to decide this question here because starch blockers are not food in either sense. The tablets and pills at issue are not consumed primarily for taste, aroma, or nutritive value under Section 321(f)(1); in fact, as noted earlier, they are taken for their ability to block the digestion of food and aid in weight loss. In addition, starch blockers are not chewing gum under Section 321(f)(2) and are not components of food under Section 321(f)(3). To qualify as a drug under Section 321(g)(1)(C), the articles must not only be articles "other than food," but must also be "intended to affect the structure or any function of the body of man or other animals." Starch blockers indisputably satisfy this requirement for they are intended to affect digestion in the people who take them. Therefore, starch blockers are drugs under Section 321 (g)(1)(C) of the Food, Drug, and Cosmetic Act.

Affirmed.

* * * * *

2.3 THE CENTRAL ROLE OF INTENDED USE

In the *Nutrilab* starch blockers case, the manufacturer's intent was clear—the fact was that the product was not consumed for its taste, aroma, or nutritive value. Thus, starch blockers were deemed other than a conventional food.

Other products, however, might not present such clear distinctions. Vitamins and minerals have generally been classified as foods unless therapeutic claims have been made for them. However, in the 1970s, reports of human toxicity emerged from the consumption of large doses of vitamins A and D. These fat-soluble vitamins create special concern because they can accumulate in the fatty tissue.

To deal with this problem, in 1972 and 1973 FDA promulgated regulations classifying certain high dosages of vitamin A and D as drugs and requiring that they should be sold by prescription.[9] However, in *National Nutritional Foods Ass'n v. Mathews*,[10] the court questioned FDA's approach and found FDA's administrative record incomplete. In particular, the court questioned whether FDA could classify vitamins as drugs when no intended therapeutic use was offered by the vendors, the labeling, or any promotional material. The court upheld the regulations, but FDA nonetheless later rescinded them.[11]

This subject is discussed in more depth in later chapters, but it is important to understand that the intended use of a product may determine whether it is a conventional food, a dietary supplement, or a drug. A generation ago, any health claim for a food or supplement moved the regulation of the

[9] 37 Fed. Reg. 26618 (Dec. 14, 1972) and 38 Fed. Reg. 20723 (Aug. 2, 1973).
[10] 557 F.2d 325 (2nd Cir. 1977).
[11] 43 Fed. Reg. 10551 (March 14, 1978).

product to "drug" status. Food–drug distinctions are less clear today because health claims no longer automatically move a food or dietary supplement over to regulation as a drug. FDA-approved health claims are permitted, for instance, without triggering drug status. In addition, structure–function claims are a category of health-related claims that are not regulated as health claims (for example, "calcium helps build strong bones").

This statutory organization is murky because, at times, it is difficult to draw distinctions between structure–function claims and drug claims. The *Nutrilab* case provides what remains one of the best rules for determining whether a product is a food or a drug. First ask, is the product a commonsense food? If not, is it consumed primarily for taste, aroma, or nutrition? If the answer is no to both these questions, then the product may not be a food. There can be other factors, but this commonsense rule still provides excellent guidance.

2.4 OTHER CONSIDERATIONS

2.4.1 Products Ordinarily Considered Foods

There have been a number of cases where products—ordinarily considered foods—were classified as drugs because of the product's therapeutic claims:

- Honey[12]
- Vinegar and honey[13]
- Tea[14]
- Water[15]
- Blue-green algae[16]
- Mussels[17]

2.4.2 Products Intended to Be Processed into Food

A number of articles have been deemed to be "food" within the meaning of the FD&C Act definition because they are intended to be processed into a food or a component of food.

- *Green Coffee Beans:* It makes no difference if the beans require further roasting and processing before they would be ready for consumption.[18]
- *Live Beef Cattle:* The edible tissues of live calves constitute "food" as defined by the FD&C Act and are therefore subject to the adulteration provisions of the act.[19]

2.4.3 Products No Longer Fit for Food

A product that is generally regarded as a food is considered a food under the FD&C Act, even if the product is decomposed or otherwise unfit for consumption. For example, a shipment of incubator-reject shell eggs was still "food," although a large percentage of them were inedible.[20] The product might not be intended to be eaten, but if there is a danger of the product being diverted to food use, the product is considered a food. Note that the intended use of the product is irrelevant to this determination, which is based on the product being in the form of a food.

2.4.4 Packaging Materials

The definition of "food" is significantly broadened by the inclusion of food additives within the definition of food. Food additives include any substance whose intended use results or *may reasonably result in its becoming a component or otherwise affecting the characteristics of any food.*[21] Thus, the definition of food includes any substances that migrate to the food from the packaging materials or containers.[22]

2.4.5 Evidence of Intended Use

In determining whether a product is a "drug" because of intended therapeutic use, the FDA is not bound by a manufacturer's subjective claims of intent.[23] Actual therapeutic intent may be found on the basis of any objective evidence. Such evidence may be inferred from "labeling, promotional material, advertising, and *any other relevant source.*"[24]

Unlike the definition of "drug," the FD&C Act definition of "food" lacks any reference to intent. Nonetheless, a court may consider the intended use of the product in considering whether it is a food. However, a manufacturer's subjective intent that a product should not be consumed will not allow the product to avoid the reach of the FD&C Act if the product looks like food and smells like food.

[12] United States v. 250 Jars . . . Cal's Tupelo Blossum U.S. Fancy Pure Honey, 344 F.2d 288 (6th Cir. 1965).
[13] Sterling Vinegar and Honey, 338 F.2d 157 (2nd Cir. 1964).
[14] United States v. Hohensee, 243 F.2d 367 (3d. Cir. 1957).
[15] United States v. 500 Plastic Bottles . . . Wilfrey's Bio Water (D. Or. 1989).
[16] United States v. Kollman, (DC Or. 1985, 1986).
[17] United States v. Articles of Drug. . . . Neptone (ND Cal. 1983).
[18] United States v. Green Coffee Beans, 188 F.2d 355 (1951).
[19] United States v. Tomahara Enterprises, Ltd., (DC ND N.Y. 1983).
[20] United States v. Technical Egg Prods., Inc., 171 F. Supp. 326 (N.D. Ga. 1959).
[21] *See* 21 U.S.C. § 321(s).
[22] *See*, Natick Paperboard Corp. v. Weinburger, 525 F.2d 1103 (1st Cir. 1975).
[23] National Nutritional Foods Ass'n v. Mathews, 57 F.2d 325 (2nd Cir. 1977).
[24] *Id.*

DISCUSSION QUESTIONS

2.2. Bottled water. Within the meaning of the FD&C Act, could bottled water be characterized as a food, a drug, or both? How? Would your answer change if the product were cherry juice concentrate?

2.3. Blackboard chalk. When would blackboard chalk be a drug?

2.4. "SkyHigh" brand glue is not only efficacious as glue, but is widely known to induce a high when sniffed. The manufacturer advertises the adhesive properties of the glue heavily in magazines that are popular in the drug culture. Can FDA regulate the glue?

2.5. Statutory drafting. Is the definition of "food" good statutory drafting?

2.6. Coffee is often consumed for its stimulant effect. Coffee is not consumed for its nutritional value. If a manufacturer promoted its coffee for the stimulant effect, would it be a drug?

2.7. Caffeine is regulated as an over-the-counter drug when sold as a stimulant pill. 21 C.F.R. § 340. However, FDA does not regulate caffeine added to foods as a drug—even when the food is promoted as a stimulant. How do you reconcile the agency's decision? Is this exception within the scope of the structure/function exception for foods within FD&CA § 201(g)(1)(C)?

2.8. Putrid and decomposed food that is clearly inedible would not be called "food" in everyday speech. What would be the regulatory consequence if putrid and decomposed food were excluded from the definition of food?