

Comparison between US and EU food trade rules with regard to health factors



8 March 2006

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Objectives of the Chair

1/To draw up perspectives in order to improve performance along food chains in identifying ways to create value and manage risks

2/To go along with companies of the food chains:

- To anticipate nutritional and sociological changes
- To take up forthcoming challenges

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Research Project

Food, nutrition, life styles & chronic diseases

- To identify scenarios of possible future
- To allow companies to be better prepared to take up challenges and modify their current strategy

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Comparison between US and EU food trade rules with regards to health factors

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U.S. REGULATORY APPROACH TO NUTRITIONAL ISSUES

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U.S. REGULATORY APPROACH TO NUTRITIONAL ISSUES

Dramatic advances in scientific research on nutrition, diet, and disease continue to occur at a rapid pace. This paper provides an overview of the legislative and regulatory responses to nutritional issues seen in the United States by both federal and state legislators, and in particular the U.S. Food and Drug Administration (FDA). By necessity, regulatory approaches to such issues will vary based on the strength of the underlying scientific evidence and the potential risk or benefit to public health. A review of the actions that followed the Nutrition Labeling and Education Act of 1990 (NLEA) suggests that the regulatory response to the obesity crisis will proceed slowly, with participation by Congress, FDA, the courts, the food industry and other interested parties.

The U.S. Regulatory History of Health Claims for Foods and Dietary Supplements

- **The Fundamental Issue: Diet and Disease Claims Evidence Drug Status**

The Federal Food, Drug, and Cosmetic Act (FDCA) provides, in general, that no claim can be made that a food is intended to cure, mitigate, treat, or prevent any disease.¹ Such a claim causes a food to be deemed a drug and therefore illegal for failure to comply with the drug requirements, such as premarket approval and adequate directions for use. Prior to 1990, FDA interpreted any reference to health or disease, whether direct or implied, in food labeling as evidence of intended use as a drug.

In the late 1980s, a revolution in scientific knowledge of the relationship between diet and health occurred.² This revolution prompted the U.S. Surgeon General to publish new dietary recommendations aimed at reducing the risk of certain chronic diseases. The food industry wanted to use these general dietary recommendations in the marketing and promotion of their specific products. However, FDA's historical aversion to health- or disease-related information in food labeling presented a significant obstacle to dissemination of such information to American consumers through labeling.

¹ The FDCA defines a drug, in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man . . ." 21 U.S.C. § 321(g)(1)(B). Prior to NLEA, FDA regulations deemed a food misbranded if its labeling suggests "(1) that the food because of presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom." See 21 C.F.R. § 101.9(i)(11) (1985). (This regulation was amended in 1993 to allow health claims authorized by NLEA).

² See National Cancer Institute, Cancer Prevention, National Institute of Health Pub. No. 84-2671 (Feb. 1984); Public Health Services Dep't of Health and Human Servs, The Surgeon General's Report on Nutrition and Health (1988); National Research Council, Diet and Health: Implications for Reducing Chronic Disease Risk (1989).

- **The Issue Becomes Critical: Kellogg’s All-Bran Campaign**

The mounting pressure to allow truthful diet and disease information in food labeling erupted in 1984, when the Kellogg Company boldly promoted its All-Bran cereal as a way to help reduce the risk of certain cancers. Rather than approach FDA, Kellogg obtained an endorsement from the National Cancer Institute for its claim that eating high fiber foods, together with other dietary practices, “may reduce your risk of some kinds of cancer. . . . That’s why one of the [National Cancer Institute’s] strongest recommendations is to eat high fiber foods [Y]ou’ll find Kellogg’s All-Bran has nine grams of fiber per serving. No cereal has more.” The claim appeared on the All-Bran label and in advertising materials.

- **FDA’s Response: Too Little and Too Late**

In response to National Cancer Institute endorsement of Kellogg’s anti-cancer claim, FDA was forced to develop a policy on health-related claims in food labeling. It was not until 1987, however, that FDA finally decided that “appropriately formulated information on food labels [could] be of value to health-conscious consumers and [be] consistent with existing laws and regulation,” and that the “mere mention of a disease condition does not, in and of itself, make a product that is otherwise a food product into a drug.”³ FDA published a proposal to allow “health-related nutritional claims,” but requested further public comment on whether health information relating to particular diseases should appear in food labeling.⁴

- **Congress Steps in: The Nutritional Labeling and Education Act**

FDA’s reluctant efforts to permit disease-specific claims moved much too slowly, so the U.S. Congress intervened. In 1990, Congress enacted the NLEA,⁵ which allowed truthful information about the relationship of diet, nutrition and disease to appear in food labeling. NLEA amended the FDCA by adding section 403(r).⁶ This section specifies that a food is misbranded if it bears an express or implied claim that characterizes the relationship of certain nutrients to a disease or health-related condition *unless* the claim meets the requirements of a regulation authorizing its use.⁷ Section 403(r) directed FDA

³ FDA Proposal to Permit the Use of Disease-Specific Health Claims on Food Labels, Hearing Before a Subcommittee of the House Committee On Government Operations, 100th Cong. 1st Sess. 239, 250, 263 (1987).

⁴ 52 Fed. Reg. 28,843, 28,848 (Aug. 4, 1987).

⁵ Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990).

⁶ 21 U.S.C. § 343(r).

⁷ *Id.*

to issue regulations authorizing health claims for nutrients in conventional foods⁸ and in dietary supplements.⁹ FDA's health claim regulations were published three years later in 1993.¹⁰ The regulations include a very broad definition for "health claim:" any claim that characterizes the relationship between a food or food ingredient and disease, damage or dysfunction of the body.¹¹ All such claims require FDA approval prior to use.¹²

- **More Congressional Action: Dietary Supplement Health and Education Act**

The NLEA did not solve the health claim issues concerning dietary supplement products, which are regulated as foods in the United States¹³ In the years following the law, it became common practice for FDA to charge that the ingredients in dietary supplements bearing health-related information were food additives, which required pre-market approval and publication of a regulation by FDA prior to use.¹⁴ Ultimately, the U.S. courts found this to be a distorted interpretation of the law and an abuse of regulatory authority by FDA.¹⁵ The Senate Committee on Labor and Human Resources concluded that "FDA . . . attempted to twist the [FDCA] statute in what the Committee sees as a result-oriented effort to impede the manufacture and sale of dietary supplements."¹⁶ Congress therefore enacted another new law, the Dietary Supplement Health and Education Act of 1994 (DSHEA), to protect consumer access to safe and popular dietary supplements.¹⁷ DSHEA exempted dietary supplements from regulation as food additives, and allowed "structure/function claims" to be made in supplement labeling without prior FDA approval.¹⁸ A structure/function claim is a claim that characterizes the relationship between a substance and the normal healthy structure or function of the body.

⁸ *Id.* § 343(r)(1)

⁹ *Id.* § 343(r)(5)(D).

¹⁰ 58 Fed. Reg. 2478 (Jan. 6, 1993)

¹¹ 21 C.F.R. § 101.14(a)(1), (5).

¹² *Id.* § 101.14(c)(e).

¹³ 21 U.S.C. § 321(f).

¹⁴ *See, e.g., United States v. 45/194kg. Drums of Pure Vegetable Oil*, 961 F.2d 808 (9th Cir. 1992).

¹⁵ *United States v. Two Plastic Drums, More or Less of an Article of Food, Labeled in Part, Viponte Ltd. Black Currant Oil Batch No. BOOSF 039*, 984 F.2d 814 (7th Cir. 1993); *United States v. Oakmont Investment Co.*, 987 F.2d 33 (1st Cir. 1993).

¹⁶ S. Rep. No. 103-410, at 22 (Oct. 8, 1994).

¹⁷ Pub. L. No. 103-417, 108 Stat. 4325.

¹⁸ 21 U.S.C. §§ 321(s)(6), 321(ff), 343(r)(6)

- **Congress Acts Yet Again: The FDA Modernization Act of 1997**

Even after NLEA and DSHEA “ordered” FDA into action, the agency remained resistant to the approval of health claims. FDA authorized a health claim only when it determined, based on the totality of publicly available scientific evidence, that there was significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, and that the claim was supported by such evidence.¹⁹ The agency did not, however, explain what constituted significant scientific agreement. Absent an FDA determination that the claim was supported by significant scientific agreement, the claim would be illegal.²⁰ Industry was frustrated by the procedural hurdle erected by FDA, which lacked a defined scientific standard and prevented truthful and non-misleading health claims about foods.²¹

Congress again stepped in and enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA).²² FDAMA added a procedure for use of health claims without prior FDA approval. FDAMA allowed health claims based on an authoritative statement of a U.S. Government scientific body with responsibility for public health protection or research directly relating to human nutrition.²³

¹⁹ 21 C.F.R. § 101.14.

²⁰ *Id.* § 101.4; A statement such as: "a study published in the *New England Journal of Medicine* reports that consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer" would not be allowed because it was not supported by significant scientific agreement.

²¹ One frequently cited example of how FDA’s procedure operated to the detriment of the public interest was FDA’s slow acceptance of the folate claim. In 1992, the Centers for Disease Control and Prevention (CDC) issued a recommendation that women of childbearing age consume folic acid. CDC estimated that folate consumption could reduce the incidence neural tube defects in the United States by fifty percent. Public Health Service, U.S. Dep’t of Health and Human Servs, Recommendation for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects, 41 MMWR No. RR-14 (Sept. 11, 1992), cited in 58 Fed. Reg. 2606. (Jan. 6, 1993). Yet, FDA refused to approve the claim in food labeling.

²² Pub. L. No. 105-115, 111 Stat. 2296.

²³ 21 U.S.C. § 343(r)(3)(C)(i).

- **Litigation Follows: The Courts Direct FDA**

Unfortunately, FDA remained rigid in its approach to health claims and adopted such a narrow view of an "authoritative" statement that it essentially eviscerated the effect of FDAMA.²⁴

The dietary supplement industry sought relief in the courts. In *Pearson v. Shalala*, FDA's rejection of four separate health claims petitions was challenged. FDA denied the health claims because the supporting scientific evidence was inconclusive, and therefore did not meet the "significant scientific agreement" standard.²⁵ FDA never provided a definition or explanation for the "significance" of scientific agreement.²⁶

The U.S. Court of Appeals for the D.C. Circuit found FDA's prohibition of the health claims to be an unconstitutional restriction on commercial free speech.²⁷ The Court concluded that FDA must consider the use of disclaimers to negate the potential misleading nature of health claims when the scientific evidence does not rise to the level of significant scientific agreement.²⁸ The Court ordered FDA to define "significant scientific agreement," and to consider whether non-misleading claims could be made with a disclaimer that qualified the strength of the scientific evidence.²⁹ When FDA then again denied one of the health claims, a second lawsuit was filed.³⁰ In *Pearson v. Thompson*, the Court found that when credible evidence supports a claim, the claim may not be absolutely prohibited by FDA.³¹

- **FDA Complies with Court Orders to Allow Qualified Health Claims**

In response to the court decisions, FDA announced in December 2002 that it would allow qualified health claims on foods and dietary supplements. The agency also announced the Consumer Health Information for Better Nutrition Initiative and created a task force

²⁴ See 63 Fed. Reg. 34,084-112 (June 22, 1998).

²⁵ 164 F.3d 650, 653 (D.C. Cir. 1999).

²⁶ *Id.* at 654.

²⁷ *Id.* at 658.

²⁸ *Id.*

²⁹ *Id.* at 661.

³⁰ *Pearson v. Thompson*, 130 F. Supp. 2d 105 (D.D.C. 2001), recon. denied, 141 F. Supp.2d 105 (D.D.C. 2001).

³¹ 130 F. Supp. 2d at 114,118.

of representatives from the FDA, the Federal Trade Commission and the National Institutes of Health.³² As recommended by the task force, FDA published guidance documents describing the interim procedure and evidence-based ranking system that the agency would follow in approving qualified health claims for conventional foods and dietary supplements.³³

Regulating an Overweight America

- **The Issue: Obesity in the United States**

In 2001, U.S. Surgeon General published a report³⁴ with the shocking news that over the past decades Americans had grown overweight at an astounding rate. Statistics suggest that 64% of all Americans are overweight, and of all Americans 30% are obese.³⁵ In addition, the percentage of children and adolescents that are overweight had tripled to 15%.³⁶

These statistics are cause for grave concern by public health policymakers. The obesity issue is of paramount economic importance as well.³⁷ Direct costs include both prevention and treatment of obesity. Furthermore, obesity results in higher morbidity and is associated with type II diabetes, arthritis, cardiovascular disease and other debilitating (chronic) diseases. Some researchers believe that obesity has become a leading cause of death in the U.S., causing up to 400,000 deaths per year.³⁸

³² <http://www.fda.gov/oc/mcclellan/chbn.html> (last visited Feb. 10, 2006).

³³ Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional and Human Dietary Supplements, *available at* <http://www.cfsan.fda.gov/guidance.html>.

³⁴ U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *The Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity* (2001) *available at* <http://www.surgeongeneral.gov/topics/obesity/calltoaction/CalltoAction.pdf> (last visited Feb. 15, 2006)

³⁵ National Institute of Health guidelines define “overweight” adults as those adults with a body mass index (BMI) of 25.0-29.9, and “obese” adults as adults with a BMI of 30 or above. BMI is the ratio of a person’s body weight in Kg divided by the square of that person’s height in meters, *available at* http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/risk.htm#limitations.

³⁶ In 2002 Congress requested that the Institute of Medicine study the childhood obesity issue and prepare a prevention-focused action plan. This report confirms that obesity continues to increase in children. *See* Institute of Medicine, *Preventing Childhood Obesity* (2004), *available at* <http://www.iom.edu/obesity> (last visited Feb. 15, 2006).

³⁷ *See* http://www.cdc/nccdphp/dnpa/obesity/economic_consequences.htm (last visited Feb. 15, 2006).

³⁸ Ali H. Makdad et al., *Actual Causes of Death in the United States, 2000*, 291 J. Am. Med. Ass’n 1238, 1239 (2004); *but see* Ali H. Makdad et al., *Correction: Actual Causes of Death in the United States, 2000*, 293 J. Am. Med. Ass’n 293 (2005); Joyce H. Price, *CDC says obesity deaths overestimated*, Wash. Times,

- **FDA’s Obesity Working Group**

FDA clearly has a role to play in reversing the obesity epidemic. FDA, together with other branches of the government, educated the American public on diet and nutrition for decades.³⁹ In 2003, two years after the Surgeon General’s report, FDA created an Obesity Working Group (OWG).⁴⁰ The OWG was formed to prepare an action plan to attack the obesity issue. Obesity is a multifaceted problem that requires action from all segments of society: the industry, government, politicians, consumer organizations, scientists, etc. The OWG enlisted input from these various parties in developing its action plan.

- **Follow-up FDA Actions**

In 2004, the OWG published its final report. The OWG report identified several actions that FDA could undertake including: strengthen food labeling, encourage restaurants to provide nutritional information at point of service, reevaluate (and adjust) the concept of serving size used for nutritional information labeling (the Nutrition Facts Panel), revise guidance on obesity drugs, and encourage research related to the obesity issue.

FDA cannot control what consumers eat, and there is no substitute for the simple formula “calories in must equal calories out.” Nonetheless, FDA can encourage consumers to make informed and healthier dietary choices by providing accurate dietary information about the foods they eat. Such was the primary goal of NLEA, and its cornerstone, the Nutrition Facts Panel (NFP) containing product-specific information on serving size, calories, and nutrient content.⁴¹ Yet, since the introduction of the NFP, obesity prevalence has increased at a staggering rate. It appears that the NFP is ineffective in the fight against obesity.

The OWG recommended that FDA make the NFP more informative, particularly with respect to calorie content and serving size.⁴² Thirteen months following the OWG report, FDA requested public comment on enhancing prominence of the calorie content and

Apr. 20, 2005.

³⁹ See Pure Food and Drug Act of 1906, Publ. L. No. 59-384, 34 Stat. 768 (1906); FDCA 21 U.S.C. §§ 301 et seq. Fred R. Shank, *The Nutrition Labeling and Education Act of 1990*, 47 Food Drug L. J. 247, 247-49 (1992) (reviewing the history of government advising Americans what to eat).

⁴⁰ See <http://www.cfscin.fda.gov/~dms/owg-Rpt.html#1> (last visited Feb. 28, 2006).

⁴¹ 58 Fed. Reg. 2079 (Jan. 6, 1993); 21 C.F.R. § 101.9(c)(1)(iii).

⁴² 70 Fed Reg. 17,008 (Apr. 4, 2005).

increasing the serving sizes in the NFP.⁴³ FDA's obesity-related rulemaking is therefore in the very early stages.

- **Action by States and other parties**

In many situations, federal law preempts state law, *i.e.* federal law and regulations supercede state laws and the states cannot enforce their own laws (that are different from the federal law). However, there are actions that a state can take in response to the obesity issue, particularly with respect to childhood obesity. A number of states have started to regulate the presence and contents of vending machines containing carbonated beverages, candy and other “junk food” in public schools.⁴⁴ More recently, some school districts have replaced whole milk with low fat and skim milk in school cafeterias.⁴⁵

- **Federal Trade Commission**

The U.S. Federal Trade Commission regulates the advertising of foods under the Federal Trade Commission Act.⁴⁶ Advertising claims for foods may not be false or deceptive, and the advertiser must possess substantiation for the claims.⁴⁷ Congress directed the FTC to submit a report by July 1, 2006 on “marketing activities and expenditures of the food industry targeted toward children and adolescents.”⁴⁸ The FTC published a *Federal Register* notice requesting submission of information and empirical data regarding food and beverage industry marketing activities by April 3, 2006.

⁴³ *Id.* @ 17,010.

⁴⁴ See Health Policy Tracking Service, *State Action to Promote Nutrition, Increase Physical Activity and Prevent Obesity: A Legislative Overview*, Thompson West (July 11, 2005), available at <http://www.rwjf.org/files/research/July%202005%20-%20Report.pdf> (last visited Feb. 15, 2006).

⁴⁵ David M. Herszenhorn, *In New York Schools, Whole Milk is Cast from the Menu*, N.Y. Times (Feb. 02, 2006). The National School Lunch Program is directed and regulated by the Food and Nutrition Service of the U.S.D.A., but it is administered by the States through state school food authorities.

⁴⁶ 15 U.S.C. §§ 41-58.

⁴⁷ *Id.* §§ 45; 52; 55.

⁴⁸ Food Industry Marketing Practices to Children and Adolescents, Request for Information and Comments, available at http://www.ftc.gov/os/2006/02/frnP064504FoodMarketingtoKids_022406.pdf.

- **Food Industry Action**

The food and restaurant industries are also joining in the fight against obesity. The packaged food industry has started to reformulate old and introduce new products. In partnership with public health organizations, many food companies now promote a healthy lifestyle.⁴⁹ Restaurants have started to introduce special menu items and provide nutritional information about their menu items and have partnered with weight loss organizations such as Weight Watchers.⁵⁰

- **Litigation by Consumer Activist Groups**

Self-styled consumer rights activists have turned their attention to the marketing practices of the food industry, primarily the fast food and snack food segments. As was seen in with the anti-tobacco litigation, the activist groups seek social change through litigation or the threat of litigation. The most publicized case is the lawsuit against McDonald's.⁵¹ Originally, the plaintiffs claimed that McDonald's was liable for their obesity.⁵² After an initial dismissal by the U.S. district court, plaintiffs shifted their focus to McDonald's advertising practices.⁵³ Meanwhile, McDonald's adjusted its serving sizes,⁵⁴ provided nutritional information on its menu items,⁵⁵ and added some "more healthful" items to its menu. In addition, consumer activists recently threatened lawsuits against food companies, such as Kellogg's, and their advertising companies, alleging unfair or deceptive commercial practices.⁵⁶ These lawsuits may prove to be more effective because the plaintiffs can avoid complicated causation issues.

⁴⁹ Alison J. Kretcher, Senior Director Grocery Manufacturers Association, *The Packaged Food Industry at IFT 2006 Midyear Symposium, Obesity What are We Doing About it?* (Jan. 24, 2006).

⁵⁰ Sheila R. Cohn, Director National Restaurant Association, *Away From Home Dining at IFT 2006 Midyear Symposium, Obesity What are We Doing About it?* (Jan. 24, 2006). Ruby Tuesday has a "Smart Eating Initiative," Burger King put its Nutrition Guide on line and prepared nutrition posters, Dairy Queen developed a low calorie, low fat ice-cream, Applebee's partner with Weight Watchers, etc.

⁵¹ *Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512 (S.D.N.Y. 2003).

⁵² *Id.*

⁵³ *Pelman v. McDonald's Corp.*, 396 F. Supp. 2d 439 (S.D.N.Y. 2005).

⁵⁴ See <http://www.cbs.com/stories/2004/03/03/health/main603735.shtml> (last visited Feb. 28, 2006).

⁵⁵ See McDonald's unveils nutrition labeling, available at www.foodfacts.info/blog/2006/02/mcdonalds-unveils-nutrition-labeling.html (last visited Feb. 28, 2006).

⁵⁶ See cspinet.org/new/pdf/Viacom_kellogg.pdf (last visited 02/28/2006) containing letter of intent and complaint that the Center of Science of Public Interest plans to file against Viacom and Kellogg unless defendants are willing to settle. Plaintiffs seek to prevent advertising of food products of poor nutritional quality directly, before, or after broadcasting of tv program for children.

Summary

Over the years, several paths were followed as government regulators responded to evolving nutritional issues in the United States. Responses ranged from enactment of new laws by Congress to rulemaking and public health policy activities by FDA. Diagram 1 offers a general overview of the various possible regulatory and legislative approaches to nutritional issues seen in the U.S. History shows that all such roads were traveled in the drive to allow health-related claims in labeling for foods and dietary supplements.

Recent actions directed at the obesity issue indicate that there remains a long road ahead in addressing this issue. Diagram 2 illustrates the actions on the obesity issue taken thus far. While the obesity issue has clearly attracted the attention of U.S. regulators, the FDA's activities remain in the very early stages. Whether Congress will feel compelled to intervene in FDA's rulemaking or FTC's investigation of food and beverage advertising remains to be seen. The food industry has altered new product development and labeling, and joined with nonprofit organizations to help fight obesity. Ongoing litigation by consumer activists may ultimately produce even more changes by the food industry.

Diagram 1. U.S. Regulatory and Legislative Responses to Nutritional

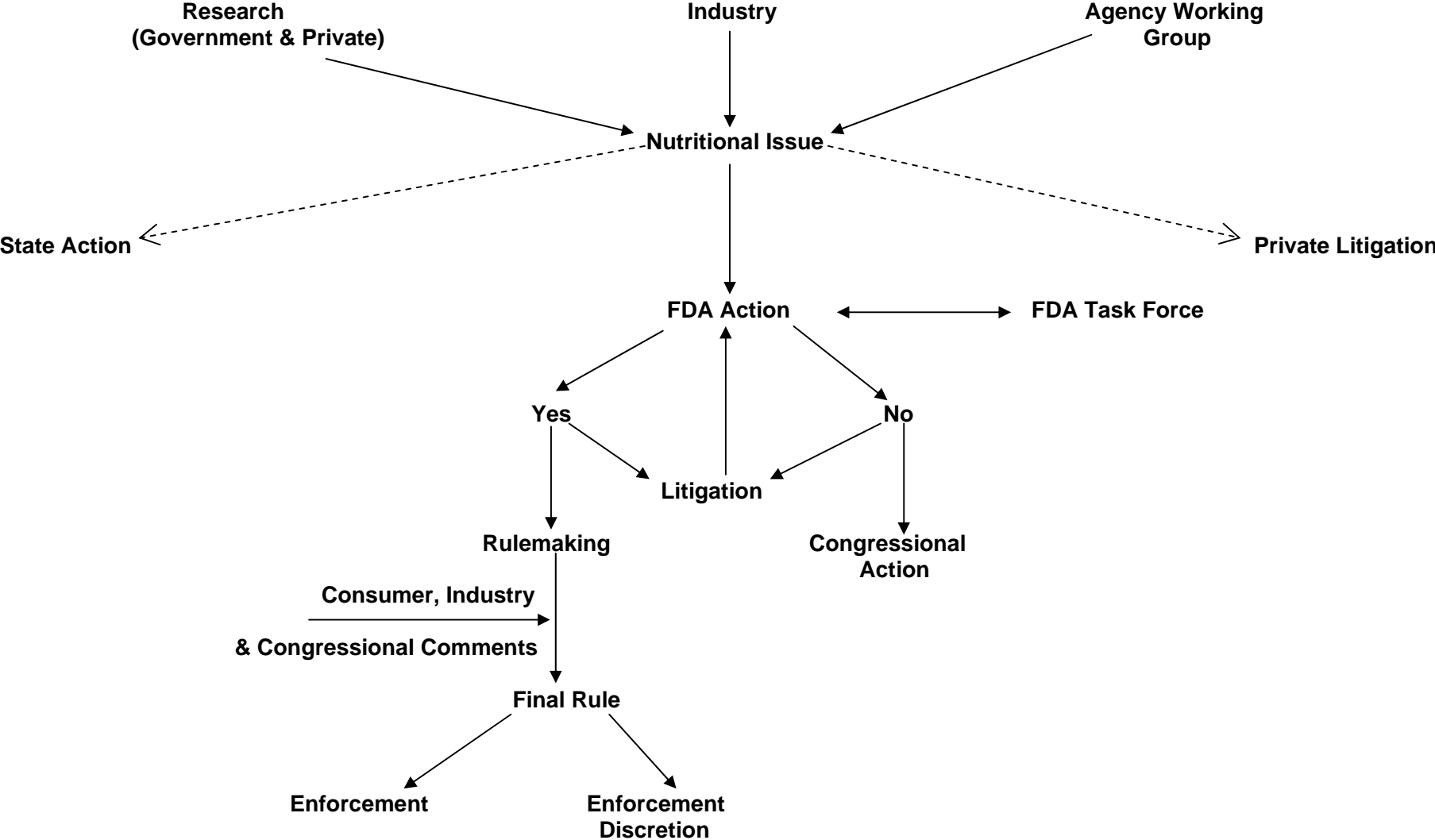


Diagram 2. The Obesity Issue

