EUROTOX specialized toxicology course 2018
Regulatory toxicology

4th - 10th November 2018

Otočec, Slovenia

Slovensko toksikološko društvo
Slovenian Society of Toxicology
http://tox.si/

Dear participants.

Welcome to the **EUROTOX specialized toxicology course 2018 – Regulatory toxicology** hosted by the Slovenian Society of Toxicology.

The course aims to provide knowledge and understanding of methods for toxicological risk assessment in regulatory processes for different categories of chemicals.

On behalf of the Slovenian Society of Toxicology, I would like to thank most sincerely to all who have contributed to the realization of this course:

- the main sponsor, the Federation of European Toxicologists & European Societies of Toxicology (EUROTOX);
- the lecturers and the tutors;
- other sponsors, i.e. the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA), the National Institute of Public Health (NIJZ), the Universities of Aberdeen, Basel, Ljubljana and Milan;
- Ms. Maja Martinčič for technical support.

I wish you an inspiring and fulfilling learning as well as networking week at Otočec.

Lucija Perharič
President of SST

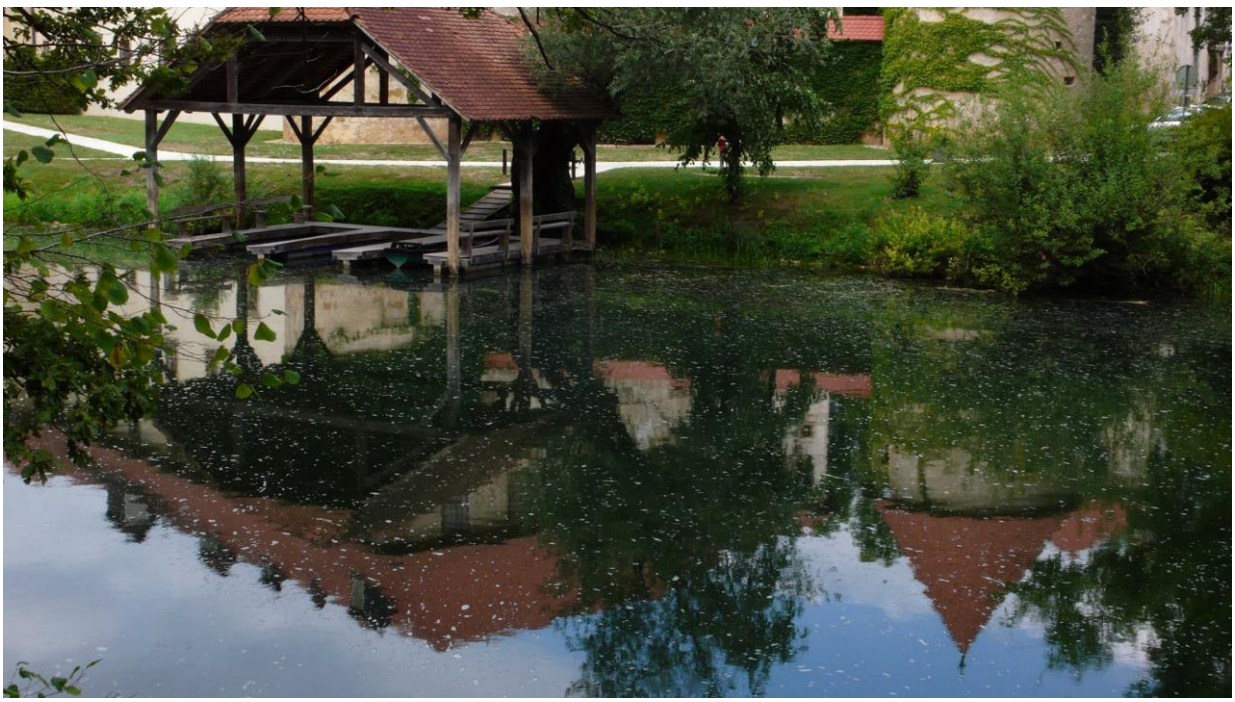

Photo by L. Perharič

EUROTOX specialized toxicology course 2018 – Regulatory toxicology

Content:

- methodology for the different steps in risk assessment (hazard identification, hazard characterisation, exposure assessment, risk characterisation);
- uncertainty in risk assessment;
- use of Adverse Outcome Pathways and Mode of Action Frameworks in risk assessment;
- derivation and use of health-based guidance values (e.g. RfD, ADI, AOEL, DNEL etc.);
- application of regulations and guidelines for different sectors (e.g. chemicals, human pharmaceuticals, veterinary pharmaceuticals, pesticides and biocides, cosmetics, household and consumer products, food additives and contaminants).

Learning outcomes:

- to understand the application of risk assessment in different regulatory systems;
- to be able to perform a basic risk assessment using toxicological and exposure data;
- to be able to interpret data submitted for the purpose of registration and labelling of different types of chemicals substances.

This is a five-day course, with 19 one hourly lectures, 5 working group sessions, and 5 rapports of outcome. A written exam will be held at the end of the course.

Attendance fees for all participants are 170 €, covering registration, course materials, full board (accommodation in two bed rooms; individual rooms are available at extra pay), and a welcome dinner.

Selection criteria for participation at the course are:

1. Knowledge and working experience in toxicology related areas
2. Upper intermediate knowledge of English language (https://www.lsf-france.com/info/cefr-language-levels/)
3. Reference Letter of the national Society of Toxicology
4. Preference will be given to participants from Slovenia and from those countries where toxicology is underrepresented
5. Preference will be given to early carrier participants

Dates: 4th- 10th November, 2018

Host Society: Slovenian Society of Toxicology

Venue: Hotel Šport, Otočec Slovenia (https://www.terme-krka.com/us/en/destinations/otocec/)

Contact and applications: Slovenian Society of Toxicology, L. Perharič, Gerbičeva 60, SI-1000 Ljubljana, Slovenia; slotox@gmail.com; tel: + 386 40 628 361

Deadline for applications: 5th October 2018

Participants: The selected participants with a range of backgrounds such as biology, biotechnology, chemistry, food science, pharmacy, and veterinary medicine, working in academia, consultancy firms, industry, public health and research institutions, come from Slovenia (11), Croatia (9), Serbia (5), Poland (2), Estonia (2) and Italy (1).

Lecturers and tutors:

E. Corsini, University of Milan, Italy (lecturer and tutor)
K. Černe, University of Ljubljana, Slovenia (tutor)
E. Fabjan, ECHA, Finland (lecturer)
T. Fatur, National Institute of Public Health, Slovenia (lecturer and tutor)
C.L. Galli, University of Milan, Italy (lecturer and tutor)
M. KrŽan, University of Ljubljana, Slovenia (lecturer)
J.M. Parra Morte, EFSA, Italy (lecturer)
L. Perharič, National Institute of Public Health, Slovenia (lecturer and tutor)
L. Peterlin Mašič, University of Ljubljana, Slovenia (lecturer)
A. Terron, EFSA, Italy (lecturer)
H.M. Wallace, University of Aberdeen, UK (lecturer)
M.F. Wilks, University of Basel, Switzerland (lecturer)

General Outline of the Course

DAY 0: Sunday, November 4th, 2018

Arrival of long distance participants, lecturers and tutors

DAY 1: Monday, 5th November 2018

Introduction to risk assessment, risk management and risk communication

9.30 - 10.30	Introduction to toxicological safety evaluation (C.L. Galli, University of Milan, Italy)
10:30 - 11:30	Toxicological protocols and guidelines (C.L. Galli, University of Milan, Italy)
11:30 - 12:00	**Coffee Break**
11:30 - 12:30	Principles of risk assessment (C.L. Galli, University of Milan, Italy)
12:30 - 14:00	**Lunch**
14:00 - 15.00	Exposure assessment and risk characterization: use of human data in chemical risk assessment (M.F. Wilks, University of Basel, Switzerland)
15:00 - 16:00	Risk communication, risk management and risk benefit analysis (H.M. Wallace, University of Aberdeen, UK)
16:00 -16:30	**Coffee Break**
16:30 - 17:30	Selection of the Study Groups (Introduction to Case Studies)
19:00	Welcome dinner

DAY 2: Tuesday, 6th November 2018

Regulatory requirements by the European agencies and methodological advances in toxicology

8:15 - 9:00 Safety evaluation of nanomaterials (C.L. Galli, University of Milan, Italy)

9:00 - 10:00 Safety evaluation of carcinogens (H.M. Wallace, University of Aberdeen, UK)

10.00-11.00 EFSA: Safety evaluation of foods and feeds (JM Parra Morte, EFSA, Italy)

11:00 - 11.30 Coffee Break

11:30-12:30 The concept of the benchmark dose and the problem of mixtures (JM Parra Morte and A. Terron, EFSA, Italy)

12:30 - 14:00 Lunch

14:00 - 15:00 Toxicology in the 21st century – principles and initiatives (M.F. Wilks, University of Basel, Switzerland)

15:00 – 15:30 Coffee Break

15:30 – 17:30 Study Groups

DAY 3: Wednesday, 7th November 2018

Methodological advances in toxicology and Examples of specific class of chemicals/products

9:00 - 10:00 Alternative methods in toxicology: the concept of the Adverse Outcome Pathway (A. Terron, EFSA, Italy)

10:00 - 11:00 Safety evaluation of cosmetics and SCCS (C.L. Galli, University of Milan, Italy, presented by Emanuela Corsini, University of Milan, Italy)

11.00-11.30 Coffee Break

11:30 - 12.30 Safety evaluation of pesticides (T. Fatur, National Institute of Public Health, Slovenia)

12:30 - 14 .00 Lunch

14:00 - 15:00 Safety evaluation of pharmaceuticals and medical devices (M. Kržan, University of Ljubljana, Slovenia)

15:00 - 16:00 Safety evaluation of veterinary medicines (L. Peterlin Mašič, University of Ljubljana, Slovenia)

16:00 – 16.30 Coffee break

16:30 - 18:30 Study Groups

DAY 4: Thursday, 8th November 2018

Regulatory requirements by the European agencies, methodological advances in toxicology and current issues in safety assessment

9:00 - 10:00 The classification, packing and labelling of chemicals (E. Fabjan, ECHA, Finland)

10:00 - 11:00 REACH (E. Fabjan, ECHA, Finland)

11:00 - 11:30 Coffee Break

11:30 - 12:30 Skin sensitization testing of chemicals using 3R methodologies and quantitative risk assessment (E. Corsini, University of Milan, Italy)

12:30 - 14:00 Lunch

14.00 -15:00 Scientific criteria for identification of endocrine disruptors – application of ECHA and EFSA guidance (L. Perharič, National Institute of Public Health, Slovenia)

15:00-15:30 Coffee Break

15:30 – 17:30 Study Groups

DAY 5: Friday, 9th November 2018

Presentations of the study groups, discussions, final exam

9:00 - 10:00 Presentations of the Study Groups

10:00 - 10:30 Coffee Break

10:00 - 12:30 Presentations of the Study Groups

12:30 - 14:00 Lunch

14:00-15.30 Final Exam

15:30 Closing

Saturday, 10th November 2018

Departure of long distance participants