

Food Law

January 2014

Syllabus

Adjunct Professor David Graham

Hamline University School of Law

General Course Information:

Credits: 2

Classroom: School of Law, Room 103

Time: January 6-9 and 13-16: 4:30 p.m. to 7:00 p.m. 7:00 M-Th

Professors: David Graham
Office Hours: please contact either of us by phone or email and make an appointment.

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Description:

Welcome to Food Law! This course will focus on the regulation of food by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). Students will learn about the statutory and regulatory framework related to these agencies and their interpretation and enforcement of related statutes and regulations and will gain insight into the agencies' decision-making processes and policies. In addition, we will discuss current food issues and news stories throughout the class term.

Course Materials:

Reading assignments are from the required text, FOOD AND DRUG LAW, Cases and Materials by Peter Barton Hutt, Richard Merrill, and Lewis Grossman (Foundation Press 3d Edition). Because

of the constantly changing legal environment, new regulations, articles and cases will be assigned and posted on TWEN from time to time.

Course Evaluation:

Subject to the caveat below regarding class preparedness, eighty percent of your course grade will be based on one, anonymous, final take-home examination, administered via TWEN, which shall include essay and objective questions. Pursuant to AR 105(B)(8): A student who does not take a scheduled examination will receive a grade of “F” for that examination unless properly excused.

Twenty percent of your grade will be based on an independent or group research project related to a current FDA or USDA regulatory issue. Topics will be assigned during the first week of class. Short presentations will be scheduled during class. Potential topics: labeling claims generally; nutrition facts; GMO influence (laws, labeling); gluten-free (impact on consumers, mfrs, labeling, economy); FSMA regulation(s); food safety – producers, restaurants, mfrs, transportation; litigation trends (natural, GMO, graphic representations/flavors, processing elements); pre-emption vs. primary jurisdiction; allergens; recalls/withdrawals; traceability; future of FDA; animal welfare (chickens, pigs, cows). Any student who does not turn in a required project on the scheduled date will receive a grade of “F” for that project, unless properly excused.

The caveat is that your course grade may be adjusted one-half of a letter (up or down) based on class preparedness in accordance with Hamline University School of Law Academic Rule 105. More specifically, we reserve the right to: 1) raise your course grade by one-half of a letter if you participate substantially when not called on or distinguish yourself when called on; or 2) lower your course grade by one-half of a letter if you are not prepared when called on. Your active participation in small group exercises will be assessed as part of your class preparedness.

Course Attendance:

At the beginning of each class, we will distribute a class roster for you to sign. If you are absent for more than 20 percent of our in-class minutes, your absences will be treated as “excessive” in accordance with Hamline University School of Law Academic Rule 108.

Bios and Disclaimer:

David P. Graham

When I am not teaching, I am a partner at Oppenheimer Wolff & Donnelly, LLP. My clients include food companies, including manufacturers, retailers and suppliers. I advise clients on a range of regulatory matters and litigation. Much of what I will be teaching about draws on my legal and practical knowledge of food law and food law organizations and the laws that impact them and the individuals they serve. However, all of the opinions I may express during this course are my own and do not represent the views of my firm or any of the firm’s clients.

Nancy Husnik

I am a Senior Legal Counsel at Target Corporation, focusing upon regulatory compliance. She advises in-house clients on Federal and State laws affecting Target's owned brand Food Safety, Quality Assurance and general FDA-related label claims. I support the Food Safety/Sanitation business units for Target's stores and distribution centers. Additionally, I work in the areas of Alcohol Licensing, Pricing Accuracy and ADA regulations affecting stores. Currently, I am the Vice-Chair of the Minnesota State Bar Association Food/Drug/Device Law section. I am a graduate of the University of Minnesota and William Mitchell College of Law, St. Paul, MN where I graduated *cum laude*. All the opinions I may express during this course are my own and do not represent the view of Target Corporation.

Learning Outcomes:

- Interpret statutes, regulations and agency guidance
- Demonstrate how to counsel clients involving food law issues
- Learn how to interact with regulators on behalf of a client
- Understand the structure and enforcement powers of the FDA and the USDA
- Apply understanding of the regulatory structure and new case law to representation of clients involved with preemption and fraud and false advertising challenges

Assignments:

This syllabus may be updated prior to the beginning and/or during the term, including changes to the research project described above.

Classes 1 and 2

Overview of the history of food regulations and the structure of the FDA and the USDA. Review the difference between the FDCA itself, regulations, and "guidance" documents. Review the Food Safety Modernization Act and its impact on food regulation enforcement. **Bring a news article on a recent food law issue involving the FDA to class.**

Reading: pages 3- 27, 1196-1241, 1262-1325, 1369-1370 and materials posted on TWEN including sections of the Food Safety Modernization Act.

Question to consider for the next day – Your client calls you. She wants to raise chickens organically for the meat and the eggs. She wants to know what she has to do differently to raise the chickens, harvest the eggs and be able to use the term "organic" on her food labels. Where will you look for applicable laws and regulations on the Federal and State levels? What types of laws will affect your client's proposed business operations?

Class 3

What is food and how would we know? What are standards of identity and why do they matter? Review the basic components of the Food Label. Begin discussing Nutrition Labeling. Discuss food advertising and food bans. How is the FTC involved in the regulation of food advertising? What is the difference between food advertising and food labeling? How does the First Amendment impact food advertising? Review verified (and unverified) health claims for foods under the FDCA and USDA regulations. Discuss terms such as “natural” and “fresh”. Discuss the labeling and regulations of “organic” foods and genetically modified organisms.

CLASS QUESTION: Your client manufactures “good for you” foods. They are looking at a new “natural” line. What kinds of questions do you ask to make a risk assessment so they can safely use that term?

Reading: pages 92-120; 130-143; 171-183; 198-218 and any materials posted on TWEN.

Class 4

Consider the laws that govern food additives. When should food additives be regulated as a food or as a drug? Discuss the Generally Recognized as Safe (GRAS) regulation scheme.

CLASS QUESTION: Your client has devised a food additive that really enhances the flavor and texture of their soup and wants to know if they can go ahead and use it in their manufacturing next month. What kinds of questions do you ask the client? Where should you look for applicable regulations or laws?

Reading: pages 393-411. GRAS regulations on TWEN.

Classes 5 and 6

Consider when food has been adulterated and what “adulterated” means: Unavoidable contaminants? Filthy substances? Discuss Good Manufacturing Practices and preventive controls. Discuss FDA’s expanded powers as a result of the Food Safety Modernization Act (FSMA). Discuss Food importation and international regulatory issues. How does foreign regulation affect food production and sales in the United States? How do we export our regulatory scheme?

Reading: pages 300-319; 326-334; 344-355; and 1242-1254 and 1261-1262 and materials and review FSMA on TWEN.

Class 7

Discussion of state and local regulation of food. Also, focus on the USDA and its powers and regulatory authority. A: (State Dept. of Health and Agriculture regulations; City and County permits; food safety training and documentation for your client’s employees; documentation

from your food vendors re: compliance with USDA and State regulations for meat; necessary food audits)

Discussion of regulation inspections and investigations; how they should be conducted and handled by business. Discussion of the limitations on regulatory authority and practical aspects of working with regulators.

CLASS QUESTION: You just received a panic call from your food manufacturing client indicating that FDA is inspecting their plant. Your client has had some mild food safety problems they are working on, but did not expect the inspection. What kinds of questions would you ask your client to see if they can survive the inspection without a negative impact from the FDA?

Class 8

Discuss food litigation as it relates to food contamination and labeling. Discuss food-borne illness outbreaks and how they are handled by regulators. Also discuss consumer fraud class actions related to food labeling.

Reading: Continuation from previous week. Article on TWEN regarding spinach outbreak.

Examine the recent case law on FDCA preemption of state law tort claims and primary jurisdiction involving food.

Reading: pages 1436-1454 and cases and materials posted on TWEN.

CLASS QUESTION: You know about many Federal laws affecting food now. Your client wants to know if they can sell certain locally-raised meats and deli products in their MN stores. Where do you look to answer your client's questions? What kinds of detailed questions should you ask your client?