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**Training Courses**

**In English**

**CEHTRA 2020**

- **Who can attend**
- **Where**
- **How long**
- **How much**

**Courses**

- Regulatory Toxidology
- Classification CLP
- Cosmetic Products
- Ecotoxicology - The Basics
- Ecotoxicology - Advanced
- ECETOC TRA Version 3
- Industrial Hygiene Monitoring
- On-site Chemical Risk Assessment
- Safety Data Sheets - 1 to 16
- Extended Safety Data Sheets
- Environmental Assessment of Pesticides
- Plant Protection Products
- Plant Protection - Residues
- OECD QSAR Toolbox
- Regulatory Genetic Toxicology
- Biocide Regulation Fundamentals
- Authorisation REACH
- Reach
INTRODUCTION TO REGULATORY TOXICOLOGY
AND RISK ASSESSMENT FOR HUMAN HEALTH

OBJECTIVES

• Understand the place of toxicology in the life of substances according to the regulations
• Know the main tests, the difficulties and issues implied
• Optimize the interactions between Managers and Experts

PROGRAMME

Part 1 – Regulatory Toxicology – Overview
Part 2 – ADME (Absorption, Distribution, Metabolism and Excretion): basics
Part 3 – Acute systemic toxicity (oral, dermal, inhalation)
Part 4 – Local tolerance: dermal and ocular
Part 5 – Skin sensitization
Part 6 – Repeated-dose and chronic toxicity
Part 7 – Reproductive toxicity and teratogenicity
Part 8 – Mutagenesis and genotoxicity
Part 9 – Carcinogenicity
Part 10 – Introduction to non-experimental alternative methods used in toxicology
Part 11 – Introduction to the determination of Toxicity Reference Values
Part 12 – Introduction to human health Risk Assessment
Part 13 – Toxicology as described in a regulatory dossier (REACH) – Case study

How to register:

1. Fill in the Pre-registration and Profile form (3 pages)
2. Send it to CEHTRA
3. Once the date confirmed, the form is sent back to you for signature
4. Finalization

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SAS au capital de 16 000 € - Intra-comm. TVA/VAT code : FR 244 347 334 40 SIREN : 434 733 440 – Code APE 7490B – RCS Bordeaux
CLASSIFICATION-CLP FUNDAMENTALS OF CLP

Site Managers
Staff without prior classification training

Paris
Lyon
Bordeaux

1 day
1 100 excl. VAT

OBJECTIVES

• Identify the data to be taken into account
• Be able to use the new classification criteria

PROGRAMME

Brief overview on the history, news and next changes

Part 1
Dangerous substances
• Class by class, input and output data, criteria:
  - Physical hazards
  - Human hazards
  - Environmental hazards
• Harmonized classification; labelling; downstream obligations

Part 2
Dangerous mixtures
• Class by class, input and output data, criteria, calculation methods; practical exercises:
  - Physical hazards
  - Human hazards
  - Environmental hazards
• Use of CLP; labelling; downstream obligations (PPC notification)

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CLASSIFICATION POUR LE TRANSPORT DES MARCHANDISES DANGEREUSES

CLASSES 3 À 9, SAUF 7

Rédacteurs de FDS rubrique 14
Logisticiens en charge du TMD

Paris
Lyon
Bordeaux

1 jour
1 100 HT

OBJECTIF

Comprendre les principes de classification en évitant les pièges

PROGRAMME

1. Idées reçues : coûts inutiles ou amendes
2. Classifications TMD et CLP : similarités et différences
3. Classe de danger et Groupe d’emballage :
   a. Identifier les marchandises déjà listées
   b. Comprendre les tests et les critères
   c. Méthode par calcul
   d. Règles de priorité, choix du nom UN, nom générique
4. Marquage et Etiquetage

Étapes à suivre:

1. Remplir Bulletin de Pré-Inscription & Votre Profil (5 pages)
2. Envoyer le tout à CEHTRA
3. Une fois date confirmée, Bulletin renvoyé par CEHTRA et à signer par vous
4. Finalisation

Intervenant
Virginie BUROSSE

Only available in French
SAFETY OF COSMETIC PRODUCTS
REGULATORY CONTEXT AND SAFETY REPORT

OBJECTIVES

• Know and understand Cosmetic Regulation No. 1223/2009
• Understand the risk assessment of a cosmetic product
• Identify the improvements allowing to comply with the regulatory compliance

PROGRAMME

Part 1
Regulatory context of Cosmetics (Europe and other countries)
  • European Cosmetic Regulation No. 1223/2009
  • Field of application
  • Borderline products
  • Responsible Person, CPNP, Product Information File
  • Post-marketing survey (cosmetovigilance)
  • Updates

Part 2
Cosmetic Product Safety Report (CSR)
  • Overview of the requirements
  • CPSR content and regulatory obligations
  • Concept of safety assessment: calculation of MoS, local tolerance…
  • Toxicological profile on ingredients
  • Data on the product

Part 3
Specific cases:
  • Products for babies, perfumes
  • Evaluating non tested ingredients
  • The interest of in silico methods
  • Updates: considering new data

Part 4
Questions / Answers

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ECOTOXICOLOGY - THE BASICS
UNDERSTAND THE STUDIES AND HOW TO PUT THEM INTO APPLICATION

People in Regulatory Affairs teams
Scientists with little or no environmental experience

Paris Lyon Bordeaux
1 day
1 100 excl. VAT

OBJECTIVE
• Understand the basics of ecotoxicology studies and how they can be used in Classification & Labelling and risk assessment

PROGRAMME

Part 1
Environment: Regulatory aspects
• Revision of the physico chemical parameteres used:
  - Solubility
  - Henry’s Constant
  - Log Kow
  - Adsorption
• Studies of abiotic degradation :
  - Hydrolysis
• Studies of biotic degradation :
  - Studies of biodegradation easy/intrinsic
  - Simulation studies

Part 2
Ecotoxicology: Regulatory Aspects
• Organisms used in regulatory ecotoxicology
• Ecotoxicology studies: methods used
• The principal of studies: essential criteria
• Statistical methods
• Introduction to risk evaluation: Derivation PNEC from ecotoxicology studies
• Introduction to alternative methods, avoiding animal testing used in ecotoxicology
• Classification
• FDS

How to register:

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Trainer
Paul THOMAS

Trainer
Blandine JOURNEL

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**ECOTOXICOLOGY - ADVANCED**

**THE STUDIES, THE RESULTS AND HOW TO AVOID PITFALLS**

**OBJECTIVES**

- Better understand why the studies are carried out, what the results mean and how they can be used in Classification & Labelling and risk assessment
- Be able to identify the pitfalls in studies and know how to avoid them

**PROGRAMME**

**Part 1**

Environment: Regulatory aspects

- Revision of the physico chemical parameters used:
  - Solubility
  - Henry's Constant
  - Log Kow
  - Adsorption
- Studies of abiotic degradation:
  - Hydrolysis
- Studies of biotic degradation:
  - Studies of biodegradation easy/intrinsic
  - Simulation studies
- Use of biodegradation data for Risk Assessment

**Part 2**

Ecotoxicology: Regulatory Aspects

- Organisms used in regulatory ecotoxicology
- Ecotoxicology studies: methods used
- The principal of studies: essential criteria
- Statistical methods
- Introduction to risk evaluation: Derivation PNEC from ecotoxicology studies
- Introduction to alternative methods, avoiding animal testing used in ecotoxicology
- Classification
- FDS
- Case studies

**How to register:**

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4. Finalization

Trainer
Paul THOMAS

Trainer
Blandine JOURNEL

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CHESAR 3
ÉVALUATION DE L’EXPOSITION ENVIRONNEMENTALE POUR REACH

Partie 1
Fondamentaux
• Démarche d’évaluation des risques dans le cadre de REACH
• Construction d’un Scénario d’Exposition
• Utilisation du facteur d’échelle (scaling, itération)

Partie 2
Fonctionnalités de l’outil CHESAR 3
• Contexte de développement
• Principaux inputs et liens avec les résultats d’exposition (exemples et cas pratiques)

Partie 3
Potentiel d’adaptation de CHESAR 3 pour l’affinement de l’évaluation des risques
• Cadre réglementaire, diversité des approches d’affinement
• Interprétation des résultats de l’évaluation en lien avec les Conditions d’Opération et les Mesures de Management des Risques
• Affinements de la STEP

Partie 4
Cas pratiques
• Utilisation de l’outil CHESAR 3 sur des cas pratiques

Étapes à suivre:
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OBJECTIFS
• Comprendre et interpréter les Scénarios d’Exposition
• Être capable d’utiliser l’outil CHESAR 3
• Savoir affiner/adapter les scénarios
• Définir les conformités entre les données des Fiches de Données de Sécurité (étendues) et les mesures de management des risques sur site

Intervenant
Emilie BIGORGNE-VIZADE

Only available in French
ECETOC TRA Version 3
Human Exposure Assessment

Objectives
- Master the ECETOC TRA V3 tool
- Understand and interpret exposure scenarios
- Define compliance between extended Safety Data Sheet data and the Risk Management Measures on-site
- Validate the regulatory framework of risk assessment tools – REACH and Member States (chemical risk at the workstation)
- Analyse potentials for adapting ECETOC TRA for risk assessment at the workstation

Programme

Part 1
Basics
- Risk assessment process according to REACH
- Building Exposure Scenarios
- Use of “scaling” principals according to REACH

Part 2
Functionalities of the ECETOC TRA V3 tool
- Development of the context
- Limits of use
- Principal inputs and links with exposure
- Results – examples and practical case studies

Part 3
Installation and use of ECETOC TRA V3
- Loading the V3 application as integrated tool
- Functionalities of user interface in the integrated version

Part 4
Practical case studies
- Use of ECETOC TRA V3 on practical cases

Part 5
Potential for adaptation of ECETOC TRA to risk assessment at the workstation
- REACH as regulatory framework and prior risk assessment at the workstation
- Interpretation of the risk assessment results at the workstation in connection with the Risk Management Measures according to REACH

How to register:
1. Fill in the Pre-registration and Profile form (3 pages)
2. Send it to CEHTRA
3. Once the date confirmed, the form is sent back to you for signature
4. Finalisation
INDUSTRIAL HYGIENE MONITORING
FROM SELECTING STRATEGY TO RESULT INTERPRETATION

OBJECTIVE
Become self-sufficient and efficient in industrial hygiene monitoring, from selecting strategy to result interpretation

PROGRAMME

Part 1
Principles and basic definitions
• Definition of product and substance
• Product classification and labelling notions
• Plan and structure the assessment actions

Part 2
Picking strategy
• Define an action plan for measurement
• Which products, which employees, number of picking samples, duration and periods of sampling?

Part 3
Methods and material for collecting and analysis
• Direct and indirect methods
• Gases and vapours, mineral and basic aerosols, acids

Part 4
Result interpretation
• Statistics
• Limit values

How to register:
1. Fill in the Pre-registration and Profile form (9 pages)
2. Send it to CEHTRA
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4. Finalization

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ON-SITE CHEMICAL RISK ASSESSMENT
THE ESSENTIALS - ALL YOU NEED TO KNOW

HSE Managers
Site Managers
Occupational physicians

Paris
Lyon
Bordeaux

1 day

1 100 excl. VAT

OBJECTIVES

• Get the indispensable elements for the practical implementation of the assessment of the prevention from chemical risk
• Structure the assessment steps to hierarchise the technical, human and financial priorities
• Be up-to-date regarding the regulatory changes and understand the futures orientations

PROGRAMME

Part 1
Chemical risk and regulatory compliance
• Regulatory news and foresight

Part 2
Assessment of the Chemical risk: a key step
• Product inventory
• Establish the priorities for action
• Analysis: from technical to organisational

Part 3
Action plans and preventive measures
• Prioritise the actions to be conducted
• Implement an efficient prevention plan
• Indicators and monitoring

Part 4
Practical exercises, case study

How to register:
1 Fill in the Pre-registration and Profile form (3 pages)
2 Send it to CEHTRA
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4 Finalization

Trainer
Charles ALARCON

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SAFETY DATA SHEETS
REDACTION OF SECTIONS 1 TO 16

OBJECTIVES

• Acquire the basic knowledge of measures related to classification
• Be able to write the 16 sections in a way that is customised to the product
• Assess the consistency of information

PROGRAMME

• Regulatory requirements:
  - which products
  - SDS mandatory/upon request
  - update
• Section by section:
  - understand the required information
  - be clear and concise
  - harmonise without standardising
• Focus on:
  - Confidentiality of compositions
  - Transport classification
  - Seveso III/ICPE (FR) classification
• Each section is illustrated with an example of redaction
• Interactions between chapters and with the extended part are highlighted

How to register:

1. Fill in the Pre-registration and Profile form (3 pages)
2. Send it to CEHTRA
3. Once the date confirmed, the form is sent back to you for signature
4. Finalization
EXTENDED SAFETY DATA SHEETS

CHEMICAL SAFETY ASSESSMENT

HSE Managers
Site Managers
Occupational physicians

Paris
Lyon
Bordeaux

1 day

1 100 excl. VAT

OBJECTIVES

• Master basics of regulatory and technical aspects of chemical safety assessment (according to the European REACH regulation), especially for downstream users
• Get an overall picture of modelling tools
• Learn about the key models and in silico methods used in REACH including ECETOC TRA
• Use “scaling” principals to their full potential
• Be able to analyse suppliers’ extended Safety Data Sheets (e-SDS)
• Integrate and adapt information from e-SDS of individual substances to transform them into a new e-SDS for a mixture (with examples)

PROGRAMME

• Master the TIER 1 assessment tools for human health and environment
• Overview of modelling tools (ECETOC TRA)
• Use of Industrial Hygiene data
• Scaling
• CSA/CSR for downstream users: scope, methods
• SDS: regulatory recap
• Extended SDS: raw materials and mixtures put on the market
• Checking the operational implementation of Operational Conditions & Risk Management Measures indicated in the Exposure Scenario

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ENVIRONMENTAL ASSESSMENT OF PESTICIDES
UNDERSTAND THE STUDIES, THE RESULTS AND THE ENVIRONMENTAL EXPOSURE ASSESSMENT AND BE ABLE TO WRITE TIER 1 RISK ASSESSMENT

OBJECTIVES

- Better understand why the studies are carried out, what the results mean and how they are used to assess the environmental exposure
- Be able to realise Tier1 environmental risk assessment for all compartments (soil, surface waters, ground waters, air)

PROGRAMME

Part 1
Regulatory context and studies
- Description
- Required data

Part 2
Models and input parameters
- Models: FOCUS, EFSA, ESCAPE…
- Determination of input parameters
- Pitfalls to avoid

Part 3
Case studies

How to register:
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4. Finalisation

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Trainer
Philippe ADRIAN

Trainer
Aurélie BARRET

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PLANT PROTECTION PRODUCTS - REGULATORY

FUNDAMENTALS AND CHALLENGES OF REGULATION (EC) No. 1107/2009

OBJECTIVES

• Understand the regulatory procedures for active substances and products
• Understand zonal assessment and dRR dossiers
• Understand the content of the regulatory dossiers for approval application of substances and product authorisation

PROGRAMME

Part 1
Regulation (EC) No. 1107/2009
• Overview of the regulation
• The various procedures concerned

Part 2
Zonal assessment
• Comparison of Zonal assessment: Northern, Central and Southern zones
• Interactions between the Notifier and the Competent Authorities

Part 3
Dossier Requirements
• New requirements: for which substances?
  For which products?
• Ensuring the compliance of an existing dossier with the new regulatory requirements

Part 4
Study case(s)

How to register:
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PLANT PROTECTION - RESIDUES

MRL and consumer risk assessment for Plant protection Product (Reg 1107/2009)

Regulatory Specialist
Paris
Lyon
Bordeaux
1 day
1 100 excl. VAT

OBJECTIVES

• Understand the principles of quantitative exposure (metabolism study),
• Understand the principles of qualitative exposure (field residue studies, livestock feeding studies, processing studies...),
• Understand the determination of the MRL,
• Understand consumer risk assessment

PROGRAMME

1. Good Agricultural Practices (GAP)
2. Qualitative exposure
3. Quantitative exposure
4. Dietary Risk Assessment
   • Specific points
   • Practical cases

How to register:
1. Fill in the Pre-registration and Profile form (3 pages)
2. Send it to CEHTRA
3. Once the date confirmed, the form is sent back to you for signature
4. Finalization
OCEC QSAR TOOLBOX
AN INTRODUCTION TO REPLACING EXPERIMENTATIONS USING READ-ACROSS AND QSAR MODELLING

Toxicologists and Ecotoxicologists
QSAR and Read-across experts
REACH consultants

Paris
Lyon
Bordeaux

1 day

1 100 excl. VAT

OBJECTIVES

• Understanding the OECD QSAR Toolbox interface and functionalities.
• Be able to use the tool to obtain profiling and Read-Across/QSAR predictions for various physicochemical, ecotoxicological and human health endpoints
• To assess the reliability in predictions derived using the OECD QSAR Toolbox.
• To generate prediction reports for the read-across and QSAR results

PROGRAMME

Part 1
Basics
• Introduction to OECD QSAR Toolbox
• Overview of all the tool functionalities

Part 2
Profiling and category formation
• Introduction to profiling and category formation approaches in the tool

Part 3
Read-Across and QSAR predictions
• Physicochemical endpoints

Part 4
Ecotoxicological and environmental endpoints
• Human health endpoints
• Training participants can choose the endpoints and the chemical structures to be used as case studies.

Read-Across/QSAR prediction reports
• Generation of prediction reports which could be used for regulatory purposes.

How to register:

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Training course delivered in partnership with

KREATIS

Trainer
Carole CHARMEAU

Trainer
Mélanie DELANNOY
REGULATORY GENETIC TOXICOLOGY
FROM THE THEORY, METHODS, REVIEW PROTOCOLS, REPORTS AND DATA INTERPRETATION

OBJECTIVES

- To acquire a basic understanding of the theory and methods of the standard genetic toxicology assays used for regulatory purposes
- To understand how to review protocols and reports and how to interpret the data
- Data-interpretation exercises including how to manage positive data

PROGRAMME:

Part 1
- Introduction
- Genetic toxicology test methods – primary in vitro and in vivo tests
- Ames test training video – optional

Part 2
- Reviewing Protocols and Reports

Part 3
- Interpretation of mammalian genotoxicity studies (chromosome aberration and gene mutation assay), including some specific examples
- What to do if you get positive results?
- Pros and cons of the various in vivo test guidelines

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Anybody who is involved in Biocide regulatory requirements

Paris
Lyon
Bordeaux
1 day
1 100 excl. VAT

OBJECTIVES
To be defined according to request

PROGRAMME:
Part 1
Introduction
To be defined

Part 2
To be defined

How to register:
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AUTHORISATION REACH
AVANT ET APRÈS INCLUSION DE VOTRE SUBSTANCE D’INTÉRÊT

Responsable HSE
Responsable réglementaire

Responsable
Paris
Lyon
Bordeaux

1 jour
1 100 HT

OBJECTIFS

• Mieux comprendre le processus réglementaire conduisant une substance à être soumise à autorisation
• Comprendre la complexité d’un dossier d’autorisation

PROGRAMME

Partie 1 : La prioritisation sous REACH
• But réglementaire de la prioritisation
• Description des différentes étapes
• Comment une substance arrive jusqu’à l’annexe XIV

Partie 2 : Qu’est-ce qu’un dossier d’autorisation
• Généralités réglementaires
• Description du rapport sur la sécurité chimique (CSR)
• Description de l’analyse des alternatives (AoA)
• Description de l’analyse socio-économique

Partie 3 : Les chiffres clés
• Review period demandées / Durées moyenne obtenues
• Nombre de dossiers soumis
• Couts interne / Couts externe

Partie 4 : Les substances concernés
• Les substances déjà listés
• Les futures substances

Partie 5 : Conclusion
• Les notions clés

Intervenant
Stéphane PIERRE

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Only available in French
REACH
FUNDAMENTALS OF REGULATION (EC) No. 1907/2006

OBJECTIVES
• Get an overview of REACH
• Understand the implementation of REACH

PROGRAMME:

Part 1
Introduction to REACH
• Global context
• Regulatory texts
• Responsibilities of the actors in the supply chain
• Objectives

Part 2
Content
• Overview
• Processes
• European Chemicals Agency: ECHA

Part 3
Scopes and technical progress
• Background
• «Already» registered substances – Pre-registered
• Total or partial exemptions
• Substances, Preparations and Articles under REACH
• Intermediates
• Polymers
• Stakeholders under REACH: communication

Part 4
SIEF and content of a registration dossier
• Mandatory data sharing
• Functions of a SIEF
• Content of a technical dossier
• Content of a CSR: risk assessment

Part 5
Key points of REACH
• The basics of REACH
• General purpose
• Data from ECHA

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4. Finalization