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Big Food, the FDA and the GRAS System:
Examining Key Factors behind Questionable Additives in Your Food

The growing skepticism among U.S. consumers with regard to the safety of their food is grounded in a reality that is more disturbing and troubling than even the worst rumors on the Internet. Numerous studies and reports recently released by nonprofit consumer advocacy organizations and reporting agencies indicate that a disturbing number of new additives ("ingredients") have been dumped into the food supply by the processed food industry using a loophole in the GRAS approval system—chemical ingredients that the FDA has not registered and not independently approved as safe.

For the past 15 years the U.S. Food and Drug Administration (FDA) has looked the other way while Big Food corporations have used a giant loophole in the GRAS system (the food additive/ingredient approval system known as "Generally Recognized as Safe") to dump numerous synthetic and industrialized food additives into the food supply sans the mandated safety testing to assure that the

additives are safe for humans (including *in utero,* infants and children) and that they have no significant short-term adverse effects or potential for long-term health complications.

"Currently, companies may determine a substance is "Generally Recognized as Safe" (GRAS) without FDA's approval or knowledge...
a few substances previously considered GRAS have later been banned;
and concerns have been raised about the safety of other GRAS substances...
GAO recommends that FDA take steps to better ensure the safety of GRAS substances, including developing a strategy to require any company that conducts a GRAS determination to provide FDA with basic information about it."

-U.S. Government Accountability Office (GAO)

Over the past decade and a half and counting systemic problems with governmental agencies charged with the task of overseeing food safety have continued, and in some cases have worsened. In a classic case of the fox guarding the hen house, a recent study conducted by the Pew Research Center and published in a prestigious American Medical Association (AMA) journal reported that a large percentage of food additives have never been reviewed or safety tested by the U.S. Food and Drug Administration (FDA) and in fact, the food manufacturers themselves have been the ones determining what additives are safe enough to inject in the public food supply.

"Because of the apparent frequency with which companies make [their own] GRAS safety determinations without telling the FDA...

We were able to identify 275 chemicals from 56 companies that appear to be marketed for use in food based on undisclosed GRAS safety determinations...

Companies found their chemicals safe for use in food despite potentially serious allergic reactions, interactions with common drugs, or proposed uses much greater than company-established safe doses.

~ Generally Recognized as Secret: Chemicals Added to Food in the United States. National Resources Defense Council (NRDC) Report

According to the Pew study and the National Resource Defense Council report, the majority of food additives ("ingredients") added to processed foods through the GRAS system in recent years are unknown even to the FDA and have not been scientifically safety tested, the adverse effects of processed food overall have. This is particularly troubling given that a number of scientific studies have linked additive-laden processed foods with a range of health problems including obesity, diabetes, depression, lethargy, cognition problems, increased incidence of tumors, heart and kidney problems, autoimmune disorders, and endocrine/hormonal problems, to name a few.

As the Washington Post recently reported,

> "A voluntary certification system [for additives] has nearly replaced one that relied on a more formal, time-consuming review — where the FDA, rather than companies, made the final determination on what is safe. The FDA's new system allows manufacturers to certify, based on the company's own research, that such ingredients are already Generally Recognized as Safe, or GRAS—which means food manufacturers no longer have to submit their research and raw data to the FDA. The result is that companies often bypass the FDA altogether. Under the rules, companies may make their own GRAS determination. Sharing it with the agency and getting it to sign off is voluntary."

The Pew Charitable Trusts study was a comprehensive examination of the FDA's GRAS system. Pew researchers conducted a three-year investigation into how food additives are regulated; Pew has called the GRAS system, "the loophole that swallowed the law." In the grandest example of the fox guarding the hen house, according to the Pew study on food additives, if a food corporation wants to include a new additive ("ingredient") in their processed food all they have to do is conduct their own study and publish safety data about it on their website (with the GRAS system they are *not* required to publish food safety data in a peer-reviewed scientific journal—the key difference between food "additives" and GRAS "ingredients" is the availability of safety information) and then pay a law firm or consulting firm to vet their own study and establish it as "generally recognized as safe"—and incredibly, they never even have to notify the FDA.

"Since 2000 almost all new chemicals have passed through the [GRAS] loophole rather than being subjected to the food additive petition process established by Congress in 1958."

~ Generally Recognized as Secret: Chemicals Added to Food in the United States. National Resources Defense Council (NRDC) Report

Legal Remedies Don't Work with the FDA

A lawsuit was recently filed against the FDA by a food safety organization for negligent oversight and for permitting harmful additives to enter the food supply. The FDA tried to get the suit dismissed based on a lack of evidence of harm resulting from the unknown and unmonitored chemicals; ultimately all that happened was that the judge compelled them to finalize the rule for their GRAS procedures initially created in 1998.

Whether this legal maneuver would amount to anything substantive to protect consumers was questionable from the onset; the FDA has been petitioned and sued numerous times over the past few decades over various food chemicals that have been found in scholarly scientific studies to be carcinogenic or otherwise a potentially serious health problem, to no avail. Between regulatory capture, a lack of legal authority and resources to set limits on the very companies they are charged with regulating, political posturing, and what appears to at least some independent scholarly researchers working with the FDA to be something bordering on scientific incompetence (more specifically, their complete resistance to modern scholarly scientific research methodology and an insistence to rigidly clinging to outdated, ineffective observational-based research, is pervasive in the agency), when it

comes to requiring rigorous testing and oversight of food chemicals, the governmental body in charge of food safety is anything but trustworthy.

It’s as Easy as Additive-Laden Cherry Pie

When the big food corporations want to introduce a new chemical additive (“ingredient”) into their processed foods (something happening with unsettling frequency these days) they may use the most efficient route—the GRAS system. GRAS (or Generally Recognized as Safe), you will recall, has a loophole large enough for a semi-tractor trailer filled with Doritos to drive through. By capitalizing on the loophole even if their applications for new additives (“ingredients”) are turned down, they can simply withdraw the applications, pay their own lawyers or consultants to claim it is safe, and—sans any scientifically published safety testing or even notifying the FDA, dump it into the food anyhow.

Of the approximate 10,000 food additives approved for use in the market today, 3,000 have never been scientifically safety tested and approved by the FDA. As researchers at the Pew Charitable Trusts and others have publicly exposed this practice as Standard Operating Procedure for Big Food's handling of new synthetic and industrialized food additives, we must assume the FDA is also aware it is going on. While FDA administrators may refuse to publicly acknowledge the stranglehold political cronyism has on their willingness and ability to act in the best interest of public health, privately a substantial number don't. Nearly a quarter of FDA respondents of a 2012 survey reported they had worked for an industry they were later tasked with regulating, which highlights the significance of the "revolving door" problem. Additionally, a substantial number of respondents (55 percent) thought that

FDA decisions were overly influenced by political interests or business interests. Just as important, over a third of the respondents reported firsthand experience of corporate political interference in their work within the past year. The bottom line for Big Food and Big Chemical corporations these days is that when you have friends with benefits working inside the FDA and longstanding, powerful friendships within the U.S. government, especially when you spend billions of dollars on lobbying efforts, getting a nod and wink for synthetic food additives that will increase your profits is apparently not that difficult.

"Robert McQuate, CEO of GRAS Associates, LLC, a food ingredient-consulting firm, says that about half of his clients do not voluntarily submit their GRAS determinations to FDA for review. GRAS information submitted to FDA becomes publicly available, so the main reason his clients do not submit GRAS determinations is to protect their trade secrets."

-Kelly Damewood, Food Safety News

The FDA Response

Either an apparent victim of regulatory capture, under-funding, or antiquated policies and protocol (there is evidence that all are present) the FDA has ignored numerous requests and lawsuits brought forward by nonprofit organizations, scientists, attorneys, physicians and private citizens to ban various additives—some of them linked in scientific studies with cancer, a finding that compels the FDA to take action according to the Delaney Clause (the 1958 Food Additives Amendment (section 409) to the 1938 Federal Food, Drug and Cosmetic Act/FFDCA). A recent lawsuit has been filed against the FDA

by an organization of food safety advocates claiming the FDA has been negligent in not requiring proper scientific safety testing studies in order for food additives (“ingredients”) to be designated as Generally Recognized as Safe (GRAS), thereby endangering the public by exposing them to potentially harmful food additives. While one might presume that the FDA is maintaining a "de minimis" argument, or that these additives pose negligible risk to consumers, in fact, they have no such evidence on numerous additives present in the food. This is because many of the food additives (“ingredients”) determined to be “generally recognized as safe” (GRAS) in recent years have been determined as such by the food manufacturers themselves, far too frequently sans published, peer-reviewed, scientific safety testing studies. Given the voluntary nature of the requirement for food manufacturers to report their GRAS additives (“ingredients”) to the FDA, it should be no surprise that Pew's research findings found that the FDA was unaware that many of these additives even existed in the food supply. In the meantime, a cadre of potentially harmful synthetic and industrialized chemicals remain in the food, leaving the onus on the consumer to self-educate and self-select which synthetic and industrialized food additives may be harmful to the health and well-being of themselves and their families.

Big Food’s Reaction to Growing Public Concern about Food Additives

As if untested mystery chemicals in the food supply is not bad enough, to add insult to injury, big food manufacturers have been overtly capitalizing on the public's concern about food additives, deceptively labeling their food products as “natural” in the hopes that consumers will not investigate

further or read the small print on the ingredients labels. Fortunately, according to a report by The Wall Street Journal, the cost of consumer lawsuits concerning this behavior has caused a number of food manufacturers to begin quietly removing the deceptive “natural” labels from their products, but some remain steadfast.

And New Chemical Additives Just Keep Coming

According to a recent NRDC report, EGCG (Epigallocatechin-3-gallate) is one of the food additives that had its GRAS notice withdrawn and despite safety concerns, has been listed as an ingredient in some food products. Not to be confused with the low-level naturally-occurring version found in green tea (polyphenol epigallocatechin-3-gallate), this industrialized version of EGCG can be found in cereal, nutrition and energy bars, soft drinks, sports and isotonic drinks, energy beverages, fruit and vegetable juices, meal replacement and soft candies. According to FDA records there are more than a dozen scientific studies linking this additive with dangerous health consequences, including one study that demonstrated it could induce toxicity in the liver, kidneys and intestine. Another study showed EGCG could produce defects in the brain and heart, and still another concluded it may contribute to infant leukemia.

"FDA's approach to regulating nanotechnology allows engineered nanomaterials to enter the food supply as GRAS substances without FDA's knowledge...

Because GRAS notification is voluntary and

companies are not required to identify nanomaterials in their GRAS substances,

FDA has no way of knowing the full extent to which engineered

nanomaterials have entered the U.S. food supply

as part of GRAS substances."

~U.S. GAO 2010 Report:

FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)

The Solution to Questionable Chemicals of Concern in the U.S. Food Supply

Given the seriousness of the potential for serious adverse illnesses and chronic conditions linked with some of the most prevalent additives in our nation's food supply there emerges a level of absurdity in what now passes for 'food safety' in the U.S. that can only be seen as a tragically amusing comedy of errors. Perhaps the FDA's current GRAS (Generally Recommended as Safe) system whereby they permit Big Food to determine on their own which new chemical additives (officially called, "ingredients" when put through the GRAS system) are safe to enter the food supply sans any peer-reviewed published scientific safety testing, can be relabeled as the National Resources Defense Council (NRDC) suggests as, 'Generally Recognized as SECRET', or alternatively as 'GRAP'...'Generally Recognized as Profitable'. In this way, while there will still be no clear-cut method for determining the short- and long-term risks of ingesting it, at least the consumer will have transparency where motive is concerned.

"If people don't know what it really is, it can't be generally recognized."

~Tom Neltner, JD., GRAS researcher for Natural Resources Defense Council

The bottom line: Consumers concerned about the potential adverse short-term and long-term health effects of synthetic and industrialized food chemicals are left on their own to self-educate and self-monitor what goes into their carts—and ultimately their bodies.

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