

USC School of Pharmacy

Pharmacy Undergraduate Programs

Fall 2022: RXRS-417, Food Safety: The Good, The Bad and The Deadly

Instructors

Roger Clemens, DrPH

Adjunct Professor, Pharmacology and Pharmaceutical Sciences

University of Southern California

clemens@usc.edu

Cell: (818) 624-2616

UPC office location is Stonier Hall 312 (STO 312)

Office Hours TBA

Daryl Davies, PhD

Professor, Department of Clinical Pharmacy

ddavies@usc.edu

Office: (323) 442-1427

HSC Office: PSC 528; USC Mail Code: MCA-9121

UPC Office: Stonier Hall 312

Office Hours: TBA

Course Coordinator

Randa Issa, PhD

Academic Program Manager, Undergraduate Programs

rissa@usc.edu

Office: (323) 442-2018

Course Weight: 4 Units

Day/Time/Location:

Tuesday/Thursday 11:00 AM to 12:20 PM, Social Sciences Building (SOS) B45

Enrollment Details:

Session – 001; Section – 49247

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

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:

Classmate evaluation:	20 pts (5%)
Ten quizzes*	100 pts (15%)
2 midterm exams @ 100 pts each:	200 pts (30%)
1 final exam @ 100 pts	100 pts (10%)
<u>Classroom project:</u>	<u>200 pts (40%)</u>
Total:	610 pts (100%)

* The quiz points will vary throughout the term. Thus, your performance percentage on the quizzes will be adjusted to 100 pts (still accounting to 15% of the grade)

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.

Participation includes asking and answering questions and being actively involved in the discussion. Students are encouraged to express freely their opinions on the topics that are discussed, being ready to articulate their reasoning in a collegial and constructive manner that incites discussion; taking into consideration all sides of a story with an open mind, given them tools to reassess dogma or preconceived ideas if applicable.

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 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 and 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 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 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.

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.

The course agenda is as follows:

Week & Date	Topic	Assigned Readings
Week 1 Aug 23	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/Page%20Annual%20Report%202014-2015.aspx)
Week 1 Aug 25	General overview of domestic and global food safety initiatives	
Week 2 Aug 30	Quiz 1 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 Sep 1	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)
Week 3 Sep 6	Quiz 2 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 Sep 8	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/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 Sep 13	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 4 Sep 15	Principles of Toxicology and Human Safety Assessment	
Week 5 Sep 20	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 Sep 22	Quiz 4 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 Sep 27	Midterm 1 (Proctored by Dr. Church) Observance: Rosh Hashana	
Week 6 Sep 29	Dr. Clemens will be in Mexico City; Guest speaker: Karina Rodriguez Produce Safety Introduction to soil science and food safety REMOTE	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 Oct 4	Quiz 5 Introduction to environmental safety assessment	EPA Report on the Environment (2014) (http://cfpub.epa.gov/roe/)
Week 7 Oct 6	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 Oct 11	Quiz 6 Food additives – safety and application (Observance: Sukkot)	FDA Food Additives and Ingredients (http://www.fda.gov/food/ingredientpackaginglabeling/foodadditivesingredients/default.htm) Look at chemistry, toxicology, microbiology and environmental guidances.
Week 8 Oct 13	USC Fall Recess No Classes	
Week 9 Oct 18	GMO & CRISPR – Safety assessment and public policy (Observance: Shemini Atzeret)	FDA GMO Labeling Guidance (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm)
Week 9 Oct 20	GMO & CRISPR – Safety assessment and public policy	FDA GMO Safety Regulations (http://www.fda.gov/Food/FoodScienceResearch/GEPlants/default.htm)
Week 10 Oct 25	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)
Week 10 Oct 27	Dr. Clemens in Singapore Safety of Food Flavors Lecture embedded in PowerPoint presentation	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 & Date	Topic	Assigned Readings
Week 11 Nov 1	Quiz 8 Dr. Clemens in Singapore Guest Speaker: Karina Rodriguez Food Quality Management System	USDA: https://www.usda.gov/our-agency/about-usda/laws-and-regulations/quality-assurance FDA: CFSAN Laboratory Quality Assurance Manual - https://www.fda.gov/media/79152/download
Week 11 Nov 3	Midterm 2 (Proctored by Dr. Church)	
Week 12 Nov 8	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 Nov 10	Controversies among sugars and non-nutritive sweeteners	
Week 13 Nov 15	Quiz 9 Generally Recognized as Safe (GRAS) – Ingredient safety criteria	FDA GRAS Guidance (http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/) FDA GRAS Notice Inventory (http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm)
Week 13 Nov 17	Dietary Supplements and NDIN Safety Assessment	
Week 14 Nov 22	Quiz 10 Food safety and consumer perceptions Food safety and emerging technologies	Zanetta et al. What Motivates Consumer Food Safety Perceptions and Beliefs? A Scoping Review in BRICS Countries. <i>Foods</i> . 2022;11(3):432. doi: 10.3390/foods11030432. Food Standards Agency, 2020; https://www.nal.usda.gov/research-tools/food-safety-research-projects/consumer-attitudes-towards-emerging-technologies
Week 14 Nov 24	Thanksgiving Recess November 23 through November 26. No class on November 24, 2022	
Week 15 Nov 29	Classroom Presentations	Students; Presentations and Papers due at the beginning of this session
Week 15 Dec 1	Course Review	Course Review
<i>Final Exam: Tuesday, December 13, 2022, from 8 to 10 AM</i>		

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 Part B, Section 11, “Behavior Violating University Standards” policy.usc.edu/scampus-part-b. Other forms of academic dishonesty are equally unacceptable. See additional information in SCampus 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
studenthealth.usc.edu/counseling

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

National Suicide Prevention Lifeline - 1 (800) 273-8255 – 24/7 on call
suicidepreventionlifeline.org

Free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week.

Relationship and Sexual Violence Prevention Services (RSVP) - (213) 740-9355(WELL), press “0” after hours – 24/7 on call
studenthealth.usc.edu/sexual-assault

Free and confidential therapy services, workshops, and training for situations related to gender-based harm.

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

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
usc-advocate.symplcity.com/care_report

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.usc.edu

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) 821-4710
campussupport.usc.edu

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
diversity.usc.edu

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
dps.usc.edu, emergency.usc.edu

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) 442-120 – 24/7 on call
dps.usc.edu

Non-emergency assistance or information.

Office of the Ombuds - (213) 821-9556 (UPC) / (323-442-0382 (HSC)
ombuds.usc.edu

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) 442-3340 or otfp@med.usc.edu
chan.usc.edu/otfp

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