

TRAINING COURSE

TSCA Workshop

Understanding the US EPA TSCA Section 5 Review Process and Application of Predictive Models



Course introduction

Over the 2.5 days, topics to be covered include US EPA and OECD approaches for:

- Determining important physical-chemical properties of a substance along with methods to identify environmental attributes of concern;
- Creating a screening-level hazard assessment for human health and primary environmental media with a focus on principles for analogue analysis and read across to fill data gaps; and
- Modelling industrial operations including manufacturing, processing, commercial and consumer use activities, and the potential environmental release and human exposure from those activities.

Background

The passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act on June 22 2016 had a profound impact on the US New Chemicals Program. This workshop will highlight important changes in the new chemical program and provide technical training on the risk assessment process. This educational course builds upon training material originally developed under the US EPA Sustainable Futures program.

During this hands-on 2.5-day workshop, you will learn about a variety of methods and models to conduct a preliminary risk assessment before submitting new chemical notifications to the US EPA to better anticipate regulatory concerns and identify critical outcomes. Speakers will highlight useful notification strategies and demonstrate tools to help identify risk-prone activities, support

targeted testing strategies and potentially reduce the Agency review time by decreasing the need for back and forth communication during the notification period. The workshop includes in-depth presentations on hazard, exposure and risk screening to address ecological and human health concerns and provides hands-on sessions with US EPA and OECD computer-based models.

Expert trainers:



Jeff Hafer
Senior Regulatory Scientist,
knoell USA

During a 36-year career in industry, Jeff held a variety of positions at Rohm and Haas and Dow Chemical including global regulatory specialist

and global product stewardship manager for the Coatings business. In 2013, he became corporate TSCA manager for Dow Chemical. After retiring from Dow in 2016, Jeff joined knoell USA as a Senior Regulatory Scientist. During his career, Jeff served as chair of the American Chemistry Council's Regulatory Advocacy and Information Network, the American Coatings Association's Product Stewardship Committee, and the Emulsion Polymers Council.



Kelly Mayo-Bean
Senior Regulatory Scientist,
knoell USA

Prior to joining knoell USA, Kelly spent 15 years at the U.S. Environmental Protection Agency's Office of Pollution Prevention and Toxics serving as a technical expert on predictive models to assess concerns for industrial chemicals. Kelly helped develop the Sustainable Futures training program to educate stakeholders on the U.S. new chemical review process and use of EPA predictive methods and participated in numerous international activities including development of the OECD QSAR Toolbox. In 2015 Kelly became Associate Branch Chief in the Risk Assessment Division, focusing on scientific assessments for new chemicals and acting as Division liaison to the Chemical Control Division responsible for issuing regulatory actions on new and existing chemicals.

08:30 Registration

09:00 TSCA Section 5 New Chemical Notification Process

- Instructors will outline changes to TSCA Section 5, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and highlight regulatory actions taken by the U.S. EPA. This session will teach regulatory specialists how staying informed and providing a robust notification package can expedite the review process.
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10:30 Refreshment break

10:45 Physical-Chemical Properties and Environmental Fate

- Instructors will teach participants how to interpret physical-chemical and environmental fate properties to determine potential endpoints of concern and inform testing needs prior to new chemical submissions.
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12:00 Lunch

13:00 US EPA EPISuite Software Hands-On Session

- Instructors will lead a hands-on session with the US EPA software and example chemicals to teach participants how to anticipate environmental fate concerns in the absence of measured data and anticipate potential regulatory concerns.
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14:00 Ecological Hazard Assessment

- Instructors will teach participants approaches for creating a screening level hazard assessment for the primary environmental media of concern in industrial chemical regulation.
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14:25 Refreshment break

15:00 US EPA ECOSAR Software Hands-On Session

- The instructors will lead a hands-on session with the US EPA software and example chemicals to show participants how to predict hazard concerns in the absence of measured data and identify data gaps and data needs for a chemical.
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16:00 Human Health Hazard Assessment

- Instructors will provide insight on approaches for creating a screening level human health hazard assessment and will focus on principles for analogue analysis and read across to fill data gaps.
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17:00 Close of day one

Trainers:

Jeff Hafer Jeff Hafer, Senior Regulatory Scientist, knoell USA

Kelly Mayo-Bean Kelly Mayo-Bean, Senior Regulatory Scientist, knoell USA



THURSDAY

27

JUNE
2019

Day two



FRIDAY

28

JUNE
2019

Day three



09:00 **OECD QSAR Toolbox Software Hands-On Session**

- The instructors will lead a hands-on session with the OECD software and example chemicals to teach participants how to predict hazard concerns in the absence of measured data and identify data gaps and data needs for a chemical.

10:30 **Refreshment break**

10:45 **OECD QSAR Toolbox Hands-On Session Continued**

12:00 **Lunch**

13:00 **Evaluating Industrial Operations and Environmental Releases**

- The instructors will provide direction on developing industrial operation diagrams to include manufacturing, processing, and commercial use and introduce methods to characterize the impact to workers and the environment from those activities.

14:00 **US EPA ChemSTEER Hands-On Session**

- The instructors will lead a hands-on session with the US EPA software and example chemicals to show participants how to develop operation diagrams, identify the most important information elements in the exposure modeling process, and inform the use of PPE recommendations.

15:15 **Refreshment Break**

15:30 **US EPA ChemSTEER Hands-On Session Continued**

16:00 **Downstream General Population and Ecological Exposure Modelling**

- The instructors will highlight approaches to model general population impacts from industrial operations and consumer use activities and discuss the various pathways of exposure.

17:00 **Close of day two**

09:00 **US EPA E-FAST Hands-On Session**

- The instructors will lead a hands-on session with the US EPA software and example chemicals to show participants how to develop identify exposure pathways of concern for the general population based on chemical use patterns and estimate environmental exposure concentrations.

10:00 **Aquatic Risk Assessment**

- The instructors will outline the process for quantifying potential risk to the aquatic environment and show participants how to bring together hazard and exposure information to identify areas of concern.

10:45 **Refreshment Break**

11:00 **Non Cancer Risk Assessment**

- The instructors will outline the process for quantifying potential human health risk and show participants how to bring together hazard and exposure information to identify areas of concern.

11:45 **Risk Assessment Hands-On Session**

- The instructors will lead a hands-on session to characterize the risk of the example chemicals and engage in discussions regarding new chemical regulatory outcomes, potential risk mitigation actions and development of informed testing strategies.

13:00 **Close of training course**



Prices

Full price – \$2120 (+VAT)

Early-bird price – \$2020 (+VAT)

CW Subscriber price – \$2020 (+VAT)

Early-bird CW Subscriber price – \$1920 (+VAT)

Early-bird discount expires 3 May 2019



Three ways to register

<https://events.chemicalwatch.com/74195>

events@chemicalwatch.com

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Baltimore, USA

Payment options

- Invoice payable by bank transfer, credit card or cheque made payable to Chemical Watch
- Online using our secure order form
- Payment must be made before the event starts
- The full price is payable in advance and includes tuition, course materials, refreshments and lunch on each day.

Event timings

Day one

26 June 2019, 09:15 – 17:00

Day two

27 June 2019, 09:00 – 17:00

Day three

28 June 2019, 09:00 – 13:00