



# THE SETAC EUROPE CERTIFICATION OF ENVIRONMENTAL RISK ASSESSORS

## *Guidance document on the procedure to become a registered SETAC Europe Certified Environmental Risk Assessor*

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## 1. Introduction and general overview

This document describes the procedures according to which one can become a registered “SETAC Europe Certified Environmental Risk Assessor” (CRA).

The **standard procedure** to become a registered “Certified Environmental Risk Assessor” (CRA) follows the steps illustrated schematically in Figure 1.



**Figure 1** Flow chart of the standard procedure to become a SETAC Europe Certified Environmental Risk Assessor (CRA).

The standard procedure follows the following steps, in the order described below:

1. Check the eligibility requirements and sign up for the programme. To proof the eligibility applicants must provide:
  - i. A curriculum vitae
  - ii. Copies of the relevant degree (MSc or PhD) including transcripts or course lists
2. Becoming a **SETAC Europe Certified Environmental Risk Assessor (CRA)** by:
  - a. Successfully showing the mastering of 9 Environmental Risk Assessment (ERA) competences. In order to demonstrate competence, the applicant must pass a multiple-choice examination (see Annex 1 for attainment levels).

AND

- b. Demonstrating sufficient theoretical and practical specialisation and advanced knowledge on at least 2 out of the 9 CRA topics. The applicant must pass the final oral examination in order to demonstrate advanced knowledge.

AND

- c. Demonstrating sufficient experience as an environmental risk assessor by at least 2-5 years<sup>1</sup> of on-the-job practical experiences in an ERA job (in government, industry or consultancy context) and confirmed by:
  - i. a risk assessment report (see [section 3.3](#) for further details)
  - ii. a letter of recommendation from the institution or company where the practical job experiences was gained
  - iii. a total of three additional letters of recommendation, preferably one from each of the three sectors (academia, business, and government). At least one letter must be written from a peer outside the sector and institution the applicant is working in. Deviations due to e.g. conflict of interests are possible but should be motivated in the motivation letter.

AND

- d. Demonstrating commitment to continued education and training in ERA, by having participated in at least 1 specialised course or training in the last 2 years, which was worth in total 3 credits<sup>2</sup>, and at least 1 active participation in a conference, symposium in the last 2 years.

AND

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<sup>1</sup> No strict time period can be given as most important is that the candidate has gained sufficient experience to meet the criteria set for passing the CRA exam; this may differ depending on the background and basic training the candidate had before starting the risk assessment job.

<sup>2</sup> One (1) credit is equal to 28 hours of total study load. The credits are based on the European Credit Transfer System (ECTS).

- e. Passing the final oral CRA examination in which an in-depth discussion is held with the examination panel to assess the competence of the applicant to act as an environmental risk assessor. The discussion will focus on the risk assessment report but also address the advanced knowledge on 2 out of 9 CRA topics, the general experience in risk assessment, continued training in the field and other elements of importance for the certification as an environmental risk assessor.

It is possible to apply for immediate **direct registration** as a CRA via the submission of a **dossier for direct registration**, when all of following criteria are fulfilled:

- Applicants must be able to clearly argue and demonstrate that they have already obtained all competences of a CRA.
- They must have more than 5<sup>1</sup> years of practical job experiences in an ERA job.
- They must demonstrate commitment to continued education and training in ERA, by regularly participating in activities (e.g. organised by SETAC) such as specialised courses or trainings (at least one of these in the last two years) worth in total 3 credits, and symposia, workshops or conferences (at least one of these in the last two years)
- They must submit a concise written risk assessment report and succeed for the final CRA examination. The submission of such a report and the final CRA examination can be waived only for applicants with at least 10 years of ERA job experience, based on a written argumentation and motivation.

Dossiers for direct registration must be submitted to the Certification Programme Committee (CPC) to check for eligibility and to decide on any requests for waiving the final CRA examination. The final decision on the certification of such a candidate (i.e. registration as a CRA) is made by the CPC, according to the same standards as for those who have followed the standard programme (i.e. considering the same competence requirements). The system of direct registration as a CRA with examination waving is intended to be in effect for a limited period of time and the end of this period will be announced 6 months in advance on the CRA website.

In the sections below, a more detailed description of each of the different steps is provided.

## 2. Eligibility Check

The check for eligibility can occur at any moment and is initiated by the applicant by submitting the necessary documentation (via the programme website).

For the eligibility check the following elements need to be provided in English:

- A Curriculum Vitae of the applicant including contact details and current affiliation.
- Copies of relevant diploma's (Master of Science or doctoral degree) including transcripts or list of courses (the Certification Programme Committee can ask for an official transcription in English and certified copies if it considers this necessary for a proper evaluation).

For early career candidates or students, we recommend seeking a mentor. This mentor must have demonstrable experience with ERA or having several competences matching those required from a CRA (this requirement is obviously fulfilled in case the mentor is a registered CRA). The mentor's role may continue until the final CRA examination (see further), and mainly includes providing advice and guidance to the candidate in seeking suitable education (e.g. basic, advanced or specialised courses), developing sufficient expertise in (different aspects of) environmental risk assessment, building and enlarging the professional network and writing a risk assessment report to be discussed at the final CRA examination.

Eligibility is decided upon by the Certification Programme Committee, based on the submitted documentation, while at the same time following the guidance with regard to the applicant's diploma('s):

- All applicants having an M.Sc. or Ph.D. diploma in a discipline that has significant affinity with environmental risk assessment (e.g., biology, ecology, toxicology, physiology, biochemistry, chemistry, statistics, environmental science) will normally be allowed to enter the programme.
- Applicants not having such a M.Sc. or Ph.D. diploma will be evaluated on a case-by-case basis. For instance, applicants already working in a risk assessment environment, but without a relevant M.Sc. or Ph.D. diploma may be allowed to enrol in the programme based on objective elements presented.

A negative decision needs to be substantially motivated by the Certification Programme Committee and communicated to the applicant. This can be accompanied with advice to the applicant for re-application. All decisions are taken by the Certification Programme Committee on the basis of a simple majority (50% or more in favour of the applicant). The programme is not time limited.

### 3. Becoming a SETAC Europe Certified Environmental Risk Assessor

#### 3.1. Basic competences in 9 topics

Table 1 presents a list of the 9 core topics or areas of expertise related to environmental risk assessment that someone needs to have basic knowledge about and needs to develop competence in to become a “SETAC Europe Certified Environmental Risk Assessor”. In **Annex 1** the specific content of each of these topics (and of associated competences and attainment levels) is described in further detail.

Table 1: List of 9 topics in which knowledge and competences needed to be obtained to become a SETAC Europe Certified Environmental Risk Assessor (CRA)

1. Ecology concepts, principles and processes
2. Concepts and principles in regulatory ecotoxicology, environmental risk assessment, and relevant legislative frameworks
3. Environmental Chemistry: fate of chemicals in the environment
4. Environmental Chemistry: exposure estimation of chemicals in the environment
5. Sub-organism level (eco)toxicology (mechanistic toxicology): molecular, cellular, biochemical and physiological effects and biomarkers
6. Organism-level ecotoxicology
7. Supra-organism level ecotoxicology or “Chemical Stress Ecology”: effects of chemicals at population, community, ecosystem and landscape-level
8. Retrospective risk assessment: chemical and bio-monitoring of exposure and effects
9. Statistics for environmental risk assessors

The applicant will complete the 9 topics (Table 1) with associated competences (Annex 1) by passing the multiple-choice examination (see section 3b). Only after passing the multiple-choice examination the applicant can be allowed to continue for the final oral CRA examination.

#### 3.2. Multiple-choice examination to proof the basic knowledge and competences in all 9 topics

Applicants proof the completion of the 9 topics (Table 1) with associated competences (Annex 1) by passing a multiple-choice examination.

The criteria to participate in the examination are:

- Passed eligibility check
- Payment of the multiple-choice examination fee

The multiple-choice examination will normally take place in the margin of the SETAC Europe Annual Meeting. Each calendar year, candidates can register for the multiple-choice examination (dates are announced on the programme website). Multiple-choice examinations can also take place at other times or locations (SETAC workshops, SETAC office) but need to be requested at least two months in advance.

The multiple-choice examination addresses the theoretical knowledge as well as transfer skills as part of the assessment of the competences of the applicant. The multiple-choice examination can be repeated, if the candidate fails.

The multiple-choice examination will meet the following criteria:

- The questions will cover all 9 CRA topics equally.
- The questions will be aimed at the level of entrance of the CRA programme (Master of Science)
- The grading procedure will be explained on the multiple-choice form and for each questions its specific topic will be identified.
- All questions will be standardised providing four (4) options with one correct choice.

With registering for the multiple-choice examination, an “**examination fee**” needs to be paid (see programme website for more information), before the candidate can sit the examination. This fee covers all administrative and organisational costs for the multiple-choice examination.

### 3.3. On-the-job experiences as an environmental risk assessor

A crucial element in the programme is that all candidates need to have sufficient experience as an environmental risk assessor by at least 2-5 years<sup>3</sup> of hands-on experiences in an ERA job, either in an industry, a consultancy or a government context. Through the on-the-job, practical experience candidates will learn about most (if not all) aspects of environmental risk assessment in a practical way and in a job of risk assessment. In addition, it will also further enable acquiring and/or developing those competences that go beyond “knowledge” and that are described by so-called “Dublin Descriptors” (see Annex 2). Applicants need to develop competences in all of the following aspects in an integrated manner:

- Data collection (in databases, papers, study reports)
- Data quality screening and data selection
- Selection and use of appropriate methods and models for exposure and effect assessment
- Performing exposure, effect and risk assessment
- Writing a risk assessment report and presenting clear conclusions about risks (and if applicable possible mitigation measures)
- Communicate about the risks and present a dossier

Once sufficient on-the-job experience has been obtained, a concise, yet critical and scientific risk assessment report is submitted to the Certification Programme Committee (on a confidential basis) (green light for this needs to be given by the employer).

The report should be written as a scientific document, and include sections such as:

- introduction, background, scope, aims
- materials and methods (exposure, effects, and risk assessment)
- results (exposure, effects and risk assessment)
- a critical discussion, including the appropriateness of methods used or guidelines followed and recommendation(s) for their improvement
- conclusions & recommendations
- list of cited references.

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<sup>3</sup> No strict time period can be given as most important is that the candidate has gained sufficient experience to meet the criteria set for passing the final CRA exam; this may differ depending on the background and basic training the candidate had before starting the risk assessment job.

The report will not only be judged in terms of its timelines, i.e. being scientifically up-to-date with current methods in exposure, effects and risk assessment, but also in terms of the critical evaluation and discussion of these methods.

Together with this submission, the applicant can register for the final CRA examination (see 3c).

Finally, it is noted that, while the programme is aimed at certification of Environmental Risk Assessors, Life Cycle (Impact) Assessment can also be a subject of the on-the-job training as long as there is a clear link with or integration of Environmental Risk Assessment principles.

### 3.4. Becoming a SETAC Europe Certified Environmental Risk Assessor

Applicants need to provide and/or update the following elements in the certification dossier:

- An updated Curriculum Vitae of the applicant.
- A motivation letter, which includes the following points:
  - a summary of past, current and envisaged future professional activities in environmental risk assessment
  - a statement about how the applicant envisages the aspects of his or her own commitment to continued education and training in the next five years
- Proof of having completed the full list of 9 competences as evidenced by passing the multiple-choice examination.
- Having sufficient theoretical and practical specialisation and advanced knowledge on at least 2 out of the 9 CRA topics. The topics should be indicated in the dossier and will be tested in the final oral examination.
- Proof of having worked at least 2-5 years<sup>4</sup> in an ERA environment.
- A recommendation letter by the institution or company where the practical, on-the-job experience was gained.
- Proof of commitment to continued training and education, by a statement in the motivation letter (see above) and also by means of providing proof of having participated (in the last two years) in at least one ERA-related specialised course or training worth in total 3 credits and at least one ERA-related symposium, workshop or conference (e.g. such as those organised by SETAC).
- A total of three additional recommendation letters preferably one from academia, one from business, and one from government (as a proof of recognition by peers). At least one letter must be written from a peer outside the sector and institution the applicant is working in. Deviations due to e.g. conflict of interests are possible but should be motivated in the motivation letter.

Together with the submission of the updated certification dossier, a “**certification fee**” needs to be paid (see programme website for more information) before the dossier will be evaluated. This fee covers all administrative and organisational costs for the evaluation and the final CRA examination (further called judgment).

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<sup>4</sup> No strict time period can be given as most important is that the candidate has gained sufficient experience to meet the criteria set for passing the final CRA exam; this may differ depending on the background and basic training the candidate had before starting the risk assessment job.



When the requirements are met, the applicant is eligible to sit the final oral CRA examination. Every final CRA examination will normally take place in the margin of the SETAC Europe Annual Meeting. Each calendar year, candidates can register for the final CRA examination (deadline 31<sup>st</sup> January).

The criteria to participate in the examination are that:

- a written environmental risk assessment report in English has been submitted (or will have before 31<sup>st</sup> March).

In the context of the flexibility of the programme, deviations from the above procedure are possible. However, any deviations from this normal registration procedure (i.e. holding the examination in a different period of the year, in a different location or via video-conferencing) should be requested from the Certification Programme Committee at least 3 months before the actual examination date, to allow ample time for the organisation of the final CRA examination. In such deviating cases, the written environmental risk assessment report has to be submitted at the latest 3 months before the actual examination date.

This examination is comparable to a dissertation defence held at universities and consists of an oral presentation (of the written report, as in 2b), followed by a discussion with the examination panel. The discussion will be held on the basis of both the oral presentation and the contents of the written report but will also address the advanced knowledge in 2 CRA topics. The total duration of the examination shall be at least 60 minutes, of which at least 2/3 is devoted to discussion. The judgment will be based on the written report, the oral presentation and the discussion.

The aim of the examination is to evaluate if the applicant has the capacity to function at high level in an environmental risk assessment job. This evaluation will also consider the five “Dublin Competence Descriptors” as guidance (see Annex 2). In the final CRA examination, the applicant will be judged on the basis of:

- His or her knowledge and the capacity to use this knowledge in environmental risk assessment
- His or her compliance with the CRA competences as described in Annex 1 (topic specific competences) and Annex 2 (programme wide competences, “Dublin Descriptors”).
- Experience gained during the on-the-job training with respect to his or her level of knowledge, understanding, skills and competences relative to what is expected from a CRA. It will therefore normally be expected that the CRA has advanced/specialised knowledge in at least 2 of the 9 topics (as listed in Table 1 and Annex 1) and also a further advanced competence level with respect to the Dublin Descriptors (Annex 2).

For every candidate a tailored CRA Examination Panel will be assembled by the Certification Programme Committee, consisting of:

- At least three members of the Certification Programme Committee (in the subject of the environmental risk assessment report), preferably including
  - i. One from Academia
  - ii. One from Business
  - iii. One from Government

- iv. The chair or his representative, acting as the chair of the examination panel
  - Up to three non-voting experts with an advisory role, if the Certification Programme Committee lacks the specific expertise in the subject of the environmental risk assessment report.
  - Two non-voting members with an advisory role may be (upon desire of the applicant):
    - i. The employer of the candidate (or his representative)
    - ii. The mentor of the candidate

The justification for including three Certification Programme Committee members in the examination panel is to safeguard consistency among the evaluations across all candidates and to guarantee that the evaluation is in line with the overall aims of the certification programme.

The justification for the employer in the examination panel in an advisory role is to enable transfer of additional relevant information to the voting jury members. If someone is not able to attend the meeting in person, possibilities for video conferencing or representation will be explored. If needed, the mentor or employer will be contacted before the meeting to obtain the relevant information and their advice.

Ultimately, the decision whether or not a candidate passes the examination and receives the registration as “SETAC Europe Certified Environmental Risk Assessor” is made by the Certification Programme Committee hearing the recommendation of the three expert members of the panel, based on a 2/3 majority vote.

Following a positive decision, the applicant will be informed as soon as possible and will be invited to undersign a **code of conduct**. Following signing the code of conduct, the applicant will be registered as “SETAC Europe Certified Environmental Risk Assessor” for five years and will be allowed to carry this title. Both a positive and a negative decision must always be accompanied with a clear motivation, and a negative decision must also contain recommendations for improvement of the dossier to enable the applicant to succeed in a future application.

In the case that it appears that a CRA has violated the code of conduct (or if the CRA was obtained based on false information), the Certification Programme Committee may decide to withdraw the registration.

#### **4. Direct registration as a Certified Environmental Risk Assessor**

As mentioned already in the introduction, in addition to the standard procedure to become a CRA, at this moment candidates can apply for immediate **direct certification** as a CRA via the submission of a **dossier for direct certification**, when they fulfil all of following criteria:

- They must be able to clearly argument and demonstrate that they have already obtained all competences of a CRA (Annex 1 and 2)
- They must have more than 5 years of practical, on-the-job experience in an ERA job
- They must demonstrate commitment to continued education and training in ERA, by regularly participating in activities such as specialised courses, trainings and symposia, workshops or conferences in the field of ERA.

- They must submit a concise written risk assessment report. The submission of such a report can be waived only for candidates with at least 10 years of ERA job experience, based on a written argumentation and motivation by the candidate.

The dossier for direct registration to be submitted should contain all of the following elements:

- A full Curriculum Vitae of the applicant
- Copies of relevant diplomas (English transcripts can be asked by the Certification Programme Committee if needed for the evaluation)
- A motivation letter, including
  - a self-evaluation with an indication of why the applicant applies
  - a summary of past, current and envisaged future professional activities in environmental risk assessment
  - a statement about how the candidate envisages the aspects of his or her own commitment to continued education and training in the next five years
  - a clear argumentation that he or she already has obtained all competences of a CRA (Table 1 and Annexes 1 and 2). This will need to include a point-by-point 'waiving' of all topics described in Table 1, based on demonstrable evidence in the Curriculum Vitae (e.g. courses followed in the past, Ph.D. thesis, reports or publications authored, etc.)
- Proof of having worked a minimum of 5 years in an ERA environment during the last four years.
- A recommendation letter by an institution or company where the candidate has recently conducted an ERA job.
- Proof of previous commitment to continued training and education at least by means of providing "certificates of attendance" for having participated (in the last two years) in at least one ERA related specialised course, training, worth in total 3 credits and at least one ERA related symposium, workshop or conference (such as those organised by SETAC).
- A total of three recommendation letters preferably one from academia, one from business, and one from government (as a proof of recognition by peers). At least one letter must be written from a peer outside the sector and institution the applicant is working in. Deviations due to e.g. conflict of interests are possible but should be motivated in the motivation letter.
- A concise, yet scientific and critical, environmental risk assessment report of recent work performed in an ERA job (in the last two years) (for further evaluation during the final CRA examination, except in cases where an applicant with >10 years ERA experience can substantially motivate why he or she should not undergo the examination). The report should be written as a scientific document, and include sections such as:
  - introduction, background, scope, aims
  - materials and methods (exposure, effects, and risk assessment)
  - results (exposure, effects and risk assessment)
  - a critical discussion, including the appropriateness of methods used or guidelines followed and recommendation(s) for their improvement
  - conclusions & recommendations
  - list of cited references.

The report will not only be judged in terms of its timelines, i.e. being scientifically up-to-date with current methods in exposure, effects and risk assessment, but also in terms of the critical evaluation and discussion of these methods.

Any deviations from this prescribed list of elements should be motivated.

Dossiers for direct certification must be submitted to the Certification Programme Committee to check for eligibility.

Together with the submission of the dossier a “**direct certification fee**” needs to be paid (see programme website for more information), before the dossier will be evaluated. This fee covers all administrative and organisational costs for the dossier evaluation (further called judgment).

In cases where the applicant needs to undergo and pass the final CRA examination (in front of an Examination Panel), the same regulation for the organisation of the examination applies as described in section 3. Such candidates can only become CRA when they have also successfully passed the final CRA examination.

The final decision on the direct certification (i.e. registration as a CRA) is made by the Certification Programme Committee, according to the same standards as for those who have followed the standard programme (i.e. considering the same competence requirements described in Annexes 1 and 2. The decision of granting the applicant with the title of “certified environmental risk assessor” will be made based on a 2/3 majority vote. A valid voting can only be organised if a quorum of at least 50% of the voting Certification Programme Committee members is reached (abstentions do not count in determining if the quorum is reached).

Following a positive decision, the applicant will be informed as soon as possible and will be invited to undersign a **code of conduct**. Following signing the code of conduct, the candidate will be registered as SETAC Europe Certified Environmental Risk Assessor for five years and will be allowed to carry this title. A negative decision must always be accompanied with a clear motivation and recommendations for improvement of the dossier to enable the applicant to succeed in a future application.

## 5. Recertification

The registration as a CRA is valid for 5 years. CRAs who wish to remain registered in the CRA database will need to renew their registration.

Certified Environment Risk Assessors can apply for **recertification** as a CRA via the submission of a **dossier for recertification**.

The dossier for recertification must contain all of the following elements:

- An updated Curriculum Vitae
- A recertification letter, including
  - a summary of the professional activities in environmental risk assessment in the last 5 years
  - a statement about how the candidate envisages the aspects of his or her own commitment to continued education and training in the next five years

- Proof of having worked a minimum of 2 years in an ERA environment during the last 5 years.
- A recommendation letter by an institution or company where the candidate has recently conducted an ERA job.
- Proof of previous commitment to continued training and education at least by means of providing “certificates of attendance” for having participated (as attendee or instructor) in the last two years in at least one ERA related specialised course, training, worth in total 3 credits and at least one ERA related symposium, workshop or conference (such as those organised by SETAC).

Any deviations from this prescribed list of elements should be motivated.

Dossiers for recertification must be submitted to the Certification Programme Committee.

Together with the submission of the dossier a “**recertification fee**” needs to be paid (see programme website for more information), before the dossier will be evaluated. This fee covers all administrative and organisational costs for the dossier evaluation.

The final decision on the recertification is made by the Certification Programme Committee. The decision of granting the title of “certified environmental risk assessor” for another 5 years will be made based on a 2/3 majority vote. A valid voting can only be organised if a quorum of at least 50% of the voting Certification Programme Committee members is reached (abstentions do not count in determining if the quorum is reached).

Following a positive decision, the applicant will be informed as soon as possible and will be invited to renew the **code of conduct**. Following signing the code of conduct, the candidate will be again registered as SETAC Europe Certified Environmental Risk Assessor for five years and will be allowed to carry this title.

A negative decision must always be accompanied with a clear motivation and recommendations for improvement of the dossier to enable the applicant to succeed in a future application.

## Annex 1 Detailed descriptions of 9 Environmental Risk Assessment topics and associated competences to be acquired to become a SETAC Europe Certified Environmental Risk Assessor

Below, with every topic (as in Table 1 of the main document) a list of ‘subtopics’ is provided.

### 1. Ecology concepts, principles and processes

- a. Populations, meta-populations, communities
- b. Species interactions (competition, predation, symbiosis, ...)
- c. Interaction of species with their abiotic environment (light, nutrients,...)
- d. Habitat and niche
- e. Micro- and macro-evolutionary processes
- f. Ecosystem functioning and stability
- g. Biodiversity
- h. Redundancy, resilience

*Description of associated competences:*

*Upon completion of this topic, the SETAC Europe Certified Environmental Risk Assessor:*

- Has a basic understanding of principles and processes governing interactions between organisms and their biotic (intra- and inter-species) and abiotic environment;
- Has a basic understanding of the hierarchical organisation, dynamics, structure, functioning and (bio)diversity of populations, communities and ecosystems;
- Has a basic knowledge of the methods used for studying ecological processes;
- Is able to communicate orally and written about basic ecological principles using scientifically accurate terminology.

### 2. Introduction: Concepts and principles in regulatory ecotoxicology and environmental risk assessment and legislative frameworks

- a. The risk assessment paradigm: hazard – exposure – effects – risk
- b. Role of various scientific disciplines needed for science-based risk assessment: analytical chemistry, ecology, physiology, statistics, (eco)toxicology
- c. Human vs. Ecological Risk Assessment
- d. Prospective vs. Retrospective Risk Assessment
- e. Risk Assessment vs. Life Cycle (Impact) Assessment
- f. Laboratory vs. field studies
- g. Epidemiological vs. experimental studies
- h. Spatial, temporal and biological scales of effects
- i. Broad comparative overview of chemical groups and classes and related existing European legislation and regulatory frameworks (and comparison with local/national, non-European or global legislation)
- j. Critical comparison of different chemical groups and why they require different approaches / legislation
- k. Overview of major legislative frameworks (e.g., REACH, WFD, GHS, Plant Protection Products, Pharmaceuticals)

*Description of associated competences:*

*Upon completion of this topic, the SETAC Europe Certified Environmental Risk Assessor:*

- *Has a basic understanding of principles and concepts of the environmental risk assessment of chemicals;*
- *Has a basic understanding of methods and models used for the environmental risk assessment of chemicals;*
- *Has a basic knowledge of the main legislative frameworks for the environmental risk assessment of chemicals, the main institutions involved at the European level and their roles and competences;*
- *Has a basic understanding of the main factors and (types of) information required for assessing the environmental risk of chemicals;*
- *Is able to communicate orally and written about the basic principles of environmental risk assessment of chemicals, using scientifically accurate terminology.*

### **3. Environmental Chemistry: fate of chemicals in the environment**

- Chemical transport (within and between compartments, short- and long-range)
- Chemical distribution within compartments: (equilibrium) partitioning, fractionation and speciation (e.g., adsorption)
- Chemical transformation (including biodegradation, hydrolysis,...) and relation to evaluation of persistence
- Environmental conditions and chemical properties that influence these processes for various classes of chemicals
- Analytical methods for analysis of various types of chemicals in different compartments (including principles about clean sampling, blanks, detection limits)
- Comparative overview of processes of importance for a variety of chemical groups
- Basics of measuring (standard tests), calculating and modelling these processes

*Description of associated competences:*

*Upon completion of this topic, the SETAC Europe Certified Environmental Risk Assessor:*

- *Has a basic knowledge of the main processes determining the fate and distribution of chemicals in the environment;*
- *Has a basic knowledge of the main environmental and chemical factors governing the fate of chemicals in the environment;*
- *Has a basic knowledge of the experimental methods and models used to determine and predict the fate of chemicals in the environment;*
- *Has a basic knowledge of experimental methods and analytical tools available for assessing environmental concentrations of chemicals, their potential use and limitations, and their application in monitoring;*
- *Is able to communicate orally and written about the basic principles of the environmental fate of chemicals, using scientifically accurate terminology.*

### **4. Environmental Chemistry: exposure estimation of chemicals in the environment**

- Emission estimation (environmental sources of chemicals)
- Overview of available monitoring databases and how to evaluate their quality and usefulness

- c. Understanding and use of exposure models (including internationally accepted software) to estimate concentrations of chemical in different compartments (in case no measurements are available)
- d. Internal exposure: bioaccumulation, biomagnification, food chain transfer, secondary poisoning (including basic modelling and calculations)
- e. Environmental conditions and chemical properties that influence external and internal exposure (including bioavailability concepts)
- f. Comparative examples of various chemical classes and related legislations

*Description of associated competences:*

*Upon completion of this topic, the SETAC Europe Certified Environmental Risk Assessor:*

- *Has a basic understanding of environmental modelling approaches available to estimate the distribution of chemicals in the environment and to estimate exposure;*
- *Has a basic understanding of the concepts, processes and factors governing the bioavailability, uptake and internal distribution in organisms, and the food-chain transfer of chemicals, and the models used to describe or predict these processes;*
- *Is able to communicate orally and written about the basic principles of the exposure assessment of chemicals, using scientifically accurate terminology;*

#### **5. Sub-organism level (eco)toxicology (mechanistic toxicology): molecular, cellular, biochemical and physiological effects and biomarkers**

- a. Uptake, biotransformation, detoxification, bioactivation, elimination pathways of different classes of chemicals
- b. Influence of chemical properties and environmental conditions on these processes
- c. Interactions of chemicals with biomolecules (molecular effects)
- d. Effects on DNA (genotoxicity, mutagenicity)
- e. Cellular effects (e.g., oxidative stress)
- f. Physiological effects (e.g. energy metabolism, ion homeostasis)
- g. Toxicity pathways, adverse outcome pathways (from molecular initiating event to organism level endpoint)
- h. Comparative, illustrative examples of selected compounds for selected important well-documented toxicity pathways (narcosis, endocrine disruption, acetylcholine-esterase inhibition)
- i. Development and application of commonly used biomarkers (e.g., metallothioneins, EROD) together with their possibilities and limitations
- j. Introduction to next-generation high throughput methods (e.g., “omics” such as transcriptomics, in vitro assays, standard methods, possibilities and limitations)

*Description of associated competences:*

*Upon completion of this topic, the SETAC Europe Certified Environmental Risk Assessor:*

- *Has a basic knowledge of different pathways and processes of uptake and internal processing of chemicals in organisms and the chemical and environmental factors involved;*
- *Has basic understanding of the different types of interaction of chemicals with receptors and the resulting effects at the below-individual and individual level;*
- *Has basic knowledge of the different mechanisms and modes of action of major groups of chemicals;*



- *Has a basic understanding of modern omics (e.g., genomics, transcriptomics, proteomics, metabolomics) techniques and other methods for assessing the potential effects of chemicals on organisms;*
- *Has basic understanding of the application of the knowledge on below-individual level effects in monitoring, e.g. in biomarkers, and their limitations;*
- *Is able to communicate orally and written about the basic principles of mechanisms and modes of action of chemicals, its assessment and its use in monitoring, using scientifically accurate terminology;*

## **6. Organism-level ecotoxicology**

- a. Experimental design of ecotoxicity assays as described in international test guideline systems (e.g. OECD, ISO), standard tests and test organisms for various compartments, including
  - i. Acute vs. chronic testing
  - ii. Types of exposure systems (static vs flow-through, single-species vs multispecies, single-generation vs. multigeneration)
  - iii. Dose (or concentration) and time response concepts and basic statistical analysis
  - iv. Quantal vs. continuous endpoints
  - v. Importance of measuring exposure doses
- b. Variation of sensitivity between individuals and between species (and building and interpretation of species sensitivity distributions)
- c. Concepts of mixture toxicity
- d. Combined and interactive effects of chemical and non-chemical (including natural) stressors
- e. Alternatives to animal testing (in vitro, QSAR, read-across, extrapolation between species and compounds)
- f. Overview of available ecotoxicity databases and how to use them (e.g. USEPA ecotox database, REACH)

### *Description of associated competences:*

*Upon completion of this topic, the SETAC Europe Certified Environmental Risk Assessor:*

- *Has a basic knowledge of the available and standardised experimental methods and test systems for assessing the toxicity of chemicals to different organisms representative of different environmental compartments;*
- *Has basic understanding of mathematical and statistical methods for analysing dose-response relationships and other data resulting from toxicity tests, and their limitations;*
- *Has a basic understanding of the concepts of mixture toxicity and the interaction of chemical and non-chemical stressors;*
- *Has basic knowledge of models to generate toxicity data based on chemical properties and on available databases, and is capable of properly judging the reliability and quality of the produced or available data;*
- *Is able to communicate orally and written about the basic principles of toxicity testing and the methods used for analysing toxicity data, using scientifically accurate terminology;*

## 7. **Supra-organism level ecotoxicology or “Chemical Stress Ecology”: effects of chemicals at population, community, ecosystem and landscape-level**

- a. Basic ecology principles and concepts relevant for “ecological” effects of chemicals: populations and communities, structure and function, resilience, redundancy, stability, recovery, evolutionary aspects
- b. Supra-organism level tests and their analysis and usefulness in regulation (e.g. microcosm, mesocosm, field enclosures)
- c. Important population-level processes (e.g. density-dependence) and community-level processes (e.g. species interactions) for effects of chemicals
- d. Evaluation of indirect effects on communities, ecosystems and metapopulations (landscapes)
- e. Extrapolation from organism-level endpoints to populations (e.g. with population models)
- f. Principles of trait-based risk assessment (including phylogenetic approaches)
- g. Basics of ecological modelling in risk assessment

*Description of associated competences:*

*Upon completion of this topic, the SETAC Europe Certified Environmental Risk Assessor:*

- *Has a basic knowledge of experimental methods and test systems for assessing the toxicity of chemicals at higher levels of biological organisation, such as populations, communities and ecosystems;*
- *Has basic understanding of the ecological processes and interactions involved in the occurrence of population, community and ecosystem level effects, and the way this may lead to direct and indirect effects;*
- *Has a basic understanding of the concepts and principles of ecological modelling that may be applied to assess direct and indirect effects at the level of populations, communities and ecosystems based on knowledge of the toxicity of chemicals at the individual level;*
- *Is able to communicate orally and written about the basic principles of determining and predicting the effects of chemicals on populations, communities and ecosystems, using scientifically accurate terminology;*

## 8. **Retrospective risk assessment: chemical and bio-monitoring of exposure and effects**

- a. The role of monitoring in various legislative frameworks related to chemical safety and environmental quality
- b. Overview of existing databases and how to critically make use of them
- c. Principles of sampling design
- d. Overview of most important analytical methods for various components; Analytical methods for analysis of various types of chemicals in different compartments (including principles about clean sampling, blanks, detection limits)
- e. Biological or Ecological monitoring methods and ecological quality assessment scoring systems (e.g. TRIAD approach).
- f. Development/use of biomarkers of exposure and effect (overview, possibilities, limitations)
- g. Development/use of biosensors and in-situ exposure systems

- h. Correlation vs. cause in field-based assessments (i.e. how to determine effect of chemicals in a multi-stress environment)
- i. Design of appropriate monitoring campaigns / schemes for inferring cause-effect

*Description of associated competences:*

*Upon completion of this topic, the SETAC Europe Certified Environmental Risk Assessor:*

- *Has a basic knowledge of experimental methods and tools available for monitoring the environment for potential (post-registration) effects of chemicals, including the assessment of waste streams (e.g. effluents) or contaminated land, their application and their limitations;*
- *Has basic understanding of the legislative frameworks at the national and European level for environmental monitoring and environmental quality and chemical safety assessment;*
- *Has a basic knowledge of experimental methods and analytical tools available for assessing environmental concentrations of chemicals, their potential use and limitations, and their application in monitoring;*
- *Is able to communicate orally and written about the basic principles of chemical safety and environmental quality assessment, using scientifically accurate terminology;*

## **9. Statistics for ecotoxicologists and environmental risk assessors**

- a. ANOVA and regression analysis (i.e. for NOEC and EC<sub>x</sub> calculation)
- b. Dose-response analysis
- c. Time-to-event models
- d. Data complexity reduction techniques: multivariate statistics, ordination, principle component analysis
- e. Outliers and below detection limit issues
- f. Species sensitivity distributions (SSD) and chemical exposure distributions
- g. Basics of probabilistic methods (variation vs. uncertainty)
- h. Basics of ecological modelling methods for effect assessment

*Description of competence:*

*Upon completion of this topic, the SETAC Europe Certified Environmental Risk Assessor:*

- *Has a basic knowledge and understanding of available mathematical and statistical tools for analysing ecotoxicological data, including laboratory, mesocosm or (semi-) field toxicity data, monitoring data and toxicokinetic data;*
- *Has a basic understanding of statistical and probabilistic methods used for estimating the risk of chemicals, and their limitations.*
- *Has a basic understanding of ecological models used for effects assessment, their applications and limitations;*
- *Is able to communicate orally and written about the basic principles of the use of mathematical and statistical methods in the environmental risk assessment of chemicals, using scientifically accurate terminology;*

## Annex 2 “Dublin Descriptors” describing competences and attainment levels to be acquired by SETAC Europe Certified Environmental Risk Assessors (CRA)

Competences and attainment levels for the **entire programme** define requirements to be met by SETAC Europe Certified Environmental Risk Assessors (CRA). The descriptions follow the system of “**Dublin descriptors**” used for evaluating higher education in Europe. Different types of descriptors are distinguished: **Knowledge and understanding, Application of knowledge, Critical judgment, Communication, and Learning**. To enable fitting these descriptors to the entire programme, they are fairly general. To achieve this, the attainment levels have been limited to just one main sentence per descriptor and a few more detailed sentences. For the descriptor “Knowledge and Understanding” the detailed sentences are equivalent to even more detailed competence descriptions per topic as provided. The descriptors ensure that competences to be acquired go beyond merely having obtained knowledge and understanding. In this context, the Dublin Descriptor competence levels are to be gained from more than just following courses, notably also from the obligatory **on-the-job training** as defined in the programme. The Dublin descriptor competence levels will form an important basis of the evaluation during the final CRA exam.

This Annex is mainly meant to provide **guidance** to:

- Applicants to know about the competences (beyond knowledge) that are required from them to become CRAs and also to prepare for the final CRA exam.
- The Examination Panel to decide whether or not a candidate passes the final CRA examination

### ***Dublin descriptor 1***

Knowledge and understanding: The CRA has a basic but broad theoretical and practical knowledge and understanding of Environmental Sciences, notably within the field of environmental risk assessment, and of the underlying and supporting fields.

The CRA

- has a basic understanding of ecology, more specific of principles and processes governing interactions between organisms and their biotic (intra- and inter-species interactions) and abiotic environment, and of the hierarchical organisation, dynamics, structure, functioning and (bio)diversity of populations, communities and ecosystems;
- has basic understanding of the concepts and principles in regulatory ecotoxicology and environmental risk assessment
- has basic understanding of the existing legislative frameworks in Europe and the main actors in the field of environmental risk assessment
- has basic understanding of the main factors and processes governing the fate and distribution of chemicals in the environment;
- has basic understanding of the factors, processes and concepts used to translate knowledge on the fate of chemicals into an exposure assessment;
- has basic understanding of the modes of action of major groups of chemicals and of (eco)toxicological concepts and theory;
- has basic understanding of methods for assessing (eco)toxicological effects at different levels of biological organisation, including their standardisation;

- has basic understanding of the linkage between ecology and ecotoxicology and its use to describe/predict and determine effects at higher levels of biological organisation;
- has basic understanding of the concepts and tools used for predictive and diagnostic ecotoxicological effects assessment;
- has basic understanding of the statistical and mathematical tools used for analysing (eco)toxicological data;
- has advanced understanding of at least 2 out of the above mentioned topics (as defined in Annex 1);
- is able to think in multidisciplinary terms, and possesses an understanding of other disciplines (and sub-disciplines) that are of importance to environmental risk assessment.

### **Dublin descriptor 2**

Application of knowledge: The CRA is able to apply scientific knowledge to problems arising in the context of environmental risk assessment.

The CRA:

- is able to apply his/her scientific knowledge to environmental risk assessment problems;
- is able to apply his/her scientific knowledge to identify weaknesses and define uncertainties in the different steps of an environmental risk assessment;
- is able to contribute to knowledge transfer to policy and risk management;

### **Dublin descriptor 3**

Critical judgment: The CRA should be able to independently and critically judge information.

The CRA:

- is able to independently acquire, analyse and critically evaluate information on the potential risk of chemicals in the environment;
- is able to select and order information, to distinguish essentials from trivialities, and to make associations;
- is able to independently and critically analyse environmental research, both in relation to its design and performance, and to the results obtained;
- has the ability to evaluate his/her own performance, both introspectively and in discussion with others.

### **Dublin descriptor 4**

Communication: The CRA should be able to transfer knowledge and skills related to his/her subject area to other persons and to adequately reply to questions and problems posed in environmental risk assessment and related topics.

The CRA:

- can communicate orally and written about such basic principles of environmental risk assessment and its supporting fields using scientifically accurate terminology;

- can report orally on issues of environmental risk assessment, in English, with support of modern presentation techniques;
- can report in written form on issues of environmental risk assessment on the level of peer-reviewed academic journals (in English);
- can make valuable contributions to scientific discussions about issues of environmental risk assessment, including plans for (experimental) research;
- can collaborate with scientists from different disciplines when needed.

### **Dublin descriptor 5**

Learning skills: The CRA has learning skills that enable him/her further (self)education and development within environmental risk assessment.

The CRA:

- is able to understand and summarise scientific literature on environmental risk assessment and related/supportive fields of science;
- is familiar with general scientific journals relevant to the field of environmental risk assessment and its supportive fields of science (including ecotoxicology, environmental chemistry, ecology, environmental monitoring, risk assessment, etc.);
- is familiar with computer software that is relevant to the field.