Project acronym: TRISK

Agreement number: 2008 11 02

Project title: European Advanced Risk Assessor Accredited Training Programme for Highly Qualified Toxicology Experts

Start date of project: 01/02/2009

Duration: 37

Annex n°: WP2 Annex2.6

Annex title: TRISK Case Study Booklet

Date: April 2010

Partner responsible: University of Milan (UMIL)
Annex 2.6 TRISK Case Study Book was written by the University of Milan (UMIL) to disseminate the results of the project European Advanced Risk Assessor Accredited Training Programme for Highly Qualified Toxicology Experts (TRISK).

TRISK is co-financed by the European Commission Second Programme of Community Action in the field of Health (2008-2013) under the priority action to improve citizens' safety for a period of 37 months starting February 2009 and ending February 2012 (agreement no. 20081102).

Sole responsibility for this publication lies with the authors and the Executive Agency for Health and Consumers is not responsible for any use that may be made of the information contained herein.
November 25, 2011

Dear Stakeholder,

TRISK, the European Toxicology Risk Assessment Training Programme, a 36-month project funded by the European Union under the framework of the Second Programme of Community Action in the field of Health (2008-2013) will be coming to an end January 2012, after its launch in February 2009.

From more than 123 applications from across Europe, a total of 26 trainees with previous training or experience in toxicology and will intention to pursue a career in risk assessment in Europe in industry, regulatory authorities, consultancy or academia were selected to participate in TRISK.

The objective of TRISK is to provide a comprehensive training in toxicological risk assessment that serves as a model for future European training in risk assessment for accredited European risk assessors. The training programme includes the following 3 key elements:

1. Eight 1-week-long course modules starting January 2010 and ending January 2011.

2. An applied training of 450 hours at an institution performing risk assessments beginning February 2011 and ending November 2011.

3. The preparation of a case study at a final examination held December 2011.

The final examination event is scheduled November 30- December 2, 2011 at the NH Grand Place Arenberg Hotel located in Rue d'Assaut, 15 – Brussels (Belgium).

Case study presentations will last about an hour and range from a variety of risk assessment topics. As a key stakeholder and supporter of TRISK, we extend an invitation to consider attending the presentation of any of the case studies prepared by the trainees listed on the enclosed book.

On behalf of the entire TRISK consortium, I thank you again for your valuable support and for making TRISK a successful project.

Cordially

Prof. Corrado L. Galli
TRISK Project Coordinator
TRISK FINAL EXAMINATION EVENT

Presentation of Case Studies written by the trainees completing the TRISK program and candidates for the European Advanced Risk Assessors Accreditation Training Programme for highly qualified toxicology experts training certification.

DATE
November 30 – December 2, 2011

VENUE
NH Grand Place Arenberg
Rue d'Assaut 15 - 1000 Brussels
Executive Summary

TRISK, European Toxicology Risk Assessment Training Programme, is a project funded by the European Union, in the framework of the Second Programme of Community Action in the field of Health 2008-2013. The general objective is to develop a training programme in risk assessment based on common European criteria, easily adoptable by institutions across Europe, and focusing on risk assessment methodology and procedure. TRISK fills an important need in the training of toxicologists into areas of risk assessment by establishing a clear and recognized definition of training criteria and a recognition mechanism to qualify risk assessors.

TRISK aims to fill the lack of training schemes and provide opportunities for practical, on the job training on the risk assessment approach for young scientists or new toxicologist graduates interested in pursuing this area of expertise, as well as trained toxicologist experts attracted by the opportunity to serve as member of the various scientific committees in regulatory, industry and governmental bodies engaged in risk assessment.

TRISK will contribute directly to the training of risk assessors across Europe in order to satisfy the constant needs for trained scientists to serve in the Commission Scientific Committees (SC) and ensure the sustainability of the EU risk assessment advice structure, while indirectly meeting the needs of industry and the private sector who also require trained risk assessors in order to satisfy the new regulatory requirements and development of new market products. It will contribute to regulatory decisions based on high-quality risk assessments, thus improving the health safety of the citizens in the Member States.

TRISK project partners

- University of Milan, Italy
- University of Surrey, UK
- Karolinska Institutet, Sweden
- University of Düsseldorf, Germany
- University of Utrecht, The Netherlands
- Technoalimenti SCpA, Italy (research consortium)

Target

The training programme is intended for individuals who have previous training or experience in toxicology and who would like to pursue a career in risk assessment in Europe in industry, regulatory authorities, consultancy or academia.

TRISK program overview

The training programme includes the following 3 key elements:

1. Eight 1-week-long course modules in key areas of risk assessment
2. An applied training period of 450 hours at an institution performing risk assessments
3. Preparation of a case study to present at a final examination

Contact Information

For more information about TRISK, please visit our website at www.trisk-project.eu
November 30, 2011

Final Examination Case Study Presentations

One hour intervals starting at 9.00 and ending at 12.00

Daniel Borg

Agathi Charistou

Ivan Dobrev
<table>
<thead>
<tr>
<th><strong>First name(s)</strong></th>
<th>Daniel</th>
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<tbody>
<tr>
<td><strong>Surname(s)</strong></td>
<td>Borg</td>
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<tr>
<td><strong>Nationality</strong></td>
<td>Sweden</td>
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</table>
| **Education**    | MSc Environmental Toxicology, Uppsala University, Sweden  
Ongoing PhD in studies in Toxicology/Environmental Medicine, Karolinska Institutet, Sweden |
| **Current Employer** | AstraZeneca, Södertälje, Sweden  
Institute of Environmental Medicine (IMM), Karolinska Institutet, Stockholm, Sweden |
| **Current Position** | Senior Research Scientist/PhD Student |
| **E-mail**       | daniel.borg@astrazeneca.com, daniel.borg@ki.se |

**TRISK study case title**  
Health Risk Assessment of Perfluoroalkylated Substances in Sweden

**Brief Abstract**  
This risk assessment, carried out in accordance with REACH guidelines, evaluated possible health risks of 19 perfluoroalkylated substances (PFAS) for the Swedish population, both for congeners individually as well as in combination. The exposure assessment was based on biomonitoring data (blood/serum levels) for the selected congeners in the Swedish population which was grouped into individuals exposed indirectly via the environment as well as occupationally exposed (ski waxers). The hazard assessment examined common toxic effects for the selected congeners, hepatotoxicity and reproductive toxicity, as well as other toxic effects of relevance. The risk characterization showed no cause for concern for hepatotoxicity or reproductive toxicity for individuals exposed indirectly via the environment, except for hepatotoxicity in a highly exposed subpopulation eating contaminated food. A cause for concern was observed for other non-standardized toxicological endpoints, immunotoxicity and effects on mammary gland development; however these effects need to be further studied. For the occupationally exposed, safe use could not be shown, based on concern for liver toxicity due to elevated levels of one compound, PFOA, and for all congeners in combination, as well as for reproductive toxicity for all congeners combined. This is the first health risk assessment evaluating a large number of PFAS, individually and in combination.

**Your TRISK experience**  
**How has your participation in TRISK helped you professionally?**  
It has broadened as well as deepened my theoretical knowledge and practical experience in health risk assessment.

**How do you plan to continue to develop your knowledge and experience in risk assessment?**  
By remaining in the field of toxicology and make use of my knowledge in health risk assessment.

**What are you plans after the conclusion of TRISK?**  
To remain in the field of toxicology and health risk assessment and make use of the experience and knowledge I have gained in TRISK.
First name(s)  Agathi  
Surname(s)  Charistou  
Nationality  Hellenic  
Education  MSc in Ecotoxicology  
Current Employer  Benaki Phytopathological Institute  
Current Position  Chemist, Regulatory Toxicologist  
E-mail  A.Charistou@bpi.gr; agathi_charistou@hotmail.com  

TRISK study case title  Core Assessment of two plant protection products - Mammalian Toxicology: Data evaluation & Risk Assessment  

Brief Abstract  The mammalian toxicology data of two plant protection products (PPPs) have been evaluated in the frames of the EC Regulation 1107/2009. Product A is intended for use as a fungicide in a wide range of crops. Product B is intended for seed treatment. A full risk assessment has been performed for operator, worker, bystander and resident. Moreover, the development of a database for the operator/worker exposure determinants has been initiated in the frames of the FP7 project BROWSE.  

Your TRISK experience  How has your participation in TRISK helped you professionally?  
TRISK modular and applied training have enriched my knowledge in toxicology and health effects risk assessment. TRISK gave me the opportunity to see more theoretical aspects of toxicology and realize the different approaches in the risk assessment of different groups of chemicals. Overall, my expertise in the area of the risk assessment was strengthened.  

How do you plan to continue to develop your knowledge and experience in risk assessment?  
The health effects risk assessment area is a dynamic area under continuous development. Therefore, I will continue to be actively involved in training (both as a trainer and as a trainee). My participation in expert meetings organised by EFSA and JRC for PPPs and biocides, respectively, and in EU funded projects related to risk assessment will also contribute in expanding my experience in the area.  

What are you plans after the conclusion of TRISK?  
Having successfully completed my participation in TRISK, I will apply to the Hellenic Society of Toxicology in order to be a Registered Toxicologist. I will continue working in the area of hazard identification and human exposure assessment for plant protection and biocidal products, anticipating new challenges.
First name(s)  Ivan  
Surname(s)  Dobrev  
Nationality  Bulgaria  
Education  PhD in Toxicology  
Current Employer  Federal Institute for Occupational Safety and Health (BAuA), Dortmund, Germany  
Current Position  Toxicologist  
E-mail  dobrev.ivan@baua.bund.de  

TRISK study case title  Pre-evaluation document on Biphenyl as a food additive  

Brief Abstract  Biphenyl has been used as a pesticide and as food additive because of its fungicidal activities. Its MOA is based on lipid peroxidation which inhibits the sporulation of fungi on the fruits. Findings from toxicity studies are discussed in light of different MOA and their relevance for humans integrating available data into a risk assessment report.

Your TRISK experience  How has your participation in TRISK helped you professionally?  
It was the perfect opportunity for me to systemize my rather scattered toxicological experience within a well-defined and assessable time frame. Recently, I was able to change my position, and TRISK played certainly a role in it.

How do you plan to continue to develop your knowledge and experience in risk assessment?  
Working in the area of modern risk assessment will further require a continuous update on the newest tests and methodologies. TRISK will definitely not remain the last training programme I’ve attended.

What are you plans after the conclusion of TRISK?  
Most likely (and hopefully), I will continue my work in the area of chemical risk assessment, with a special focus on the regulatory aspects of the new REACH regulation. I would be very happy to remain in touch with my TRISK colleagues and mentors, both professionally and private. The world of toxicologists is really small.
November 30, 2011

Case Study Presentations

One hour intervals starting at 13.00 and ending at 18.00

Jacek Ciesla

Carmen Estevan

Antonio Fernandez Dumont

Ilse Gosens

Dana Guljasova (no cv provided)
First name(s) Jacek
Surname(s) Cieśla
Nationality Polish
Education MSc in Environmental Engineering
Current Employer Bureau for Chemical Substances
Current Position Chief Specialist
E-mail jacek.ciesla@chemikalia.gov.pl

TRISK study case title Toxicological risk assessment under REACH

Brief Abstract Preparation of part of a registration dossier (toxicological part) for a group of four industrial chemical substances including chemical safety assessment (human health part) for one of the substances. Analysis of all available data, data-gap filing. Analysis of possibilities of use read-across and category approach and setting proposals for new studies; DNELs derivation.

Your TRISK experience How has your participation in TRISK helped you professionally?

I have gained more confidence and experience in the field of toxicological risk assessment. As a representative of regulators I have had a wonderful opportunity to work with people from the industry which has given me more exposure and a better understanding of the way people from industry work. Additionally TRISK has given me possibility to met very experienced people from different institutions with diverse backgrounds working in the field of risk assessment. Finally, I will start cooperating with a new institution responsible for the evaluation of the dossier submitted for authorization of plant protection products, I will be responsible for ‘inter alia’ toxicological risk assessment.

How do you plan to continue to develop your knowledge and experience in risk assessment?

I will be involved in the evaluation of the dossier submitted for authorization of plant protection products so I shall also gain new experience in this area and next year will be included in the process of substance evaluation according to REACH legislation which I hope will give me the possibility to develop my knowledge and experience.

What are you plans after the conclusion of TRISK?

I shall continue work in the field of risk assessment also including toxicological risk assessment of industrial chemicals and plant protection products for Polish REACH Competent Authority.
First name(s) Carmen
Surname(s) Estevan Martínez
Nationality Spanish
Education PhD in Environmental Sciences
Current Employer University Miguel Hernández
Current Position Scientific researcher
E-mail cestevan@umh.es

TRISK study case title Risk assessment of biocidal substances

Brief Abstract The activity consisted on the performance of the steps for the risk assessment process. Data (exposure and human health effects) from a group of biocides were evaluated and the active substance and the biocidal product are classified and authorized.

Your TRISK experience How has your participation in TRISK helped you professionally?

It has helped me to increase my knowledge about risk assessment, to apply this knowledge in practical cases. Apart from that, it has helped me to meet professionals working in risk assessment.

How do you plan to continue to develop your knowledge and experience in risk assessment?

My plan to develop my experience is to work in the field of risk assessment. Apart from that, I plan to do more courses, as the Eurotox Advanced Toxicology Course and other programmes for training toxicologists.

What are you plans after the conclusion of TRISK?

My future plans are still to be working in the field of toxicology and risk assessment. Apart from continuing working in this subject I am willing to continue my training, by the attendance to courses and by getting the experience in the in-hands work.
First name(s): Antonio  
Surname(s): Fernandez Dumont  
Nationality: Spain  
Education: PhD Molecular Biology, MSc in Veterinary Sciences  
Current Employer: European Food Safety Authority  
Current Position: Scientific Officer  
E-mail: antonio.fernandezdumont@efsa.europa.eu  

TRISK study case title: Evaluation of nitrates (E251, E252) as a food additive  

Brief Abstract: Sodium nitrate (E251) and potassium nitrate (E252) are food additives generally authorised in specific foodstuffs in Europe. The present report bases its evaluation on previous evaluations and additional scientific literature that became available since then.

Your TRISK experience: How has your participation in TRISK helped you professionally?

The TRISK program helped me to acquire a broader knowledge on toxicology risk assessment and added great value to my professional career enriching my existing expertise in this area and complementing those on allergenicity assessment.

How do you plan to continue to develop your knowledge and experience in risk assessment?

The knowledge acquired will be applied in my daily work to better support the EFSA Panel experts in its toxicology risk assessment. Working together with EFSA experts will help me to further develop my experience in risk assessment.

What are your plans after the conclusion of TRISK?

I will apply and further develop my knowledge in toxicology and allergenicity risk assessment to perform my job in a more efficient way and with higher standards.
First name(s) Ilse
Surname(s) Gosens
Nationality Dutch
Education PhD Medical Sciences
Current Employer National Institute for Public Health and the Environment (RIVM)
Current Position Inhalation toxicologist
E-mail ilse.gosens@rivm.nl

TRISK study case title Aggregate exposure assessment of chemicals in consumer products – paraben exposure in children as a case-study

Brief Abstract Aggregate exposure is the total exposure to a chemical that arises from multiple sources and multiple exposure routes. A deterministic approach will be compared to a probabilistic approach for several parabens as a case-study. The advantages and disadvantages of both approaches will be mapped and the added value of increasing refinement in the exposure assessment will be indicated.

Your TRISK experience How has your participation in TRISK helped you professionally?

The TRISK training has augmented my knowledge on the different toxicological disciplines as well as exposure assessments. After obtaining experience with risk assessment terminology and concepts and performing a risk assessment project, my professional interaction with risk assessors both within and outside our institute has improved.

How do you plan to continue to develop your knowledge and experience in risk assessment?

I will participate in a working group on risk assessment of nanomaterials at our institute and I will collaborate with other risk assessors in an European project on developing a method for risk assessment of nanomaterials (ENPRA).

What are you plans after the conclusion of TRISK?

Write a publication on aggregate exposure assessment for chemicals in consumer products and participate in more risk assessment projects at the RIVM.
December 1, 2011

Case Study Presentations

One hour intervals starting at 8.00 and ending at 12.00

Miroslava Hrivnáková (no cv provided)

Agnieszka Jankowska

Merja Korkalainen

Katarzyna Malikiewicz
First name(s)  Agnieszka
Surname(s)  Jankowska
Nationality  Poland
Education  MSc in Biology
Current Employer  Nofer Institute of Occupational Medicine
Current Position  Research-and-teaching assistant
E-mail  ajan@imp.lodz.pl

TRISK study case title  L(+)lactic acid (PT3) competent authority report

Brief Abstract  This training report have been prepared in the context to the application for the inclusion of L(+)lactic acid in Annex I of Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market. Performed risk assessment of L(+)lactic acid is related to its use in veterinary hygiene biocidal product (PT3).

Your TRISK experience  How has your participation in TRISK helped you professionally?
My ordinary work regards hazard assessment and risk characterization of chemicals. TRISK was excellent opportunity to develop my competencies. Currently I use improved skills and gained knowledge at work, often in international projects.

How do you plan to continue to develop your knowledge and experience in risk assessment?
I am going to start PhD study in risk assessment.

What are you plans after the conclusion of TRISK?
I intend to continue my career in health risk assessment. I hope I will have an opportunity to use my knowledge and skills in new tasks in international projects carried out in Nofer Institute within the framework of the European Union programmes.
First name(s)        Merja Kaarina  
Surname(s)          Korkalainen  
Nationality        Finnish  
Education          PhD Toxicology  
Current Employer   National Institute for Health and Welfare, Finland  
Current Position   Researcher  
E-mail             merja.korkalainen@thl.fi

TRISK study case title  Risk assessment of non-dioxin-like PCBs present in food – focus on reproductive, developmental and endocrine effects

Brief Abstract  Non-dioxin-like PCBs form the major part of all contaminating PCBs in the food. Their toxic effects on reproductive, developmental and endocrine functions were studied and assessed not to raise concern in general population including highly exposed breastfed infants.

How has your participation in TRISK helped you professionally?
I have acquired a lot of knowledge about different aspects of toxicology, which form the basis for risk assessment. I have learned the methods and procedures used in health risk assessment and also how to use them in practice.

How do you plan to continue to develop your knowledge and experience in risk assessment?
I will hopefully adopt new tasks in the field of risk assessment in order to deepen my knowledge and gain more experience in risk assessment work.

What are you plans after the conclusion of TRISK?
In addition of continuing my present research work, I will increasingly participate in health risk assessment work, which is one of the key tasks in our toxicology unit.
**First name(s)** Katarzyna  
**Surname(s)** Malkiewicz  
**Nationality** Polish / Swedish  
**Education** PhD in Toxicology  
**Current Employer** Swedish Chemicals Agency  
**Current Position** Risk Assessor  
**E-mail** Katarzyna.Malkiewicz@kemi.se

**TRISK study case title** Toxicological Risk Assessment of Zinc Oxide (ZnO) with Focus on Nano-ZnO - Is data registered within REACH sufficient for safety evaluation?

**Brief Abstract**
My practical training in toxicological risk assessment (RA) of chemicals, realized at the Swedish Chemicals Agency (Kemi) as a part of TRISK aimed at: 1) clarification of how nano forms of ZnO have been registered under REACH, 2) analysis of the extent of data concerning human health hazard that have been considered for RA, 3) analysis of assumptions and approaches in RA, 4) critical revision in light of independently collected scientific literature on nano-specific properties versus bulk in the context of RA.

**Your TRISK experience**
Building on my toxicological knowledge and research experience in the field of toxicology and chemicals regulation REACH, during the TRISK theoretical courses in RA and practical training I have gain qualification and competence in working as a chemicals’ risk assessor. This is reflected by the recent (September 2011) change in my employment from the researcher at the Royal Institute of Technology to the risk assessor at the Swedish Chemicals Agency (Kemi).

**How do you plan to continue to develop your knowledge and experience in risk assessment?**
My work as a risk assessor offers continuity in the development of knowledge and experience in the RA of chemicals within REACH. I am involved in the Kemi’s, as a Member State Competent Authority, activities including: identification of Substances of Very High Concern (SVHC), substance evaluation and testing proposals. Activities include preparation, commenting on and revision of proposals and dossier documents, workshops etc.

**What are your plans after the conclusion of TRISK?**
I intend to continue my recently appointed work at the Swedish Chemicals Agency. It gives opportunity to use and develop qualifications as a risk assessor, is interesting, challenging and satisfactory.
December 1, 2011

Case Study Presentations

One hour intervals starting at 13.00 and ending at 18.00

Lars Mecklenburg

Kirsi Myöhänen

Carmen Purdel

Claudia Röhl

Pierre Serfass
**TRISK study case title**

Benchmark Dose Modelling as a Way for Integrated Hazard Analysis in Human Pharmaceutical Risk Assessment: An Example of Oral Phosphodiesterase-4 Inhibitors in First-In-Human Clinical Trials

**Brief Abstract**

The project evaluates application of the BMD approach for the risk assessment of pharmaceuticals, particularly to support FIH clinical trials. For this purpose, I have reviewed data from 4-week oral toxicity studies in mice, rats and dogs that had been conducted with 4 different compounds, all belonging to the pharmaceutical class of phosphodiesterase type 4 (PDE4) inhibitors. The observed mean responses together with their variance were used to fit a dose-response model, and this was used for estimating the BMD and a lower bound confidence interval of the BMD (BMDL). BMD modeling provided an equally robust reference point for determination a starting dose for FIH clinical trials as did the conventional NOAEL. However, BMD modeling made extended use of the dose-response data and provided a quantification of the uncertainty and variability in the data set. It allowed determination of the most critical toxicological endpoint, allowed determination of relationships between different toxicological endpoints, and allowed comparison of the exposure-response relationship across different compounds. BMD modeling is therefore proposed as a valuable tool to make extended use of toxicity data that serves as a basis for deriving a MRSD and a comprehensive risk assessment of drug candidates that enter clinical development.

**Your TRISK experience**

How has your participation in TRISK helped you professionally?

TRISK has considerably broadened my understanding of toxicological risk assessments, particularly in the area outside of pharmaceuticals. In addition, I have learned additional techniques that are useful in risk assessment and that I have started using on a regular basis.

How do you plan to continue to develop your knowledge and experience in risk assessment?

I have become responsible for all toxicological risk assessments within the corporate Nycomed organization and I hope to be able to continue this responsibility. I will be extending my experience in this area by conducting and supervising risk assessments.

What are you plans after the conclusion of TRISK?

I would appreciate opportunities to broaden my experience in risk assessments both within and outside of the field of pharmaceuticals. I plan for intensive interactions with other scientists in this field.
First name(s): Kirsi  
Surname(s): Myöhänen  
Nationality: Finland  
Education: PhD Pharmacy, MSc in Toxicology  
Current Employer: Finnish Safety and Chemicals Agency  
Current Position: Senior Adviser  
E-mail: kirsi.myohanen@tukes.fi

TRISK study case title: Exposure Assessment of Glutaraldehyde

Brief Abstract
Since my current tasks are more related to hazard assessment than exposure assessment, I wanted to develop my skills in exposure assessment. Therefore, I chose to concentrate in exposure assessment in my TRISK case study.

Glutaraldehyde is used as a biocide to kill bacteria, fungi and viruses in several applications. My task was to assess the relevant exposure scenarios for different uses in several different product types. I have also selected appropriate methods, models and indicative values for the assessment. After conducting the assessment, I used the results in risk characterization. The final result for the assessment was that glutaraldehyde should not be used in certain open applications, where chronic inhalation exposure is possible. Moreover, personal protection should be applied for several uses.

Your TRISK experience
How has your participation in TRISK helped you professionally?
I have gained more scientific and practical experience for conducting regulatory risk assessment in my work. Moreover, I have got an appreciated proof of my education and skills in toxicological risk assessment into my CV.

How do you plan to continue to develop your knowledge and experience in risk assessment?
My desire is to continue working with hazard assessment focusing more to the whole risk assessment. Being passionate about my work, I am enthusiastic about learning new things striving continuously to incorporate new knowledge in practice. Therefore, I will continue participating into toxicological risk assessment related seminars, courses, workshops and congresses. As a member of Executive Board of Finnish Society of Toxicology, I will continue promoting the networking of toxicologist.

What are you plans after the conclusion of TRISK?
I will continue my work in the field of toxicology developing my skills on that area.
First name(s)  Purdel
Surname(s)  Nicoleta Carmen
Nationality  Romanian
Education  PhD Toxicology
Current Employer  University of Medicine and Pharmacy Carol Davila, Faculty of Pharmacy
Current Position  Lecturer
E-mail  carmen_purdel@yahoo.com

TRISK study case title  Risk assessment of parabens in child care products

Brief Abstract  Based on published toxicological data that suggest that parabens exhibit endocrine-disrupting effects, we performed a risk assessment of two most used parabens (metyl paraben and propyl paraben) with focused on endocrine disrupting effects and to investigate estrogenic burden.

Your TRISK experience  How has your participation in TRISK helped you professionally?
I was co-opted by the Romanian National Medicine Agency and Medical Devices and involved in elaboration of the first Romanian guideline in environmental risk assessment field (HCS 28/1.11.2010), which was released on November 2010.

How do you plan to continue to develop your knowledge and experience in risk assessment?
Definitely I will try to continue my education through courses, seminars, post PhD projects and to acquire more experience in health risk assessment of non-pharmaceutical field.

What are you plans after the conclusion of TRISK?
I am attracted by the opportunity to serve as member of the various scientific committees in regulatory, industry and governmental bodies engaged in risk assessment.
TRISK study case title
Toxicological risk assessment of di-iso-butylyphthalate (DiBP), derivation of a health-based biomarker value for DiBP and an approach to assess mixture effects of phthalates

Brief Abstract
The risk assessment includes collection of existing data for di-iso-butylyphthalate (DiBP), assessment of exposure scenarios / biomonitoring data, identification and characterization of hazards and finally a proposal of a health-based guidance value, i.e. a derived no effect level (DNEL) value. In the second part the DNEL value served as a basis to derive a health-based biomarker value for DiBP according to the requirements of the human biomonitoring (HBM) I value initiated by the German Federal Environment Agency (UBA). Furthermore, this biomarker value was evaluated in the context of data collected from different biomonitoring studies like the last German Environmental Survey for Children (GerES IV). Finally, the need to consider mixture effects in the risk assessment of phthalates and possible approaches will be discussed.

Your TRISK experience
How has your participation in TRISK helped you professionally?
- further skills and knowledge in toxicological risk assessment
- new input for my student toxicology lectures
- network among different European risk assessors from academia, authorities and industry and professional national and international risk assessment institutions
- improved insight in national and European structures in the field of health risk assessment
- by getting a professional qualification and hopefully also professional certification

How do you plan to continue to develop your knowledge and experience in risk assessment?
- continuous training in advanced topics of risk assessment
- performing scientific projects on subjects relevant for risk assessment
- performing regular expert opinions in risk assessment
- working in national and international health risk assessment committees, if there are needs
- continuous exchange with other TRISK participants on risk assessment questions

What are you plans after the conclusion of TRISK?
This depends on the job market, but if there are attractive offers the field of health risk assessment would be definitely an interesting choice for me.
First name Pierre
Surname Serfass
Nationality French
Education Doctor of Veterinary Medicine; Toxicology Study Direction (DUFDET)
Current Employer CIT
Current Position Project Manager
E-mail Serfass_p@yahoo.fr

TRISK study case title Risk assessment of Branched AlkylBenzene for REACH based on experimental data, read-across from Linear and/or Sulfonated analogs and QSAR

Brief Abstract Read-across was reliable for acute toxicity, local tolerance, sensitisation and genotoxicity. The substances diverged for repeated-dose/reproductive toxicity and environmental fate. Risks from direct and indirect exposure were assessed using ECETOC-TRA and residue levels in mussels.

Your TRISK experience
How has your participation in TRISK helped you professionally?
Participating demonstrated my active involvement in, and personal interest for, risk assessment. This recently enabled me to get a new position in a major French chemical industry as a product manager, where I’ll be responsible for risk assessment and registration of a portfolio of chemicals.

How do you plan to continue to develop your knowledge and experience in risk assessment?
I also submitted a dossier to become a Eurotox Registered Toxicologist (ERT). My new position will focus and increase my knowledge and experience in the field of chemical exposure and risk assessment. I will continue to follow new developments in chemical risk assessment, notably thanks to the experts who I met in the TRISK program.

What are you plans after the conclusion of TRISK?
Apart from my new position, if I find the time, I think about writing a publication on chemical risk assessment themes such as use and relevance of read-across or adaptation of testing requirements and methods to UVCB substances (Unknown or Variable composition, Complex reaction products or Biological materials).
December 2, 2011

Case Study Presentations

One hour intervals starting at 8.00 and ending at 12.00

Emese Sipter

Maria Soufi

Reinhard Stidl

Annemarie Losert
TRISK study case title
Risk assessment of the diabetogenic effects of arsenic

Brief Abstract
The relationship between arsenic and diabetes is a novel theory. The aim of my study was to analyse the toxicological studies of arsenic induced diabetes and the correlation between arsenic exposure and the prevalence of diabetes in Hungary.

Your TRISK experience
How has your participation in TRISK helped you professionally?
TRISK helped me to become familiar with different toxicological aspects. I can integrate the processes and evaluate different risk assessment data and reports. TRISK also helped me to understand the European concepts of risk assessment.

How do you plan to continue to develop your knowledge and experience in risk assessment?
I try to be involved in the scientific part of risk assessment. I keep my interest in the new guidelines, methods or approaches of the scientific committees. I also try to attend some training course to increase my knowledge.

What are you plans after the conclusion of TRISK?
I try to make some interdisciplinary research in the field of environmental health and risk assessment. I plan to join some international research project and/or participate in the work of some European agencies dealing with risk assessment.
First name(s)  Maria
Surname(s)  Soufi
Nationality  Greek
Education  PhD in Toxicology
Current Employer  DuPont Crop Protection
Current Position  Regulatory Toxicologist
E-mail  maria.soufi@dupont.com

TRISK study case title  TiO$_2$ as contaminant in plant protection products

Brief Abstract  Titanium dioxide is present in certain formulations of plant protection products as a low level contaminant. This compound has been classified as “possibly carcinogenic to humans, Group 2B” by IARC. In this project the focus is on the assessment of exposure to TiO2 through the use of plant protection products and the associated risk for operators, workers, and bystanders.

Your TRISK experience  How has your participation in TRISK helped you professionally?
I have acquired more knowledge, more experience, became more open-minded, and learned to work with different teams. Also, I have met highly qualified colleagues, who I feel I can always consult.

How do you plan to continue to develop your knowledge and experience in risk assessment?
By keeping on working as a toxicologist and risk assessor, acquiring more experience, and participating in relevant seminars/congresses/meetings.

What are you plans after the conclusion of TRISK?
Have Christmas Holidays with my family!
**TRISK study case title**
Extractables and Leachables in Parenteral Drug Products – A Safety Assessment Strategy

**Brief Abstract**
Plastic disposables such as packaging materials, closure systems, filter/tubes/gels etc are widely used in the production process of parenteral drug products, but the qualification of such materials is only minimally focused on the safety impact of possible extractables or leachables and the regulatory guidance is limited. Since modern state of the art analytical methods are capable to identify and quantify even traces of such compounds in extracts (extractables) or drug products (leachables), it is nowadays possible to characterize the majority of substances that may originate from disposables. The crucial part of this characterization is the safety evaluation, partly with limited compound specific toxicity data only. Aim of the applied training was to establish a strategy how to assess safety impact for patients.

**Your TRISK experience**

How has your participation in TRISK helped you professionally?

The TRISK education helped me to deepen and sharpen my toxicological expertise. Many participants are known experts in specific branches of toxicology; group discussions with TRISK students and teachers were comprehensive and helped me to solve toxicological problems at my work. I consider networking with toxicologists all over Europe as a very positive side effect of the TRISK courses.

How do you plan to continue to develop your knowledge and experience in risk assessment?

I will participate in specific toxicological risk assessment courses in the next years in order to gain further insights in the research and development of risk assessment. Alternatives to animal testing (in silico and in vitro) will be a focus within.

What are you plans after the conclusion of TRISK?

My job at Baxter is many-sided, exciting and a perfect environment to further progress my career as toxicologist. I am sure that the TRISK students will stay in contact and also that scientific problems will be discussed in the TRISK community in the upcoming years.
First name(s) Annemarie
Surname(s) Losert
Nationality Austrian
Education PhD Biology, MSc Toxicology
Current Employer Environment Agency Austria
Current Position Regulatory toxicologist
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TRISK study case title Human health risk assessment of DCPP (5-Chloro-2-(4-chlorophenoxy)-phenol) in the frame of the Biocidal Products Directive (98/8/EC)

Brief Abstract The risk assessment of DCPP covers human health hazards including read-across from triclosan for endpoints for which no data on DCPP were available. The exposure to DCPP resulting from 3 different product types was assessed and the risk characterised.

Your TRISK experience How has your participation in TRISK helped you professionally?

What we have learned from the lecturers in the different modules is very useful for my present work. At the same time my fellow trainees were a good source of new information. We are now part of a very useful network, with experts from the different fields of toxicology.

How do you plan to continue to develop your knowledge and experience in risk assessment?

Risk assessment is very often learning by doing. I will try to use and expand the knowledge I have gained during the TRISK training in my daily work and I will also try to get the chance to attend similar courses and activities like the single modules of TRISK as often as possible.

What are your plans after the conclusion of TRISK?

I will stay at the chemicals department and continue my work as a regulatory risk assessor. The experience I have gained during the TRISK training will help me to fulfil my work within the chemicals department and within EU working groups dealing with the risk assessment of chemicals.
December 2, 2011

Case Study Presentations

One hour intervals starting at 13.00 and ending at 17.00

Joanne Gartlon

Helene Stockmann-Juvala

Mathieu Vinken

Vitcheva Vessela
First name(s) Joanne
Surname(s) Gartlon
Nationality British
Education PhD In Vitro Neurotoxicology
Current Employer European Food Safety Authority
Current Position Scientific Officer
E-mail joanne.gartlon@efsa.europa.eu

TRISK study case title Evaluation of titanium dioxide (E 171) as a food additive

Brief Abstract This report deals with the re-evaluation of the safety of titanium dioxide (E 171) when used as a food colouring substance. Titanium dioxide (E 171) is authorised as a food additive in the EU under European Parliament and Council Directive 94/36/EC on colours for use in foodstuffs.

Your TRISK experience How has your participation in TRISK helped you professionally?
The knowledge gained from the TRISK training has enabled me to perform my duties at work more efficiently and to a higher standard.

How do you plan to continue to develop your knowledge and experience in risk assessment?
I will gain further knowledge and experience in risk assessment through my daily work activities for EFSA. I also plan to attend relevant training courses in the areas of risk assessment and toxicology.

What are you plans after the conclusion of TRISK?
I plan to continue to work for EFSA which gives me the opportunity to apply the knowledge I have gained from attending the TRISK course and to gain further experience in risk assessment.
First name(s)  Helene
Surname(s)    Stockmann-Juvala
Nationality  Finnish
Education    PhD (Pharmaceutical Chemistry)
Current Employer   Finnish Institute of Occupational Health (FIOH)
Current Position  Senior specialist
E-mail         helene.stockmann-juvala@ttl.fi

TRISK study case title  Criteria document on carbon monoxide

Brief Abstract
A Nordic Expert Group criteria document on carbon monoxide was prepared. The document will be published and can be used by the regulatory authorities as a scientific basis for the setting of occupational exposure limits.

Your TRISK experience
How has your participation in TRISK helped you professionally?
TRISK has provided a unique package of courses on the most important issues related to toxicological risk assessment. Although I had some experience in this field, I do now feel much more confident about the issues that have to be considered when evaluating the health hazards and risks of chemicals.

How do you plan to continue to develop your knowledge and experience in risk assessment?
The next step is to use my knowledge in practise, and get hands-on experience from different types of risk assessment.

What are you plans after the conclusion of TRISK?
I have a permanent position at FIOH. My main tasks are related to preparation of background documents for occupational exposure limit values, risk assessment in nanotoxicology projects, and chemical safety reports for the REACH registration of chemicals.
First name(s)  Mathieu  
Surname(s)  Vinken  
Nationality  Belgian  
Education  Pharmaceutical Sciences (PhD), Postgraduate Course in Laboratory Animal Sciences (FELASA C)  
Current Employer  Department of Toxicology, Vrije Universiteit Brussel (VUB)-Belgium.  
Current Position  Tenure Track Professor  
E-mail  mvinken@vub.ac.be

**TRISK study case title**  Establishment of cosmetic product information files for the practical training of European risk assessors.

**Brief Abstract**  The Department of Toxicology of the VUB-Belgium organizes a yearly course entitled “Safety Evaluation of Cosmetics in the EU” which intends to teach the skills necessary to act as a safety assessor in the area of cosmetics. An essential part of this course implies a practical exercise, in which the participants have to scrutinize a so-called product information file (PIF) of 2 cosmetic products. The overall purpose of this exercise is to discover deliberately introduced errors in the PIF in order to get acquainted with the complex legislative framework of the safety evaluation of cosmetic products. Given the success of this course, there was a need for establishing a third PIF. Since hair dye products are nowadays heavily discussed because of potential health risks, it was decided to focus the new PIF on this kind of cosmetic products during my applied TRISK training.

**Your TRISK experience**  How has your participation in TRISK helped you professionally?

Clearly, TRISK has significantly contributed to the development and specification of my skills as European chemical risk assessor, which as such opens a plethora of perspectives for job opportunities. In addition, TRISK allowed me to elaborate my European network of connections with people from academic settings, industry and regulatory bodies in the field of toxicology and risk assessment.

**How do you plan to continue to develop your knowledge and experience in risk assessment?**

Since my own research is situated in the field of *in vitro* toxicology, and because I am involved in a number of European research consortia and societies in this direction, I am continuously faced with risk assessment topics. I also regularly attend conferences, workshops and courses to update my toxicological and risk assessment knowledge.

**What are you plans after the conclusion of TRISK?**

I have been recently assigned a Tenure Track Professorship at the VUB-Belgium. This will allow me to build a academic career. In a first instance, my ongoing research track in the area of *in vitro* toxicology will hereby be pursued. At the same, compilation of safety evaluations of a variety of chemical compounds, which has been done by the host laboratory for industry and regulatory bodies for many years, will be continued.
TRISK study case title  Risk Assessment of Dicofol

Brief Abstract

Dicofol is an organochloride pesticide structurally similar to DDT. Currently is registered only in Japan for use on tea crop. Dicofol is unlikely to pose carcinogenic effect to humans at anticipated dietary exposure levels. It is not genotoxic and teratogenic and does not appear to be a specific or selective neurotoxicant. The calculated ADI was 0.002 mg/kg bw, the ARID was 0.20 mg/kg bw, the AOEL was 0.02 mg/kg bw. The level of operator and worker exposure to dicofol from tea was below the AOEL only when personal protective equipment was used. Bystander and resident exposure was lower than AOEL. Based on the estimated IESTI and IEDI there is no public health concern of dicofol from acute and chronic consumption from tea.

Your TRISK experience

How has your participation in TRISK helped you professionally?

Started to lead a course on Risk assessment as an optional subject to pharmacy students

How do you plan to continue to develop your knowledge and experience in risk assessment?

I won a position as a visiting scientist in FDA where I am going to harvest data related to the in vivo toxicity of cosmetic ingredients and to assess them in terms of quality in order to be used for development of appropriate data schema and an open access data entry tool. (FW 7 – COSMOS Project)

What are you plans after the conclusion of TRISK?

Spending at least 1 year in FDA
CONFIDENTIALITY STATEMENT

If you are planning to attend a case study presentation, please note that you will be required to complete and sign the enclosed confidentiality statement.
CONFIDENTIALITY STATEMENT

I, the undersigned [name, name of your institution and function] hereby state that I will be involved in the project TRISK* Final examination activities with the role of:

[Please, select one or more of the following reported options]:

- member of TRISK final examination committee
- tutor
- mentor
- reader
- trainee attending to the oral presentation
- other (specify): …………………….

I hereby confirm that I will keep strictly confidential all information and documents (oral presentations, written reports, slides, etc..) acquired for three years starting from the date of this statement.

During this time, I will not disclose in any fashion to any third party, including any company, any information beyond generalities, without prior written permission from the TRISK Coordinator, Prof. Corrado L. Galli, University of Milan, Via Balzaretti 9, 20133 Milan, Italy. Email: corrado.galli@unimi.it

Signed in _________________ on this ___ day of ___, 2011
Full name: ...........................................................................................................
Signature: .......................................................................................................... 

Company: ........................................................................................................
Title: ..................................................................................................................
Address: .............................................................................................................
Phone number: .................................................................................................
Email address: .................................................................................................

* = European Advanced Risk Assessors Accredited Training Programme for highly qualified toxicology experts