

Food Laws and Regulations
SAFE/AGEC 452/652
Spring 2012



• **Course Overview**

Overview of U.S. federal and state food laws and international food standards with emphasis on U.S. federal regulatory agencies. Cross-listed between SAFE and AGECE.

The safety of food is a global concern because everyone needs to eat. Food safety is an increasing concern as technology alters the practices of producing, processing, storing, transporting, and preparing food. Society is responding by imposing expectations on the food industry through government oversight and market forces. This course discusses the evolving oversight by society through government and the emerging expectations among food businesses.



• **Course Goals**

Introduce U.S. statutes, regulations and court cases relating to food safety concerns so students are prepared to handle real-world situations involving food safety. Students will gain an understanding of where and how to locate laws relating to food safety; the relationship between a statute, a regulation, and a court decision; and who has the authority to interpret them. The course also provides an overview of the interaction among federal and state food safety laws, and the expanding role of international food standards.

Upon completing the course, students will be familiar with

- U.S. (federal and state) agencies and international organizations involved in or responsible for administering food laws;
- the different sectors of the U.S. food industry and the varying legal strategies for assuring that firms are taking steps to minimize the risk of unsafe food,
 - for example, food processing and food service sectors are highly regulated whereas agricultural production and consumers are offered information and education on how to reduce the risk of unsafe food products;
- the evolving nature of food law as a result of changes in the food industry and global economy (e.g., the increasing regulation of production agriculture); and
- the application of food laws to a food product.

The course also is an opportunity to practice "being a professional in the information age." This skill will be demonstrated through writing assignments and class presentations. Points to consider in practicing to be a professional in the information age may include

- are your thoughts logically organized; can a reader or listener easily understand your thinking;
- are you relying on (citing) credible references;
- have you presented your thoughts in a concise manner;

- do your thoughts address the issue that has arisen (or the question that was posed);
- have you addressed the full-breadth of the issue; that is, have you reviewed (i.e., critically thought about) the issue, and identified and addressed the obvious and not-so-obvious secondary issues;
- are your thoughts presented in a professional manner (e.g., complete sentences, no misspellings, appropriate citation method, proper use of subtitles to guide the reader, appropriate introduction and conclusion/summary, etc);
- have you considered alternative solutions (that is, review your first solution; can it be improved);
- do you recognize your assumptions and the implications of those assumptions;
- have you answered the "why" questions (e.g., why is this the answer, or why have others done it this way in the past, or why have others not done it this way in the past); and
- do your thoughts achieve the goal/objective of addressing the issue/question.

This course bears a close resemblance to SAFE 408/608; they both address government regulation of the food industry. However, SAFE 408/608 does not address all the topics discussed in this course. For students who have already taken SAFE 408/608, that course should provide an introduction to this course. For students who will take SAFE 408/608 at a later time, that course should provide a review of this 3-credit course. Please contact me (david.saxowsky@ndsu.edu) if you have questions about the relationship between this course and SAFE 408/608.

Bloom's Taxonomy

An overall objective is to enhance student thinking skills -- similar to the ideas set forth by Bloom. For an introduction to Bloom's Taxonomy, see http://education.calumet.purdue.edu/vockell/edpsybook/bloom/bloom's_taxonomy.htm. Also see

- <http://www.coe.uga.edu/epltt/bloom.htm>
- <http://www.coun.uvic.ca/learn/program/hndouts/bloom.html>
- <http://www.officeport.com/edu/blooms.htm>, and
- <http://faculty.washington.edu/krumme/guides/bloom1.html>.

Bloom's Taxonomy is the idea that individuals enhance their skills as they proceed through their education. For example when first beginning to study a topic or concept, the students begin to **know** and **comprehend** the concept. As they continue to refine their understanding, students are able to **apply** the concept and **analyze** situations. Finally, when the topic has been mastered, the students should be able to **evaluate** ideas and **create** new ones.

In SAFE 452/652, we will focus on **knowing** and **comprehending** legal concepts. We work at this level because this may be the first time many students are studying legal concepts. We also should be able to **apply** some of the concepts because we are adults

and experienced learners. At this point in our career, we should be able to go beyond simply knowing and comprehending, even if the concepts are new to us. For our graduate students (SAFE 652), we will focus on achieving Bloom's levels of **application** and **analysis**. Thus the expectations for graduate students (relative to undergraduate students in SAFE 452) are more thorough research and in-depth description, application, and analysis. Likewise, graduate students are expected to demonstrate strong logical thinking; clear and concise communication; correct application of the rules for grammar, capitalization, abbreviation, paragraph organization, and citation method; and an ability to format a document in a professional manner. These higher expectations will be critical in demonstrating graduate-level work.



Detailed Learning Objectives

Food law has developed over time in response to problems. Food law has seldom been adopted in anticipation of a problem.

Most U.S. food law has been created since the beginning of the 20th century.

- Food laws were established in the previous centuries in Europe; states enacted food laws during the 19th century; there were demands for federal food law in the United States since the mid-19th century, but it was at the beginning of the 20th century that the United States began enacting federal food laws.

Food businesses respond to both regulatory demands and market desires. Both forces motivate industry changes.

When a more encompassing entity begins to address food laws, smaller entities feel pressure to align with the expectations of the larger entity.

- For example, states enacted food laws before the United States created national or federal food laws, but once the U.S. Congress began to address food issues, the states felt both legal and economic pressures to align their food laws with the federal food laws. Similarly as international food standards emerge, nations interested in exporting and importing food products will feel economic pressure to align their national laws with the international standards.
- Appreciate how the rules and expectations of a higher level of the food industry refines the laws of the lower level of food law; that is, federal requirements direct state and local laws, and international standards are now influencing national food laws.
- As international organizations advance expectations for food products in the 21st century, nations, including the United States feel economic pressure to align their laws with the emerging international standards (even though the nations will participate in and influence the development of the international standards).

U.S. food law imposes different expectations on the various sectors of the food industry.

- Food law has implicitly divided the food industry into several sectors: production, processing, retail/food service (both food to be consumed

at home and food prepared to be consumed away-from home), and consumers.

- Consumers will not be told what to eat; they will be educated and informed, but they will make their own decision.
- Regulation of producers appears to be evolving from education to market forces and government mandates, even though the evolution may be somewhat slow.
- The processing sector is highly regulated, primarily by federal law. The retail sector also is extensively regulated, but primarily by state and local government.

Several agencies of the U.S. federal government share responsibility for regulating the processing sector of the U.S. food industry: Food & Drug Administration (FDA) and USDA. The role of other agencies in regulating the food industry is expanding, such as the Environmental Protection Agency (EPA).

- Many other nations have government agencies overseeing their food industry, however, some nations have not yet developed a food regulatory structure.
- The processing sector was the first sector of the U.S. food industry to be addressed by federal law.
- There are some similarities as well as some differences between how the FDA and USDA fulfill their respective responsibilities. Some of these differences are mandated by the underlying federal statutes; that is, some of these differences reflect the political process that influences Congress.

Students need to be able to

- Locate U.S. federal regulations.
- Describe the different role of USDA and FDA.
- Locate information resources of USDA and FDA, especially web-based resources, and use these resources to answer relevant questions.
- Understand, locate and use standard of identity for food items.
- Recognize the role of state regulation of food products.
- Understand the type of procedures used to verify the source of food products, especially products being imported into the United States.
- Understand some history of food law; recognize we reached the current legal structure as the result of government responses to food safety problems.
- Apply their understanding of food law to a food product; use the course project to emphasize the need to be able to consider numerous legal issues relating to a food product.
- Understand which issues need to be addressed by a food company, such as developing a nutrition list, ingredient list, etc.
- Understand good manufacturing practices (GMPs) and Sanitation Standard Operating Procedures (SSOPs) as they apply to the processing sector, understand good agricultural practices (GAP) as it applies to producers, and understand the Food Code as it applies to the retail/food service sector.

Students need to demonstrate their ability to be life long learners, to work as a team, and to present their thoughts in writing and by speaking.

- Demonstrate the ability to comprehend new topics by writing concise summaries after reading a discussion of the topic.
- Experience the process of working as a team to prepare a written report and three presentations over several months.



• **Meeting Times and Place**

3:30 - 4:45 on Tuesday and Thursday

Harris Hall 11

The first day of class is Tuesday, January 10, 2012



• **Expected to Attend Class**

Although class attendance is not required, it is EXPECTED.

A substantial part of this course is a team project and there will be opportunities for the teams to work together during class time. Failure to attend class to participate in these team activities is UNFAIR to the person(s) on your team. If you need to miss class, communicate with me -- before class if you know you will be missing (e.g., travel); as soon as possible if you miss class unexpectedly (e.g., illness).

As discussed in another section of the syllabus, there is a requirement of evidence of teamwork. Failure to regularly attend class will raise the presumption that you are not meeting your expected team involvement.



• **Instructor**

Mr. David Saxowsky

E-mail: david.saxowsky@ndsu.edu (*I generally do not check e-mail between Saturday noon and Monday morning; nor do I check e-mail between 10:00 pm and 7:00 a.m. most weekdays*)

Phone: 701-231-7470 (*please leave a message if I am unavailable*)

Fax: 701-231-7400 (*this is the department's fax number; your fax may be seen by others before I receive it; use your discretion in deciding whether to send confidential information to me via fax*)

Mailing address: David Saxowsky, Agribusiness & Applied Economics, NDSU
Dept 7610, PO Box 6050, Fargo, ND 58108-6050

Office: Barry Hall 428

Office Hours: Anytime between 8:00 and 5:00 Monday through Friday but I cannot guarantee availability; I recommend you make an appointment or contact me by phone or e-mail. To make an appointment, visit with me before or after class, call, or e-mail.



Text

There is no text for this course; instead, we will rely on materials available on the web and from other sources. The first set of materials for the course can be found at <http://www.ag.ndsu.edu/foodlaw>; these are the materials that will be addressed during the course.



Course Format

The class meets twice a week for discussion, lecture and team work. In preparation for each week, every student will be REQUIRED to submit a "weekly message" (more information about weekly messages is available in another section of this Blackboard site). There will be assigned seating during our class meetings with a expectation/requirement that students professionally participate in the discussion. In addition to the weekly messages and weekly discussions, there will be series of assignments -- four assignments throughout the semester (additional information about the assignments also is available in another section of this Blackboard site). This course relies exclusively on writing assignments and presentations; there are no exams or quizzes. All assignments will be submitted and returned by e-mail. My e-mail address is david.saxowsky@ndsu.edu. I STRONGLY encourage you to use your NDSU e-mail address for this course. Experience has clearly demonstrated that this system works much better for the purposes of this course than does "hotmail" or other e-mail systems.



Assignments

In addition to the weekly messages, student learning will be assessed through a series of short papers and brief presentations assigned and completed throughout the semester. There will be no exams.

1. The first assignment (Assignment 1) will be due January 13. It is an opportunity for you to introduce yourself to me. Indicate your name, major, your professional or career interests, recent work, business or other experiences, and what you hope to gain by completing this course. See the Assignment page of this web site for more details.
2. The major part of the course will be a multi-step project that will involve three papers and three presentations (assignments 2, 3 & 4).

Each paper/assignment (excluding the weekly messages) will be submitted twice. I will comment on the first version and return it; students will have an opportunity to revise the assignment and submit it a second time for grading. All assignments will be submitted as attachments to e-mail messages (david.saxowsky@ndsu.edu).

Factors considered in grading papers will focus on your explanation of the food safety topic and the clarity of your writing.

- Sample score sheet

Score sheet for initial (first progress) report -- assignment 2, SAFE/AGEC 452/652, Spring 2012

Draft Report (maximum of 33)

Appropriate topics (8)

Well-organized; logical order; proper use of subtitles (5)

Adequate but concise discussion of topics (8)

Suggested topics for next report (4)

Grammar; understandable/complete sentences (2)

Spelling, punctuation (2)

Cited references (4)

Handout (maximum of 17)

Well-organized (5)

Provided adequate but concise background information and references (8)

Reflects draft report (4)

Presentation (maximum of 17)

Visuals -- visible, concise, well-organized (5)

Presentation -- concise, well-organized, clear oral statements (8)

Reflects handout (4)

Total

Total for assignment 2 (maximum of 67)

- All assignments will be submitted as an attachment to an e-mail message.
- My e-mail address is david.saxowsky@ndsu.edu.
- I urge everyone to use Word (not Works) and Powerpoint to complete your assignments. On rare occasion, you may find yourself using a spreadsheet such as Excel, but I expect assignments 2 and 3 will be short documents (8-10 paragraphs or a detailed outline) and presentation slides. Assignment 4 will be a complete report.
- Be sure to indicate in the subject line of the e-mail message the course and assignment number; e.g., "SAFE 452/652, assignment 1." This is necessary because I will be receiving assignments by e-mail for several courses throughout the semester.

Assignments 2, 3 & 4 will be opportunities for you to describe and apply concepts we discuss in class. More detailed instructions for the project, and each paper and presentation is provided in another section of this Blackboard site. Due dates will be discussed and announced in class, as well as posted to this web site. Preliminary due dates are suggested in the Schedule (another section of this Blackboard site). We also will review rules for citing the reference materials you rely on.



Required Evidence of Team Work

Each team must provide evidence of team work in two formats.

Format 1 -- each team member will participate in the three report presentations.

Format 2 -- each team will provide four examples of team effort in developing and refining the progress/final reports, handouts, and visuals. These examples require students to e-mail a draft they developed to the teammate and the teammate to return comments to member who drafted the document. Throughout the semester, each

teammate must draft twice and comment twice, so there needs to be a minimum of four exchanges among the two team members.

For example, Person A e-mails a Word or Powerpoint file with a draft to Person B, and Person B (within a day or two) e-mails comments back to Person A (perhaps by using Track Changes in Word). Both of these e-mails need to be copied to the instructor (david.saxowsky@ndsu.edu). The exchange of e-mail has to happen a minimum of four times during the semester in preparation of the three reports, handouts, or visuals. Each team is expected to copy the instructor on at least one exchange for each report (i.e., assignments 2, 3 and 4). All other e-mail communication between the teammates does not need to be copied to the instructor. The purpose of the exchange of e-mails with copies to the instructor is to demonstrate that both teammates have participated in drafting, reviewing, and revising. The revised materials will be seen by the instructor when it is submitted and graded as the progress and final reports. These drafts and comments will NOT be graded. The instructor will look at them to assure each team member is participating in drafting, reviewing, and revising.



• **Additional Expectation for Graduate Students**

Students earning graduate credit for this course (SAFE 652) will be held to a higher expectation than undergraduate students. The first difference will be the overall performance; for example, more in-depth discussion of topics addressed in the writing assignments, more effective oral presentations, and provide additional leadership when working as a team with undergraduate students.

Graduate students are expected to achieve Bloom's levels of **application and analysis**. Thus the expectations for graduate students (relative to undergraduate students in SAFE 452) are more thorough research, and in-depth description, application, and analysis. Likewise, graduate students are expected to demonstrate strong logical thinking; clear and concise communication; correct application of the rules for grammar, capitalization, abbreviation, paragraph organization, and citation method; and an ability to format a document in a professional manner. These higher expectations will be critical in demonstrating graduate-level work.



• **Summary of Assignments & Grading**

Assignment 1	Introduce Yourself; 22 points (5% of final grade)	January 13
Weekly Message	13 or 14 weekly messages completed throughout the semester; 10 points each (30% of final grade)	Each Tuesday
.	Organize two-person teams and teams identify the food product they will work on throughout the semester	January 27
Initial Report (Assignment	First paper (33 points), handout (17 points) and presentation (17 points); 67	6th Week (Feb. 15)

2)	points total; also, at least one exchange of e-mails between team members copied to instructor during preparation of report (15% of final grade)	
Progress Report (Assignment 3)	Second paper (48 points), handout (20 points) and presentation (20 points); 88 points total; also, at least one exchange of e-mails between team members copied to instructor during preparation of report (20% of final grade)	11th Week (March 29)
Final Report (Assignment 4)	Final paper (65 points), handout (30 points) and presentation (38 points); 133 points total; also, at least one exchange of e-mails between team members copied to instructor during preparation of report (30% of final grade)	Last Week (May 3)
Additional Graduate Work	Held to a higher level of expectations	.

This is a total of 440 points.



More thoughts about the Assignments

Each assignment must be submitted as a draft and as a final version. The initial (draft) papers will NOT be scored/graded; if the redo or final paper is not submitted, the score for that assignment will be 0 (zero) even though an initial or draft paper had been submitted.

It is NOT the student's privilege to decide to redo a paper after it has been assigned a score by the instructor.

Due dates for all assignments will be determined as we proceed through the semester; as due dates are set, they will be announced in class and posted to this web site.

Assignments sent to the instructor by the deadline (according to the computer-generated time and date indicated on the e-mail message) will be considered as submitted "on time" even if there are technical (computer) problems and the assignment needs to be resent.

The instructor will make every effort to acknowledge receiving an assignment; students who have sent an assignment but have not received an acknowledgement from the

student within a reasonable time (e.g., a day) should contact the instructor (see me in class, or call 701-231-7470, or send a second e-mail).

Students are expected to carefully indicate the purpose of the message in the subject line; such as "SAFE 452/652; Assignment 1". This will reduce the chance that the instructor will overlook your e-mailed assignment.

Assignments will be scored by the instructor. Factors the instructor will consider in scoring a paper include grammar; spelling; logical organization; proper use of subtitles and other techniques to "guide" your reader through your paper; careful, accurate and thorough description of the legal concept(s); appropriate description and application of legal concept(s); appropriate use and citation of others' ideas; thorough discussion of how you apply the legal concepts to your situation; and the conciseness of your writing and the relevance of the legal concept you are applying to your situation.

Students are encouraged to contact the instructor if they have any questions about the assignments or grading procedures.

I chose this style of assignments because I believe you will be required in the "real world" to write memos and short papers far more often than you will be required to take a quiz or an exam. Hopefully, these assignments will provide opportunities for you to practice concise and accurate thinking and communication.



- **Special Circumstances**

Any student with special needs or who need specific accommodations during this course to ensure access to campus programs and facilities is invited and encouraged to share these concerns or requests with the instructor as soon as possible.

Veterans and student soldiers with special circumstances or who are activated are encouraged to notify the instructor in advance.



- **Academic Conduct**

All work in this course must be completed in a manner consistent with NDSU University Senate Policy, Section 335: Code of Academic Responsibility and Conduct at <http://www.ndsu.edu/fileadmin/policy/335.pdf> and Code of Student

Behavior at <http://www.ndsu.edu/fileadmin/studentlife/StudentCode.pdf>.

All NDSU students taking any course in the College of Agriculture, Food Systems and Natural Resources are under the Honor System

(<http://www.ag.ndsu.edu/academics/honor.htm>). The Honor System is governed by students and operates on the premise that most students are honest and work best when their honesty, and the honesty of others, is not in question. It functions to prevent cheating as well as penalize those who are dishonest. It is the responsibility of the

student to report any violations of the honor pledge to the instructor, honor commission, or the Dean of the College of Agriculture.

Some of you may be familiar with the Honor System from other NDSU agriculture courses in which you had to sign the following statement when taking an exam or quiz: *HONOR PLEDGE: Upon my honor, I have not given nor received aid in writing this examination.*

Academic conduct also is critical in the preparation of assignments. Student are expected to adhere to appropriate practices when relying on the thoughts of others, for example, when using an idea from a publication or another person. Properly citing reference materials and submitting one's own work are important components of appropriate academic conduct.

- It is a violation of university policy, unprofessional, and unethical to use someone's words without identifying the quote and citing the source.



Course Outline

Introduction

- Why be concerned about the safety of food?
- What are some key points about food safety law?
- Why do food safety concerns extend from "farm-to-table"?

Overview of Food Safety Law

- Origins for regulating food safety
- United States Response to food safety concerns
- Adulterated food
- Misbranded food

The Government "Players"

- Agencies involved in food safety
- How law is created
- Where to find information about food safety law
- International response to food safety concerns

Requirements

- Production (pre-harvest)
- Processing (post-harvest) including standards, additives (GRAS), inspections, GMP and HACCP, labeling, records, recalls, and enforcement
- Retail Sales & Food Service (Food Code)
- Consumer Education
- Producer, Processor or Preparer Liability
- Food safety laws and standards of other nations

Looking Forward and Future Issues



Course Letter Grade

Student learning will be assessed through short papers and class presentations. Final letter grades will be assigned according to the following criteria, but there may be a curve.

- Students whose score is within 90% of the possible points will receive an A.
- Students whose score is between 80 and 90% of the possible points will receive a B.
- Students whose score is between 70 and 80% of the possible points will receive a C.
- Students whose score is between 60 and 70% of the possible points will receive a D.
- Students whose score is below 60% of the possible points will not receive a passing grade.



Necessary Computer Skills

This course requires students to be able to use an internet web browser, Blackboard, email, word processing (Word), presentation software (PowerPoint), and email attachments.