Programme: Health Risk Assessment-Principles and Applications
March 13 - 17, 2023
IMM Institute of Environmental Medicine, Karolinska Institutet, Online course (Zoom)
Course leader: Anna Beronius

Monday March 13	**Tuesday March 14**	**Wednesday March 15**	**Thursday March 16**	**Friday March 17**
9.00-9.45 Welcome and introduction to the course (AB). Concepts in risk assessment (AB)	9.00-9.45 Adverse effects and derivation of health-based guidance values including exercise (AH)	9.00-9.45 Regulatory frameworks and Risk assessment under REACH (DK)	9.00-9.45 Case study: Risk assessment of bisphenol A (AB)	9.00-9.45 Presentation and discussion of group work (AB, LW, AG)
9.45-10.15 Coffee break	9.45-10.15 Coffee break	9.45-10.15 Coffee break	9.45-10.15 Coffee break	9.45-10.15 Coffee break
10.15-11.00 Concepts in risk assessment, continued (AB)	10.15-11.00 Adverse effects and derivation of health-based guidance values including exercise, cont. (AH)	10.15-11.00 Regulatory frameworks and Risk assessment under REACH (DK)	10.15-11.00 Epidemiology in risk assessment – the cases of cadmium and lead (MK)	10.15-12.30 Presentation and discussion of group work (AB, LW, AG)
11.15-12.00 Exposure assessment (AB)	11.15-12.00 Assessment and integration of toxicity data (AB)	11.15-12.00 Case study: Risk assessment of PFAS (MÖ)	11.15-12.00 New approaches and next generation risk assessment (AB)	
12.00-13.00 Lunch	12.00-13.00 Lunch	12.00-13.00 Lunch	12.00-13.00 Lunch	12.30-13.00 Course ending
13.00-13.45 Toxicity testing and test guidelines (AB)	13.00-13.45 Assessment and integration of toxicity data (AB)	13.00-13.45 Case study: Hazard assessments of occupational N-Methyl-2-Pyrrolidone exposure (LS)	13.00-13.45 Group work (AB, LW, AG)	13.00 – 17-00 Take home exam to be handed in by 17:00.
13.45-14.15 Coffee break	13.45-14.15 Coffee break	13.45-14.15 Coffee break	13.45-14.15 Coffee break	
14.15-15.45 Web-based information sources – lecture and exercise (LW)	14.15-17.00 Group work (AB, LW, AG)	14.15-17.00 Group work (AB, LW, AG)	14.15-17.00 Group work (AB, LW, AG)	
16.00-17.00 Presentation of participants				

Teachers:
AB – Anna Beronius, IMM, KI
AG – Anda Gliga, IMM, KI
AH – Annika Hanberg, IMM, KI
DK – Diana Kättström, ACES, SU
LS – Linda Schenk, IMM, KI
LW – Lars Wiklund, RegSafe
MÖ – Mattias Öberg, IMM, KI
MK – Maria Kippler, IMM, KI

Course information

Learning outcomes:
Upon completion of the course, the student should be able to:

- describe the basic concepts and principles of health risk assessment of chemical substances
- explain how different types of data from in vivo/animal, epidemiological and in vitro studies as well as exposure data are used in risk assessment
- assess the relevance and reliability of data used in risk assessment
- derive health based guidance values such as Acceptable Daily Intake (ADI) based on the data
- reflect on the role of health risk assessment in regulatory decision making

Content of the course:

Health risk assessment of chemicals is the scientific method to assess the risk to humans of exposure to different types of chemical substances, such as pharmaceuticals, environmental pollutants, chemicals in cosmetics, clothing or other everyday products and pesticide residues, food additives and other substances in food.
The course starts off with introducing the concepts in risk assessment, e.g. aims of risk assessment, role of risk assessment in risk analysis (risk assessment, risk management, risk communication), different steps in risk assessment (hazard identification, hazard characterisation, exposure assessment, risk characterisation). It moves on to the different types of data from in vivo/animal, epidemiological and in vitro studies as well as exposure data that are used in risk assessment. We discuss how the relevance and reliability of the data is assessed, and how different kind of evidence is integrated (for example from animal and epidemiological studies). The principles on how to derive health-based guidance values such as Acceptable Daily Intake (ADI) and to derive Margins of Safety values based on the data are exercised. The course provides examples of the role of risk assessment in regulatory decision making. Lectures and discussions on different cases exemplify how health risk assessment is carried out in practice, and typical challenges. The course also covers discussions on how research connects to risk assessment activities.

Content of individual teaching and learning activities:

<u>Concepts in risk assessment (lecture)</u>
Introduction to the main concepts in risk assessment that will be dealt with in more depth in the rest of the course. Including e.g. aims of risk assessment, role of risk assessment in risk analysis (risk assessment, risk management, risk communication), different steps in risk assessment (hazard identification, hazard characterisation, exposure assessment, risk characterisation), introduction to different kind of data used in risk assessment (animal data, epidemiological data, in vitro data).

<u>Web-based information sources in risk assessment (lecture and exercise)</u>
Identification and assessment of web-based data sources to be used in risk assessment, including exercise to familiarize the participants with the information sources.

<u>Toxicity testing and test guidelines (lecture)</u>
Overview of in vivo animal studies used for risk assessment, including test guidelines.

In vitro studies used for risk assessment (lecture)
Development of in vitro methods and the use of in vitro data in risk assessment.

Assessment and integration of toxicity data (lecture)
Assessment of different types of data (animal studies, epidemiological studies, in vitro studies) for risk assessment. How can the data be used, of the data, criteria for use of data, systematic approaches to the evaluation of reliability and relevance of data and integration of different types of data, weight of evidence evaluation. Discussions on how research can contribute to risk assessment.

Exposure assessment (lecture)
Principles of exposure assessment for use in risk assessment.

Derivation of health-based guidance values (lecture and exercise)
Principles on how to identify point-of departure and derive health-based guidance values. Calculation of different health-based guidance values (ADI, TDI, DNEL, RfD) and Margin of Safety/Exposure.

Epidemiology in risk assessment (lecture)
Principles for epidemiological studies, use of epidemiological data in risk assessment, challenges in evaluation of epidemiological data. Example from own experience.

Risk assessment within the REACH legislation (lecture)
REACH legislation and risk assessment procedures including example from own experience.

Case studies of risk assessments (lectures)
Examples of risk assessments given by IMM researchers with specific expertise in the different cases. Examples are chosen to show a variety of risk assessments for different types of scenarios and based on different types of data.

Group work
Group work to apply the knowledge in the course on a real example. The groups analyse critically a risk assessment of a compound and present their results orally. Each group presentation is followed by discussions by all participants of the principles applied and specific challenges in each case.

Take home exam

- Short answer questions on factual knowledge of important principles of health risk assessment.
- Essay/reflection on the role of health risk assessment in regulatory decision making.