UNIVERSITÀ DEGLI STUDI DI MILANO
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E BIOMOLECOLARI - DiSFeB

Mapping Study on Academic Courses Relevant to REACH and CLP [Tender ECHA/2011/141]

Final Report
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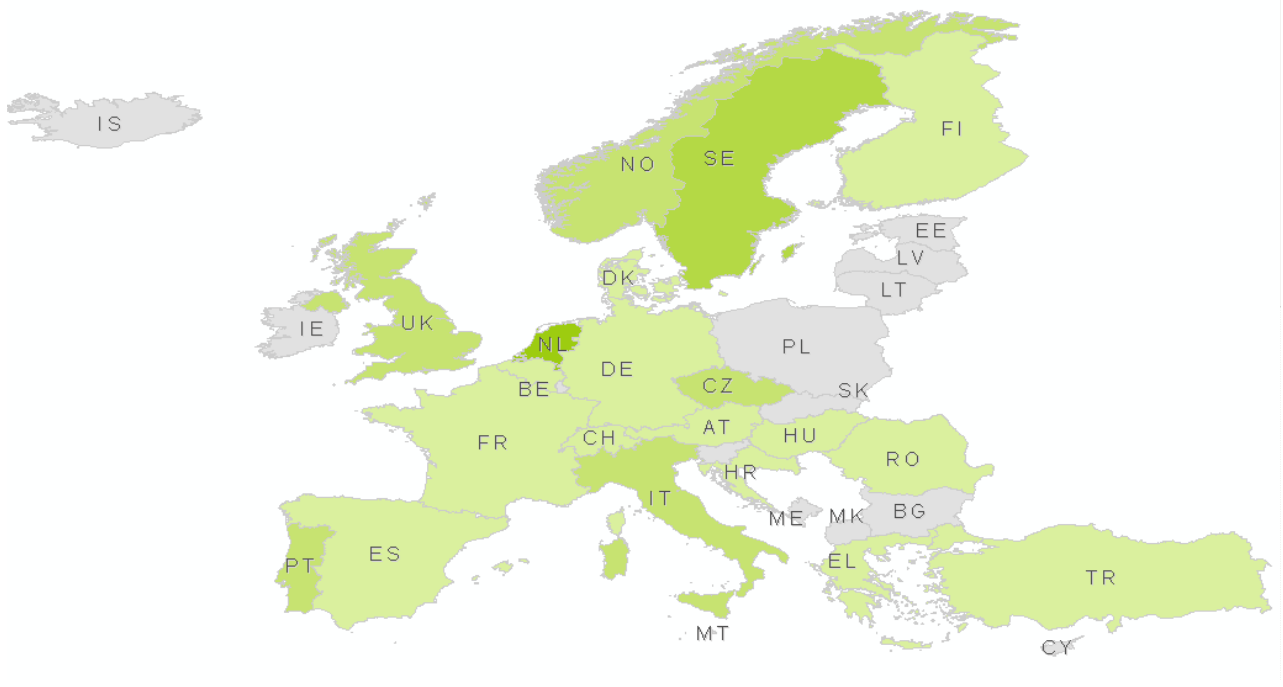

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Preparation of a mapping existing courses relevant to REACH and CLP available from universities, other academic institutions and professional organisations within the European Economic Area (EEA).

This report made every effort to collect accurate information at the time of the study however some inaccuracies are possible but do not diminish the overall objective of the study.

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Executive Summary

The aims of this study are two-fold. Firstly, it aims to identify the number and type of available graduate courses in the fields of REACH and CLP across Europe. Secondly, it is conducted to indicate areas in which input could be provided in order to improve training opportunities for regulatory scientists in the field of chemicals.

The study aims to identify the deficiencies in the current market in terms of REACH and CLP training, and to analyse the duration of the courses that are REACH and CLP specific. It is believed that risk assessment courses should aim to be multidisciplinary in order to cover main areas such as toxicology, environmental fate, ecotoxicology and exposure, as well as provide practical training programmes with hands-on experience.

The key findings indicate that the types of courses that are available throughout Europe are varied in terms of their duration, number of credits, practical training period, and the weight given to scientific based topics such as toxicology, ecotoxicology, environmental fate and exposure as well as the latest developments such as alternative methods, mixtures, derivations of health-based guidance, the benchmark dose (BMD) approach and derived-no-effect-levels (DNELs). The time given to subjects that are relevant to risk management such as socio-economic, uncertainty analysis and risk communication is also very limited, with no specific full courses found for these subjects.

The results of the study show that only a limited number of comprehensive full courses available throughout Europe offer the necessary training requirements. There is, however, a vast array of individual, short-courses that offset this limited number of long-term courses. Whilst this can be useful for individuals who wish to bolster their existing skills, it leads to a fragmented situation in which the training systems in place do not offer the opportunity for individuals to follow a comprehensive course in the overall science of risk assessment.

As such, it would be advantageous to devise a 'fit for purpose' scheme, i.e which could benefit students, universities, industry and ECHA alike by offering education and training for young graduates, providing more competent staff to ECHA and by providing a training network which could be profitable for universities. Such a tailored and comprehensive training scheme would be of even higher value as a 'marketable' recognised qualification if included in an academic accreditation scheme.

The authors of this mapping study make suggestions on possible options. One possibility could be to expand the experience gained during the DG SANCO European Toxicology Risk Assessment Training (TRISK) initiative, as this was a successful proof of concept focusing on human heath risk assessment. Another approach could be to build on the current initiative by the Italian Ministry of Health and Research, to set up postgraduate courses in the field of REACH/CLP; this has provided positive results for the training of professionals and could be considered as an initiative to replicate across other European countries. Finally the ECHA graduate scheme could be developed to work with European academic institutions to develop further education programmes, possibly linked with some form of internship or research positions for newly qualified graduates within ECHA.

In addition, the authors foresee that any of these three suggestions would help to fulfil the requirements leading to the certification or accreditation of trained human health risk assessors currently under development by the European Committee for Standardisation (CEN) under the project CEN/TC 416[1] "Health risk assessment of chemicals – Requirements for the provision of training" supported the Health and Consumers Directorate General (DG SANCO). There is a strongly-supported view that the recognition of professional risk assessors would not only promote quality through continued education assuring a high level of competence, but may also stimulate the organisation of long-term courses to ultimately address the limited number of training courses currently available across Europe.

1 http://www.cen.eu/cen/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/Pages/default.aspx?param=915651&title=Project Committee - Health risk assessment of chemicals

Introduction

The introduction of REACH and CLP in Europe has greatly increased the need for trained risk assessors to carry out regulatory activities and related assessments for both human health and the environment. Today, a limited number of training courses in risk assessment across Europe are available and basic training in health and environmental risk assessment is often included in some university programmes.

The demand for and interest in training in risk assessment is significant as exemplified by the high number of applicants for training courses organised by the EU-funded projects RA-COURSES[2] and TRISK[3] as well as results of the health risk assessors survey performed by the EU-funded project Risk ASSETs[4].

However, today there is no comprehensive information on the available courses in Europe that are relevant for risk assessment in general, and in particular applicable to the REACH and CLP Regulations. The identification of such courses is a prerequisite for ECHA to strategically improve and enhance the overall training of regulatory scientists in the field of chemicals legislation as described in the new graduate scheme that is currently under development.

The purpose of this mapping study is to investigate and report on the courses which offer training on scientific/technical/legal knowledge and practice relevant to REACH and CLP that are already available from academic institutions, and professional organisations within the European Economic Area (EEA).

Based on the data, a high-level gap analysis will enable needs to be identified and suggestions of possible specific action areas for improvements in risk assessment training, specifically those courses pertaining to REACH and CLP. The analysis takes the following aspects of a training scheme into consideration:

1) Implementation phases of the various planned initiatives over time (i.e. creation of network and traineeship opportunities in the short term, possibly leading to a structured, training programme incorporating a combination of coursework and practical assignments).

2) Fostering a career path throughout the various working levels (i.e. undergraduate, post-graduate, expert, etc.) of qualified risk assessment professionals across Europe.

The study also makes general suggestions how the existing courses might be developed further and indicates potential areas for cooperation and partnership with institutions, with a view to supporting ECHA's new graduate scheme[5].

2 http://www.cascadenet.org

3 http://www.eurotox.com/trisk/

4 http://www.hpa.org.uk/riskassets/

5 http://echa.europa.eu/web/guest/about-us/jobs/graduate-scheme

Subject matter

The work focused on the examination of existing courses offered by universities, other academic institutions and professional organisations relevant to the training of regulatory scientists in the field of chemicals. Such courses typically cover four distinct topic areas:

1. Risk assessment methodologies and practice, including hazard and exposure assessment for humans and the environment.
2. Basic disciplines supporting REACH and CLP legislation such as toxicology, ecotoxicology, environmental fate and exposure.
3. Other relevant disciplines such as socio-economic analysis.
4. Courses on all relevant methodologies to assess the properties of chemicals, including non-animal (alternative) approaches such as computational methods (QSARs), methods for grouping of chemicals and read-across and in-vitro methods that have regulatory relevance.

Geography

The project investigated existing courses especially relevant in the field of chemicals for REACH and CLP within the entire European Economic Area (EEA).

Timing

The first survey mailing was performed during the week of March 6, 2012 using contact lists 1 and 2 mentioned on page 9. A follow up reminder email was sent out during the week of March 19, 2012. Due to the low return rate, the original deadline of March 24 was extended an additional week to March 31. One final extension was carried out during the month of April.

The fact that the great majority of courses submitted belonged to the human health risk assessment field with very few courses of ecotoxicology and environmental fate being submitted generated a skew potential of the analysis and results. This could be attributed to the use of contact lists of institutions commonly known for organising mostly human health risk assessment courses.

Hence, it was decided along with ECHA officials to perform a second mail out using a list of suggested contacts complied by Dr José Tarazona from his personal knowledge in the area (contact list 3 mentioned on page 9). The list contained contact names of institutions linked to organisation of specific courses in the field of ecotoxicology and environmental fate. The original survey was mailed out during the months of June and July, while a follow up phone call to remind participants to complete the survey was carried out during the month of August. The effort generated a total of 21 additional courses in the area of ecotoxicology and environmental fate and helped to offset the biased of the initial results.

Scope of Work

1. Online Survey

A comprehensive investigation of available REACH and CLP courses currently offered by academic institutions, professional organisations, or any other relevant entity within the EEA was carried out.

2. Two types of assessments performed

a) Assessment by course language: English and Non-English

The assessment includes the consultant's expert opinion regarding the relevancy of the courses, geographic distribution, and other key emerging issues/opportunities.

b) Assessment by ECTS

Using the ECTS provided by organisers, courses were classified as long-term, mid-term and short-term and groups were analyzed based on key characteristics on the likely relevance and usefulness of each course for training professional in the area of REACH and CLP.

Course relevancy considered important in development and training of professionals was measured using the DG SANCO Guidelines for an Advanced Training Programme in Human Health Risk Assessment of Chemicals (RAAP) and the positive results obtained by TRISK, a training course for European risk assessors co-financed by the 2008-2013 EU Health Programme, which in the expert's opinion depicts the ideal risk assessment course as multi-disciplinary and covering the scientific areas of 1) toxicology, 2) environmental fate, 3) ecotoxicology, and 4) exposure.

Furthermore, trained risk assessors to carry out regulatory activities and related assessments should also be familiar with specific issues by REACH and CLP including 1) alternative methods (3R principle), 2) mixtures, and 3) derivation of health based guidance.

Finally, some form of practical training programme which allows trainees to gain hands-on experience and apply classroom knowledge to complement the field of study was considered as valuable but recognised simply as an additional benefit rather than directly penalizing the course if not offered.

3. Gap Analysis

A generalized high level gap analysis using both assessments was completed specifying the course's pro's and con's that are especially relevant for working as a regulatory professional in the field of chemicals for REACH and CLP, and serves to assess possible areas of improvements, and in the development of courses.

Methodology

The project was executed using a questionnaire consisting of 22 close or open-ended questions using multiple choice, matrix of choice or menu answer type to collect general information about the course organisation and gain a good understanding of the course content and extend of the learning programme.

The questionnaire was set up online (Figure 1) to allow for easy distribution via email and response tracking. Respondents were sent the link http://www.icps.it/ixps/survey/registration.asp to follow in order to complete the survey online. The login and password screen served to monitor respondent's reply and allowed to follow up, if necessary. Using this online method was vital since it allowed for the entire data collection and analysis process to be managed more efficiently.

Figure 1 - ECHA online survey

Parallel to the survey, web search using key words listed below was also carried out to identify relevant courses not included in the original contact list.

Key Words: Course/master and risk assessment, combined with chemical, environment, QSAR, alternative methods, REACH, CLP (classification, labelling, packaging), computational, read-across, in vitro methods, epidemiology, toxicology, ecotoxicology, fate, chemistry, socio-economic, cumulative, mixture.

A total of 17 websites offering potentially relevant courses were identified and 10 email contacts were included in the survey distribution list for further investigation.

Contact list

The survey was distributed to a contact list consisting of a total of 355 emails[6] coming from:

1. Existing databases collected by SANCO7 and ECHA8. The list consisted of universities across Europe involved in the organisation of toxicology related courses or modules.

2. Network: Consisting of EUROTOX training committee, members of professional associations such as national toxicology societies, scientific partners and academia contacts, and TRISK course participants. This list of contacts was used to identify potential new courses primarily in smaller countries and countries with recent inclusion in the EU.

3. ECOTOX database list complied and supplied by Dr José Tarazona from ECHA. The list consisted of 47 unique potential contacts of institutions involved in the organisation of ecotoxicology related courses or modules.

All lists were cleaned to eliminate duplicate emails and checked also for email validity.

Despite this, however close to 3% of undeliverable emails were received.

6 See Annex 1- ECHA mapping study contact list (final September 2012)

7 http://ec.europa.eu/health/dyna/training/training_en.cfm

8 http://echa.europa.eu/documents/10162/13602/universities_with_reach_courses_en.pdf

Information collected in the survey

Using the online survey[9], the following information was collected:

1. USER PROFILE
    a. Name and contact points of the respondent (email, nationality, age, education)
2. COURSE ORGANISATION
    a. Name and type of institution (University, Government/governmental, Research institute, Private) organising the course
    b. Geographic location (Country) of the institution
    c. Website where additional course information can be found
    d. Collaboration with other institutions
    e. Course language used
    f. Course duration (1-3 days, 1 week, 2 weeks, 1 month, 1-6 months, more than 6 months)
3. COURSE CONTINUITY
    a. Frequency (more than once a year, once a year, occasionally)
    b. Average number of participants (1-10, 11-20, more than 20)
    c. Number of years course is active (1 year, 2-4 years, more than 5 years)
4. EUROPEAN CREDIT TRANSFER AND ACCUMULATION SYSTEM (ECTS) AWARDED
5. PRACTICAL TRAINING
    a. Practical training requirements
    b. Number of hours
6. COURSE CONTENT
    a. Subjects
    b. Number of hours (1-5 hours, 6-15 hours, more than 15 hours)

6.1 REACH/CLP Relevance

- Legislative framework (Presentation of different regulatory domains)
- REACH
- CLP
- Others (specify)

6.2 Chemical characterization

9 See Annex 2 - Online Survey questionnaire

6.3 Experimental Design (Guidelines and GLP), Biometry and Statistics

6.4 Testing strategy, Tier (stepwise) approach

6.5 Toxicology
- ADME (and PBPK modelling)
- Organ toxicity and pathological signs
- Cancerogenicity
- Epidemiology and Toxicogenetics
- Mechanism (mode) of action of toxicants
- Interpretation of data (Weight of Evidence)

6.6 Alternative methods (3R principle)
- Threshold of Toxicological Concern (TTC)
- Read-across
- QSAR
- In vitro

6.7 Mixtures

6.8 Derivation of health-based guidance (NOAEL, BMD, DNEL, DMEL, AEOL, etc.)
- Threshold/non threshold effects
- Linear/non-linear extrapolation
- Use of biomonitoring data

6.9 Environmental fate

6.10 Ecotoxicology
- Use of environmental monitoring data

6.11 Exposure scenario development
- Exposure analysis
- Modelling exposure
- Deterministic and probabilistic assessment

6.12 Socio-economic analysis

6.13 Uncertainty, transparency, perception and communication in risk assessment

7. TYPE OF FACULTY

    a. National

    b. International

8. FINAL COURSE ASSESSMENT

    a. Oral examination

    b. Written examination

    c. Home assignment

    d. Report
    e. Other

9. E-LEARNING vs. ONSITE LEARNING
10. ENTRY REQUIREMENTS
    a. University degree (Master or similar)
    b. Previous working experience
    c. Research experience
    d. Curriculum vitae
    e. Reference letter
    f. Motivation letter
    g. Other
11. COMPOSITION OF COURSE PARTICIPANTS
    a. Academia
    b. Government
    c. Industry
    d. Consulting
    e. Other
12. ANY ADDITIONAL INFORMATION OR COMMENTS: Essay box

Individual replies where collected in word format to view details of a particular respondent or to read the comments of open-ended questions, while data was collected in a searchable format (e.g.: excel file) which allows global viewing of results in aggregate and to the creation of custom reports and charts, in addition to dynamic analysis through built-in filters.

General Survey Findings

Raw data

Contacting close to 275 European universities and academic institutions, a total of 91 questionnaires were received from 20 different countries belonging to the European Economic Area (EEA) and resulting in a response rate of close to 33%, which is considered an acceptable output to carry out the mapping study.

Despite not being part of the EEA, contacts from Turkey were included in the distribution list, as we feel that this area is currently offering a good number of valid courses to trainees from nearby European countries such as Greece, Estonia, Romania and Croatia.

From the total number of questionnaires, four were retained invalid because incomplete and therefore excluded from the study leaving a total of 87 surveys taking part in the study. Figure 2 shows the distribution (%) of courses by countries.

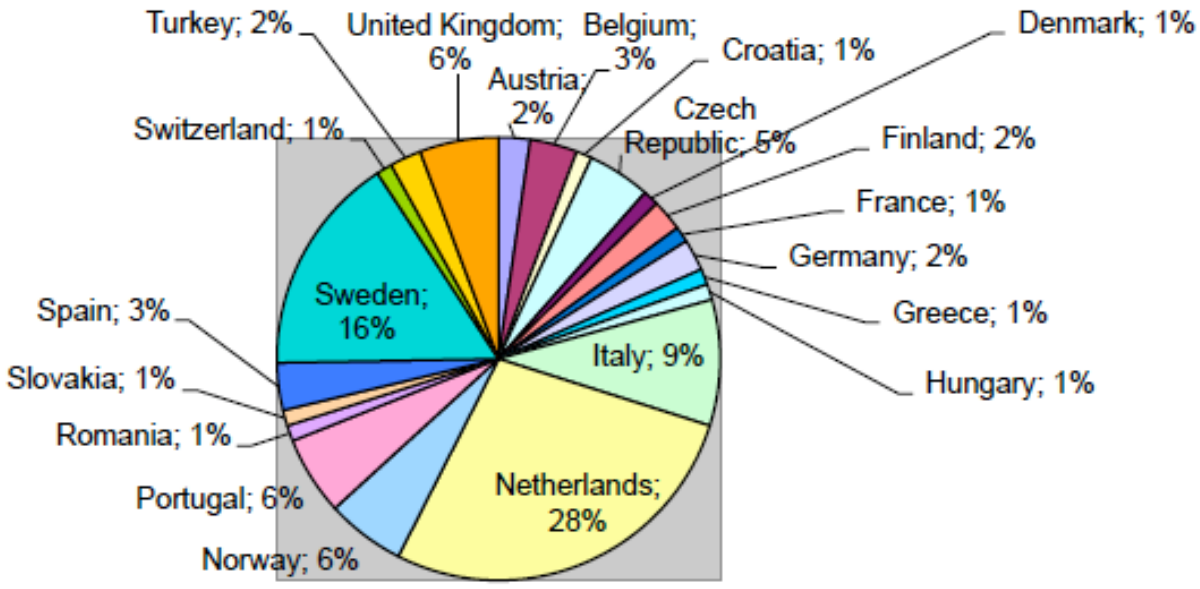

Figure 2 – Distribution of courses by country

The Netherlands and Sweden submitted the highest number of courses, 28% and 16%, respectively, followed by Italy (9%), and UK, Norway and Portugal with 6% each. Such results are in line with expectations since all countries are represented by a number of organisations that over the past years have established themselves as influential hubs in the field of risk assessment training, in particular; Postgraduate Education in Toxicology (P.E.T.) in the Netherlands which groups a number of universities around Europe organising one and two week courses covering a variety of topics applicable to REACH and CLP.

Similarly, Karolinska Institute located in Sweden, offers a variety of courses also lasting one to two weeks several times a year in specific areas of toxicology and risk assessment. They also collaborate with other universities helping to expand the training to interested individuals across Europe. Worthy of note is Portugal's role in the organisation of ecotoxicology related courses.

Interestingly, Italy submitted the third highest number of courses (Masters lasting one year) with content very focused to REACH and CLP training. The reason is driven by the initiative by the Italian Ministry of Health and Research which in the past years have worked closely with universities by offering a series of tenders with the aim to set up postgraduate courses to stimulate the training of REACH and CLP professionals as a way to contribute to the national shortage of experts in these two areas.

From the courses submitted, 70% are held in English, primarily those organised by countries in The Netherlands, Sweden and UK, while non-English courses (i.e. local language) account for 30% including 8% of the Italian courses held in Italian. Figure 3 shows the distribution (%) of courses by language.

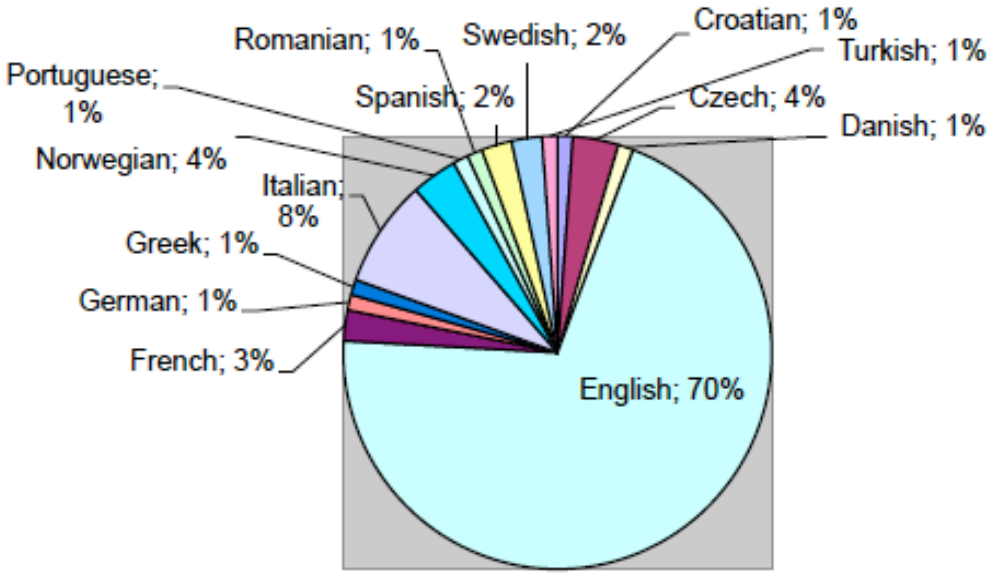

Figure 3 - Distribution of courses by language

A large portion of the courses (59%) as reported in Figure 4 claim to last between one week (46%) and two weeks (13%). The characteristics of these courses are inline with self-standing modules that provide the basic scientific base in specific subjects such as toxicology, environmental fate, ecotoxicology and/or exposure, which are areas necessary to conduct REACH and CLP risk assessments.

A smaller portion of courses (33%) reported as lasting more than six months (21%) or between one and six months (12%). The characteristics of longer lasting courses in particular those lasting more than six months are consistent with post-graduate courses covering a full range of topics and offering some type of formal academic recognition.

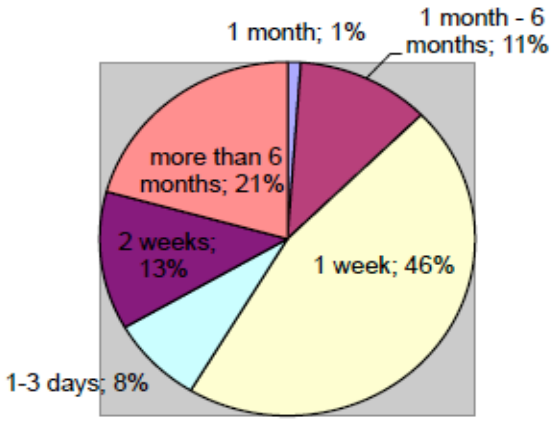

Figure 4 - Course duration

Figure 5 shows that almost 92% of courses submitted offer ECTS inline with European standards and based on course duration.

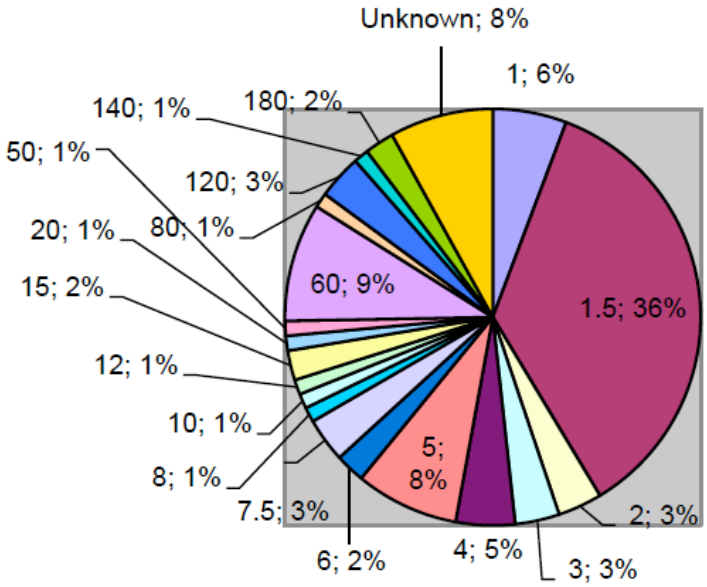

Figure 5 - ECTS offered

Importantly, as shown in Figure 6, is the fact that submitted courses can be considered to hold a long-standing status with more than 85% reported as the course being active “2-4 years” (24%) and “more than five years” (61%).

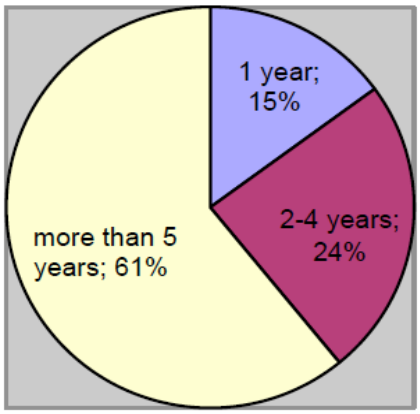

Figure 6 - Course edition

Figure 7 reports that a good number of courses (76%) claim to offer some form of hands-on training, although the number of hours can vary dramatically from course to course with long-term duration courses lasting from one to two years offering the greatest number of hours, and hence greater training experience. Of interest is the amount of courses reported as lasting over six months but not offering some form of hands-on training.

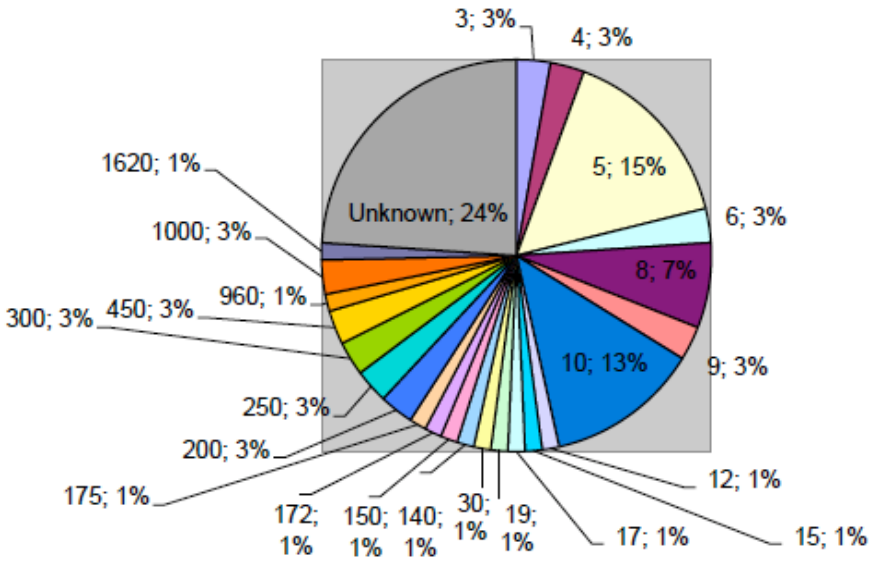

Figure 7 - Training hours

Other key results include:

The majority of courses (83%) report a good distribution of course participants between 11-20 (37%) and more than 20 (46%).

Onsite learning was reported as the most frequent method to deliver the course (77%) while distance learning was reported as used less or not used at all (81%).

High continuity of the organisation of the courses, was reported with 85% being organised at least once a year (44%) and occasionally (41%).

Research Key Findings

1. Overview

On the basis of the collected data, we can conclude that much effort was dedicated to identifying and obtaining information from academic institutions across Europe in order to compile an extensive list of the most relevant and applicable courses for this study with the limitation that a complete list of all European courses is likely to be unattainable.

From the 87 courses submitted, 64 (73%) reportedly cover topics in the areas of legislative framework (presentation of different regulatory domains), REACH, and/or CLP, although the number of hours varies depending on the course. The remaining 24 (27%) courses indicated that they did not cover these specific areas. Despite this, the courses were not excluded from the study as an individual analysis of each course showed that they covered other relevant areas in the training of professionals in REACH and CLP.

Although the survey included a wide range of questions to uncover as much details as possible about the courses, the scoring system featured in the course sheets was used internally for aggregation and management and not for direct comparison of courses or as a ranking tool.

Courses were analysed based on language (English and non-English) and duration. The total course European Credit Transfer and Accumulation System (ECTS)[10] reported on the survey was selected in order to categorise courses as long-term, mid-term or short-term to assess key characteristics on the likely relevance and usefulness of each course for the purpose of training professionals in REACH and CLP.

ECTS is a student-centred system based on the student workload required to achieve the objectives of a programme; objectives preferably specified in terms of the learning outcomes and competences that need to be acquired. Furthermore, since its introduction in 1989, ECTS has made study programmes easy to read and compare for all students, both native and non-native. The use of ECTS also facilitates mobility and academic recognition.

ECTS is based on the principle that 60 credits measure the workload of a full-time student during one academic year. The student workload of a full-time study programme in Europe amounts in most cases to around 1500 to 1800 hours per year and in those cases one credit stands for around 25 to 30 working hours.

Based on this, the duration of the course was cross-checked against the ECTS to tentatively verify the consistency of the information and help to classify the courses as long-term (60-180 ECTS), mid-term (10-50 ECTS) or short-term (< 10 ECTS). The classification is used in the next section to provide analysis of the courses submitted and recalled in Table 1 found on page 23.

No courses were eliminated from the analysis if the cross-check was uncertain as we took the ECTS provided in the survey as reliable. In addition, only a few courses were submitted without an ECTS value.

10 http://ec.europa.eu/dgs/education_culture/publ/pdf/ects/en.pdf

This could be attributed to the lack of information at the time the survey was completed. However, the fact that the courses may not offer ECTS was also considered as a possibility. Hence, in order not to penalise non-ECTS courses, we individually analysed each course and if it was ascertained that they were valid and relevant, we assigned a "hypothetical" ECTS value, which was used during the analysis process.

2. Course assessment

a) By course language

Results show that 30% or a total of 26 non-English training courses were submitted by a number of institutions in countries across Europe and primarily lead by Italy (seven), Czech Republic (three), Norway (three), Spain (two), Sweden (two) and France (two). The remaining countries, submitting one course each were Romania, Croatia, Greece, Turkey, Denmark, Austria and Portugal.

It is possible that the low number of non-English language courses could be attributed to the true inexistence of relevant courses in countries not responding to our survey, since every effort was made to include institutions from all Member States in our contact list. In fact, several messages were received from Member States such as Estonia, Poland and Latvia that their institutions did not offer courses relevant to our study.

Of particular significance, is the fact that only eight courses are classified as long-term courses, lasting between one and two years and offering between 60 to 180 ECTS. We considered these courses "highly relevant" because they deal with:

1. The four main pillars of the ECHA issues (toxicology, ecotoxicology, environmental fate and exposure);
2. The modern tools used globally to assess the risk of chemicals (QSAR, alternative methods, computational toxicology, read-across, in vitro methods, cumulative, mixture, TTC) and;
3. Offering some form of hands-on training

Although it might seem that more "highly relevant" long-term courses would be available in English, this is not the case. In fact, results from courses in English indicated that only seven were submitted; a much lower number than expected.

The results however once again help to confirm the overall notion that regardless of language, a relatively limited number of courses across Europe cover the themes of REACH and CLP.

A large number of English language courses were submitted from countries (besides the UK where English is the official language) that culturally have a strong usage of English, both professionally and academically, in particular we highlight the countries of Sweden (one), Finland (one), and Austria (one).

While results indicated that a limited number of long-term courses exist across Europe, we can report that a higher number of English and non-English individual, short-term courses are offered by numerous institutions in the same countries. In particular, the reported number of individual English courses dealing with REACH and CLP consisted of 55, or 89% of reported courses, while for non-English courses the number was more modest at 18 (70%), yet this is nevertheless significant.

It is possible to assume that the reasons for the proliferation of individual short-term courses (compared to long-term courses) are driven by the lack of expertise in certain areas, costs and timing. Flexibility or being able to organise a course based on current market needs (i.e. the REACH

Regulation) can certainly be considered another reason. Notwithstanding, short-term, individual courses (or modules) provide an important aspect in the training of risk assessment professionals (primarily those working already in the field and seeking to upgrade their skills and career paths) because they are able to focus on more expertise driven and knowledge demanding fields such as specific issues and approaches, exposure, socio-economic analysis, uncertainty, and risk communication in a short timeframe.

After careful analysis of the data submitted for both English and non-English courses, apart from the long-term courses that adequately cover the broad number of REACH and CLP Regulation subjects offering above average number of hours of classroom and hands-on training, mid-term courses deal unevenly in both hour allocation and REACH/CLP topics. In general, some mid-term courses may offer a sufficient number of hours but do not cover all the REACH/CLP topics required (i.e. environmental, ecotoxicology). On the other hand, some courses try to cover a wide range of topics but the number of hours allocated (classroom/hand-on training) is insufficient for fully acquiring the basis of REACH/CLP.

Short-term courses can certainly provide professionals with sufficient options for gaining a good base of training in their distinct areas of competence, whether single topics (i.e. exposure) or specific multiple topics (i.e. environmental and health). Results indicate that the majority of the short-term courses tend to deal mainly with one topic which in our opinion is ideal because the allocation of hours coving the specific topic is optimal for covering the multiple facets of complexity of the risk assessment process related to REACH/CLP. Furthermore, we consider them useful for individuals already with a good educational background and working base that want to better understand the technical issues related to REACH/CLP, or seek to move to a specific direction in their career. Finally, we feel that these courses are an excellent option to offer individuals seeking to fulfil a professional gap (i.e. four main pillars and the modern tools).

The results, however, also indicate that some short-term courses lasting between one and two weeks try to cover too many topics is a short timeframe. Such courses are considered as inefficient because they provide only an overview of REACH/CLP topics by allocating a limited number of hours, which is below average to the parameters that, in our opinion, offer an adequate training base.

b) By ECTS

As previously indicated, the total European Credit Transfer and Accumulation System (ECTS) was used to group courses as long-term, mid-term and short-term in order to assess key characteristics on the likely relevance and usefulness of each course for training professionals in the areas of REACH and CLP.

Key observations are highlighted below:

LONG-TERM COURSES (60 -180 ECTS)

A total of 15 courses are classified as long-term courses, offering between 60 to 180 ECTS.
More than half of these courses (eight) are found in Southern Europe, mainly Italy (seven) and Turkey (one) and held in the local languages, Italian and Turkish, respectively. The remaining courses (seven) are found in Northern Europe, including the United Kingdom (three), Austria (two), Finland (one) and Sweden (one) and mostly held in English.

Most courses include toxicology, ecotoxicology, fate, exposure, and REACH and CLP in the programme. Some address specific and relatively new issues such as TTC, read-across, computational ecotoxicology etc. Toxicology is the main focus of the vast majority of these courses (12), while very

few courses (two) focus on ecotoxicology. Only one course specifically addressed both. Furthermore, all courses with the exception of one (in the UK) provide a long period of training (>180 hours). More than 50% of the courses lead by the Italian courses (seven) and the UK (one) specifically addressed REACH and CLP.

MID-TERM COURSES (10 - 50 ECTS)
A total of six courses are classified as mid-term courses, offering between 10 to 50 ECTS. Interestingly, with the exception of TRISK[11], which was given in English, the rest are held in local languages (Czech Republic, France, Norway). Three were on ecotoxicology (one only on water). Two had a long training period. In this group, the TRISK course should be highlighted because it was organised by five European Universities or Research Institutes, the faculty and the participants came from most European countries, the training period was long and dedicated to a full risk assessment of specific agents.

SHORT-TERM COURSES (<10 ECTS)
A total of 58 courses, offering less than 10 ECTS comprise this list. Approximately 29 courses were identified that could be considered as a module either with a preparatory or a more in-depth approach to some subjects. Around 25 courses have been identified that addressed toxicology. With respect to ecotoxicology and/or environmental fate there were 10 identified courses. Exposure issues were addressed in 19 courses, but very few were specifically addressed on this subject. REACH, sometimes associated with CLP, was addressed in about 20 courses. Specific issues, such as 3Rs, QSAR, read-across, etc. have been addressed in about 20 courses, although, generally not all in the same course, with different degrees of detail. The courses were mainly held in the Netherlands (14) and Sweden (seven), and most were taught in English (26).

Socio-economic, uncertainty and communication issues

Socio-economic analysis was presented in 41 courses. However, only in 12 courses were there six or more hours being devoted. Uncertainty and communication were more frequently addressed (66 courses), but in only 17 courses, were there six or more hours being devoted.

3. Summary of results

It is instructive to draw general conclusions, based on the consultant's reading of the detailed survey results, and to make a generalised gap analysis (shown in Table 1), to give a good picture of the courses and training.

- There seems to be a good proportion of courses offering traditional toxicology, although these are mainly located in only a few countries.
- Very few long-term courses were identified, with the exception of Italy.
- Most long-term courses offer a significant period of practical training.
- Mid-term courses are infrequent.
- Mid-term courses are mainly taught in the local language.
- Short-term courses (one-two weeks) are mainly taught in English.
- Most short-term courses are provided in the Netherlands and in Sweden.

11 The authors declare an interest since they organised the course and were part of the faculty.

- More courses are devoted to toxicology rather than ecotoxicology.
- Exposure is addressed in many courses but is rarely the main subject. The same applies to specific issues such as 3Rs, QSAR, read-across, etc.
- Socio-economic, uncertainty and communication issues are rarely the main subjects of courses, and generally only a few hours are devoted to these areas.
- The offer for courses on ecotoxicology and environmental fate is fairly scarce.
- There seems to be a lack of courses on exposure and on specific more recent assessment tools, and more so on socio-economic analysis, uncertainty and communication.

Table 1 - Generalised Gap Analysis

60 to 180 ECTS	Pro's
	1. Courses last between one to two years. 2. Courses in this category are considered highly relevant to REACH and CLP training since they cover the key scientific base topics and are supported by an adequate number of hours for each topic which should approximately be quantified at least in: toxicology (comprehensive of specific tools alternative methods, mixtures, derivation of health based guidance) > 150, ecotoxicology > 60, fate > 50, exposure > 75). 3. Courses in this category, fulfil the basic requirements of the specific REACH/CLP training issue supported by a number of hours > 25. 4. Courses in this category offer some form of hands-on training to allow trainees to apply classroom knowledge, which is highly endorsed. 5. Courses in this category include a final examination, which in our opinion ensures better preparation and participation of trainees by making a final review of the topics covered and assessment of the knowledge acquired. 6. Overall, we consider courses in this category a good training choice for young scientists interested in graduate specialisation in the field.
	Con's
	1. Mainly located in Italy. 2. Held in Italian, hence limiting to non-Italian speakers. 3. Programmes linked to Italian Ministry initiative and potentially subsequent editions could be affected by budget cuts. 4. Faculty mostly limited to national staff with limited international representation. 5. Normally long term commitment (between one to two years) of full-time work restrictive to field professionals.

10 to 50 ECTS	**Pro's**
	1. Normally courses lasting between one to six months. 2. Based on the submitted data, mid-term courses are considered to have a specific relevance to REACH/CLP training since they may focus mainly on one specific scientific base topic (i.e. ecotoxicology) and supported by an adequate number of hours ecotoxicology > 40. 3. Suitable for individuals seeking to better understand specific issues related to REACH/CLP in a short time. 4. Normally held in English, hence may appeal to a larger European student base.
	Con's
	1. Depending on duration, course may not cover in depth issues. 2. Faculty may be limited to national staff. 3. May include a final examination. 4. Depending on course duration, opportunities for hand-on training may be limited.
<10 ECTS	**Pro's**
	1. Considered self-standing modules or individual, short-term courses usually lasting between one and two weeks and providing specific training on an area related to a single area of REACH/CLP. 2. Normally held in English, hence may appeal to a larger European student base. 3. May serve professional seeking to fill an existing educational gap in a specific area of REACH/CLP to better understand the risk assessment process or further their career.
	Con's
	1. Depending on the organisation, some courses could be considered inefficient because they seek to cover too many topics in a short-time frame. 2. Normally courses do not offer hands-on training. 3. Faculty mostly limited to national staff. 4. Do not include a final examination.

Conclusions

The University of Milano Toxicology Lab under the supervision of Prof. Corrado L. Galli, and with the support of Prof. Angelo Moretto and his staff at ICPS, undertook the "Mapping study on academic courses relevant to REACH and CLP". The consulting team used a contact list of 355 emails to survey approximately 275 European universities and academic institutions, obtaining a response rate of close to 32%, which is considered a satisfactory result for carrying out the mapping study considering that the study was conducted during the European holiday period. The efforts served to identify a total of 87 REACH and CLP related graduate courses. The consultants are fully confident (based on the team's knowledge of toxicology and risk assessment training experience) that all the important toxicology courses are covered and that overall there is a fair degree of confidence in an adequate mapping of environmental courses.

As the key findings indicate, courses throughout Europe are very different with regards to the duration, number of credits, practical training period, and the different weight represented to scientific based topics such as toxicology, ecotoxicology, environmental fate, exposure and also the implementation of the most recently developed special issues such as alternative methods, mixtures and derivations of health-based guidance, the benchmark dose (BMD) approach, and derived-no-effect-levels (DNELs) to name a few.

While, at present, we can recognise good teaching experience on toxicology throughout Europe, the same is not true for less developed areas such as ecotoxicology, environmental fate and exposure as a limited number of courses dealing with the latter topics were found.

Other relevant subjects, not directly pertaining to ecotoxicology risk assessment, but that are relevant for the proper risk management such as socio-economic, uncertainty analysis and risk communication are very limited. Courses specifically devoted to such issues could not be found, although some courses covered some of these subjects for a few hours.

Fortunately, short, individual courses help to offset this limited number of long-term, full range courses. This is not in itself a bad situation because some individuals may have the need to attend a full course to familiarise themselves with the overall science of risk assessment, while others, being already skilled in some part of the risk assessment process in the ECHA procedures or other regulatory frameworks, only need to attend specific short courses lasting one or two weeks (modules) to explore specific areas of risk assessment.

The result, however, is that existing training is rather fragmented. The general picture is that there are relatively few courses offering a comprehensive training in all elements: so far they have found three masters programmes targeted to REACH (notably the Italian 'bespoke' courses) and approximately 10 courses that could be developed to become complete. There are a large number of other courses covering particular aspects that are still useful for training regulatory affairs professionals. Overall, most of the courses identified are of short duration. Altogether, 16 more comprehensive long-duration courses had been identified in seven countries; many of which also included practical training.

The courses are split into those taught in English and those in other European languages. The picture is a bit different between toxicology and environmental courses. Altogether, more courses are devoted to toxicology (mainly located in a few countries and many taught in the local language) than to ecotoxicology and environmental fate. There seems to be a deficit of courses on exposure assessment. Regarding complementary areas such as socio-economic analysis, uncertainty and communication there is also a deficit regarding courses considering specifically the REACH and CLP needs.

Consultant's suggestions and recommendations

The findings of this summary and the 'high level' gap analysis, serve as a first indication on where input could give added value to improve the overall training of regulatory scientists to work in the field of chemicals, and enable the consultant to include suggestions on how training and courses could be developed, and how possible partners could be found to facilitate this.

There is a clear 'gap in the market' for REACH and CLP related training. More long duration courses with practical training could be established and combined with more specific short-term courses. An integration of different courses in the EU is proposed in order to broaden the number of students from different countries, exchange teachers and have a common understanding of approaches to risk assessment, combined with practical training periods for students.

Ideal risk assessment courses relevant to REACH and CLP should be multidisciplinary and cover toxicology, environmental fate, ecotoxicology and exposure. Practical training programmes with hands-on experience should also be part of these courses.

The different EU bodies should adopt a common approach to training in order to achieve a harmonised approach to risk assessment in Europe. There would need to be motivation at EU level and/or nationally, not just demand driven changes.

There is a case for putting effort into devising a 'fit for purpose' scheme to educate and train young graduates to become chemical risk assessors and regulatory professionals (based on a combination of academic education and professional hands-on experience) leading to some form of 'marketable' recognised qualification, ideally with some form of accreditation.

This would be of benefit to:

- Students who will be able to get education and training leading to employment.
- ECHA, other administration and industry who will be able to recruit more competent staff.
- Universities who would profit from a training network.

One possibility could be to expand the experience gained during the DG SANCO European Toxicology Risk Assessment Training (TRISK) initiative, as this was a successful proof of concept focusing on human health risk assessment. The new training programme could be in the format of

blended learning which would combine classroom and distance learning allowing face-to-face time to be used for engaging trainees in advanced interactive training while the distance course would provide trainees with multimedia-rich theoretical content.

Another approach could be to build on the current initiative by the Italian Ministry of Health and Research, to set up postgraduate courses in the field of REACH/CLP; this has provided positive results for the training of professionals and could be considered as an initiative to replicate across other European countries.

Finally the ECHA graduate scheme could be developed to work with European academic institutions to develop further education programmes, possibly linked with some form of internship or research positions for newly qualified graduates within ECHA.

It can be foreseen that any of these three suggestions would help to fulfil the requirements leading to the certification or accreditation of trained human health risk assessors currently under development by the European Committee for Standardisation (CEN) under the project CEN/TC 416 "Health risk assessment of chemicals – Requirements for the provision of training" supported the Health and Consumers Directorate General (DG SANCO).

There is a strongly-supported view that the recognition of professional risk assessors would not only promote quality through continued education assuring a high level of competence, but may also stimulate the organisation of long-term courses to ultimately address the limited number of training courses currently available across Europe.

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