O'Neill

Lead for the Greater Good

O'Neill School of Public and Environmental Affairs

E400, E514 Spring 2025 SYLLABUS
The changing landscape of toxic chemical regulations
SECTION: 8042, 8530
ROOM: PV275
TIME: T Th 11:10a - 12:25p

Professor: Joseph (Joe) Shaw,
Email: joeshaw@iu.edu
Office Location: MSBII 312; SPEA 459; Laboratory Location, SPEA 472
Phone: (812) 855-1392

Office Hours: TTR 10:00 –11:00a and by appointment
(email or phone me to set up the appointment).

Course description: Worldwide, our indoor and outdoor environments are increasingly saturated with chemicals, many of which have the potential to be harmful to human health and the environment. Fortunately, diseases and impacts caused by chemical pollution are some of the most preventable, simply by eliminating or reducing exposure. However, our current regulatory approaches for toxic substances resemble a game of chance whose outcome can leave us guessing whether chemicals are safe or not. This uncertainty exists in large part, because slow, costly, and outdated regulatory practices have resulted in less than 5% of the thousands of chemicals that are used to manufacture consumer goods having ever been evaluated for safety. As a result of these shortcomings, there is a global movement to break from current methods that force us to react to chemical threats, and modernize regulatory toxicology by embracing 21st century technologies to proactively reveal, which chemicals are prevalent in our environments, how we are exposed to them, and how they affect our health.

This class uses a combination of lectures, discussion, research, readings, and peer evaluation to review current toxicological practices, policies, and regulations, and discusses proposed changes in regulatory toxicology. These proposed changes incorporate 21st Century innovations and these are covered in context of their scientific underpinnings, and the promises and challenges they offer to regulatory toxicology. The course examines the almost science fiction like edges of biotechnology, reviews and compares regulatory policies around the world, and tasks its participants with envisioning their own strategy for chemical safety regulations that takes advantage of modern tools. In terms of these modern tools, the course draws from the fields of molecular biology, medicine, genomics/genetics, evolutionary biology, engineering, and computer science –though these are not prerequisites for enrolment and no prior knowledge of these subject areas are required. Theory and concepts will be highlighted through course readings, student led presentations, and individual and group projects drawn from real world applications described in the scientific and regulatory literature. Given that this landscape is

experiencing rapid change, it is possible that connections between our course and current and/or historical events outside the classroom will come up in (lectures/class discussions/ assignments). Those connections may require careful thought rather than being immediately obvious, but the ability to understand and analyze connections among ideas and events is a core skill in professional career and will stand you in good stead in your life beyond IU.

Context: This course compliments other courses in the environmental toxicology, chemistry, and risk assessment concentration within the environmental science program. It discusses the scientific basis and regulatory implications of changes in chemical safety regulations that are ongoing.

Learning Outcomes: Students completing this course will gain an understanding of (1) the challenges facing current regulatory approaches, (2) recent revolutions in biology, biotechnology and computer science that extract meaningful endpoints from massive (big) datasets, (3) applications of these new techniques to toxicology, and (4) what is needed to implement these proposed changes and if successful how they stand to transform the protection of human health and the environment. Students will ultimately develop their ability to understand and analyze the current and/or historical toxic chemical regulatory landscape through the lens of concepts from this course.

Content covered throughout the semester include:

Toxicology---the basics (plus molecular biology 101)

Current methods in regulatory toxicology

Toxicology for the 21st Century as proposed by the National Research Council

Modern technologies and their scientific applications to modern toxicology

- Genome
- Transcriptome
- Proteome
- Metabolome
- Cell screens
- Artificial organs
- Adverse Outcome Pathways
- Computational biology
- Informatics
- Others

Integration of modern toxicology into chemical regulations

- Considerations for protecting human health
- Considerations for protecting the environment

Revisiting Toxicology for the 21st Century

- *Implementation strategies*
- *Missing pieces*
- *Recommendations*

Resources: There is no required textbook for this course. We will make extensive use of the NRC report, which can be freely accessed (http://www.nap.edu/catalog.php?record_id=11970#toc). We will also make use of the scientific literature, working together to develop reading lists. Most readings will be posted on Canvas or distributed in class. I will make additional text material available in the SPEA Information Commons.

Learning assessment:

Opinion paper: This paper will be an agenda-setting, authoritative, informed and provocative piece calling for action on topical issues pertaining to Toxicology for the 21st Century, and its environmental, political, ethical and social ramifications. The goal of this assignment is to use your opinions to present a proposed direction through scholarly reasoning. These will be brief (~2 double spaced pages). Your first opinion piece will be solicited early in the semester (**Feb. 6**).

Opinion paper revisited: We will revisit your opinions (on the same topic) near the end of the semester (**Thurs, April 24**) to see how they have been influenced by your research.

Project: You will select a key step in the pathway for the proposed paradigm for 21st Century Toxicology (See Fig. 1, Collins et al. 2008) and prepare a "mini-white paper" that advocates for the integration of these methods (**Draft-April 17, Edits-April 24, Submit-on or before the final exam, Thursday, May 8 10:20-12:20p**).

Debate: We will explore current and proposed changes in toxic chemical regulation around the globe considering their environmental, political, ethical and social ramifications (**April 29 and May 1**).

Participation: As the resident expert on the method you cover for your techniques review, you will be the facilitator of two discussions on this topic. These include 1) a general discussion on the method of choice and 2) a focused discussion on its application to Tox21. In this role, you will distribute relevant literature to the class and prepare a few questions that you will use to direct our debate on the topic. In addition, your participation will be based on attendance, preparedness, and participation in class discussions and assignments. **Bottom-line: If you read (both assigned and independent readings) about the topics and look over current and past lecture notes before class, then you should be well prepared for lecture.** All that is left is for you to apply this knowledge to class discussions. If participation wains, I reserve the right to introduce quizzes to determine preparedness.

Grading:

Assignment	**Contribution to final grade (%)**
Opinion paper	5
Opinion paper revisited	5
Project	45
Debate	15
Participation	30

Grade scale:

97 - 100% = **A+**	93 - 96.9% = **A**	90 - 92.9% = **A-**
87 - 89.9% = **B+**	83 - 86.9% = **B**	80 - 82.9% = **B-**
77 – 79.9% = **C+**	73 – 76.9% = **C**	70 – 72.9% = **C-**
67 – 69.9% = **D+**	63 – 66.9% = **D**	60 – 62.9% = **D-**
<60% = **F**		

Policies: The O'Neill School takes matters of honesty and integrity seriously because O'Neill is the training ground for future leaders in government, civic organizations, health organizations, and other institutions charged with providing resources for the public, and for members of society who are vulnerable and who are lacking in power and status. Precisely because O'Neill graduates tend to rise to positions of power and responsibility, it is critical that the lessons of honesty and integrity are learned early. We are governed by an honor code that established expectations of civility and professional conduct, https://myspea.indiana.edu/doc/ugrad-doc/ugrd-student-honor-code.pdf. Needless to say, academic dishonesty (i.e., cheating and plagiarism) will not be tolerated. Violations will be dealt with according to the University's Code of Student Ethics.

Attendance is not optional and to emphasize this 10% of your grade is based on participation. If you cannot come to class, please let me know why/what happened. Failure to do so **will** affect your grade.

Make-ups for any assignment or exams will only be given for excused absences (requires prior approval) or documented emergencies.

Well-Being:
I care about the well-being of all students in my classes. If you need assistance, please ask me. I will help to the best of my ability. The University also has many resources available for students, such as:

1. Counseling and Psychological Services: for information about services offered to students by CAPS, please visit http://healthcenter.indiana.edu/counseling/index.shtml

2. Disability Services for Students: for information about support services or accommodations available to students with disabilities, and for the procedures to be followed by students and instructors, please visit https://studentaffairs.indiana.edu/disability-services-students

3. Food: Did you know that the Crimson Cupboard is available to all in the IU community? http://crimsoncupboard.indiana.edu/home.php

4. Sexual Harassment: As your instructor, one of my responsibilities is to create a positive learning environment for all students. Title IX and IU's Sexual Misconduct Policy prohibit sexual misconduct in any form, including sexual harassment, sexual assault, stalking, and dating and domestic violence.

   If you have experienced sexual misconduct, or know someone who has, the University can help. If you are seeking help and would like to speak to someone confidentially, you can make an appointment with:

   - The Sexual Assault Crisis Services (SACS) at (812) 855-8900 (counseling services)
   - Confidential Victim Advocates (CVA) at (812) 856-2469 (advocacy and advice services)
   - IU Health Center at (812) 855-4011 (health and medical services)

   It is also important that you know that Title IX and University policy require me to share any information brought to my attention about potential sexual misconduct with the campus Deputy Title IX Coordinator or IU's Title IX Coordinator. In that event, those individuals will work to ensure that appropriate measures are taken and resources are made available. Protecting student privacy is of utmost concern, and information will only be shared with those that need to know to ensure the University can respond and assist. I encourage you to visit http://stopsexualviolence.iu.edu/index.html to learn more.