

USC Mann

Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences

Fall 2023: RXRS 417 – Food Safety: The Good, The Bad, and The Deadly

Course Weight: 4 Units

Instructor(s):

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Course Coordinator:

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Day/Time/Location:

Tuesday/Thursday, 11 am to 12:20 pm, HED 103

Catalog Description:

Critical thinking, science translation, effective communications, personal health, and public policy development are at the interface of food safety, nutrition intervention and health controversies.

Introduction:

Public policies and practices continue to intersect with consumer concerns regarding the safety of food ingredients. The future of food and farming is at a critical crossroads in 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 to 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 individuals hoping to pursue a career in any healthcare-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 microbial factors that affect food safety applied to produce and dairy products
- the important attributes of risk assessment and its management

Deliverables, Evaluation, and Grading:

Class participation	20 pts (5%)
Four quizzes @ 20 pts each	80 pts (15%)
2 midterm exams @ 100 pts each	200 pts (30%)
1 final exam @ 100 pts	100 pts (20%)
Classroom project:	200 pts (30%)
Total:	600 pts (100%)

Letter Grading:

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.

Course 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/288329/1-546-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/>)

Topical Required Reading:

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 they do not understand from the readings or class discussions. Participation levels in-class discussions 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 the 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 a take-home experience. 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 (APA6) and juxtaposed with the response.

The exam will be posted on Blackboard during the last week of class and sent to each student. The completed exam must be posted on Blackboard AND submitted to the course instructor (clemens@usc.edu) consistent with university final exam requirements. Please format MSWord file titles with your last name, initial, course number, and submission name, for example, **Washington_G_MEDS_567_Takehome_Exam**. Also, be sure to include your name (last name, first name), the course number, and the title as a header on each page. Add the completion date juxtaposed to the page number on the bottom right of each page.

Course Outline

Fall 2023 Course Outline: Tuesday/Thursday

Week	Date	Topic	Assigned Readings
Week 1	Tues. Aug. 22	Introduction: expectations and goals of this class. Food safety in the news	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 1	Thur. Aug. 24	General overview of domestic and global food safety initiatives	
Week 2	Tues. Aug. 29	Food Safety in Developing Countries	Food Safety and Agricultural Health Standards, World Bank 2005 (http://siteresources.worldbank.org/INTRANETTRADE/Resources/TOPICS/Standards/standards_challenges_synthesisreport.pdf)
Week 2	Thur. Aug. 31	Produce Safety and Agricultural Water	Produce Safety Rule and Agricultural Water (http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm ; http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM3_60242.pdf)
Labor Day, University Holiday, Monday, September 4, 2023			
Week 3	Tues. Sept. 5	Quiz 1 Introduction to food microbiology	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
Week 3	Thur. Sept. 7	Introduction to Risk Analysis and Management	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/Event_s_2_010/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	Tues. Sept. 12	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 4	Thur. Sept. 14	Principles of Toxicology and Human Safety Assessment	
Week 5	Tues. Sept. 19	Quiz 2 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 5	Thur. Sept. 21	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	Date	Topic	Assigned Readings
Week 6	Tues. Sept. 26	Midterm 1	
Week 6	Thur. Sept. 28	Produce Safety Introduction to soil science and food safety	FSMA Final Rule on Produce Safety: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety Zhu YG. Soil science in the understanding of the security of food systems for health. Asia Pac J Clin Nutr. 2009;18(4):516-9. Pozza LE & Field DJ. The science of Soil Security and Food Security, Soil Security, 2020; https://doi.org/10.1016/j.soisec.2020.100002 . Brevik et al. Assessing the Complex Links Between Soils and Human Health: An Area of Pressing Need. Front Soil Sci. 2021; https://doi.org/10.3389/fsoil.2021.731085
Week 7	Tues. Oct. 3	Introduction to environmental safety assessment	EPA Report on the Environment (2014) (http://cfpub.epa.gov/roe/)
Week 7	Thur. Oct. 5	Harmonization of food safety recommendations	International Conference on Harmonization (Safety: http://www.ich.org/products/guidelines/safety/article/safety-guidelines.html) Human Exposure and Health (2014) (http://cfpub.epa.gov/roe/chapter/health/index.cfm)
Week 8	Tues. Oct. 10	Quiz 3 Food additives – safety and application	FDA Food Additives and Ingredients (http://www.fda.gov/food/ingredientpackaginglabeling/foodadditivesingredients/default.htm) Look at chemistry, toxicology, microbiology and environmental guidances.
Fall Recess, Thursday, Oct. 12 to Friday, Oct. 13, 2023			
Week 9	Tues. Oct. 17	Genetic Literacy: GMO & CRISPR – Safety assessment and public policy	FDA GMO Labeling Guidance (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm)
Week 9	Thurs. Oct. 19	Genetic Literacy: GMO & CRISPR – Safety assessment and public policy	FDA GMO Safety Regulations (http://www.fda.gov/Food/FoodScienceResearch/GEPlants/default.htm)
Week 10	Tues. Oct. 24	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)

Week	Date	Topic	Assigned Readings
Week 10	Thurs. Oct. 26	Safety of Food Flavors	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 Adams TB, Smith RL. Issues and challenges in the safety evaluation of food flavors. Toxicol Lett. 2004;149(1-3):209-13. doi: 10.1016/j.toxlet.2003.12.032 Smith et al. Expert Panel of the Flavor and Extract Manufacturers Association. Criteria for the safety evaluation of flavoring substances. The Expert Panel of the Flavor and Extract Manufacturers Association. Food Chem Toxicol. 2005 Aug;43(8):1141-77. doi: 10.1016/j.fct.2004.11.012.
Week 11	Tues. Oct. 31	California & New York ban food additives	California and New York Could Ban 5 Food Additives Linked to Health Concerns - The New York Times (nytimes.com) FDA Bans 7 Cancer-Causing Food Additives Found in Popular Foods Environmental Working Group (ewg.org)
Week 11	Thurs. Nov. 2	Midterm 2	
Week 12	Tues. Nov. 7	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)
Week 12	Thurs. Nov. 9	Controversies among dietary fats	USDA Dietary Guidelines (2015-2020 & 2020-2025)
Week 13	Tues. Nov. 14	Food Safety-Real World Experiences Guest: Greg Pincar	
Week 13	Thurs. Nov. 16	Generally Recognized as Safe (GRAS) – Ingredient safety criteria	FDA GRAS Guidance (http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/)
Week 14	Tues. Nov. 21	Quiz 4 Dietary Supplements and NDIN	FDA GRAS Notice Inventory (http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm)
Thanksgiving Holiday, Wednesday, Nov. 22 to Sunday, Nov. 26, 2023			
Week 15	Tues. Nov. 28	Classroom Presentations	Students; Presentations and Papers due at the beginning of this session
Week 15	Thurs. Nov. 30	Course Review	Practicum: Sensory Experiences Course Review
Fri. December, 1: Last Day of the Fall Semester			
Saturday, December 2 to Tuesday, December 5, 2023 – Study Days			
FINAL EXAM: Tuesday, December 12, 2023 - 8-10 am			

Course Content Distribution and Synchronous Session Recordings Policies

USC has policies that prohibit the recording and distribution of any synchronous and asynchronous course content outside of the learning environment. Recording a university class without the express permission of the instructor and announcement to the class, or unless conducted pursuant to an Office of Student Accessibility Services (OSAS) accommodation. Recording can inhibit free discussion in the future, and thus infringe on the academic freedom of other students as well as the instructor. ([Living our Unifying Values: The USC Student Handbook](#), page 13).

Distribution or use of notes, recordings, exams, or other intellectual property, based on university classes or lectures without the express permission of the instructor for purposes other than individual or group study. This includes but is not limited to providing materials for distribution by services publishing course materials. This restriction on unauthorized use also applies to all information, which had been distributed to students or in any way had been displayed for use in relation to the class, whether obtained in class, via email, on the internet, or via any other media. ([Living our Unifying Values: The USC Student Handbook](#), page 13).

Academic Integrity:

The University of Southern California is foremost a learning community committed to fostering successful scholars and researchers dedicated to the pursuit of knowledge and the transmission of ideas. Academic misconduct is in contrast to the university's mission to educate students through a broad array of first-rank academic, professional, and extracurricular programs and includes any act of dishonesty in the submission of academic work (either in draft or final form).

This course will follow the expectations for academic integrity as stated in the [USC Student Handbook](#). All students are expected to submit assignments that are original work and prepared specifically for the course/section in this academic term. Students may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s). Students may not submit work prepared by AI sources. Students suspected of engaging in academic misconduct will be reported to the Office of Academic Integrity.

Other violations of academic misconduct include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

For more information about academic integrity see the [student handbook](#) or the [Office of Academic Integrity's website](#), and university policies on [Research and Scholarship Misconduct](#).

Students and Disability Accommodations:

USC welcomes students with disabilities into all of the University's educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at osas.usc.edu. You may contact OSAS at (213) 740-0776 or via email at osasfrontdesk@usc.edu.

Support Systems:

Counseling and Mental Health - (213) 740-9355 – 24/7 on call

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

988 Suicide and Crisis Lifeline - 988 for both calls and text messages – 24/7 on call

The 988 Suicide and Crisis Lifeline (formerly known as the National Suicide Prevention Lifeline) provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week, across the United States. The Lifeline is comprised of a national network of over 200 local crisis centers, combining custom local care and resources with national standards and best practices. The new, shorter phone number makes it easier for people to remember and access mental health crisis services (though the previous 1 (800) 273-8255 number will continue to function indefinitely) and represents a continued commitment to those in crisis.

Relationship and Sexual Violence Prevention Services (RSVP) - (213) 740-9355(WELL) – 24/7 on call

Free and confidential therapy services, workshops, and training for situations related to gender- and power-based harm (including sexual assault, intimate partner violence, and stalking).

Office for Equity, Equal Opportunity, and Title IX (EEO-TIX) - (213) 740-5086

Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

Reporting Incidents of Bias or Harassment - (213) 740-5086 or (213) 821-8298

Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

[The Office of Student Accessibility Services \(OSAS\)](#) - (213) 740-0776

OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

[USC Campus Support and Intervention](#) - (213) 740-0411

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

[Diversity, Equity and Inclusion](#) - (213) 740-2101

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

[USC Emergency](#) - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call

Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

[USC Department of Public Safety](#) - UPC: (213) 740-6000, HSC: (323) 442-1200 – 24/7 on call

Non-emergency assistance or information.

[Office of the Ombuds](#) - (213) 821-9556 (UPC) / (323-442-0382 (HSC)

A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

[Occupational Therapy Faculty Practice](#) - (323) 442-2850 or otfp@med.usc.edu

Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.