

Course Information

Course Number: SCSC 634
Course Title: Regulatory Science Principles
Section: 699, 700
Time: N/A
Location: Online (<https://canvas.tamu.edu/>)
Credit Hours: *Credit Hours*

Instructor Details

Instructor: Dr. Tim Herrman, Professor, Department of Soil and Crop Sciences, State Chemist and Director, Office of the Texas State Chemist
Office: Office of the Texas State Chemist, 445 Agronomy Rd, College Station TX 77843
Phone: 979 845-1121
E-Mail: tjh@otsc.tamu.edu
Office Hours: Please call to schedule

Course Description

Regulatory tools, standards and practices to improve the protection and compliance of regulated systems; interdependence of regulatory agencies; models of risk analysis with emphasis on conducting a qualitative and quantitative risk assessment; and implications of compliance.

This course will address the following topics:

- Emerging Field of Regulatory Science
- Food Safety Modernization Act
- Role of Risk Analysis in Regulatory Science
- Conducting a Risk Assessment
- Current Issues and Problems

Course Prerequisites

None

Special Course Designation

N/A

Course Learning Outcomes

After completing this course, students will:

- Gain a practical knowledge of how to apply risk analysis to hazards in regulated products;

- Be able to participate in policy development and manage risk at a corporate and government level ; and
- Be able to utilize standards to evaluate conformance based on regulatory science principles.

Textbook and/or Resource Materials

There are no required textbooks. All course materials, readings and activities will be presented through the Canvas Learning Management System. However, if you need an immediate answer to a question, please send an email directly to Dr. Herrman at tjh@otsc.tamu.edu or Prabha Vasudevan at prabha@otsc.tamu.edu

Technology Requirements

You will need Microsoft Word and Excel software to complete homework assignments. Software is available to students at a discounted price through the. You will need the free [Adobe Acrobat Reader](#)) to view course materials. Please report technical difficulties to prabha@otsc.tamu.edu or (979) 845-1121.

Students will be provided access to @Risk Software to complete homework assignments and course project. If you are using a Mac, please contact the course coordinator. (@Risk is only compatible with Windows platform)

Grading Policy

Grades will be determined as follows:

Discussions (4)	10 pts
Homework (8)	60 pts
Project # 1	20 pts
Project # 2	20 pts

Grades Breakdown:

A	100 – 90 pts
B	80 – 89 pts
C	70 – 79 pts
D	60 – 69 pts
F	<60 pts

Course Assessments

Discussions (4)

There will be four graded discussions held on the discussion forum in Canvas. Your responses to the questions posted to the discussion board will be evaluated and included in your final grade.

Homework Assignments (8)

Homework will involve applying a model for risk assessment using Decision Tools Suite and writing essays analyzing assigned readings.

Projects (2)

Project #1 will be to perform a Qualitative Risk Assessment. Project #2 will be to perform a Quantitative Risk Assessment

Late Work Policy

Please inform the course instructor or coordinator if you cannot submit an assignment on the due date to arrange for alternative submission date. A request for extension should be made prior to the assignment due date.

Course Schedule

Week	Topic	Assignments	Due Date
Unit 1 – Emerging Field of Regulatory Science			
1	What is Regulatory Science?	Self-intro. Homework	<i>TBD</i>
2	Origins and Rationale behind US FDC Act; Application of Regulatory Science to the Food Safety Modernization Act	Homework	<i>TBD</i>
Unit 2 –Risk Analysis and Food Protection System			
3	Risk and Uncertainty; Risk Analysis – FAO/WHO Model	Discussion	<i>TBD</i>
4	Risk Analysis – OIE Model, NAS-NRC Model Risk Assessment - OIE	Homework	<i>TBD</i>
Unit 3 – Probability Distribution and Risk Assessment			
5	Introduction to @ Risk Probability Principles Review Binomial Process	Homework	<i>TBD</i>
6	Poisson and Hypergeometric Processes Normal Distribution, Central Limit Theorem	Homework	<i>TBD</i>
Unit 4 – Risk Assessment Modeling			
7	Risk Assessment Modeling; Probabilistic Scenario Modeling; Introduction to Precision Tree	Homework	<i>TBD</i>
8	Infectious Disease Modeling	Homework, Class Project	<i>TBD</i>
9	Dose Response	Homework	<i>TBD</i>

10	Bootstrap and Bayesian Modeling	Discussion	<i>TBD</i>
Unit 5 – Current Issues and Problems			
11 -12 October 31 – November 13, 2022	Work on Risk Assessment Projects	Class Project	
13-15	Whose Science should we use?; Social and Economic Implications of Compliance	Class Project Discussion # 3 & 4	<i>TBD</i>

Technology Support

Please contact Prabha Vasudevan at prabha@otsc.tamu.edu, if you have problems accessing course materials.

University Policies

Attendance Policy

The university views class attendance and participation as an individual student responsibility. Students are expected to attend class and to complete all assignments.

Please refer to [Student Rule 7](#) in its entirety for information about excused absences, including definitions, and related documentation and timelines.

Makeup Work Policy

Students will be excused from attending class on the day of a graded activity or when attendance contributes to a student's grade, for the reasons stated in Student Rule 7, or other reason deemed appropriate by the instructor.

Please refer to [Student Rule 7](#) in its entirety for information about makeup work, including definitions, and related documentation and timelines.

Absences related to Title IX of the Education Amendments of 1972 may necessitate a period of more than 30 days for make-up work, and the timeframe for make-up work should be agreed upon by the student and instructor" ([Student Rule 7, Section 7.4.1](#)).

"The instructor is under no obligation to provide an opportunity for the student to make up work missed because of an unexcused absence" ([Student Rule 7, Section 7.4.2](#)).

Students who request an excused absence are expected to uphold the Aggie Honor Code and Student Conduct Code. (See [Student Rule 24](#).)

Academic Integrity Statement and Policy

“An Aggie does not lie, cheat or steal, or tolerate those who do.”

“Texas A&M University students are responsible for authenticating all work submitted to an instructor. If asked, students must be able to produce proof that the item submitted is indeed the work of that student. Students must keep appropriate records at all times. The inability to authenticate one’s work, should the instructor request it, may be sufficient grounds to initiate an academic misconduct case” ([Section 20.1.2.3, Student Rule 20](#)).

Texas A&M at College Station

You can learn more about the Aggie Honor System Office Rules and Procedures, academic integrity, and your rights and responsibilities at aggiehonor.tamu.edu.

Americans with Disabilities Act (ADA) Policy

Texas A&M University is committed to providing equitable access to learning opportunities for all students. If you experience barriers to your education due to a disability or think you may have a disability, please contact the Disability Resources office on your campus (resources listed below) Disabilities may include, but are not limited to attentional, learning, mental health, sensory, physical, or chronic health conditions. All students are encouraged to discuss their disability related needs with Disability Resources and their instructors as soon as possible.

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Disability Resources is located in the Student Services Building or at (979) 845-1637 or visit disability.tamu.edu.

Title IX and Statement on Limits to Confidentiality

Texas A&M University is committed to fostering a learning environment that is safe and productive for all. University policies and federal and state laws prohibit gender-based discrimination and sexual harassment, including sexual assault, sexual exploitation, domestic violence, dating violence, and stalking.

With the exception of some medical and mental health providers, all university employees (including full and part-time faculty, staff, paid graduate assistants, student workers, etc.) are Mandatory Reporters and must report to the Title IX Office if the employee experiences, observes, or becomes aware of an incident that meets the following conditions (see [University Rule 08.01.01.M1](#)):

- The incident is reasonably believed to be discrimination or harassment.
- The incident is alleged to have been committed by or against a person who, at the time of the incident, was (1) a student enrolled at the University or (2) an employee of the University.

Mandatory Reporters must file a report regardless of how the information comes to their attention – including but not limited to face-to-face conversations, a written class assignment or paper, class discussion, email, text, or social media post. Although Mandatory Reporters must file a report, in most

instances, a person who is subjected to the alleged conduct will be able to control how the report is handled, including whether or not to pursue a formal investigation. The University's goal is to make sure you are aware of the range of options available to you and to ensure access to the resources you need.

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Students wishing to discuss concerns in a confidential setting are encouraged to make an appointment with [Counseling and Psychological Services](#) (CAPS).

Students can learn more about filing a report, accessing supportive resources, and navigating the Title IX investigation and resolution process on the University's [Title IX webpage](#).

Statement on Mental Health and Wellness

Texas A&M University recognizes that mental health and wellness are critical factors that influence a student's academic success and overall wellbeing. Students are encouraged to engage in healthy self-care by utilizing available resources and services on your campus

Texas A&M College Station

Students who need someone to talk to can contact Counseling & Psychological Services (CAPS) or call the TAMU Helpline (979-845-2700) from 4:00 p.m. to 8:00 a.m. weekdays and 24 hours on weekends. 24-hour emergency help is also available through the National Suicide Prevention Hotline (800-273-8255) or at [suicidepreventionlifeline.org](#).

Campus-Specific Policies

Classroom Access and Inclusion Statement

Texas A&M University is committed to engaged student participation in all of its programs and courses and provides an accessible academic environment for all students. This means that our classrooms, our virtual spaces, our practices and our interactions are as inclusive as possible and we work to provide a welcoming instructional climate and equal learning opportunities for everyone. If you have an instructional need, please notify me as soon as possible.

The Aggie Core values of respect, excellence, leadership, loyalty, integrity and selfless service in addition to civility, and the ability to listen and to observe others are the foundation of a welcoming instructional climate. Active, thoughtful and respectful participation in all aspects of the course supports a more inclusive classroom environment as well as [our mutual](#) responsibilities to the campus community.

Statement on the Family Educational Rights and Privacy Act (FERPA)

FERPA is a federal law designed to protect the privacy of educational records by limiting access to these records, to establish the right of students to inspect and review their educational records and to provide guidelines for the correction of inaccurate and misleading data through informal and formal hearings. Currently enrolled students wishing to withhold any or all directory information items may do so by going to [howdy.tamu.edu](#) and clicking on the "Directory Hold Information" link in the Student

Records channel on the MyRecord tab. The complete [FERPA Notice to Students](#) and the student records policy is available on the Office of the Registrar webpage.

Items that can never be identified as public information are a student's social security number, citizenship, gender, grades, GPR or class schedule. All efforts will be made in this class to protect your privacy and to ensure confidential treatment of information associated with or generated by your participation in the class.

Directory items include name, UIN, local address, permanent address, email address, local telephone number, permanent telephone number, dates of attendance, program of study (college, major, campus), classification, previous institutions attended, degrees honors and awards received, participation in officially recognized activities and sports, medical residence location and medical residence specialization.

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