

Just a Spoonful of Sugar Will Land You Six Feet Underground: Should the Food and Drug Administration Revoke Added Sugar's GRAS Status?

MELISSA MARIE CARD
AND JOHN FRANCIS ABELA*

INTRODUCTION

The average American consumes 22 teaspoons of added sugar daily, amounting to 350 excess calories.¹ Intake of excess calories leads to health adversities such as obesity, diabetes, heart disease, hypertension, metabolic syndrome, and polycystic ovary syndrome.² Unfortunately, stigmas against individuals that suffer from these adversities—such as blaming these individuals for failing to control their added sugar consumption—has limited government action regarding added sugar.³ Specifically, the Food and Drug Administration (“FDA”) has not spoken to the issues surrounding added sugar since 1976, when FDA concluded that there was no conclusive evidence that added sugar demonstrated a hazard to public health, as long as added sugar continued to be consumed at the then-current levels.⁴ New research shows that added sugar does pose health hazards because American consumers’ intake of added sugar is too high.⁵

* Melissa Marie Card J.D. 2014, University of Minnesota Law School; B.A. 2011, University of Michigan. John Francis Abela B.S.Ed. 2012, University of Michigan. Thank you to our families and friends for your continued love and support.

¹ *Added Sugar in the Diet*, NUTRITION SOURCE, <http://www.hsph.harvard.edu/nutritionsource/carbohydrates/added-sugar-in-the-diet/> (last visited Jan. 12, 2015) (asserting that while Americans sometimes add sugar to food, most added sugar comes from processed and prepared foods, such as sugar-sweetened beverages and breakfast cereals).

² See Melissa Card, *America, You Are Digging Your Grave with Your Spoon—Should the FDA Tell You That on Food Labels?*, 68 FOOD & DRUG L.J. 309, 309 (2013) (assessing whether FDA has the authority to mandate manufacturers to include warnings on their labels).

³ See Rebecca M. Puhl & Chelsea A. Heuer, *Obesity Stigma: Important Considerations for Public Health*, 100 AM. J. PUB. HEALTH, 1019, 1019, 1024 (2010), available at http://www.yaleruddcenter.org/resources/upload/docs/what/bias/ObesityStigmaPublicHealth_AJPH_6.10.pdf (finding that society blames obese persons for their weight in hopes that the individuals will adopt healthier behaviors).

⁴ See generally Walter Glinsmann et al., *Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners: Report of Sugars Task Force*, 116 J. NUTRITION, S5, S15 (1986) (“Other than the contribution to dental caries, there is no conclusive evidence on sugars that demonstrates a hazard to the general public when sugars are consumed at the levels that are now current and in the manner now practiced.”); Cf. Laurie J. Beyranevand, *Generally Recognized as Safe?: Analyzing Flaws in the FDA’s Approach to GRAS Additives*, 37 VT. L. REV. 887, 914 (2013) (stating that FDA has not reviewed the status of sugar since 1986).

⁵ Robert Lustig, *Sugar: The Bitter Truth, Remarks Given at the University of San Francisco*, YOUTUBE (May 26, 2009), available at <http://www.youtube.com/watch?v=dBnniua6-oM> (arguing that too much fructose, a monosaccharide of sugar, and not enough fiber is the cornerstone of the obesity epidemic through its effects on insulin); Cf. Walter Willett & David Ludwig, *Science Souring on Sugar*, BMJ, 346:e8077 (2013) (“[R]

In the past, the government has acted to decrease the health adversities generated from food consumption. For instance, in 2006 FDA mandated that manufacturers list the amount of trans fatty acids (“trans fats”) on the Nutrition Facts labels.⁶ FDA’s mandate caused food manufacturers and restaurants to switch to healthful sources of fat, which caused American consumers’ blood levels of trans fat to drop.⁷ In addition, FDA issued a Final Determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially-produced *trans* fatty acids (IP-TFA) are generally recognized as safe (GRAS) for any use in human food.⁸ FDA issued a Final Determination that PHOs are not GRAS; FDA now requires manufacturers to obtain premarket approval when using such oils as food additives.⁹ The Final Determination issued by FDA opens a door for FDA to further expand its regulatory scheme. If FDA can issue a Final Determination for PHOs, can the agency combat the health adversities from added sugar consumption through issuing a *Federal Register* notice determining that added sugar is no longer GRAS?

This article assesses whether FDA should combat the health adversities stemming from added sugar consumption through issuing a *Federal Register* notice stating that added sugar is not GRAS. Part I explains the history of food additives. Part II explains why natural sugar was necessary for human evolution, and why added sugar poses a threat to modern consumers’ health. Part III describes the current standard FDA uses to determine whether a substance is GRAS. Lastly, Part IV demonstrates that added sugar no longer meets FDA’s GRAS standard. This article advocates that FDA should issue a *Federal Register* notice determining that added sugar is not GRAS because there is reasonable certainty amongst scientists that added sugar is unsafe based on its intended use.

educating the amount of sugar consumed in drinks deserves special attention because of the strength of the evidence and the ease with which excessive sugar is consumed in this form.”).

⁶ See Food Labeling: *Trans* Fatty Acids in Nutritional Labeling, 68 Fed. Reg. 41,434, 41,434 (July 11, 2003) (“The Food and Drug Administration (FDA) is amending its regulations on nutrition labeling to require that *trans* fatty acids be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fatty acids.”).

⁷ Cf. Card, *supra* note 2, at 321 & n.127 (explaining that a survey completed in response to the Nutrition Labeling and Education Act of 1990 disclosed that 30% of respondents changed their minds about buying certain products after reading the nutrition facts labels).

⁸ Final Determination Regarding Partially Hydrogenated Oils, 80 Fed. Reg. 34,650, 34,650 (June 17, 2015) (“Based on the available scientific evidence and the findings of expert scientific panels, the Food and Drug Administration (FDA or we) has made a final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs), which are the primary dietary source of industrially-produced *trans* fatty acids (IP-TFA) are generally recognized as safe (GRAS) for any use in human food. This action responds, in part, to citizen petitions we received, and we base our determination on available scientific evidence and the findings of expert scientific panels establishing the health risks associated with the consumption of *trans* fat.”).

⁹ See 21 U.S.C. § 348(a) (2012) (“A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause . . . unless . . . there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used . . .”).

I. OVERVIEW: FDA'S REGULATION OF FOOD ADDITIVES

FDA is a public health agency responsible for regulating food additives.¹⁰ This section begins with the evolution of food additive regulations and then delves into a brief description of the Delaney Clause, which bans any chemical found to induce cancer from being used as a food additive. Lastly, this section exemplifies FDA's regulatory authority of food additives by banning harmful substances.

A. *The Regulation of Food Additives*

FDA's mission includes protecting public health through "assuring the safety, efficacy and security" of the nation's food supply.¹¹ Historically, FDA has carried out its mission by regulating food additives.¹² FDA began regulating food additives as a result of the 1958 Food Additives Amendment.¹³ FDA had been provoked to regulate food additives because manufacturers used consumers as guinea pigs for a host of new chemical compounds of unknown safety.¹⁴ To ensure consumer's safety, the 1958 Food Additives Amendment subjected food additives to premarket approval by FDA, unless an exception, like GRAS status, applied.¹⁵

A significant provision of the 1958 Food Additives Amendment was the Delaney Clause, which stated, "the Secretary of the Food and Drug Administration shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals."¹⁶ FDA initially opposed the Delaney Clause. FDA argued that if an additive was used at very low levels, then it need not be banned even though it may cause cancer when used at high levels.¹⁷ However, proponents of the Delaney Clause justified the clause on the basis that cancer experts were not able to determine a safe level for any carcinogen.¹⁸

¹⁰ See 21 U.S.C. § 348 (d) (2012) ("The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor.").

¹¹ *About FDA: What We Do*, FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/whatwedo/default.htm> (last visited Jan. 22, 2015).

¹² See, e.g., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-246, FOOD SAFETY: FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE, at 22 (2010) (stating that FDA prohibited the use of sulfites on fruits and vegetables because of potentially severe allergic reaction to people with sulfite sensitivities) [hereinafter GAO Report]. "Food additive" is defined as any substance in which its intended use "results or may reasonably be expected to result in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized . . . to be safe . . ." 21 U.S.C. § 321(s) (2012).

¹³ FOOD ADDITIVES 201 (Lary Branen et al. eds., 2d ed. 2005).

¹⁴ Wallace Janssen, *About FDA: The Story Behind the Labels*, FOOD & DRUG ADMIN. <http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm> (last visited Jan. 22, 2015) (stating, "the law prohibited poisonous substances but required no showing that food ingredients were safe.").

¹⁵ See 21 U.S.C. § 348(b) (2012); see also Beyranevand, *supra*, note 4, at 888–89 (stating that Congress passed the Food Additives Amendment of 1958 which presumed that all additives were unsafe and must receive pre-market approval by the Agency unless they were exempted as prior approved or GRAS substances).

¹⁶ See generally Richard Merrill, *Food Safety Regulation: Reforming the Delaney Clause*, 18 ANN. REV. PUB. HEALTH, 313, 318, 323 (1997) (discussing the prevailing view in 1958 that Delaney Clause would not have broad application because only a handful of chemicals had been shown to induce cancer in animals).

¹⁷ Janssen, *supra* note 14.

¹⁸ *Id.*

The 1958 Food Additives Amendment, specifically the Delaney Clause, continually has worked to ensure consumer safety. For example, in 1968 FDA banned cyclamate salts as food additives because research showed that rats were developing tumors after ingesting cyclamate salts.¹⁹ Similarly, in 1985 FDA banned cinnamyl anthranilate, which research linked to causing cancer in mice.²⁰

FDA's current regulatory scheme of food additives is effective in keeping American consumers safe from immediate toxins or substances causing cancer.²¹ But, FDA should use its authority to revoke GRAS status from substances that cause health adversities, such as heart disease or diabetes, after long-term consumption. If FDA's regulation of food additives focuses on both immediate toxins and "chronic toxins," FDA's regulation of food additives could significantly increase American consumers' health.

II. EVOLVING TO METABOLIZE SUGAR

Added sugar, arguably an immediate as well as chronic toxin, leads to health adversities.²² First, this section explains why natural sugar was imperative for human evolution, and why the current amounts of added sugar consumed by Americans poses a public health crisis. Second, this section demonstrates how added sugar consumption leads to immediate and long-term health adversities by explaining the biochemistry of metabolizing added sugar.

A. *Evolution and Sugar*

"Added sugar" is any caloric sweetener that is added in food preparation, at the table, in the kitchen, or in a manufacturing processing plant.²³ Added sugar does not include sugar that naturally is found in food.²⁴ While added sugar is a modern day commodity, humans can blame their sweet tooth on their primate ancestors.²⁵ Millions of years ago,

¹⁹ See 21 C.F.R. § 189.135(b) (2014) ("Food containing any added or detectable level of cyclamate is deemed to be adulterated in violation of the act based upon an order published in the Federal Register of October 21, 1969."); see also Cyclamic Acids and its Salts, 34 Fed. Reg. 17,063 (Oct. 21, 1969) (explaining that FDA banned the use of cyclamate salts, which were previously GRAS, because they were a catalyst in the formation of tumors in rats).

²⁰ See 21 C.F.R. § 189.113 (2014) ("Food containing any added cinnamyl anthranilate is deemed to be adulterated in violation of the act based upon an order published in the Federal Register of October 23, 1985."); see also Cinnamyl Anthranilate, Prohibition of Use in Human Food, 50 Fed. Reg. 42,929, 42,929 (Oct. 1985) (stating that cinnamyl anthranilate, a flavor agent previously holding GRAS status, was banned due to studies linking cinnamyl anthranilate to cancer in mice).

²¹ See note 12, *supra*, and accompanying text.

²² See Beyranevand, *supra* note 4, at 919–20 (referencing the myriad health problems scientists and health professionals attribute to the overconsumption of sugars).

²³ Quanhe Yang et al., *Added Sugar Intake and Cardiovascular Diseases Mortality Among U.S. Adults*, JAMA INTERN. MED. E1, E2 (2014), available at <http://www.drperlmutter.com/wp-content/uploads/2014/02/Sugar-cv.pdf> (stating that added sugars include all sugars used in processed foods and/or prepared foods, such as: sugar-sweetened beverages, grain-based desserts, fruit drinks, dairy desserts, candy, ready-to-eat cereals, and yeast breads).

²⁴ *Id.* (explaining that added sugar does not include naturally occurring sugar, such as sugar found in fruits).

²⁵ See RICHARD JOHNSON ET AL., THE SUGAR FIX: THE HIGH-FRUCTOSE FALLOUT THAT IS MAKING YOU FAT AND SICK 20 (Simon & Schuster, Inc. 2008) ("Our cave-dwelling ancestors may have craved Sweet foods all the more intensely because they were hard to come by.").

apes survived on a sugar-rich diet of fruit because the sweetness of sugar triggered the brain to know that a particular food was safe to eat.²⁶

Sugar was important in the primate diet not only because it indicated what was safe to eat, but also because sugar helped with fat storage.²⁷ It is postulated that humans' earliest ancestors went through a period of significant starvation about 15 million years ago during a time of global cooling.²⁸ During that time, a mutation occurred that increased the apelike creatures' sensitivity to fructose so that even small amounts were stored as fat.²⁹ This adaptation was a survival mechanism; if the apelike creature ate fructose, then there was a decreased likelihood that the creature would starve to death.³⁰

All the food challenges that humans' prehistoric ancestors faced have caused humans to crave sugar.³¹ For millions of years, humans' cravings and digestive systems were balanced because sugar was rare.³² But, industrial and farming technologies have made natural sugar, as well as added sugar, bountiful.³³ The problem today is that humans have too much sugar available to them.³⁴

B. *Metabolizing Sugar*

Due to evolution, sugar, whether it is added sugar or natural sugar, has unique characteristics specifically in the way the human body metabolizes the fructose in it that allowed our ancestors to evolve and survive during periods of famine. However, due to the human body's response to metabolizing fructose, if added sugar is consumed in sufficient quantities, then people experience significant health adversities.³⁵ Three types

²⁶ Elsa Addressi et al., *Taste Perception and Food Choices in Capuchin Monkeys and Human Children*, 6 PRIMATOLOGIE 101, 103–04 (2004) (asserting that substances high in calories, such as sugars, are perceived as sweet by humans and are readily accepted by both humans and non-human primates; but bitter taste is associated with the presence of plant secondary compounds, such as alkaloids and glycosides, whose taste can function as a cue to inhibit their ingestion).

²⁷ *Sugar, Fat and Brain Function*, (IFBB, Briefing Paper No.7, 2014), available at http://www.ifbb.org.uk/data/resources/23/BR7_sugarvfat.pdf (asserting that excessive sugar intake is converted into body-fat).

²⁸ Kenneth Miller & Richard Fairbanks, *Evidence for Oligocene–Middle Miocene Abyssal Circulation Changes in the Western North Atlantic*, 306 NATURE 250, 250–253 (1983) (explaining that a major and permanent cooling step occurred between 14.8 and 14.1 Ma, associated with increased production of cold Antarctic deep waters and a major growth of the East Antarctic ice sheet).

²⁹ See Richard Johnson, *The Evolution of Obesity: Insights from the Mid-Miocene*, 121 TRANSACTIONS AM. CLINICAL & CLIMATOLOGICAL ASS'N 295, (2010) (stating that fructose was the primary nutrient in fruit which was the main staple of early primates' diet, but this food likely became less available during the global cooling that occurred, which is why a mutation occurred in primates enabling them to better metabolize fructose).

³⁰ See MARY MAXWELL, *HUMAN EVOLUTION: A PHILOSOPHICAL ANTHROPOLOGY* 152 (1984) (“And in our ancestral hominid days, those who had the kind of taste buds for sweet things may have survived preferentially because those foods contained the needed high calories.”).

³¹ GARY CROSS & ROBERT PROCTOR, *PACKAGED PLEASURES: HOW TECHNOLOGY AND MARKETING REVOLUTIONIZED DESIRE* 3 (2014) (stating that humans have evolved to seek high-energy foods because in prehistoric conditions of scarcity, eating such foods greatly improved their ancestors' chances of survival).

³² See *id.*

³³ See JOHN YUDKIN, *PURE, WHITE, AND DEADLY: HOW SUGAR IS KILLING US AND WHAT WE CAN DO TO STOP IT* 94 (3rd ed. 2012) (arguing that society should be coerced to give up sugar because of society's ability to separate sugar's palatability from its nutritional value)

³⁴ See *id.*

³⁵ See generally Robert Lustig, *Fructose: Metabolic, Hedonic, and Societal Parallels with Ethanol*, 110 J. ACAD. NUTRITION & DIETETICS, 1307, 1307 (2010) (asserting that “rates of fructose consumption continue to rise nationwide and have been linked to rising rates of obesity, type 2 diabetes, and metabolic syndrome.”).

of saccharides, or sugars, are relevant: glucose, fructose, and sucrose.³⁶ Sucrose, table sugar, is a disaccharide formed by one glucose molecule and one fructose molecule.³⁷ Glucose and fructose are simple sugars, or monosaccharides, and are naturally found in fresh fruits and vegetables.³⁸ While glucose and fructose are both monosaccharides, they have differing molecular structures. Glucose is a six carbon ringed structure,³⁹ and fructose is a five carbon ringed structure.⁴⁰ Due to their structural differences, the body metabolizes fructose and glucose differently.⁴¹ Glucose can be metabolized by all organs; consequently, only 20% of ingested glucose is metabolized in the liver.⁴² Fructose, however, can only be metabolized in the liver, thus, 100% of ingested fructose is metabolized in the liver.⁴³

When the liver metabolizes fructose or glucose, the liver converts the monosaccharide into fat.⁴⁴ Subsequently, the liver converts the fat into very-low-density lipoprotein (VLDL), free fatty acids, or lipid droplets.⁴⁵ VLDL is toxic for the liver, and must be transported into the blood stream or surrounding tissues.⁴⁶ High levels of VLDL cause coronary artery disease, stroke, and high blood pressure.⁴⁷ VLDL is also a substrate for obesity.⁴⁸ The fat that the liver fails to convert into VLDL, may exit the liver as free fatty acids.⁴⁹ Some free fatty acids settle into one's muscle cells, causing muscle insulin resistance.⁵⁰ Lastly, the fat turned into lipid droplets activates the enzyme JNK-

³⁶ HANS-DIETER BELITZ ET AL., *FOOD CHEMISTRY* 862 (3rd ed. 2004) (stating that only a few of the sugars occurring in nature are used extensively as sweeteners: sucrose, glucose, invert sugar, maltose, lactose, and fructose).

³⁷ SUGAR: USER'S GUIDE TO SUCROSE 47 (Neil Pennington & Charles Baker eds., 1990).

³⁸ *Id.* at 307.

³⁹ *See id.* (stating that the chemical formula for glucose is C₆H₁₂O₆).

⁴⁰ *See id.* (stating that the chemical formula for fructose is C₅H₁₂O₆).

⁴¹ *See* Barbara L. Atwell, *Is Sugar the New Tobacco? How to Regulate Toxic Foods*, 22 ANN. HEALTH L. 138, 144 (2013) (reiterating that fructose is only metabolized by the liver; thus, fructose calories are more likely to contribute to obesity than calories from other sources).

⁴² Lustig, *supra* note 5.

⁴³ Atwell, *supra* note 41.

⁴⁴ Lustig, *supra* note 5.

⁴⁵ *Id.*

⁴⁶ *Cf.* THOMAS HALEY & William O. Berndt, *TOXICOLOGY* 94 (Christine Flint Lowry et al. eds, 1987) (explaining that mere accumulation of fat in the tissue does not necessarily represent a toxic response of the liver tissue to injury inflicted by toxic chemicals).

⁴⁷ *See* SHARON ROLFES ET AL., *UNDERSTANDING NORMAL AND CLINICAL NUTRITION* 814 (Elesha Feldman et al. eds., 9th ed. 2012) (asserting that people that have small, dense LDL frequently have elevated VLDL and low HDL levels, which is prevalent in individuals with metabolic syndrome and type 2 diabetes, and has been associated with approximately threefold increased risk of coronary heart disease).

⁴⁸ Lustig, *supra* note 5 (stating that VLDL serves as a substrate for adipose deposition into your fat cells).

⁴⁹ *Id.*

⁵⁰ *See* ROLFES, *supra* note 47, at 807 (suggesting that one theory that explains the relationship between obesity and insulin resistance argues that obesity leads to an increase in fatty acid contraction in the blood, resulting in the abnormal deposition of triglycerides in the blood, which results in the abnormal deposition of triglycerides in the muscle, liver, and abdominal region).

1,⁵¹ which increases insulin blood levels causing insulin resistance.⁵² Insulin resistance raises your blood pressure,⁵³ creates adipose tissue,⁵⁴ and decreases the brain's ability to detect leptin leading to overconsumption.⁵⁵ In addition, insulin resistance increases one's risks of obesity, heart disease, type-2 diabetes, and cancers.⁵⁶

For human evolution, it was advantageous for apelike creatures to consume foods high in sugar to combat famine.⁵⁷ Advancements in technology associated with industrial life have given humans the unique evolutionary advantage to produce and separate sweetness from all of their dietary nutrients.⁵⁸ By doing this, humans have increased their consumption of added sugar to an unprecedented high. This extreme sugar consumption is not something that the human body has adapted to;⁵⁹ it is evolutionarily unhealthy. As this section has shown, fructose is a catalyst for a plethora of biological reactions in the body. The end result of these biological reactions leads to metabolic syndrome,⁶⁰ which in turn causes hypertension, insulin resistance, hyperinsulinemia, dyslipidemia, type-2 diabetes, cancer, heart disease, muscle insulin resistance, and obesity.⁶¹ While natural sugar was imperative for human evolution and continued survival, the abundance of added sugar and the unique characteristics of fructose cause modern day people to experience significant health adversities.

III. GENERALLY REGARDED AS SAFE

FDA accomplishes its mission to protect the public's health through regulating food additives, which are subject to premarket approval.⁶² First, this section explains that

⁵¹ See generally Harmeet Malhi et al., *Free Fatty Acids Induce JNK-dependent Hepatocyte Lipooptosis*, 281 J. OF BIOLOGICAL CHEMISTRY 12093 (2006) (examining the role of JNK activation in free fatty acid induced lipooptosis because JNK activation is pivotal in both the metabolic syndrome accompanying non-alcoholic fatty liver disease and cellular apoptosis).

⁵² Jiro Hirosumi et al., *A Central Role for JNK in Obesity and Insulin Resistance*, 420 NATURE 333, 333–336 (2002) (arguing that an absence of JNK1 results in decreased adiposity, significantly improved insulin sensitivity and enhanced insulin receptor signaling capacity in two different models of mouse obesity).

⁵³ See ROLFES, *supra* note 47, at 807 (stating that both insulin resistance and hyperinsulinemia may be implicated in raising blood pressure).

⁵⁴ See generally Malhi, *supra* note 51 (examining the role of JNK activation in free fatty acid induced lipooptosis).

⁵⁵ P.J. Havel, *Control of Energy Homeostasis and Insulin Action by Adipocyte Hormones: Leptin, Acylation Stimulating Protein, and Adiponectin*, PUB.MED.GOV (Feb. 13, 2002), available at <http://www.ncbi.nlm.nih.gov/pubmed/11790963> (asserting that results from studies of individuals with absolute leptin deficiency, and more partial leptin deficiency, reveal leptin's critical role in the normal regulation of appetite and body adiposity in humans).

⁵⁶ Atwell, *supra* note 41, at 145 n.58 (affirming that having chronically elevated insulin levels has harmful effects such as heart disease, obesity, and diabetes).

⁵⁷ See Maxwell, *supra* note 30 and accompanying text.

⁵⁸ See Yudkin, *supra* note 33 and accompanying text.

⁵⁹ See generally Katharine Milton, *Nutritional Characteristics of Wild Primate Foods: Do the Diets of Our Closest Living Relatives Have Lessons for Us?*, 15 NUTRITION 488 (stating that the widespread prevalence of diet-related health problems, particularly in highly industrialized nations, suggests that many humans are not eating in a manner compatible with their biology).

⁶⁰ See Atwell *supra* note 41 at 145.

⁶¹ See Lustig, *supra* note 5.

⁶² See generally GAO REPORT, *supra* note 12 and accompanying text.

GRAS substances are exempt from premarket approval. Second, this section describes the GRAS standard.

The Federal Food, Drug, and Cosmetic Act divides food ingredients into those that are food additives and those that are not.⁶³ Under 21 U.S.C. § 321(s), food additives are presumed unsafe and subject to premarket approval, unless the use of a substance is GRAS.⁶⁴ A substance is GRAS if it is generally recognized among experts, qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use.⁶⁵ Unanimity among experts as to whether the substance is safe is not required.⁶⁶ But, extreme conflict among experts regarding the safety of a substance prevents a finding of general recognition.⁶⁷

A GRAS determination, therefore, has two components. First, a GRAS product must be shown to be safe, in which FDA considers to be true when:

(1) the probable consumption of the substance and of any substance formed in or on food because of its use[;] (2) the cumulative effect of the substance in the diet[;] . . . [and] (3) the safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.⁶⁸

Secondly, GRAS status requires that the information and data that establishes safety be “generally available” and that there “be a basis for consensus in the scientific community regarding the safety of the substance” for its intended use.⁶⁹ A substance is also classified as GRAS if the substance was used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food.⁷⁰

⁶³ See 21 U.S.C. § 348 (a) (2012) (stating that food additives may only be used if FDA has issued a regulation “prescribing the conditions under which such additive may be safely used”).

⁶⁴ 21 U.S.C. § 321 (s) (2012); see also 78 Fed. Reg. 67,169, *supra* note 8 and accompanying text.

⁶⁵ See 21 U.S.C. § 321 (s) (2012). See also Beyranevand, *supra* note 4, at 906–07. (A determination of GRAS status requires “both technical evidence of safety and a basis to conclude that this technical evidence of safety is generally known and accepted.” (Quoting Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,940 (Apr. 17, 1997)).

⁶⁶ See, e.g., *U.S. v. Articles of Drug Consisting of Following: 5,906 Boxes*, 745 F.2d 105, 119 n.22 (1st Cir. 1984); *U.S. v. Articles of Food & Drug (Coli-Trol 80)*, 518 F.2d 743, 746 (5th Cir. 1975) (stating that general recognition, not unanimous recognition, is required).

⁶⁷ *Cf. Premo Pharm. Lab. v. U.S.*, 629 F.2d 795, 804 (2d Cir. 1980) (“Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background. The determination whether a drug is generally recognized as safe and effective within the meaning of § 201(p)(1) necessarily implicates complex chemical and pharmacological considerations. Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court stays its hand.”) (citing *Wienberger v. Bentex Pharm., Inc.*, 412 U.S. 645 (1973)).

⁶⁸ Beyranevand, *supra* note 4 at 907 (quoting 21 C.F.R. § 170.3(i) (2012)).

⁶⁹ *Id.* See also Lars Noah & Richard Merrill, *Starting from Scratch: Reinventing the Food Additive Approval Process*, 78 B.U. L. Rev. 329, 352 (1998) (“It is generally agreed that GRAS requires a fairly high level of scientific consensus.”).

⁷⁰ See, e.g., 21 C.F.R. § 184.1854(d) (exemplifying sucrose as never being defined as a food additive due to usage in accordance with a sanction or approval granted prior to September 6, 1958); 21 C.F.R. § 184.1857(d) (demonstrating corn sugar as never being defined as a food additive due to usage in accordance with a sanction or approval granted prior to September 6, 1958); 21 C.F.R. § 184.1859(d) (invert sugar); 21 C.F.R. § 184.1865(d) (corn syrup).

GRAS status is time dependent.⁷¹ As new scientific data becomes available, expert opinion regarding the safeness of a substance may change.⁷² Moreover, history of the safe use of a substance in food prior to 1958 is not sufficient to support continued GRAS status, if new evidence demonstrates that there is not a consensus that the substance is safe.⁷³ If a substance is not deemed safe amongst experts, FDA may determine that a substance is no longer GRAS.⁷⁴ For instance, FDA issued a Final Determination that PHOs are no longer generally recognized as safe for any use in human food.⁷⁵

FDA effectuates its mission to protect public health through regulating food additives, which are subject to premarket approval.⁷⁶ Some substances are not subject to premarket approval because they are GRAS.⁷⁷ GRAS status, however, is evanescent.⁷⁸ FDA has the authority to reclassify a GRAS substance as a food additive.⁷⁹ If FDA can issue a Final Determination stating that PHOs are not GRAS, then FDA can issue a *Federal Register* notice stating that added sugar is not GRAS. Whether FDA's reclassification would be justified depends on the current scientific findings surrounding added sugar.

IV. REVOKING ADDED SUGAR'S GRAS STATUS

FDA has the authority to issue a *Federal Register* notice stating that a substance is not GRAS based on new scientific evidence.⁸⁰ This section demonstrates that there is reasonable certainty amongst scientists that added sugar is harmful based on its intended use due to: (1) the probable consumption of the substance; (2) the cumulative effect of the substance in the diet; and (3) safety factors of the substance which are generally recognized as inappropriate.⁸¹ This article advocates that FDA should issue a *Federal Register* notice determining that added sugar is not GRAS, which would then classify added sugar as a food additive requiring manufacturers to seek premarket approval.

⁷¹ See generally 21 C.F.R. § 170.6(c) ("In the interest of public health, such articles which have been consider in the past by [FDA] . . . to be generally recognized as safe for their intended use . . . or not to be food additives under the conditions of intended use, must be reexamined in the light of current scientific information and current principles for evaluating the safety of food additives if their use is to be continued.").

⁷² See 21 C.F.R. § 170.30(l) ("New information may at any time require reconsideration of the GRAS status of a food ingredient.").

⁷³ See, e.g., 21 C.F.R. § 189.135 and 34 Fed. Reg. 17,063, *supra* note 19 and accompanying text.

⁷⁴ 21 C.F.R. § 170.38(a) ("The Commissioner may, in accordance with §170.35(b)(4) or (c)(5), publish a notice in the FEDERAL REGISTER determining that a substance is not GRAS and is a food additive subject to section 409 of the Act.") (emphasis in original).

⁷⁵ See 80 Fed. Reg. 34,650 *supra* note 8 and accompanying text.

⁷⁶ See, e.g., GAO REPORT, *supra* note 12 and accompanying text.

⁷⁷ See 21 C.F.R. § 182.1.

⁷⁸ See, e.g., 78 Fed. Reg. 67,169 *supra* note 8; GAO REPORT, *supra* note 12 at 21 (despite FDA's abilities to revoke GRAS status, "FDA has not systemically reconsidered the safety of substances considered to be GRAS as new scientific information has come to light.").

⁷⁹ Beyranevand *supra* note 4, at 905 (explaining that FDA addressed the issue that substances might be safe now, but might not be later upon new information through developing a de-GRAS provision in the regulations, which allowed for the removal of GRAS status upon reevaluation).

⁸⁰ *Id.*

⁸¹ *Id.* at 907 (quoting 21 C.F.R. § 170.3(i) (2012)).

A. *The Probable Consumption of Added Sugar*

Added sugar is not GRAS based on American consumers' probable consumption of the substance. The average American consumes between 150 and 170 pounds of added sugar each year.⁸² Consuming 150 to 170 pounds of added sugar in one year is equivalent to consuming 1/4 to 1/2 pounds of added sugar each day, which is 30 to 60 teaspoons of added sugar in a 24-hour period.⁸³ The American Heart Association recommends that women consume no more than six teaspoons of added sugar per day and men consume no more than nine teaspoons of added sugar per day.⁸⁴ If the average American consumes 30 to 60 teaspoons of added sugar per day, then that American is consuming at least three to five times more added sugar than the recommended amount.⁸⁵

One could argue that added sugar should continue having GRAS status because American consumers are responsible for moderating their own added sugar intake. Unfortunately, American consumers are unlikely to be successful in moderating their own added sugar consumption, even if they are diligent in reading Nutrition Facts labels, because added sugar does not appear as "added sugar," but rather manufacturers can list the ingredient under one of sixty different pseudonyms.⁸⁶ In addition, some consumers may think that certain types of added sugar are healthy, such as "evaporated cane juice," and would not be deterred from consuming the product due to a particular pseudonym that is used.⁸⁷

Even if consumers were aware that added sugar was present in their food, consumers may be unaware of just how much added sugar existed in their diet in the aggregate. Some products contain the amount of added sugar that a consumer should have in an entire day in just one serving. For instance, a 12-ounce can of non-diet soda contains about nine teaspoons of added sugar.⁸⁸ Similarly, foods that consumers deem to be

⁸² See GARY TAUBES, *GOOD CALORIES, BAD CALORIES: FAT, CARBS, AND THE CONTROVERSIAL SCIENCE OF DIET AND HEALTH* 199 (2008) (explaining that by 2000 sugar consumption had jumped to almost 150 pounds per year).

⁸³ FED UP (Sundance 2014).

⁸⁴ See, *Added Sugar in the Diet*, *supra* note 1 and accompanying text (similarly, the Center for Science in the Public Interest filed a petition with FDA requesting that FDA establish a Daily Reference Value for "added sugars" of 40 grams); Beyranevand, *supra* note 4, at 917.

⁸⁵ See, *Added Sugar in the Diet*, *supra* note 1 and accompanying text.

⁸⁶ *Sugar 101*, AM. HEART ASS'N (Nov. 19, 2014), http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/HealthyEating/Sugar-101_UCM_306024_Article.jsp (exemplifying sugar pseudonyms to include: brown sugar, corn sweetener, corn syrup, fruit juice concentrates, high-fructose corn syrup, honey, invert sugar, malt sugar, molasses, raw sugar, and syrup). This article does not consider the proposed FDA Nutrition Fact labels that will mandate manufactures to include a line that notes how many "added sugars" are used in a product. See *Factsheet on the New Proposed Nutrition Facts Label*, FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm387533.htm> (last visited May 2, 2015). "Sugars" listed Nutrition Fact labels include both "added sugars" and sugars that are naturally occurring in food. Currently, "Sugars" are required to be labeled on packages, but FDA is proposing to require the declaration of "Added Sugars" indented under "Sugars" so that both would be listed. *Id.* However, even if FDA mandated that manufactures list the amount of "added sugar" on the Nutrition Facts label, the label fails to include a daily reference value for sugar. Julie Corliss, *Eating Too Much Added Sugar Increases the Risk of Dying With Heart Disease*, HARVARD HEALTH PUBLICATIONS (Feb. 6, 2014), <https://www.health.harvard.edu/blog/eating-too-much-added-sugar-increases-the-risk-of-dying-with-heart-disease-201402067021>.

⁸⁷ See generally *Morgan v. Wallaby Yogurt Co.*, 2014 U.S. Dist. LEXIS 34548, at *4–5 (N.D. Cal. Mar. 13, 2014) (assessing whether "evaporated cane juice" allows a consumer to determine if a product has any added sugars).

⁸⁸ See Corliss, *supra* note 86.

“healthy,” such as Clif Bars and Chobani Greek Yogurt, contain almost a day’s worth of added sugar.⁸⁹ For example, the Carrot Cake Clif Bar has 25 grams of sugar per bar, and one cup of Chobani Blended Strawberry Greek Yogurt contains 27 grams of sugar. Thus, one Clif Bar or one serving of Chobani yogurt contains just over six teaspoons of added sugar, which is more than the American Heart Association recommends that women should have for an entire day.⁹⁰ Keep in mind, this is just one product that the consumer will eat in a day and the consumer has already had her fill of added sugar. The American consumer that shovels a bowl of cereal and milk down for breakfast, chases a peanut butter and jelly sandwich with a 12 oz. Coke for lunch, and scarfs down half a frozen pizza and seven Oreos cookies for dinner has consumed, in the aggregate, about 28 teaspoons of sugar.⁹¹ One could argue that this meal plan is an exaggeration of the American diet. However, soda, cereal, frozen dinners, snack foods, and peanut butter are among the top ten grocery store items that Americans buy.⁹² In addition, these foods are inexpensive and persons with low socio-economic status lack resources to buy foods and drinks that are not sweetened with added sugar.⁹³ Therefore, since the probable consumption of added sugar for the average American consumer is at least three to five times more than what is recommended by the American Heart Association, and consumers cannot moderate their own added sugar intake due to added sugar pseudonyms as well as manufacturers’ excessive use of added sugar in processed foods, FDA should issue a *Federal Register* notice that added sugar is not GRAS.

B. *Cumulative Effect of Added Sugar in the Diet*

Added sugar is not GRAS because of the health adversities it causes after continuous consumption. Experts have stated that added sugar is a “chronic toxin,” meaning “not toxic after one meal, but after 1,000 meals.”⁹⁴ As stated above, the long-term consumption of excessive added sugar leads to obesity, metabolic syndrome, heart disease, lipid problems, hypertension, type-2 diabetes, dementia, cancer, polystic ovaria syndrome,

⁸⁹ See *Carrot Cake*, CLIF BAR, <http://www.clifbar.com/products/clif-bar/clifbar/carrot-cake> (last visited May 9, 2015) (exemplifying that the Carrot Cake flavor Clif Bar has 25 grams of sugar); see also *Blended Strawberry*, CHOBANI, <http://www.chobani.com/products/blended#strawberry> (last visited May 9, 2015) (stating that Chobani Strawberry Blended Greek Yogurt contains 27 grams of sugar per serving).

⁹⁰ See, *Added Sugar in the Diet*, note 1 *supra* and accompanying text. Since products do not differentiate between added sugar and natural sugar on the Nutrition Facts label, this article assumed that the “sugar” listed on the Clif Bar and the Chobani yogurt was solely added sugar. However, it is likely that some of the listed sugar was natural sugar.

⁹¹ See COCA-COLA, <http://productnutrition.thecoca-colacompany.com/> (last visited May 9, 2015) (showing that a 12 oz. serving of regular Coca-Cola has 39 grams of sugar); *Total Product List*, GENERAL MILLS, <http://www.generalmills.com/Brands/Cereals/total/brand-product-list> (last visited May 9, 2015) (depicting one serving of Total Raisin Bran to have 17 grams of sugar); *Hawaiian Style*, DIGIORNO, <http://www.digiorno.com/products/rising-crust/rising-crust/11423/hawaiian> (last visited May 9, 2015) (stating that one serving of DiGiorno pizza has 7 grams of sugar); *Oreo Chocolate Sandwich Cookies*, FATSECRET, <https://www.fatsecret.com/calories-nutrition/oreo/chocolate-sandwich-cookies> (last visited May 9, 2015) (asserting that one serving of Oreos has 14 grams of added sugar); *Jif Hazelnut Spreads*, JIF, <http://www.jif.com/products/chocolate-hazelnut-spread> (last visited May 9, 2015) (depicting that one serving of Jif Chocolate Hazel Nut Spread has 22 grams of sugar).

⁹² See Laurie Dove, *Top 10 Groceries Americans Buy*, HOWSTUFFWORKS, <http://money.howstuffworks.com/personal-finance/budgeting/10-groceries-americans-buy.htm#page=0> (last visited January 12, 2015).

⁹³ F.E. Thompson, *Interrelationships of Added Sugars Intake, Socioeconomic Status, and Race/Ethnicity in Adults in the United States: National Health Interview Survey, 2005*, 109 J. AM. DIET ASS’N 1376, available at <http://www.ncbi.nlm.nih.gov/pubmed/19631043> (last visited Jan. 31, 2015).

⁹⁴ FED UP (Sundance 2014).

and non-alcoholic fatty liver disease.⁹⁵ Under the Delaney Clause, research suggesting that added sugar contributes to cancer should be enough to declassify the GRAS status of this substance.⁹⁶

One could argue that Americans will never be completely free from consuming “sugar,” since it exists naturally in foods.⁹⁷ However, the sugar that a person consumes naturally, through fruits and vegetables, does not cause the health adversities that are caused by added sugar.⁹⁸ Fruits and vegetables package sugar with fiber.⁹⁹ When fiber is added to the diet, the body’s satiety signal occurs sooner, preventing the health adversities that added sugar causes.¹⁰⁰ Therefore, since added sugar consumption leads to a plethora of health adversities, FDA should issue a *Federal Register* notice finding that added sugar is not GRAS.

C. *Safety Factors Generally Recognized as Inappropriate*

Added sugar is not GRAS because of safety factors, which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as inappropriate.¹⁰¹ The Center for Science in the Public Interest together with a coalition of 10 public health departments, 20 national health organizations, and 41 health and nutrition experts, submitted a 55-page petition (“The Petition”) to FDA requesting that FDA initiate a rule-making proceeding to ensure that the content of sucrose and High-Fructose Corn Syrup in beverages was limited to safe levels consistent with authoritative recommendations.¹⁰² In the Petition, these experts presented evidence to support their position that excessive added sugar found in a typical American diet has created a public health problem of crisis proportions.¹⁰³ In addition, other health experts have stated that added sugar consumption leads to both immediate and long-term health adversities.¹⁰⁴ For example, according to the Journal of the American Medical Association, added sugar consumption increases the risks of

⁹⁵ Lustig, *supra* note 5.

⁹⁶ See Merrill, *supra* note 16 and accompanying text.

⁹⁷ Cf. Alice Park, *Too Much Sugar Increases Heart Risks*, TIME (Apr. 21, 2010), <http://content.time.com/time/health/article/0,8599,1983542,00.html> (stating any sugar that a food does not contain naturally, provides no nutritional value and serves only as a source of empty calories).

⁹⁸ Lustig, *supra* note 5.

⁹⁹ *Id.*

¹⁰⁰ FED UP (Sundance 2014) (asserting that consumption of 500 calories of plant food will fill the human stomach signaling the brain that the body is satisfied; however, 500 calories of processed food will not trigger the brain that the body is satisfied tricking the body into eating more calories).

¹⁰¹ Cf. 21 U.S.C. § 321(s) (2006) (explaining the term “food additive” to include those substances “not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use”).

¹⁰² See generally *Petition to Ensure the Safe Use of “Added Sugars,”* CENTER FOR SCI. PUB. INT. (Feb. 13, 2013) <http://www.cspinet.org/liquidcandy/sugarpetition.html> (arguing that unsafe levels of added sugar in soda and other sugar-containing beverages cause, obesity, diabetes, heart disease, the metabolic syndrome, tooth decay, and gout).

¹⁰³ *Id.* at 3–4 (stating that numerous authorities including the U.S. Department of Agriculture and Health and Human Services, have concluded in recent years that over-consumption of added sugar contributes importantly to overweight, obesity, and many obesity-related health problems).

¹⁰⁴ Lustig, *supra* note 5.

dying from cardiovascular disease;¹⁰⁵ according to the American Heart Association, added sugar consumption increases the risks of developing obesity and heart disease;¹⁰⁶ and according to the American Institute for Cancer Research added sugar consumption increases the risks of having colon, postmenopausal breast, endometrial, esophageal, kidney, and pancreatic cancers.¹⁰⁷

One may argue that added sugar consumption does not lead to health adversities except for dental cavities. In fact, this was FDA's conclusion on the safety evaluations of the Select Committee on GRAS Substances in 1976.¹⁰⁸ However, the Select Committee of 1976 specifically acknowledged that its conclusion regarding the GRAS status of added sugar might change, should consumption dramatically increase.¹⁰⁹ Added sugar consumption has dramatically increased since the 1970's: American consumers' intake has, in fact, increased by 30% since the 1970's.¹¹⁰ In conclusion, FDA should issue a *Federal Register* notice determining that added sugar is not GRAS because of safety factors that are generally recognized by experts as inappropriate.

D. *Added Sugar Is Not GRAS*

FDA should issue a *Federal Register* notice determining that added sugar is not GRAS because there is reasonable certainty amongst scientists that added sugar is harmful based on its intended use,¹¹¹ due to (1) the probable consumption of added sugar; (2) the cumulative effect of the added sugar in the diet; and (3) the safety factors of added sugar that are generally recognized as inappropriate. One could argue that there is a safe level of added sugar consumption. So why not argue that FDA should condition continued GRAS status for added sugar on content limitation, rather than revoke GRAS status completely?¹¹² This argument fails for two reasons. First, even if manufacturers

¹⁰⁵ *Added Sugars Add to Your Risk of Dying from Heart Disease*, AM. HEART ASS'N, http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/HealthyEating/Added-Sugars-Add-to-Your-Risk-of-Dying-from-Heart-Disease_UCM_460319_Article.jsp?appName=MobileApp (last visited Jan. 31, 2015).

¹⁰⁶ *Added Sugar in the Diet*, *supra* note 1 (stating that American Heart Association has recommended that Americans drastically cut down on added sugar consumption to help slow the obesity and heart disease epidemics).

¹⁰⁷ *The Many Names of Sugar*, AM. INST. CANCER RES., <http://preventcancer.aicr.org/site/News2?id=20852> (last visited Jan. 31, 2015).

¹⁰⁸ Beyranevand, *supra* note 4, at 914 (“Other than the contribution to dental caries, there is no conclusive evidence on sugars that demonstrates a hazard to the general public when sugars are consumed at the levels that are now current and in the manner now practiced.”); see also EVALUATION OF THE HEALTH ASPECTS OF SUCROSE AS A FOOD INGREDIENT, SELECT COMMITTEE ON GRAS SUBSTANCES, LIFE SCIENCE RESEARCH OFFICE, FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY 13 (1976); EVALUATION OF THE HEALTH ASPECTS OF CORN SUGAR (DEXTROSE), CORN SYRUP, AND INVERT SUGAR AS A FOOD INGREDIENT, SELECT COMMITTEE ON GRAS SUBSTANCES, LIFE SCIENCE RESEARCH OFFICE, FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY 17 (1976).

¹⁰⁹ Beyranevand, *supra* note 4, at 916 (explaining that the Committee stated that it had no means of determining whether different consumption rates might present a dietary hazard).

¹¹⁰ Barbara Howard & Judith Wylie-Rosett, *A Statement for Healthcare Professionals From the Committee on Nutrition of the Council on Nutrition, Physical Activity, and Metabolism of the American Heart Association*, AHA SCIENTIFIC STATEMENT, <http://circ.ahajournals.org/content/106/4/523.full> (finding that the average American consumed 120 pounds of added sugars per year in 1970).

¹¹¹ See 21 C.F.R. § 170.3(i). To establish such recognition, there must be a consensus of expert opinion regarding the safety of the use of the substance. See, e.g., *United States v. W. Serum Co., Inc.*, 666 F.2d 335, 338 (9th Cir. 1982) (citing *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609, 629–32 (1973)).

¹¹² See Noah & Merrill, *supra* note 69, at 358 (“GRAS substances are not exempt from all FDA controls. For instance, users must comply with any specific usage limitation in a GRAS affirmation regulation.”).

decreased the amount of added sugar in their processed foods to one teaspoon or less per serving, Americans would still consume more than the recommended amount of added sugar per day when their added sugar consumption is considered in the aggregate.¹¹³ Second, due to the magnitude of the public health problem that added sugar has created, a more aggressive approach is necessary.

Without GRAS classification, added sugar would be a “food additive.”¹¹⁴ As a food additive, manufacturers would have to obtain premarket approval from FDA before using added sugar in their products.¹¹⁵ If added sugar was a food additive, then manufacturers would be forced to use added sugar in compliance with FDA’s approved uses, specifications, and restrictions.¹¹⁶ This would give FDA the authority to limit the amount of added sugar used in processed foods or to require food manufacturers to exclude added sugar from processed foods. Moreover, if foods contained added sugar in a manner that conflicted with FDA’s approved uses, specifications, and/or restrictions, then the product would be deemed adulterated under 21 U.S.C. § 342 subjecting manufactures to civil and criminal penalties.¹¹⁷ Thus, FDA should issue a *Federal Register* notice determining that added sugar is not GRAS, allowing FDA to regulate added sugar consumption by restricting the amount of added sugar that can be used in a product.

V. CONCLUSION

GRAS status is time-dependent. When new scientific data suggests that a substance is not safe, FDA can revoke GRAS status. Whether FDA could issue a *Federal Register* notice finding a substance, like added sugar, is not GRAS depends on whether the substance is generally recognized among experts as having been adequately shown, through scientific procedures, to be safe under the conditions of its intended use.

FDA should issue a *Federal Register* notice finding that added sugar is not GRAS, because the probable consumption of added sugar is three to five times higher than experts recommend; research has found that added sugar is a chronic toxin having a cumulative effect on one’s health; and experts no longer generally recognize added sugar as safe due to its immediate and long-term adverse health effects. FDA’s issuance of a *Federal Register* notice that added sugar is not GRAS will require manufacturers to obtain premarket approval when using added sugar as a food additive. The premarket approval will allow FDA to regulate the amount of added sugar in a processed food, thus decreasing added sugar consumption in the American population and the health adversities that stem from added sugar consumption.

¹¹³ See *supra* text accompanying note 91 (for examples of sugar in common foods). If the average consumers’ daily food listed *supra* Part IV.A was remanufactured to contain one teaspoon or less of added sugar per serving, then the consumer would consume over ten to fifteen teaspoons of added sugar, which is still more than the recommended amount.

¹¹⁴ See 21 U.S.C. § 321(s), *supra* note 101 and accompanying text.

¹¹⁵ See 78 Fed. Reg. 67,169, *supra* note 8 and accompanying text.

¹¹⁶ *Is It Really FDA Approved?*, FOOD & DRUG ADMIN., <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm047470.htm> (last visited Jan. 31, 2015).

¹¹⁷ See, e.g., *supra* and accompanying text note 8.