SLOVENSKI STANDARD
SIST EN 16736:2015

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Ocenjevanje tveganja za zdravje zaradi kemikalij - Zahteve za zagotavljanje usposabljanja

Health risk assessment of chemicals - Requirements for the provision of training

Bewertung von Gesundheitsrisiken durch Chemikalien - Anforderungen an die Ausbildung

Évaluation des risques sanitaires causés par les substances chimiques - Exigences relatives à la dispensation de formation

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Health risk assessment of chemicals - Requirements for the provision of training

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN 16736:2015) has been prepared by Technical Committee CEN/TC 416 “Project Committee - Health risk assessment of chemicals”, the secretariat of which is held by ASI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2016, and conflicting national standards shall be withdrawn at the latest by April 2016.

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Introduction

Health risk assessment of chemicals is essential to prevent harmful effects of chemicals to humans. Currently risk assessment is required by different European regulations (e.g. REACH, biocidal products regulation, plant protection products regulation). To ensure consistent and high-quality assessments, it is essential to provide risk assessors with adequate education and training.

The course programme specified by this document is intended for institutions that offer or intend to offer training to individuals who would like to pursue a career in human health risk assessment and work within European agencies, scientific panels and corresponding organisations within Member States, industry, consultancy or academia.

Training programs exist within different European Organisations and Universities, but currently there are no agreed European Standards on the training of chemical health risk assessors. The requirements for the provision of training in the field of human health risk assessment of chemicals described below draw on the experiences gained from many training initiatives throughout Europe, for example training qualifying for European Registered Toxicologist ERT [1], the EU-funded-projects Risk Assessment Advanced Training Programme (RAAP) [2], European Toxicology Risk Assessment Training (TRISK) [3] and Risk Assessment and Management – European Training Programme (Risk Assets) [4].

1 Scope

This European Standard specifies the minimum requirements for a course programme to train risk assessors to be competent to assess the health risks posed by chemicals.

This European Standard does not comprehensively cover requirements for qualifications for workplace risk assessment according to Directive 98/24/EC.

Training of risk assessors consists of both course programs and on-the-job, practical experience. Only the course-based programme is covered in the current standard.

This European Standard sets out the requirements, which may be delivered as a complete course programme or as a series of individual courses.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
applied training
part of the course programme containing different kinds of practical exercises in which the student actively applies the knowledge acquired in the courses

EXAMPLE assignments and home-exercises, group discussions, and case studies or examples of concrete risk-assessments.

2.2
course programme
taught courses as well as applied training leading to a formal assessment

2.3
taught courses
formal lecture to give information about or instruction in a subject or skill

2.4
training
development and improvement of a skill through instruction or practice

2.5
training programme
planned series of steps to develop and improve a skill through instruction or practice

3 Objectives of the course programme

3.1 General

Health risk assessment of chemicals consists of three steps: hazard assessment, exposure assessment, and risk characterization which can be provided by one or more persons with complementary skills. Health risk assessment is the first step in the risk analysis process which also includes risk management and risk communication.

3.2 Required knowledge and skills

3.2.1 General

The course programme shall cover the knowledge and skills described below. The domains reflect the intended learning outcomes, not necessarily the structure of the course. A risk assessor shall appreciate the complexities and inter-disciplinary nature of health risk assessment and the need to consult and integrate other expertise in the process when required.

3.2.2 General health risk assessment principles

The course programme shall ensure that a future risk assessor

1) knows and understands:

   a) health risk assessment principles, terminology and methodology, including the following steps: hazard assessment, exposure assessment and risk characterization;

   b) the basic principles of statistics of relevance to health risk assessment;

   c) the application of health risk assessment in EU regulatory and public health contexts, including how these regulations differ for specific groups of products;

   d) the principal physico-chemical properties of chemicals of relevance to health risk assessment;

   e) the principles of deriving a health-based guidance and guideline values, as well as standards, and the use of such values;

   f) principal sources of data and information;

   g) uncertainty in health risk assessment and methods of characterizing and reducing uncertainty;

   h) the overarching principles of strategies used in health risk assessment when considering aggregate and cumulative risks;

   i) test methods in toxicology including computational toxicology, *in vitro* and *in vivo* testing methods, and national and international guidelines for testing of chemicals;

   j) factors that influence the susceptibility of different population sub-groups and how health risk assessment approaches differ for population sub-groups;

   k) priority setting and tiered approaches in health risk assessment.

2) is able to:

   a) define the scope, boundaries and purpose of a health risk assessment to address the practical needs of decision making;

   b) conduct comprehensive literature searches and query relevant databases to identify and obtain relevant information for use in a health risk assessment;

   c) critically appraise and evaluate the quality of data for use in health risk assessment applying, where applicable, approaches such as weight of evidence, grouping of substances and read-across;

d) critically evaluate a health risk assessment, identify its limitations and assess the adequacy of its conclusions in a regulatory or public health context;

e) contribute to a documented health risk assessment, clearly setting out and demonstrating a good understanding of health risk assessment methodology and principles, including hazard identification and characterization, exposure assessment and risk characterization.

3.2.3 Toxicology

The course programme shall ensure that a future risk assessor

1) knows and understands:

a) the principles of toxicology in order to be able to communicate effectively with specialists in toxicology;

b) how chemical substances reach the human body and what is their fate in the body, including the major kinetic determinants and the major pathways of metabolism;

c) the relationship between external dose and internal dose at target site;

d) different types of toxicity (e.g. local/systemic, acute/chronic, single/repeat dose);

e) different end points and biomarkers of toxicity (e.g. reversible/irreversible effects, mutagenicity, carcinogenicity);

f) factors influencing toxicity, including chemical properties, biological systems, routes and patterns of exposure, individual susceptibility and interaction with other chemicals;

g) dose-response relationships;

h) concepts of threshold and non-threshold effects and the differences in health based guidance values for each and their derivation;

i) point of departure (such as benchmark dose or no observed adverse effect level) and how to identify suitable toxicity end points on which the point of departure is based;

j) the principles of dose extrapolation, of route-route extrapolation, and the application of assessment/uncertainty factors to account for intra- and inter-species variability, including sensitive groups as well as uncertainties in the derivation of health based guidance values;

k) different types of health based guidance values and how regulatory and health-based guideline levels/standards are derived from health-based guidance values;

l) major toxicological databases and other information sources of relevance to health risk assessment, and how to use these informations, and how to assess their reliability;

m) the toxicity of mixtures, and that substances may interact in a way that affects their overall level of toxicity, and be aware of methods of assessing the health risk of mixtures;

n) the strengths and limitations of toxicological approaches and different test methods for assessing health risks;

o) how sensitive groups of the population and stages of development may increase susceptibility of exposure.