USC School of Pharmacy

RXRS 417: Food Safety: The Good, The Bad and The Deadly
Subject to change

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Office Location:
Office Hours: 1 hour before class (TBD)

Course Weight: 4 Units

Days/Time/Location: Wednesday: 2:00pm to 4:50pm, VKC 211

Introduction

Public policies and practices continue to intersect with consumer concerns regarding the safety of food ingredients. The future of food and farming are at a critical crossroads of feeding a growing population with diminishing natural resources (e.g., land, water, and energy). Genetically Modified Organisms (GMOs), natural, sugar, sodium, fat, food additives, food colors and flavors, processing technologies and organic continue to capture the consumers' attention. The concept of functional foods, also known as nutraceuticals, is a food product category not endorsed by the U.S. FDA, yet continues to appeal to consumers. Social media are contemporary drivers that expand consumer concerns, despite the evidence of safety, environmental compatibility, and health benefits. Within the United States, the 2011 Food Safety Modernization Act continues to be a significant factor in assuring the safety, affordability, accessibility, and nutritional quality of the food supply. This course will critically examine the quantity and quality of scientific evidence, health potential, policy implications and consumer responses in these and other food ingredients and foods "in the news." This course should have broad appeal to many USC undergraduates – and will certainly be attractive to individual hoping to pursue a career in any health care related profession, the pharmaceutical, food or dietary supplement industries or in consumer products and/or consumer protection.

Objectives

Upon successful completion of this course, the student should be able to demonstrate a working knowledge of:

- the fundamental principles of food safety assessment
- the dynamic regulatory environment that impacts global food safety
- the safety practices within agriculture
- the basic of microbial factors that affect food safety applied to produce and dairy products
- the important attributes of risk assessment and its management

Textbooks: There is not a textbook for this course.

Required Background Readings:

- World Food Programme, 2015 (https://www.wfp.org/hunger/malnutrition)
- Future of Food and Farming, 2011 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/288329/11-546-future-of-food-and-farming-report.pdf)
- Code of Federal Regulations, Title 21 (Food Additive Sections 182, 184, 186) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm)
- Global Food Safety Initiative, 2000 (http://www.mygfsi.com/)
- Food Safety Modernization Act, 2011 (http://www.fda.gov/Food/GuidanceRegulation/FSMA/)

Assignments and Grading:

Class participation:	20 pts (5%)
9 quizzes @ 10 pts each plus	100 pts (15%)
1 GRAS Take Home worksheet @10 pts	
2 midterm exams @ 100 pts each:	200 pts (30%)
1 final exam @ 100 pts	100 pts (10%)
Classroom project:	200 pts (40%)
Total:	620 pts (100%)

Final Exam:

Friday December 9 from 2 to 4 pm (set by the University)

Letter Grading:

Students will be assessed based on the following Grading Scale:

Letter Grade:	Percentage:
A	≥ 93%
A -	90% ≥ 92.9%
B +	87% ≥ 89.9%
B	83% ≥ 86.9%
B -	80% ≥ 82.9%
C +	77% ≥ 79.9%
C	73% ≥ 76.9%
C -	70% ≥ 72.9%
D	≤ 69.9%

Participation:

You are expected to arrive on time, remain for the entire class period, and to engage in active, thoughtful, respectful class participation. Class participation will be based on active engagement in class; students arriving significantly late to class will not receive participation credit. No excuses will be accepted, including: illness, interviews, or schedule conflicts.

Topical Required Readings:

These readings will be provided for identified topics and class presentations (see topical readings in the

agenda below). Students are expected to come to class prepared to discuss the assigned reading for that day. During class, students are expected to be prepared to discuss important points from the topical readings, and to ask questions if there is something you do not understand from the readings or class discussions. Participation levels in class discussion are student-determined, but those expecting to excel in this course will take the time to both read and analyze the assigned reading material.

Deliverables:

Presentations, papers and exams must be completed on the day that they are scheduled for submission. Failure to make appropriate arrangements in case of justifiable delay will result in a penalty of 10% in the assigned mark.

Presentation & Critical Review Deliverables:

The presentation and critical review (<2500 words plus cover page, abstract, table(s), graph(s) and references based on APA 6th Edition style [http://www.lib.jjay.cuny.edu/research/apastyle1.pdf]) will address one of the following questions. Other questions may be posed by student groups. Your presentation and critical review must be evidence-based with a foundation in food safety assessment. The presentation and accompanying paper will be products of groups. There may be no more than 4 people in a group.

- How should safety assessment "natural" be defined as applied to food and food ingredients?
- What are the food safety implications with respect to the GRAS process within the USA?
- How should ingredient safety be assessed relative to ingredients for personal care and cosmetics?
- Should there be differences in safety assessment standards for food ingredients vs food flavors?
- What criteria should be considered in assessing ingredient safety and chronic exposure?
- Should standard safety assessment criteria be modified when evaluating nanomaterials intended for food applications?
- What are the social and safety implications associated with food fraud?

Final Examination:

The final exam will be administered according the university policy. The format will include a variety of required responses, including multiple choice, completion and essay. The multiple choice and completion questions will be based on all course materials (lectures and readings). The essay questions will address current and emerging global nutrition issues. Students may use all class and electronic resources. Each resource must be appropriately cited juxtaposed to the response.

The exam will be posted on blackboard the last week of class and sent to each student. The completed exam must be submitted to blackboard AND to the course instructor (clemens@usc.edu) consistent with university final exam policy. Please format MSWord file titles with your last name, initial, course number and submission name, for example:

Washington_G_RXRS_417_Final_Exam. Also, be sure to include your name (last name, first name), the course number and title as a header on each page. Add the completion date juxtaposed to the page number on the bottom right of each page.

Additional Policies:

Policy on Late Work and Absence from Classes:

Make-up exams will only be offered prior to regularly scheduled exams, except in the case of documented personal/family emergencies. In these exceptional cases, appropriate documentation (for example, a note from a physician or counselor) is required for a student to make-up a missed exam. All other work is expected to be turned in on time, so please plan accordingly.

Controversy and Respect:
This course covers a wide range of cultural issues, some of which may be controversial. You are expected to be courteous and respectful to fellow students, professors, and guest speakers.

Midterm Exam Materials:
Notes, books, calculators, electronic dictionaries, regular dictionaries, cell phones or any other aids are not allowed during exams.

For all exams, bring a #2 pencil; Scantrons will be provided.

Course Evaluation:
You will be asked to complete an anonymous critical evaluation of the course at its completion.

Topical Readings:

These readings will be noted in the course agenda.

Course Format:

This course will be in the format of a directed seminar/lecture under the guidance of the instructor for the specific session. During each weekly session the instructor will engage you with questions and draw comments or interpretations primarily based on the assigned reading. You are expected to ask questions and participate in an interactive fashion.

Course agenda is as follows:

Week & Date	Topic	Assigned Readings
Week 1 Aug 24	Introduction: expectations and goals of this class. General overview of domestic and global food safety initiatives	Food Safety Modernization Act, 2011 (see website) Food Standards of Australia and New Zealand, 2014-15 (http://www.foodstandards.gov.au/publications/annualreport201415/Pages/Annual%20Report%202014-2015.aspx)
Week 2 Aug 31	Quiz 1 Food Safety in Developing Countries Produce Safety and Agricultural Water	Food Safety and Agricultural Health Standards, World Bank 2005 (http://siteresources.worldbank.org/INTRANETTRADE/Resources/Topics/Standards/standards_challenges_synthesisreport.pdf) Produce Safety Rule and Agricultural Water (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm; http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM360242.pdf)
Week 3 Sept. 7	Quiz 2 Introduction to food microbiology Introduction to Risk Analysis and Management	FDA Food microbiological standards (https://fsrio.nal.usda.gov/sanitation-and-quality-standards/microbiological-standards-and-guidelines) Olaimat & Holley. Food Microbiol 2012;32:1-19 Ledenbach & Marshall. Microbiological spoilage of dairy products, Food Microbiology and Food Safety, 2009 FAO, Introduction to risk analysis – basic principles of risk assessment, risk management and risk communication, 2010 (http://www.fao.org/fileadmin/user_upload/Europe/documents/Events_2010/GMO2010/RiskA_en.pdf) Manitoba, Introduction to risk analysis in agriculture (https://www.gov.mb.ca/agriculture/food-safety/at-the-food-processor/intro-to-risk-analysis.html) JIFSAN, Food risk, 2011 (http://foodrisk.org/ra/)
Week 4 Sept. 14	Quiz 3 Principles of Toxicology and Human Safety Assessment	Guidance for industry – Toxicological principles for the safety assessment of food ingredients; Redbook 2000. (http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM222779.pdf)
Week 5 Sept. 21	**Midterm 1**	
Weeks 5 & 6 Sept. 21 & Sept. 28	Quiz 4 Assessment of plant diseases and disease management	Teng PS, Annu Rev Phytopathol 1993;31:495-521 Mahlein et al., Eur J Plant Pathol 2010;133:197-209

Week & Date	Topic	Assigned Readings
Weeks 6-7 Sept. 28, Oct. 5	Quiz 5 Understanding plant protection practices in agriculture	FAO, Integrated Pest Management (http://www.fao.org/agriculture/crops/thematic-sitemap/theme/spi/scpi-home/managing-ecosystems/integrated-pest-management/ipm-how/en/) FAO, Plant Protection http://www.fao.org/ag/save-and-Grow/en/6/index.html) Aktar et al., Interdisc Toxicol 2009;2:1-12
Week 8 Oct. 12	Quiz 6 Introduction to environmental safety assessment	International Conference on Harmonization (Safety: http://www.ich.org/products/guidelines/safety/article/safety-guidelines.html) EPA Report on the Environment (2014) (http://cfpub.epa.gov/roe/) Human Exposure and Health (2014) (http://cfpub.epa.gov/roe/chapter/health/index.cfm)
9 – Oct 19	**Midterm 2**	
Weeks 9-10 Oct. 19, Oct. 26	GMO – Safety assessment and public policy	FDA GMO Labeling Guidance (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm) FDA GMO Safety Regulations (http://www.fda.gov/Food/FoodScienceResearch/GEPlants/default.htm)
Week 11 Nov. 2	Quiz 7 Food colorants – safety and application	Barrows JN, Lipman AL, Bailey CJ. Color Additives: FDA's Regulatory Process and Historical Perspectives. FDA (Reprinted from Food Safety Magazine October/November 2003 issue). 17 December 2009. (http://www.fda.gov/ForIndustry/ColorAdditives/RegulatoryProcessHistoricalPerspectives/default.htm) Food Standards Authority, Food Colours and Hyperactivity. (https://www.food.gov.uk/science/additives/foodcolours) McCann et al., The Lancet 2007;370(9598):1560-7
Week 12 Nov. 9	Quiz 8 Food additives – safety and application	FDA Food Additives and Ingredients (http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/default.htm) Look at chemistry, toxicology, microbiology and environmental guidances.
Week 13 Nov. 16	Quiz 9 Controversies among sugars and non-nutritive sweeteners	USDA Nutritive and non-nutritive sweetener resources (https://fnic.nal.usda.gov/food-composition/nutritive-and-nonnutritive-sweetener-resources)
14 Nov 23 (**No class per USC policy**)	(Take Home Quiz available online; Self-review of GRAS; Worksheet Assignment)	Material to be "completed" outside of class: FDA GRAS Guidance (http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/) FDA GRAS Notice Inventory (http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm)
15 Nov 30	Classroom Presentations	Students; Presentations and Papers due at the beginning of this session
Dec 9		FINAL EXAM; 2- 4 pm

Statement on Academic Conduct and Support Systems

Academic Conduct
Plagiarism – presenting someone else's ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in *SCampus* in Section 11, *Behavior Violating University Standards* https://scampus.usc.edu/1100-behavior-violating-university-standards-and-appropriate-sanctions. Other forms of academic dishonesty are equally unacceptable. See additional information in *SCampus* and university policies on scientific misconduct, http://policy.usc.edu/scientific-misconduct.

Discrimination, sexual assault, and harassment are not tolerated by the university. You are encouraged to report any incidents to the *Office of Equity and Diversity* http://equity.usc.edu or to the *Department of Public Safety* http://capsnet.usc.edu/department/department-public-safety/online-forms/contact-us. This is important for the safety of the whole USC community. Another member of the university community – such as a friend, classmate, advisor, or faculty member – can help initiate the report, or can initiate the report on behalf of another person. *The Center for Women and Men* http://www.usc.edu/student-affairs/cwm/ provides 24/7 confidential support, and the sexual assault resource center webpage http://sarc.usc.edu describes reporting options and other resources.

Support Systems
A number of USC's schools provide support for students who need help with scholarly writing. Check with your advisor or program staff to find out more. Students whose primary language is not English should check with the *American Language Institute* http://dornsife.usc.edu/ali, which sponsors courses and workshops specifically for international graduate students. *The Office of Disability Services and Programs* http://sait.usc.edu/academicsupport/centerprograms/dsp/home_index.html provides certification for students with disabilities and helps arrange the relevant accommodations. If an officially declared emergency makes travel to campus infeasible, *USC Emergency Information* *http://emergency.usc.edu* will provide safety and other updates, including ways in which instruction will be continued by means of blackboard, teleconferencing, and other technology.

Emergency Preparedness/Course Continuity:
In case of emergency, and travel to campus is difficult, USC executive leadership will announce an electronic way for instructors to teach students in their residence halls or homes using a combination of Blackboard, teleconferencing, and other technologies. Instructors should be prepared to assign students a "Plan B" project that can be completed at a distance. For additional information about maintaining your classes in an emergency please access: http://cst.usc.edu/services/emergencyprep.html