BS EN 16736:2015

BSI Standards Publication

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

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN 16736:2015.

The UK participation in its preparation was entrusted to Technical Committee HCM/1, Health risk assessment of chemicals.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2015

ISBN 978 0 580 85758 4

ICS 03.100.30; 71.100.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 October 2015.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 16736

October 2015

ICS 03.100.30; 71.100.01

English Version

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

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

Bewertung von Gesundheitsrisiken durch Chemikalien - Anforderungen an die Ausbildung

This European Standard was approved by CEN on 29 August 2015.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 16736:2015 E

Contents

Page

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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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.

2) is able to:

   a) identify and characterize the inherent hazardous effects of a chemical substance using available toxicological data sources;

   b) critically evaluate the quality of and interpret toxicity studies and reports;

   c) evaluate the derivation of health based guidance values.

3.2.4 Epidemiology

The course programme shall ensure that a future risk assessor

1) knows and understands:

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

   b) the role of epidemiology in regulatory and public health risk assessment;

   c) measures of health and disease and the main measures of association;

   d) the basic principles, structure of, and advantages and disadvantages of the different epidemiological study designs and issues concerning data quality, exposure misclassification, confounding, bias, power/chance;

   e) the principles of systematic review, meta- and pooled analyses;

   f) the relevance of disease clusters, small area statistics and disease burden calculations and their use in health risk assessment.

2) is able to:

   a) read and interpret an epidemiological study with understanding and critically evaluate its quality with a view to contributing to the health risk assessment process;

   b) apply epidemiological data in identifying and characterizing health outcomes and exposure response relationships for health risk assessment.

3.2.5 Exposure assessment

The course programme shall ensure that a future risk assessor

1) knows and understands:

   a) the principal physico-chemical properties of chemical substances and how they influence the chemical fate and behaviour pathways of chemicals in indoor and outdoor environments;

   b) the principal sources, pathways and routes of exposure and their relative significance in different exposure settings, and different types and patterns of exposure;

   c) sampling principles, strategies and techniques including analytical chemistry and biomarkers for sampling biological and environmental materials and their suitability when considering different health risks and the implication this has for risk assessment;

d) suitability of sampling when considering different health risks and its implication for risk assessment;

e) the principal information sources of relevance to human exposure assessment, including regulatory guidance;

f) exposure assessment strategies for different regulations and purposes;

g) major analytical methods and their suitability for different analyses, including the limitations of analytical techniques, particularly in determining low levels of a substance and the implications this has for exposure and health risk assessment;

h) established methods of exposure assessment and novel means of assessing these;

i) the unique exposure characteristics of sensitive groups of the population and the implications for exposure assessment;

j) the importance of exposure factors and time activity patterns in assessing human exposure;

k) principles of exposure models used for estimating human exposure to chemicals in order to ensure that the models used are fit for purpose;

l) the fundamental principles of deterministic and probabilistic exposure modelling, and how to critically assess and interpret the outputs of these exposure models for health risk assessment;

m) the limitations of calculation models and monitoring data (including uncertainty and variability), including means of characterizing and expressing uncertainty in exposure assessment;

n) the application of tiered approaches in assessing exposure.

2) is able to:

a) critically evaluate the quality of exposure assessment data and assess its relevance for health risk assessment;

b) critically evaluate the suitability and applicability of use of different exposure estimation techniques and models in exposure assessment, and assess how they relate to actual exposure and the quality of data produced;

c) contribute to the discussion on the development of exposure scenarios in public health and regulatory contexts.

3.2.6 Risk characterization

The course programme shall ensure that a future risk assessor

1) knows and understands:

a) how to combine different information types (e.g. epidemiological, toxicological and exposure data) in characterizing risk;

b) the factors that can influence risk characterization (e.g. extrapolation, uncertainties and data gaps);

c) techniques for handling uncertainty in health risk assessment, including sensitivity analysis, and the impact this has on overall risk characterization;

d) the role of 'expert judgement' in health risk assessment and the strengths and limitations of this weight of evidence approach;

e) the need for and the importance of transparency in reporting assumptions, handling of uncertainties, etc., in risk characterization;

f) the significance of exceedances of health criteria values in public health and consumer protection practice and the variables considered when assessing risk to human health.

2) is able to:

a) evaluate and integrate toxicological, epidemiological and exposure information, taking into consideration their limitations, to reach a balanced and objective conclusion;

b) characterize the risk of a hazard to human health taking into account all available sources of information and reach an objective conclusion based on scientific evidence as to the risk posed by a health hazard;

c) clearly articulate risks including uncertainties to different target audiences.

3.2.7 Ethics and quality control

The course programme shall ensure that a future risk assessor

1) knows and understands:

a) relevant ethical considerations, including acceptability of risk and research ethics (e.g. animal testing and human volunteer studies);

b) the overarching principles of data protection, data confidentiality issues and conflicts of interest;

c) the principles of Good Laboratory Practice and its relevance in the assessment of data quality for health risk assessment;

d) the potential regulatory, legal and/or public health importance of a health risk assessment.

2) is able to:

a) appreciate the complexities and inter-disciplinary nature of health risk assessment and the need to consult peers and individual experts;

b) act in a professional, unbiased, open and transparent manner throughout the health risk assessment process, focusing primarily on health considerations.

3.2.8 Implications for risk management and risk communication

The course programme shall ensure that a future risk assessor

1) knows and understands:

a) the principles of risk management and risk management frameworks;

b) the range of risk management controls (for example engineering, legislation, social controls) that can be applied when managing risks;

c) the range of contexts and conditions that influence risk management decisions and the role of health risk assessment in the decision making process;

d) the precautionary principle and its relevance in risk management;

e) approaches to transform risk assessments into practical safety measures and risk management;

f) the principles of risk communication and their application in health risk assessment;

g) the principles of risk perception and factors of importance influencing perceptions of risk in different settings;

h) approaches to communicating risks to different audiences and how an understanding of risk perception impacts the principles and practice of effective risk communication;

i) the importance of communicating uncertainty in health risk assessments.

2) is able to clearly and effectively communicate risks and risk assessments, including uncertainties, to professionals both in written and verbal contexts.

4 Course programme

4.1 Teaching level for the course programme

Training shall be provided for candidates with pre-existing qualification of at least Bachelor level or equivalent in a science relevant to risk assessment and either:

a) training equivalent to 60 ECTS[1] (if not included in the Bachelor degree) and thereof at least 30 ECTS from training equivalent in a relevant science field such as for example toxicology or exposure assessment, or

b) at least one year professional or research experience in toxicology or other human health risk assessment related areas (industry, national governments, consultancy companies, associations, academia etc.).

The provider of the course shall establish transparent rules for admitting participants and consider transfer of credits from previous postgraduate education.

4.2 Requirements for the course programme

The course programme may be taught as one or more courses. The course programme shall consist of a minimum of 24 ECTS in taught courses and 24 ECTS in applied training.

The course programme, including course lectures, applied training and examinations, shall be organized by an institution with expertise in health risk assessment training. Teachers shall be experts with experience on the subject of their course. The training may either be incorporated in an educational programme (for example a master's programme) or be given as continuing professional education.

[1] ECTS = European Credit Transfer System. ECTS credit designates an amount of work load. Typically, one year corresponds to 60 ECTS-credits. A 3-year Bachelor program has therefore usually 180 ECTS-credits; a 2-year Master program usually 120 ECTS-credits.

4.3 Programme structure

The course programme should consist of different stand-alone modules of intensive, self-contained, advanced courses which should cover the different areas of risk assessment defined above. Teaching methods may include lectures, tutorials, demonstrations, discussion panels, e-Learning sessions, or applied training sessions e.g. case studies, e-learning, home assignments and individual applied projects under supervision.

The course programme shall include modules which cover the required skills and knowledge as specified in Clause 3.

4.4 Applied training programme

The objective of the applied training programme is to ensure that the knowledge provided in the lectures can be put into practice. This may be done e.g. in assignments, discussion panels, different steps in the complete health risk assessment process or oral and written examinations.

4.5 Examination

At the end of each module an exam may be conducted and at the end of the course programme an exam shall be conducted. The objective of the examination is to assess the participants' broader and deeper knowledge and skills to independently apply the knowledge presented in the taught courses and be able to perform a full risk assessment integrating the different elements of the risk-assessment-process.

The examination may consist of different parts: e.g. home examinations / assignments, written and oral presentation and defence of a risk assessment performed in the applied training or a portfolio demonstrating the acquired knowledge and skills. The examination may be included in the applied training programme. Also alternative ways of examinations are possible, as long as the knowledge and skills in Clause 3 are covered.

Bibliography

[1] FOWLER. J. and GALLI, C. EUROTOX's view regarding the ROLE and TRAINING of certified European registered toxicologists (ERT). *Toxicology Letters.* 2007, **168**(3), 192-199. ISSN 0378-4274

[2] PROGRAMME R.A.A.T. (RAAP). Guidelines. Final Draft revised April 24, 2009. Available from: http://ec.europa.eu/health/archive/ph_risk/documents/cons_guidelines_en.pdf

[3] European Toxicology Risk Assessment Training (TRISK). [viewed 10 February 2014]. Available from: http://www.eurotox.com/trisk/

[4] Risk Assessment and Management – European Training Programme (Risk Assets). [viewed 10 February 2014]. Available from: http://webarchive.nationalarchives.gov.uk/20140714084352/http://www.hpa.org.uk/ProductsServices/ChemicalsPoisons/ChemicalInternationalResearchActivities/RISKAssets/

[5] Central Science Laboratory DEFRA [Sand Hutton]. Preparation of an Inventory of Formal (Graduate and Post Graduate) and "On-the-Job" Risk Assessment Training Schemes of Relevance to the Work of the Non-Food Scientific Committees Established by Commission Decision 2004/210/EC [online]. Final Report, October 2007. Available from: http://ec.europa.eu/health/dyna/training/training_en.cfm

This page deliberately left blank

This page deliberately left blank

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™