

NFS 253
Food Regulation – An Online Course
Fall 2019

Instructor: Dr. Stephen J. Pintauro
Associate Professor Emeriti
Phone: 802-598-8551
email: stephen.pintauro@uvm.edu

Office Hours: I work from home. But if necessary, I can arrange to meet at UVM, by appointment.

Course Prerequisite: NFS 153, or equivalent course or training with instructor permission.

Course Objectives: The objective of this course is to have you gain a thorough understanding of the extent, applicability, and flexibility of United States food laws and regulations, and their relationships to the safety of the US food supply. Over the course of the semester, we will focus on the structure of the federal government, how laws and regulations are enacted and enforced, detailed examination of selected food regulation topics, and how the food safety decision-making process works within the framework of the associated federal laws and regulations.

The specific objectives of the course can be assigned “levels of learning” according to the hierarchical classification system known as Bloom’s Taxonomy. There are six “levels of learning” comprising this classification system, with learning at the higher levels dependent on having successfully attained the lower levels of learning. These six levels, from lower to higher, are as follows; knowledge, comprehension, application, analysis, synthesis, and evaluation. The UVM Center for Teaching and Learning provides a good overview of this method for writing and classifying course learning objectives (see <https://www.uvm.edu/ctl/?Page=resources-teaching/course-design/learning-objectives.php>). A detailed list of the specific learning objectives for this course, with the associated “levels of learning” assigned according to Bloom’s Taxonomy, can be found at the end of this syllabus. The course quizzes and examinations are designed to assess the extent to which the students have met these specific learning objectives.

There is no required textbook for this class. All of the course materials are available from the course Blackboard site in the form of video lessons and readings. You should move through each of the lesson topics in order, according to the schedule outlined in the course syllabus. You are responsible for learning the course materials from these online video lessons and supplemental readings.

There will be two exams for this class. The mid-term exam will be scheduled for Thursday, October 10th. The final exam will be scheduled for Thursday, December 5th. These exams will be completed online and consist of a combination of multiple choice questions and some essay questions.

There will also be 10 online quizzes over the course of the semester. These will need to be completed in order, and by midnight of the dates indicated on this syllabus. The quizzes will consist of either 10 short answer questions (multiple choice, true/false, matching), or a short essay question.

Finally, all students will need to write a relatively short (2-3 page, typewritten, double-spaced) paper on the topic of GMO food labeling. Details at the end of this syllabus. The paper is due by Friday, November 22nd (the Friday before Thanksgiving break).

Students enrolled in the class for graduate credit will need to complete additional course requirements. Please see the “Graduate Credit Requirements” section at the end of this syllabus.

Grading:

Undergraduate Credit:

Quizzes	20 points
Regulation paper	20 points
Mid-term exam	30 points
Final exam	30 points

Graduate Credit:

Quizzes	15 points
Regulation paper	10 points
Mid-term exam	30 points
Final exam	30 points
Grad Credit Assignment	15 points (see below for details)

Grades Map (for both Undergrad and Graduate grading):

A+	97-100 points
A	90-96 points
B+	87-89 points
B	80-86 points
C+	77-79 points
C	70-76 points
D+	67-69 points
D	60-66 points
F	Less than 60 points

Course Syllabus – Lesson Topics

NOTE: Although this is an online class, lecture topics will only be made available on Blackboard at the end of the deadline for the previous topics' quiz. For example, the video lesson on the topic of "Overview of the Food Drug, and Cosmetic Act will be made available on Blackboard on Sept. 10th.

History of U.S. Food Regulation.

The Three Branches of Government.

The Legislative Process.

Quiz #1 (Due Monday, Sept. 9th)

U.S. Food Regulatory Agencies.

Use of Government Documents.

Quiz #2 (Due Monday, Sept. 9th)

Overview of the Food, Drug, and Cosmetic Act.

Quiz #3 (Due Monday, Sept. 16th)

FDA Enforcement of the FD&C Act.

The FTC and the Regulation of Food Advertising.

Quiz #4 (Due Monday, Sept. 23rd)

Overview of The Food Safety Modernization Act

Regulation of Food Sanitation.

Quiz #5 (Due Tuesday, Oct 8th)

Regulation of Meat and Poultry.

Regulation of Imports and Exports.

Food Standards.

Quiz #6 (Due Monday, Oct 21st)

Regulation of GMO's

Food Irradiation

Quiz #7 (Due Monday, Oct 28th)

Regulation of pesticides in foods

Quiz #8 (Due Monday, Nov 4th)

Regulation of Dietary Supplements.

Product Liability.

Quiz #9 (Due Friday, Nov 15th)

Toxicological Testing Methods.

Application of Risk Assessment in Food Regulation

Quiz #10 (Due Monday, Dec 2nd)

Important Dates:

Mid-term exam (online) – Thursday, October 10th

“Prevagen” Paper due – Friday, November 15th

Final exam (online) – Thursday, December 5th

Written Paper Assignment – “Prevagen” Advertising Case:

I am sure most of you have seen television ads for the dietary supplement product PREVAGEN. If not, you should watch the video of the ad that I have uploaded to the course Blackboard page. The makers of PREVAGEN (Quincy Bioscience LLC) claim that the dietary supplement improves brain function and memory. In January 2017, the Federal Trade Commission (FTC) and the New York Attorney General’s Office filed a “Complaint for Permanent Injunction and Other Equitable Relief” against Quincy Bioscience, claiming that the ads constitute “a deceptive act or practice and the making of false advertisements” and are therefore in violation of the law. For this research paper, I would like you to address each of the following points regarding this product and the case against it.

1. First, read the complete FTC complaint of January 9, 2017. I have uploaded a copy to the course Blackboard site.
2. Based on your understanding of basic nutrition and physiology, why does it make little sense that a protein (apoeaquorin) which was originally discovered in jellyfish, would be able to have any effect on brain function or memory? [NOTE: Please address this from the standpoint of how the human body digests and metabolizes protein.]
3. The television ads for PREVAGEN claim that human clinical trials (double-blind, placebo-controlled) with the dietary supplement resulted in statistically significant improvement in short term memory assessed at 8, 30, and 90 days. Why is the FTC arguing that this claim is “false”? [NOTE: I would like you to address this issue from a statistical analysis perspective. In other words, what did the Quincy Bioscience researchers do to obtain these significant results, and why does the FTC believe that this resulted in a “false claim”?]
4. Since the original complaint was filed in January 2017, the case has been working its way through the long and tedious legal process. Briefly outline what has happened with the case since the original complaint was filed, and what is the status of the case today.

I do not have a specific page length for this assignment. But I would expect that you should be able to address the above points in a 4-7 page paper (typed, double-spaced). The finished paper (in MS Word or pdf format) needs to be uploaded to the course Blackboard assignment link by no later than midnight on Friday, November 15, 2019.

Graduate Credit Requirements:

Certainly, an important goal of a graduate education is to gain experience in teaching. Therefore, the objective of the additional graduate student course requirement for NFS 253 will be to require the graduate student to prepare and deliver (online) a course lecture. Since NFS 253 is a completely online class,

this lecture assignment will take the form of a recorded PowerPoint screencast presentation on a new or expanded topic related to Food Regulation. The presentation should be approximately 20 minutes in length. The course instructor (S. Pintauro) will provide the graduate student with the tools and tutorials for preparing a screencast lecture. There will be specific deadlines for completion of this project over the course of the semester. Based on a 15 week semester:

End of Week Two: Graduate student must submit a selected topic for the PowerPoint screencast to the instructor for review and approval, along with the learning objectives associated with the topic.

End of Week Five: Graduate student must submit the completed PowerPoint slide presentation for review by the instructor, along with an outline/notes of what the graduate student's audio recording will cover.

End of Week Eight: Graduate student will submit a completed recording of the PowerPoint screencast for review by the instructor.

End of Week Ten: Final PowerPoint screencast will be posted on the class Blackboard site and assigned to others in the class to view and review. The graduate student will also prepare a short online quiz to be administered to the other students in the class, assessing the extent to which the learning objectives were met by the class. The quiz will not count toward the grading of the other students in the class.

End of Semester: The graduate student will submit a short (2-3 page) self-evaluation of the experience that will address what worked well, what didn't work well, and how it can be improved (or what would the student do differently next time).

Specific Course Objectives (and associated “Levels of Learning”)

- I. Structure of the Federal Government
 - a. Define the three branches of the federal government. (Knowledge)
 - b. Explain the function of the three branches of government. (Comprehension)
 - c. Explain the concept of “checks and balances,” related to the three branches of government. (Comprehension)
 - d. Explain the roles of the major federal agencies responsible for food regulation. (Comprehension)

- II. The Legislative Process
 - a. Identify the major provisions of a law. (Knowledge)
 - b. Describe the how our laws are made. (Comprehension)
 - c. Explain the difference between a law and a regulation. (Comprehension)
 - d. Describe how regulations are established. (Comprehension)

- III. Use of Government Documents
 - a. Explain the difference between the major federal government documents. (Comprehension)
 - b. Demonstrate the use of the major government documents. (Application)

- IV. The FD&C Act
 - a. Describe the various enforcement options of the FDA. (Comprehension)
 - b. Describe the purpose and usefulness of food standards. (Comprehension)
 - c. Outline the factors that contribute to food poisoning outbreaks. (Comprehension)
 - d. Summarize the process by which the FDA regulates food sanitation. (Comprehension)
 - e. Differentiate between the regulation of imported foods and domestically produced foods. (Analysis)
 - f. Summarize the attempts by the FDA to regulate the dietary supplement industry. (Comprehension)
 - g. Assess the implications of the Dietary Supplement Health and Education Act on the safety of dietary supplements. (Evaluation)
 - h. Describe the differences and overlap between food labeling and food advertising. (Comprehension)
 - i. Summarize the conditions under which the FTC may consider an advertisement unfair or deceptive. (Comprehension)

- V. Toxicological Testing of Food Ingredients

- a. Distinguish between the various safety standards for substances in foods. (Analysis)
 - b. Calculate the risk associated with exposure to a carcinogen, based on linear extrapolation model. (Application)
 - c. Describe the various stages of a complete food safety assessment. (Comprehension)
 - d. Explain the relationship between diet and the metabolism of chemical carcinogens. (Comprehension)
 - e. Assess the usefulness of the Delaney Clause for regulating carcinogens in the food supply. (Evaluation)
 - f. Propose and justify an alternative to the Delaney Clause. (Synthesis)
- VI. Regulation of Food Irradiation
- a. Outline the differences between the various sources of ionizing radiation and their potential application in food irradiation. (Analysis)
 - b. Evaluate the controversies surrounding the use of ionizing radiation in food processing. (Evaluation)
 - c. Explain the steps in a typical food irradiation process. (Comprehension)
- VII. Regulation of Pesticide Residues in/on Foods
- a. Describe the mechanism of action of the major classes of chemical pesticides. (Comprehension)
 - b. Outline the process by which the EPA establishes acceptable residue levels for pesticides in/on foods. (Analysis)
 - c. Assess the risk associated with the use of chemical pesticides in/on foods. (Evaluation).
- VIII. *Graduate Credit Assignment (for students enrolled for graduate credit)*
- a. *Select a lesson topic and develop learning objectives. (Analysis)*
 - b. *Design the PowerPoint lesson slides and narration content. (Synthesis)*
 - c. *Produce the final PowerPoint video lesson. (Application)*
 - d. *Prepare a self-evaluation of the experience, including an assessment of what worked well, what didn't work as well, and how it could be improved. (Evaluation)*

