Negative Brief: GRAS List

By “Coach Vance” Trefethen

The plan reforms the process for additives to be put on the list of food chemicals “Generally Regarded As Safe” (GRAS) by the FDA. They are “GRAS” because they’ve been used for a long time and haven’t been regarded as needing extensive testing like new chemicals, or else they have been reviewed by outside scientists and don’t need FDA review.

The FDA has been allowing more chemicals to be added to the list by accepting food companies’ word for it when they attest that the chemicals are safe. Some are concerned that public health may be endangered, and the AFF will close or amend this “GRAS loophole” and require the FDA itself to test every chemical before letting it onto the market.

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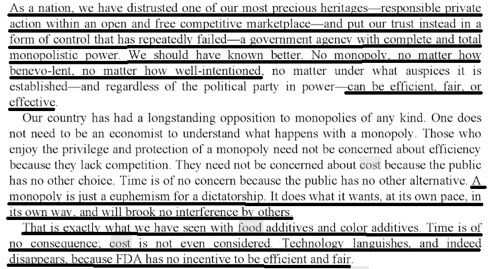
CASE NOTES

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OPENING QUOTES / NEGATIVE PHILOSOPHY

FDA regulation of food additives is the work of a failed monopoly, another word for dictatorship

Peter Barton Hutt 2002 (senior counsel in the Washington, DC law firm of *Covington* & Burling, specializing in Food and Drug Law ) Chapter 8 Regulation of Food Additives in the United States, FOOD ADDITIVES – Second Edition <https://books.google.com/books?id=87XK5Uwvs94C&pg=PA218&lpg=PA218&dq=delay+GRAS+list+food+cost&source=bl&ots=clfFWmikO9&sig=wXQuRJh98xksr17kSbEdee7znkg&hl=en&sa=X&ved=0ahUKEwjPp9CitPTPAhVMPT4KHWMJCr8Q6AEIUDAI#v=onepage&q=delay%20GRAS%20list%20food%20cost&f=false>



Potential risk does not justify government ban: We tried that with alcohol and we realize it was a mistake

**[And isn’t alcohol far more dangerous than anything in the Affirmative’s case?]**

Doug Bandow 2012 (law degree, Stanford Univ.; Senior Fellow at the Cato Institute; formerly the Bastiat Scholar at the Competitive Enterprise Institute, the Cobden Fellow at the Institute for Policy Innovation, and a Visiting Fellow at the Heritage Foundation; served as a Special Assistant to President Reagan ) “From Fighting the Drug War to Protecting the Right to Use Drugs Recognizing a Forgotten Liberty” <http://object.cato.org/sites/cato.org/files/articles/towards-worldwide-index-10-bandow.pdf>

It seems particularly odd to leave alcohol use legal if “social costs” is the chief criterion for a government ban. The failure to reinstitute Prohibition demonstrates that even those inclined towards prohibition believe the mere existence of social problems does not warrant a government ban.

VOTING CRITERION: Individual Liberty

Individual liberty should be the voting issue in this round. It is the paramount political value, underlying all human actions

Doug Bandow 2012 (law degree, Stanford Univ.; Senior Fellow at the Cato Institute; formerly the Bastiat Scholar at the Competitive Enterprise Institute, the Cobden Fellow at the Institute for Policy Innovation, and a Visiting Fellow at the Heritage Foundation; served as a Special Assistant to President Reagan ) “From Fighting the Drug War to Protecting the Right to Use Drugs Recognizing a Forgotten Liberty” <http://object.cato.org/sites/cato.org/files/articles/towards-worldwide-index-10-bandow.pdf>

The presumption of this paper is that individual liberty is the paramount political value. There is more to life than the freedom to act without political constraint, but that liberty underlies the rest of human action, including the pursuit of the transcendent. Steven Wisotsky, a law professor at Nova Southeastern in Florida, argued that “the fundamental moral premise of our political, economic, and legal systems” is “that the individual is competent to order his life to vote, to manage his own affairs and be responsible for whatever results he produces in life” (1986: 201).

A fundamental human right: the right to control your own body

Doug Bandow 2012 (law degree, Stanford Univ.; Senior Fellow at the Cato Institute; formerly the Bastiat Scholar at the Competitive Enterprise Institute, the Cobden Fellow at the Institute for Policy Innovation, and a Visiting Fellow at the Heritage Foundation; served as a Special Assistant to President Reagan ) “From Fighting the Drug War to Protecting the Right to Use Drugs Recognizing a Forgotten Liberty” <http://object.cato.org/sites/cato.org/files/articles/towards-worldwide-index-10-bandow.pdf> (brackets added)

Anyway, changing one’s physical and mental state is among the most personal of decisions. Some legal analysts contend that drug use should be viewed as part of the “zone of privacy” or “personal autonomy” that most Americans have come to expect (Hill, 1992: 103-05). Four years ago the Argentine supreme court ruled unconstitutional the prosecution of people for possessing drugs for personal use. Explained the judges: “adults should be free to make lifestyle decisions without the intervention of the state” (quoted in Jenkins, September 3, 2009). [psychiatrist Thomas] Szasz put it another way: “How can a person lose the right to his body? By being deprived of the freedom to care for it and to control it as he sees fit” (Szasz, 1992: 6).

SOURCE INDICTMENT

Center for Food Safety: A marketing group for the organic food industry

**[Meaning: they have financial incentives to trash anything other than organic food in order to boost profits for the industry their directors profit from.]**

Center for Organizational Research and Education 2013 (nonprofit dedicated to research and education about a wide variety of activist groups. Ethical disclosure about the date: the webpage is copyrighted 2016 but the latest information on the page comes from 2013, so we took the older date just to be completely ethical) Center for Food Safety <https://www.activistfacts.com/organizations/11-center-for-food-safety/>

The Center for Food Safety, under its façade of nonprofit watchdogging, has all the marks of a black-marketing campaign, run on behalf of organic and “natural” foods. Its advisory board is packed with organic-foods activists, including a registered “natural foods” lobbyist, prominent members of the Chefs Collaborative, the research director for Rodale Publishing’s Organic Gardening magazine, and the director of the organic-foods industry’s largest accreditation service. In addition, Andrew Kimbrell was the brains behind the multi-million-dollar Turning Point Project campaign, which ran a series of full-page New York Times advertisements trashing biotechnology and conventional agriculture.

Center for Food Safety: Easily fooled by junk science

Genetic Literacy Project 2015 (part of the Science Literacy Project, a 501(c)(3) nonprofit funded by grants from independent foundations and charities. The GLP accepts tax-deductible donations from individuals, but not from corporations. Executive Director is Jon Entine, senior research fellow at the Institute for Food and Agricultural Literacy at the University of California ) “Biotech Gallery - Center for Food Safety: Legal swat team of anti-GMO movement” <https://www.geneticliteracyproject.org/glp-facts/center-for-food-safety-2/>

CFS unabashedly promotes and defends organic-only agriculture, and opposes GMOs, food irradiation, aquaculture, animal cloning, and rBGH. It was one of the earliest adopters of a later debunked theory that mad cow disease was exclusively the result of non-organic livestock agriculture.

Marion Nestle

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Marion Nestle is one of the country’s most hysterical anti-food-industry fanatics. The New York University nutrition professor is the author of Food Politics: How the Food Industry Influences Nutrition and Health, in which she writes: “Sellers of food products do not attract the same kind of attention as purveyors of drugs or tobacco. They should.” Nestle’s vision of a brave new food world includes the notorious “Twinkie tax,” federal price controls on high-calorie foods and beverages, restricted food advertising, print advertisements that warn consumers of calorie content, and nutritional labeling on fast-food restaurant packages. She believes that “food is too cheap in this country.” To accomplish her radical goals, Nestle has worked with the Center for Science in the Public Interest, the uncontested leader among America’s dietary scolds. When an interviewer asked Nestle if CSPI is her “covert ally,” she replied: “Overt is more like it. I was on CSPI’s board for five years, then slipped off quietly, but I’m a big supporter of what they do. By and large, they’re the major game in town.” Speaking to the New York Times in 1996, Nestle made it very clear that her primary agenda is not pro-nutrition, but instead anti-corporate: “I like it better when Mike [Jacobson of CSPI] takes on the big corporations like McDonald’s,” she said. “I like it less well when he takes on mom and pop outfits like Chinese restaurants.” Nestle is so obsessed with blaming corporations that she doesn’t believe parents can exercise responsibility over their children’s diets or that adults are able to regulate their weight.

Marion Nestle

Steven Milloy 2002 (*attorney; adjunct scholar at the Cato Institute* ) 22 Feb 2002 “New Nutrition Book Choking on Bad Science” <http://www.foxnews.com/story/2002/02/22/new-nutrition-book-choking-on-bad-science.html>

What really needs to be exposed, though, is Nestle's own concealed bias. Nestle derides the American Council on Science and Health, a nonprofit group that frequently comments on food issues, for not disclosing the extent to which the ACSH is funded by the food companies. She adds, "... but ACSH's nemesis, the Washington, D.C.-based consumer advocacy group the Center for Science in the Public Interest (CSPI), has noted such connections since 1982 ..." This is only one of her numerous references to the "heroic" CSPI, the hyper-activist group best known for labeling Fettuccine Alfredo as "heart attack on a plate," and its nutritional lynching of Chinese food and movie popcorn. But while chastising ACSH for lack of disclosure, Nestle hypocritically omitted disclosing her close and long-time connection with CSPI — like her five-year stint as a CSPI board member. This deception isn't new. Nestle and CSPI are often presented as mutually supporting, independent sources in media reports on food controversies. Mention of the Nestle-CSPI relationship is usually omitted from this coverage. Nestle is even presented as an independent source in articles about CSPI campaigns, such as those against Coca-Cola's sponsorship of the *Harry Potter* movie and Procter and Gamble's fat substitute olestra. Finally, Nestle is simply biased against the food industry. She told *The New York Times* in 1996: "I like it better when CSPI takes on the big corporations like McDonald's. I like it less well when CSPI takes on mom-and-pop outfits like Chinese restaurants."

INHERENCY

1. Status Quo solves.

FDA has ample authority under current law and is already removing bad additives

Dr. Robert S. McQuate and Dr. Richard C. Kraska 2015 (McQuate – PhD in chemistry. Kraska – PhD in pharmacology; formerly worked for the FDA on GRAS review and food additives) REGULATORY MAGAZINE 4 Mar 2015 “The Future of GRAS Regulations“ <http://www.nutritionaloutlook.com/regulatory/future-gras-regulations>

Existing GRAS practices enable FDA to take actions to remove unsafe substances if scientific documentation supports such actions. Two examples associated with GRAS substances and potential public health concerns surfaced in the past few years, and in each case FDA took steps to address the concerns: 1) the use of caffeine in alcoholic beverages was deemed to not meet the GRAS safety criteria, thereby disallowing the direct use of caffeine in alcoholic beverages, and 2) FDA initiated regulatory proceedings in November 2013 to remove GRAS status for partially hydrogenated oils when added to foods because the reported safety was not generally recognized. Thus, current law provides FDA with ample authority to challenge the status of substances that have been designated as GRAS if inadequate documentation is available to support such a finding.

1. New Rules. Improvements to GRAS rules are already underway

In August 2016, FDA announced new rules for strengthening standards for GRAS, and more rules to follow

Food & Drug Administration 2016. “FDA Issues Final Rule on Food Ingredients that May Be "Generally Recognized as Safe"” Aug 2016 <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm516332.htm>

In a step to strengthen its oversight of food ingredients, the U.S. Food and Drug Administration today issued a final rule detailing the criteria for concluding that the use of a substance in human or animal food is “generally recognized as safe” (GRAS). Unlike food additives, GRAS substances are not subject to FDA pre-market approval; however, they must meet the same safety standards as approved food additives. The rule addresses the types of scientific evidence that can be used to demonstrate safety as well as the role of publications in evaluating whether the scientific evidence of safety is “generally available and accepted.” The GRAS criteria require that the safe use of ingredients in human and animal food be widely recognized by the appropriate qualified experts. The final rule also formalizes the voluntary GRAS notification procedure, which was originally established under an interim policy and pilot program for human food in 1997 and animal food in 2010. The FDA strongly encourages companies to inform the agency of GRAS conclusions through the notification procedure finalized with today’s rule. While the FDA can question the basis for an independent GRAS conclusion, whether notified or not, and take action as appropriate, the notification procedure yields important information that aids the agency’s food safety monitoring efforts. The GRAS final rule is the most recent step we are taking to strengthen the FDA’s oversight of substances added to human and animal food. Next steps include issuing additional guidances related to the GRAS regulations. As part of the Foods and Veterinary Medicine Program’s Strategic Plan, the FDA will develop and implement innovative regulatory and compliance strategies to improve premarket oversight and safety evaluation of human and animal food additives and GRAS substances.

Impact: Inherency/Solvency dilemma.

Affirmative cannot indict the FDA and say they’re lying about the new rules being workable. If FDA is corrupt, dishonest or incompetent, then the Affirmative’s plan will fail because FDA implements their plan. If FDA is correct and the new rules are workable, then we don’t need the plan. Or, at least, let’s wait and see if the new rules work and then come back in a year or two and investigate this issue again later.

1. New risk evaluation system.

FDA is developing the Chemical Evaluation & Risk Estimation System to better evaluate risk in food ingredients

Dr. Robert S. McQuate and Dr. Richard C. Kraska 2015 (McQuate – PhD in chemistry. Kraska – PhD in pharmacology; formerly worked for the FDA on GRAS review and food additives) REGULATORY MAGAZINE 4 Mar 2015 “The Future of GRAS Regulations“ <http://www.nutritionaloutlook.com/regulatory/future-gras-regulations>

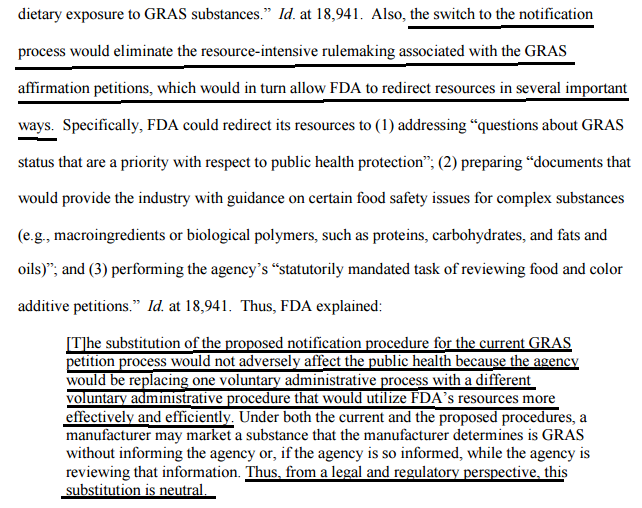
Meanwhile, FDA says it is committed to increasing transparency in its programs while ensuring the application of high-quality and up-to-date science in the administration of the GRAS program. FDA is actively developing its Chemical Evaluation and Risk Estimation System (CERES), a cutting-edge system that will help FDA evaluate and estimate risks in pre- and post-market review of food ingredients. The system will enable FDA to fully leverage available data through modern computational and predictive methods for pre-market review as well as post-market monitoring of food ingredients and packaging materials.

HARMS / SIGNIFICANCE

1. Shift of resources means GRAS rule has no impact on public health

The GRAS rule change allows FDA to shift resources to other important issues that better uphold public health

Attorneys for US Health & Human Services Secretary Kathleen Sebelius and FDA Commissioner Margaret Hamburg 2014. Brief filed in the case of CENTER FOR FOOD SAFETY v. SEBELIUS and HAMBURG 14 May 2014 <http://www.hpm.com/pdf/blog/CFS%20GRAS%20-%20FDA%20MTD.pdf>

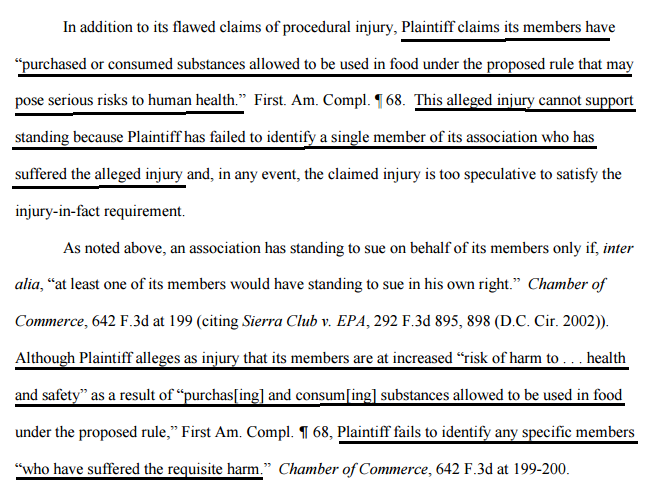


1. Nobody’s been harmed

Even advocates for the plan cannot name 1 person who has been harmed by the GRAS process

**Defending themselves from a lawsuit filed by an activist group that advocates the Affirmative plan, Attorneys for US Health & Human Services Secretary Kathleen Sebelius and FDA Commissioner Margaret Hamburg pointed out in their legal brief in 2014 QUOTE:**

Attorneys for US Health & Human Services Secretary Kathleen Sebelius and FDA Commissioner Margaret Hamburg 2014. Brief filed in the case of CENTER FOR FOOD SAFETY v. SEBELIUS and HAMBURG 14 May 2014 <http://www.hpm.com/pdf/blog/CFS%20GRAS%20-%20FDA%20MTD.pdf>

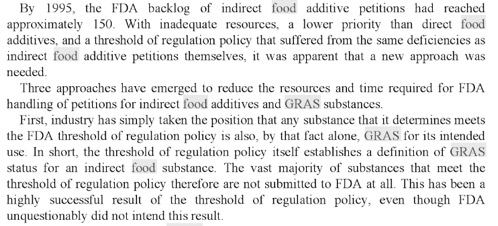


SOLVENCY

1. FDA backlog

The reason why the GRAS rules were implemented was because the FDA was so backlogged. The new rules successfully solved the backlog

Peter Barton Hutt 2002 (senior counsel in the Washington, DC law firm of *Covington* & Burling, specializing in Food and Drug Law ) Chapter 8 Regulation of Food Additives in the United States, FOOD ADDITIVES – Second Edition <https://books.google.com/books?id=87XK5Uwvs94C&pg=PA218&lpg=PA218&dq=delay+GRAS+list+food+cost&source=bl&ots=clfFWmikO9&sig=wXQuRJh98xksr17kSbEdee7znkg&hl=en&sa=X&ved=0ahUKEwjPp9CitPTPAhVMPT4KHWMJCr8Q6AEIUDAI#v=onepage&q=delay%20GRAS%20list%20food%20cost&f=false>



FDA not capable of doing any more than it is today with regard to GRAS substances

Lydia Zuraw 2014 (journalist) “Settlement Reached in GRAS Lawsuit Against FDA” 21 Oct 2014 FOOD SAFETY NEWS <http://www.foodsafetynews.com/2014/10/gras-settlement-reached/#.WA7HTo8rKUl>

Speaking to reporters at the United Fresh Washington Conference in September, Michael Taylor, FDA deputy commissioner for foods and veterinary medicine, said that the agency would like to do more to ensure that it can vouch for the safety of GRAS substances, but that there are “some big resource constraints.” “Post-market surveillance is something we think is necessary and needs to be enhanced for both food safety and consumer confidence perspectives,” Taylor said, adding that although FDA’s food additive program has been funded to do the market-entry work, it “hasn’t really been funded to do the post-market surveillance.”

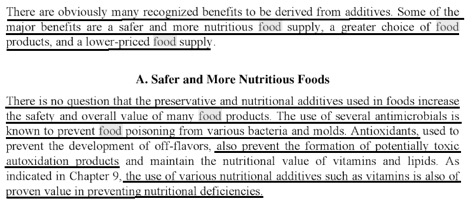
DISADVANTAGES

1. Loss of beneficial additives

Link: Plan results in fewer additives going onto the market. If not, it doesn’t do anything

Impact: Reduction in human health

Prof. Larry Branen and Prof. R.J.Haggerty 2002 ( Branen – food scientist, Univ. of Idaho. Haggerty – agricultural economics, Univ. of Idaho.) Chapter 1 Introduction to Food Additives FOOD ADDITIVES – Second Edition <https://books.google.com/books?id=87XK5Uwvs94C&pg=PA218&lpg=PA218&dq=delay+GRAS+list+food+cost&source=bl&ots=clfFWmikO9&sig=wXQuRJh98xksr17kSbEdee7znkg&hl=en&sa=X&ved=0ahUKEwjPp9CitPTPAhVMPT4KHWMJCr8Q6AEIUDAI#v=onepage&q=delay%20GRAS%20list%20food%20cost&f=false>



1. Lost liberty

Link: AFF bans humans from ingesting substances without the government’s permission

Impact: Loss of human liberty. Adults are morally entitled to ingest substances. Government attempts to eliminate risk cause a violation of liberty that outweighs the benefit

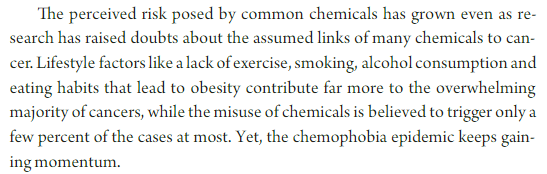
Doug Bandow 2012 (law degree, Stanford Univ.; Senior Fellow at the Cato Institute; formerly the Bastiat Scholar at the Competitive Enterprise Institute, the Cobden Fellow at the Institute for Policy Innovation, and a Visiting Fellow at the Heritage Foundation; served as a Special Assistant to President Reagan ) “From Fighting the Drug War to Protecting the Right to Use Drugs Recognizing a Forgotten Liberty” <http://object.cato.org/sites/cato.org/files/articles/towards-worldwide-index-10-bandow.pdf>

The basic moral case was famously articulated by John Stuart Mill (Bakalar and Grinspoon, 1984: 1). Adults are entitled to ingest substances even if a majority views that decision as foolish. Drug use can have negative social consequences, but that does not set it apart from other products and activities. After all, most any human action—smoking cigarettes, driving cars, climbing mountains—may have some negative impact on someone. To justify government regulation, harms must be serious and direct. Moreover, any restrictions must be crafted to minimize the violation of liberty. In criminalizing substance use, wrote dissident psychiatrist Thomas Szasz, then “Like medieval searchers for the Holy Grail, these modern seekers look for the correct answer to an absurd question, namely: How can we reduce or eliminate the risks and undesirable consequences of liberty, while retaining its rewards and benefits?”

1. Masking Disadvantage. Affirmative distracts us from real threats to public health

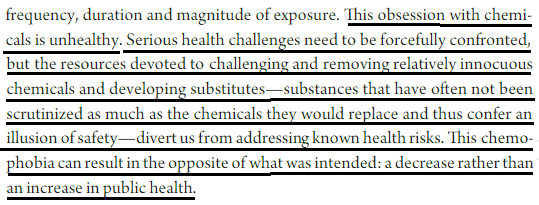
Link: We’re focused on small traces of chemicals and ignoring things that are really killing lots of people every year

Jon Entine 2011 ( senior research fellow at the Institute for Food and Agricultural Literacy at the University of California ) SCARED TO DEATH – How Chemophobia Threatens Public Health <https://www.scribd.com/document/48504531/Scared-to-Death-How-Chemophobia-Threatens-Public-Health>



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