

Fall 2008

Law 940: Law and Contemporary Problems

Transnational Regulation: Increasing the Safety of Globally Sourced Products

3 Credits

12:05-2:05 Thursdays

Room 2260 Law Building

Instructors: David M. Trubek with Stephanie Tai, Peter Carstensen
Vicki Bier, and Lorna Zach

Syllabus

This seminar will explore ways to increase the safety of products produced through global supply chains and imported into the United States and Europe. Recent incidents indicate that globally sourced products can create serious safety issues and present regulatory challenges. Imports from global supply chains cross several borders and their regulation is affected by both national and international law. To understand the special challenges of transnational regulation of this type, we will focus measures to ensure the safety of foodstuffs entering the US and EU markets with special attention to products originating in China. We will look at food safety law in the US, EU and China, explore such measures as improved testing and self-regulation by firms, better and more effective regulation by both exporting and importing countries, increased harmonization, and the role of the WTO and other global actors.

1) The Collaborative

The seminar is designed to help launch the Collaborative on **Managing Challenges of Import Safety in a Global Market** of the Center for World Affairs and the Global Economy (WAGE). The collaborative will conduct research on this topic over the next three years. It builds on expertise housed in the College of Engineering, Law School, School of Business, College of Agriculture and Life Sciences and the School of Human Ecology. It is led by Professors Vicki Bier (Industrial and Systems Engineering and Engineering Physics) and Stephanie Tai (Law) and will examine market, regulatory, and hybrid approaches to managing risk from contamination of food commodities in the global supply chain. Part of the goal of the seminar is to help the Collaborative team identify key issues for future research. As a result, the seminar represents an initial probe into many key issues and the faculty as well as the students may often be exploring new territory.

2) Faculty team and contact info

The faculty team includes Professors David M. Trubek, Stephanie Tai, Peter Carstensen, Vicki Bier and Scientist Lorna Zach from the Center for Human Performance and Risk Analysis. Professor Trubek serves as coordinator.

David Trubek, dmtrubek@wisc.edu, 233-0910
Peter Carstensen, pccarste@facstaff.wisc.edu, 263-7416
Stephanie Tai, tai2@wisc.edu, 890-1236
Vicki Bier, bier@engr.wisc.edu, 262-2064
Lorna Zach, lzach@engr.wisc.edu, 890-0987

3) Speaker series

The seminar is also linked to a speaker series sponsored by the Collaborative. Four public talks will be held during the semester and will form part of the seminar's regular sessions and students are expected to attend all the talks. Additional, optional talks will be held outside of class time, and students are welcome to attend.

4) Requirements for students

Students are expected to participate in all class sessions and in-class public talks, select a topic to specialize in, and prepare a paper on that topic. Papers should be between 15-20 pages and are due on December 5. In addition, students are expected to prepare at least 2 response papers during the semester. Students should try to do one response paper on the topic they will write on. Response papers for sessions in which we have an outside speaker should include questions for the speaker. Response papers should be 1-2 pages in length and must be sent to the class list 2 days in advance of the session. Students should be prepared to discuss their response papers in class. The class list address is law940-1-f08@lists.wisc.edu

5) Topics

Students are expected to select a topic relevant to the seminar on which to write their paper. Below is a list of the topics to be covered: students are expected to select their topic from this list but a student may ask permission to write on another topic if it is relevant to the theme of the seminar and they can show that there is a researchable subject. For each topic there are one or more faculty team members who can serve as the topic resource person and can be consulted for advice on papers in that topic. The topics and resources persons are:

EU Food Safety System – Trubek
US Food Safety System – Tai and Zach
Chinese Food Safety Law – Tai
Management-Based Regulation – Trubek
Risk-Based and Performance-Based Regulation – Bier and Zach
Private Governance I: The Role of the Firm – Bier and Zach
Private Governance II: Trade Associations – Carstensen
Torts – Carstensen
The World Trade Organization and the SPS Agreement – Trubek

Students should select topics as soon as possible and consult with the relevant resource persons concerning specific issues they might explore. Students wishing to write on a topic not on the list should seek permission from Professor Trubek. One page descriptions of proposed topic, along

with a short bibliography, should be sent to Professor Trubek by Friday October 3. Meetings to discuss the paper topics will be scheduled during the week of October 6.

6) Reserve Books

The following books are on reserve in the Law Library and are available for use by students.

Reba A. Carruth (Editor). *Global Governance of Food And Agriculture Industries: Transatlantic Regulatory Harmonization and Multilateral Policy Cooperation for Food Safety*. Edward Elgar Publishing (2006).

Raymond O'Rourke. *European Food Law*. Third Revised Edition. Butterworths Law (2005).

Ellen Vos and Frank Wendler. *Food Safety Regulation in Europe: A Comparative Institutional Analysis*. Intersentia Uitgevers (2007).

Joanne Scott. *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* Oxford University Press (2007).

Course Outline

September 4: Introduction

Heparin

David Wahlberg, *Heparin Crisis a Blow to Company*, WIS. ST. J., May 31, 2008, at A1.

David Barboza, *China Orders New Oversight of Heparin, With Tainted Batches Tied to U.S. Deaths*, N.Y. TIMES, Mar. 22, 2008, at A5.

Hepatitis in Onions

Christopher Snowbeck, *Hepatitis Outbreaks Spur FDA to Stop Onion Shipments from Mexican Suppliers*, PITTSBURGH POST-GAZETTE, Nov. 21, 2003.

Christopher Snowbeck, *Mexico Closes 4 Green Onion Exporters Government Calls Action a Precaution*, PITTSBURGH POST-GAZETTE, Nov. 25, 2003, at A1.

Press Release, U.S. Food & Drug Admin., FDA Update on Recent Hepatitis A Outbreaks Associated with Green Onions from Mexico (Dec. 9, 2003), <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00993.html>.

Mad Cow Disease

The Cow Who Stole Christmas; BSE in America, ECONOMIST, Jan. 3, 2004, at 29.

September 11: European Union Food Safety System

EUROPEAN COMM'N, DIRECTORATE-GEN. FOR PRESS AND COMM'N, *FROM FARM TO FORK: SAFE FOOD FOR EUROPE'S CONSUMERS* (2004).

ELLEN VOS & FRANK WENDLER, *Food Safety Regulation at the EU Level*, in *FOOD SAFETY REGULATION IN EUROPE: A COMPARATIVE INSTITUTIONAL ANALYSIS* (2006).

Stephen Castle, *Europe Fails to Endorse Milk and Meat from Clones*, N.Y. TIMES, July 25, 2008.

Additional Resources:

Commission White Paper on Food Safety, COM (1999) 719 final (Jan. 12, 2000).

Council Regulation 178/2002, 2002 O.J. (L31).

Council Regulation 882/2004, 2004 O.J. (L191).

Alberto Alemanno, *The European Food Safety Authority at Five*, 1 EUROPEAN FOOD AND FEED L. REV. 2 (2008).

RAYMOND O'ROURKE, EUROPEAN FOOD LAW (Butterworths Law 2005) (1999).

ELLEN VOS & FRANK WENDLER, *FOOD SAFETY REGULATION IN EUROPE: A COMPARATIVE INSTITUTIONAL ANALYSIS* (2007).

GLOBAL GOVERNANCE OF FOOD AND AGRICULTURE INDUSTRIES: TRANSATLANTIC REGULATORY HARMONIZATION AND MULTILATERAL POLICY COOPERATION FOR FOOD SAFETY (Reba A. Carruth ed., 2006).

September 18: United States Food Safety System

Part One: A U.S. Food Safety Primer

TRUST FOR AMERICA'S HEALTH, *FIXING FOOD SAFETY: PROTECTING AMERICA'S FOOD SUPPLY FROM FARM-TO-FORK* (2008).

U.S. FOOD & DRUG ADMIN, *FOOD PROTECTION PLAN: AN INTEGRATED STRATEGY FOR PROTECTING THE NATION'S FOOD SUPPLY* (2007).

Caroline Smith DeWaal, Dir. of Food Safety, Ctr. for Science in the Pub. Interest, Testimony before the Senate Committee on Health, Education, Labor, and Pensions (Dec. 4, 2007).

Part Two: A Case Study in Food Regulation

Sandra B. Eskin, *Putting All Your Eggs in One Basket: Egg Safety and the Case for a Single Food-Safety Agency*, 59 FOOD & DRUG L.J. 441 (2004).

Additional Resources:

U.S. FOOD & DRUG ADMIN. & U.S. DEP'T OF AGRIC., U.S. FOOD SAFETY SYSTEM (2000), <http://www.foodsafety.gov/~fsg/fssyst2.html>.

U.S. FOOD & DRUG ADMIN, FOOD SAFETY: A TEAM APPROACH (1998), <http://www.cfsan.fda.gov/~lrd/foodteam.html>.

Lorna Zach, Report Summary of Association of Food and Drug Officials (AFDO) Recall Workshop, 2008.

NEAL D. FORTIN, FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE (forthcoming 2008).

PETER B. HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS (Third Edition 2007).

VAND. . OF TRANSNAT'L L., Volume 40 (2007)

September 25: Alternative Forms of Regulation I – Management-Based Regulation

*Confirmed roundtable presentation by Cary Coglianese, Professor of Law,
University of Pennsylvania Law School*

Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, in REGULATION AND REGULATORY PROCESSES 423 (Cary Coglianese & Robert A. Kagan, eds., 2007).

Cary Coglianese, Jennifer Nash & Todd Olmstead, *Performance-Based Regulation: Prospects and Limitations in Health, Safety and Environmental Protection* (Harvard Univ. Faculty Research Working Paper Series, RWPO2-050, 2002).

Additional Resources:

Karen L. Hulebak & Wayne Schlosser, *Hazard Analysis and Critical Control Point (HACCP) History and Conceptual Overview*, 22 RISK ANALYSIS 547 (2002).

Karl Ropkins & Angus J. Beck, *Evaluation of Worldwide Approaches to the use of HACCP to Control Food Safety*, TRENDS IN FOOD SCI. & TECH., 2000, at 10.

October 2: Alternative Forms of Regulation II – Risk-Based and Performance-Based Regulation

Part One: Risk-Based Regulation

Vicki M. Bier & Rae Zimmerman, *Risk Assessment of Extreme Events* (Columbia-Wharton/Penn Roundtable on “Risk Management Strategies in an Uncertain World, 2002), available at http://www.ldeo.columbia.edu/chrr/documents/meetings/roundtable/white_papers/zimmerman_wp.pdf.

U.S. FOOD & DRUG ADMIN & U.S. DEP’T AGRIC., QUANTITATIVE ASSESSMENT OF RELATIVE RISK TO PUBLIC HEALTH (2003).

U.S. DEP’T AGRIC., RISK-BASED SAMPLING FOR ESCHERICHIA COLI 0157:H7 IN GROUND BEEF AND BEEF TRIM (2008), http://www.fsis.usda.gov/PDF/Ecoli_Sampling_RA_ExecSumm_Feb08.pdf

Douglas Powell, *Risk-Based Regulatory Responses in Global Food Trade: Guatemalan Raspberry Imports Into the U.S. and Canada, 1996-1998*, available at http://www.foodsafetynetwork.ca/articles/443/guatemalan_rasp_imports.pdf.

Warren Perry, *Putting the Teeth into Risk-Based Regulation*, RAJ PHARMA, Oct. 2007, at 681, http://www.qumas.com/files/QUMAS_RAJ_Pharma_10-1-07.pdf.

Part Two: Performance-Based Regulation

Review: Cary Coglianese, Jennifer Nash & Todd Olmstead, *Performance-Based Regulation: Prospects and Limitations in Health, Safety and Environmental Protection* (Harvard Univ. Faculty Research Working Paper Series, RWPO2-050, 2002).

Additional Resources:

Stephen D. Sugarman & Nirit Sandman, *Fighting Childhood Obesity Through Performance-Based Regulation of the Food Industry*, 56, 1403-1429 Duke L.J. (2007).

U.S. Food and Drug Administration, The Food Defect Action Levels, Levels of Natural or Unavoidable Defects in Foods That Present No Health Hazards For Humans, <http://vm.cfsan.fda.gov/~dms/dalbook.html>.

October 9: No Class

Students will meet individually with instructor to discuss final papers.

October 16: Private Governance I – Internal Company Management, Suppliers, and Trade Associations

YOSSI SHEFFI, *THE RESILIENT ENTERPRISE: OVERCOMING VULNERABILITY FOR COMPETITIVE ADVANTAGE* 3-34, 270-85 (2005).

John T. Hoffman & Shaun Kennedy, *International Cooperation to Defend the Food Supply Chain: Nations are Talking; Next Step—Action*, 40 *VAND. J. TRANSNAT'L L.* 1171 (2007).

Larry Margasak, *Food Industry Bitten by Its Lobbying Success*, ASSOCIATED PRESS, July 25, 2008.

GROCERY MANUFACTURERS ASSOCIATION, *FOOD SUPPLY CHAIN HANDBOOK* (2008).

Draft Conclusions and Recommendations, Pre-UNCTAD XII Event on Making Sustainability Standards Work for Small-Scale Farmers, Apr. 7-9, 2008

15 U.S.C. § 4301

October 23: Private Governance II – Internal Company Management, Suppliers, and Trade Associations

*Confirmed presentation by Dale Morton on the
“Management of International Suppliers at Quaker Oats”*

October 30: Food Safety in China

Confirmed presentation by Yuanyuan Shen, Brandeis University

David Barboza, *China Moves to Improve Quality of Its Seafood*, *N.Y. TIMES*, Dec. 28, 2007.

Ken DeWoskin, *The ‘Made in China’ Stigma Shock*, *FAR E. ECON. REV.*, Sept. 2007, at 9.

November 6: SPS Agreement

Confirmed presentation by Mike Firko, USDA APHIS

Agreement on the Application of Sanitary and Phytosanitary Measures.

Terence P. Stewart & Caryn Schenewerk, *The Conflict Between Facilitating International Trade and Protecting U.S. Agriculture from Invasive Species: APHIS, the U.S. Plant Protection Laws, and the Argentine Citrus Debate*, 13 *J. TRANSNAT'L L. & POL'Y* 305 (2004).

Additional Resources:

James F. Smith, *From Frankenfood to Fruit Flies: Navigating the WTO/SPS*, 6 U.C. DAVIS J. INT'L L. & POL'Y 1 (2000).

JOANNE SCOTT, *International Standards, in THE WTO AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES: A COMMENTARY* (2007).

November 13: Torts

Confirmed presentation by Denis Stearns, Marler Clark LLP

Denis W. Stearns, *Deadly Food and Product Liability: A Law-in-Action Perspective* (2008) (draft article).

Jean C. Buzby, *Paul D. Frenzen & Barbara Rasco, Product Liability and Microbial Foodborne Illness* (2001).

U.S. DEP'T OF AGRIC., *THE ECONOMICS OF FOOD SAFETY: THE CASE OF GREEN ONIONS AND HEPATITIS A OUTBREAKS* (2004).

Complaint, *Miller v. Castellini Co.* (W.D. Pa.) (No. 03-1838).

Chi-Chi's Inc. v. Sysco Corp., Arbitration Award.

Additional Resources:

Jean Caspers-Simmet, *Foodborne Illnesses Need to be Kept in Perspective*, AGRI NEWS, Jan. 29, 2008.

John Munsell, *Will the Real FSIS Please Stand Up?* MEATNEWS, June 28, 2006.

Lauren Neergaard, *Food Poisoning Can Be Long-Term Problem*, ASSOCIATED PRESS, Jan. 21, 2008.

UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, *FOOD SAFETY: USDA AND FDA NEED TO BETTER ENSURE PROMPT AND COMPLETE RECALLS OF POTENTIALLY UNSAFE FOOD* (October 2004).

November 20: Current Issues in the U.S. Congress

Confirmed presentation by Benjamin Cohen, Center for Science in the Public Interest

Readings to be determined.

Internet Resources

United States:

www.FoodSafety.gov, Gateway to Government Food Safety Information.

Centers for Disease Control and Prevention, Food Safety Office,
<http://www.cdc.gov/foodsafety/>.

U.S. Department of Agriculture, National Agriculture Library, Food and Nutrition Information Center, http://fnic.nal.usda.gov/nal_display/index.php?tax_level=1&info_center=4.

U.S. Department of Health and Human Services, <http://www.hhs.gov/>.

U.S. Environmental Protection Agency, <http://www.epa.gov/>.

U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition,
<http://www.cfsan.fda.gov/>.

European Union:

European Commission Directorate-General for Health and Consumers, Food Safety,
http://ec.europa.eu/food/index_en.htm

European Food Safety Authority (EFSA), http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm.

Activities of the European Union – Food Safety, http://europa.eu/pol/food/index_en.htm.

International Organizations:

World Health Organization, Food Safety, <http://www.who.int/foodsafety/en/>.

Food and Agricultural Organization (FAO), <http://www.fao.org/>.

Codex Alimentarius, http://www.codexalimentarius.net/web/index_en.jsp.

International Portal on Food Safety, Animal & Plant Health,
<http://www.ipfsaph.org/En/default.jsp>.

Speaker Biographies

Cary Coglianese

Cary Coglianese serves as Associate Dean and Edward B. Shils Professor of Law and Professor of Political Science at the University of Pennsylvania Law School. Mr. Coglianese specializes in the study of regulation and regulatory processes, with a particular emphasis on the empirical evaluation of alternative regulatory strategies and the role of disputing, negotiation, and business-government relations in regulatory policy making. He is the founder and co-chair of the Law & Society Association's international collaborative research network on regulatory governance, and he is a founding editor of the international, peer-reviewed journal, *Regulation & Governance*. His work has appeared in, among other journals, the *Administrative Law Review*, *Duke Law Journal*, *Law & Society Review*, *Michigan Law Review*, *University of Pennsylvania Law Review*, and *Stanford Law Review*.

Benjamin Cohen

Benjamin Cohen is a Senior Staff Attorney at the Center for Science in the Public Interest, a non-profit organization that seeks to educate the public, advocate for government policies that are consistent with scientific evidence on health and environmental issues, and counter industry's powerful influence on public opinion and public policies. Mr. Cohen offers commentary and analysis on U.S. food safety laws and has testified before committees of the United States House of Representatives.

Mike Firko

Mike Firko is Assistant Director of Biological and Technical Services for the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA), a service with a broad mission that includes protecting and promoting U.S. agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage management activities. In 2006, Mr. Firko accepted an Intergovernmental Solutions Award on behalf of APHIS from the American Council for Technology (ACT). The award recognized the ePermits system, an online verification tool which enhances the integrity and efficiency of the APHIS permits process.

R. Dale Morton

Dale Morton is the Director of Food Safety Programs for Quaker Tropicana Gatorade (QTG) and Pepsi Cola North America (PCNA). He is responsible for Crisis Management, HACCP, Thermal Processing, Sanitation, Quality Improvement and Quality Systems. Dale has a B.S. degree in Agriculture from Ohio University and a M.S. degree in Food Microbiology from University of Maryland. He started his career at the National Food Processors Association in the Microbiology and Thermal Processing area and then worked for Armour – Dial before moving to PepsiCo. Dale is a recognized Process Authority and has published work on inactivation of various spore-forming organisms in foods and beverages. He is a member of IFT, IAFF, IFTPS, and AFDO.

Yuanyuan Shen

Yuanyuan Shen is a Lecturer in Economics at Brandeis University and a Lecturer in Law at Harvard Law School. Ms. Shen is a graduate of the People's University in Beijing and Harvard Law School and holds a doctorate in law from the University of Wisconsin. She has written extensively on human rights and women's issues in contemporary China.

Denis Stearns

Denis W. Stearns is a principal in Marler Clark LLP. Mr. Stearns received an undergraduate degree in philosophy from Seattle University and a law degree from the University of Wisconsin Law School. As a trial attorney, Mr. Stearns has extensive experience with complex litigation, in both state and federal court. Notably, Mr. Stearns was one of the lead attorneys who represented Foodmaker Inc. in the widespread litigation that arose from the January 1993 Jack in the Box E. coli 0157:H7 outbreak. Mr. Stearns has also written several articles regarding product liability law and subjects related to foodborne illness litigation.