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WORKSHOP

AGREEMENT

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Biosafety professional competence

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

The main activity of a CEN Workshop is the development and publication of the CEN Workshop Agreement (CWA). The CWA is a voluntary agreement applicable internationally and does not have the force of regulation. The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation. This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop commenced in December 2009 with a combined kick-off and first plenary meeting. It had its third and final plenary meeting in May 2011. There was also a public comment phase. More information on CEN and the CEN Workshops can be found at: www.cen.eu

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties on 2011-06-30, the constitution of which was supported by CEN following the public call for participation made on 2009-12-17.

NEN, the Netherlands Standardization Institute, provided the secretariat of the Workshop.

A list of the individuals and organizations which supported the technical consensus represented by the CEN Workshop Agreement is available to purchasers from the CEN Management Centre. These organizations were drawn from the following economic sectors: American Biological Safety Association (ABSA), Basler & Hofmann AG, CH, Bayer CropScience, BE, Belgian Biosafety Professionals (BBP), BE, BioSafety Solutions (LLC), US, Biosafety training & consultancy (BT&C), NL, Bundesforschungsinstitut für Tiergesundheit (FLI), DE, Centro Nacional de Biotecnología (CSIC), ES, Centro de Investigación en Sanidad Animal, ES, Chinese Center for Disease Control and Prevention, CN, Det Norske Veritas (DNV), NO, Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, DE, European Biosafety Association (EBSA), Federal Ministry for Health and Women, AT, Federal Office of Public Health, CH, GlaxoSmithKline, ES, Hannover Medical School, DE, Health Protection Agency, GB, Instituto de Diagnóstico y Referencia Epidemiológicos (InDRE), MX, Instituto Valenciano de Investigaciones Agrarias (IVIA), ES, Institute of Reference Materials and Measurement, BE, Institute of Infectious Diseases Japan, JP, Institute of Safety in Technology and Research, GB, International Federation of Biosafety Associations (IFBA), Karolinska Institutet, SE, Leids Universitair Medisch Centrum (LUMC), NL, Medical Research Council, GB, Mexican Biosafety Association, MX, National Institute for Occupational Safety and Health at Work, ES, Public Health Agency of Canada, CA, Sandia National Laboratories, US, Sanofi-Aventis, FR, Statens Serum Institute, DK, Swedish Institute for Infections, SE, Swiss Federal Office for the Environment, Office of waste, water, energy and air Kanton Zürich, CH, Telstar Projects (Tpro), ES, University of Edinburgh, GB.

The formal process followed by the Workshop in the development of the CEN Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of the CEN Workshop Agreement or possible conflict with standards or legislation. This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its members.

The final review/endorsement round for this CWA was started on 2011-05-11 and was successfully closed on 2011-06-30.The final text of this CWA was submitted to CEN for publication on 2011-07-26.

This CEN Workshop Agreement is publicly available as a reference document from the CEN National Members of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN-CENELEC Management Centre.

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European Commission - Directorate-General Home Affairs"

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Introduction

This CEN Workshop Agreement (CWA) addresses the broad range of competences and abilities required by individuals who advise management and personnel on the safe and secure use of biological material and who manage and support the development and implementation of relevant management programmes or systems. It takes into account the roles that these individuals play in the workplace and the tasks that they are required to perform. While this document is primarily intended for biosafety professionals, it will also be of interest for employers (managers) and trainers.

As stated by WHO (WHO/CDS/CSR/LYO/2004.11, 2004), “effective biosafety practices are the very foundation of laboratory biosecurity activities”, hence biosafety and biosecurity cannot be dissociated. The application of biosafety and laboratory biosecurity management, also called biorisk management (CWA 15793:2008), is the working area of the biosafety professional.

The job titles of persons with relevant biosafety and biosecurity responsibilities show significant variation from organization to organization. Moreover, within a given organization there may be more than one person assigned relevant responsibilities which, especially in larger and/or more complex organizations may vary according to their specific roles. In many organizations, the roles will include responsibilities for both biosafety and biosecurity. Irrespective of this variability there are common elements of competence and this document lists the requirements to ensure that such individuals, however their job is titled, have appropriate attributes that can be recognized at all levels, within an organization and across regional or national borders.

This CWA was developed in response to identified needs across the international community informed by the experience of practitioners through professional organizations and WHO.

While this CWA is not intended to provide guidance on certification or accreditation of courses or programmes, it is written and structured in such a way that it could provide a means to facilitate future initiatives of this type. In this context it may be useful in the development of new programmes as well as courses integrated into existing certified trainings.

Application

This document is intended to provide a framework for those who work in the biosafety and biosecurity fields to evaluate their competence as a professional and to identify areas for development. In the context of this document biosecurity is restricted to laboratory biosecurity.

The requirements of this CWA are intended to be applicable to all organizations, regardless of type or size of the facility and biological materials used, where the management has identified the need to appoint a biosafety professional. In general, a biosafety professional is appointed where the risk posed by the work with biological materials requires biosafety and biosecurity measures.

This document does not in itself impose any obligation upon anyone to follow it. However, such an obligation may be imposed, for example, by legislation or by a contract. In order to be able to claim compliance with this document, the user needs to be able to identify the requirements he/she is obliged to satisfy. The user also needs to be able to distinguish these requirements from other provisions where there is a certain freedom of choice.

This document is structured in a manner where the specific requirements pertaining to each individual clause are defined and stated in regular text. A requirement is indicated by use of the verbal form "shall". Informative guidance has been provided as an aid in interpreting the requirements where considered appropriate. This guidance is in the form of notes, in association with the pertaining requirements clause and uses the terms “should” (recommendation), “may” (allowance) and “can” (possibility). Contents of the notes shall not in any way be construed as being requirements; the same is valid for the text in the informative Annexes.

The main activity of a CEN Workshop is the development and publication of the CEN Workshop Agreement (CWA). The CWA is a framework applicable internationally. It does not have the force of regulation.

Where any requirements of this document are not applicable, these can be considered for exclusion. Where exclusions are made, claims of conformity to this CWA are not acceptable, unless such exclusions do not affect the biosafety professional's ability to perform in the manner required by the CWA. Any claims of exclusion shall be explained and documented.

Compliance with national and local regulatory standards and regulations is a requirement for any organization. International, national or regional regulations or directives may address specific topics covered in this CWA. Where any part of this document is in conflict with any legal requirement, the conflicting part of the document may be eligible for exemption. If the legal requirements neither meet nor exceed the intent of the CWA, compliance with the CWA cannot be claimed.

1 Scope

This CEN Workshop Agreement (CWA) describes competence areas of a biosafety professional. International, national or regional regulations or directives take precedence over this CWA.

This CWA provides in informative annexes a model role profile and model tasks of a biosafety professional in an organization; these help to define competence requirements. It also provides model training specifications for reaching competence.

2 Informative references

Three central guidance documents for biosafety professional competence and the development of this CWA are:

— CWA 15793:2008 Laboratory biorisk management standard;

— WHO Laboratory Biosafety Manual (WHO/CDS/CSR/LYO/2004.11, 2004);

— WHO Biorisk Management: Laboratory Biosecurity Guidance (WHO/CDS/EPR/2006.6, Sept. 2006).

3 Terms and definitions

For the purposes of this document, the terms and definitions given in CWA 15793:2008 apply except where they have been adapted and are defined below.

3.1
biological agent
naturally occurring or genetically modified organism, capable of replication or transferring genetic material and potentially able to provoke infection, allergy or toxicity in humans, animals or plants. This includes bacteria, fungi, viruses, viroids, prions, endoparasites, human, animal and plant cell cultures

3.2
biological material
any material which includes:

— biological agents;

— any substance that may contain biological agents;

— any substance produced by or derived from a biological agent that may present a hazard to health (for example toxins, allergens) or the environment;

— animals and plants or parts thereof that may contain biological agents;

— animals and plants or parts thereof that are genetically modified;

— animals and plants or parts thereof that may provoke infection, allergy or toxicity in humans, animals or plants.

3.3
biorisk management
management of risks arising from adverse events, including accidental release, unintentional exposure, loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release