



## **Slovensko toksikološko društvo** **Slovenian Society of Toxicology**

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### **EUROTOX specialized toxicology course 2018**

#### **Regulatory toxicology**

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

**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:** 4<sup>th</sup>- 10<sup>th</sup> November, 2018

**Host Society:** Slovenian Society of Toxicology

**Venue:** Hotel Sport, Otocec Slovenia (<https://www.termo-krka.com/us/en/destinations/otocec/>)

According to a Decree No. 6171-1208012000 of the Slovenian Ministry of Education, Science and Sports, The Slovenian Society of Toxicology holds a status of a society acting in public interest. The Slovenian Society of Toxicology is a member of international toxicological associations EUROTOX (<http://www.eurotox.com/>) and IUTOX (<https://www.iutox.org/>).

**Contact and applications:** Slovenian Society of Toxicology, L. Perharic, Gerbiceva 60, SI-1000 Ljubljana, Slovenia; [slotox@gmail.com](mailto:slotox@gmail.com); tel: + 386 40 628 361

**Deadline for applications:** 5<sup>th</sup> October 2018

**Lecturers and tutors:**

E. Corsini, University of Milan, Italy (lecturer and tutor)  
K. Cerne, 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. Krzan, University of Ljubljana, Slovenia (lecturer)  
J.M. Parra Morte, EFSA, Italy (lecturer)  
L. Perharic, National Institute of Public Health, Slovenia (lecturer and tutor)  
L. Peterlin Masic, 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)

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**General Outline of the Course**

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**DAY 0:** Sunday, November 4<sup>th</sup>, 2018

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**Arrival of long distance participants, lecturers and tutors**

**DAY 1:** Monday, November 5<sup>th</sup>, 2018

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**Introduction to Hazard identification, Risk Assessment and Risk Management**

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

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**DAY 2:** Tuesday, November 6<sup>th</sup>, 2018

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**Regulatory requirements by the European agencies**

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 21<sup>st</sup> century – principles and initiatives (M.F. Wilks, University of Basel, Switzerland)

**15:00 – 15:30 Coffee Break**

15:30 – 17:30 Study Groups

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**DAY 3:** Wednesday, November 7<sup>th</sup>, 2018

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**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, Parma)

10:00 - 11:00 Safety evaluation of cosmetics and SCCS (C.L. Galli, 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. Krzan, University of Ljubljana, Slovenia)

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

**16:00 – 16.30 Coffee break**

16:30 - 18:30 Study Groups

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**DAY 4: Thursday, November 8<sup>th</sup>, 2018**

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**Methodological Advances in Toxicology**

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

10:00 - 11:00 Safety evaluation of nanomaterials (C.L. Galli, University of Milan, Italy)

**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 REACH (E. Fabjan, ECHA, Finland)

**15:00-15:30 Coffee Break**

15:30 – 17:30 Study Groups

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**DAY 5: Friday, November 9<sup>th</sup>, 2018**

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**Current issue in safety assessment**

9:00 - 10:00 Scientific criteria for identification of endocrine disruptors – application of ECHA and EFSA guidance (L. Perharic, National Institute of Public Health, Slovenia)

**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

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**Saturday, November 10<sup>th</sup>, 2018**

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**Departure of long distance participants**