Instructor: Dr. Stephen J. Pintauro  
Associate Professor Emeriti  
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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 13th. The final exam will be scheduled for Thursday, December 8th. 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 (4-5 page, typewritten, double-spaced) paper on a topic to be assigned before the start of the semester. This syllabus will be updated soon as I select this semester’s topic. The paper is due by Friday, November 18th (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:

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<th>Undergraduate Credit:</th>
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<tr>
<td>Quizzes</td>
<td>20 points</td>
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<td>Regulation paper</td>
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<td>Mid-term exam</td>
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<td>Final exam</td>
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<tr>
<th>Graduate Credit:</th>
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<tbody>
<tr>
<td>Quizzes</td>
<td>15 points</td>
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<tr>
<td>Regulation paper</td>
<td>10 points</td>
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<tr>
<td>Mid-term exam</td>
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<td>Final exam</td>
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<tr>
<td>Grad Credit Assignment</td>
<td>15 points (see below for details)</td>
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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. 14th.

History of U.S. Food Regulation.

The Three Branches of Government.

The Legislative Process.

Quiz #1 (Due Monday, Sept. 12th)

U.S. Food Regulatory Agencies.

Use of Government Documents.

Quiz #2 (Due Monday, Sept. 12th)


Quiz #3 (Due Monday, Sept. 19th)

FDA Enforcement of the FD&C Act.

The FTC and the Regulation of Food Advertising.

Quiz #4 (Due Monday, Sept. 26th)

Overview of The Food Safety Modernization Act

Regulation of Food Sanitation.

Quiz #5 (Due Tuesday, Oct 11th)

Regulation of Meat and Poultry.

Regulation of Imports and Exports.

Food Standards.
Quiz #6 (Due Monday, Oct 24th)
Food Irradiation
Regulation of GMO’s

Quiz #7 (Due Monday, Oct 31st)
Regulation of pesticides in foods

Quiz #8 (Due Monday, Nov 7th)
Regulation of Dietary Supplements.
Product Liability.

Quiz #9 (Due Friday, Nov 18th)
Toxicological Testing Methods.
Application of Risk Assessment in Food Regulation

Quiz #10 (Due Monday, Dec 5th)

Important Dates:
Mid-term exam (online) – Thursday, October 13th
“Assigned” Paper due – Friday, November 18th
Final exam (online) – Thursday, December 8th
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 (apoaequorin) 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 4-5 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 18, 2022.

**Assignment Grading Rubric:** As indicated above, the paper counts 20 points toward your final grade (based on a final grade maximum of 100 points). Of the 20 points for the assignment, 12 will be based on how well you address the points to be covered (see above). The remaining 8 points will be based on the writing quality of the paper. That is, grammar, organization, sentence structure, clarity. I would strongly recommend that you consider using the UVM Writing Center to assist with the writing quality. This is especially important for those of
you for whom English is not your primary language. It is important that you work
with them as early in your drafting process as possible. The Writing Center is a
terrific service and one that many of my students have used in the past.

**NOTE:** If you prefer, you may choose to do your paper on a different topic. But
it should be focused on the regulation of a particular food product (of your
choice). If you decide to do the paper on a topic other than Prevagen, please let
me know what topic you have selected by no later than the third week of class.

**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 Three:** 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 Twelve:** Final PowerPoint screencast will be submitted to
the instructor. The graduate student will also prepare a short online quiz,
assessing the extent to which the learning objectives were met by the
students viewing the lesson.

**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)