Position paper of the Committee for Biological Agents (ABAS) concerning CWA 16335:2011 “Biosafety professional competence”

(formerly CEN Workshop 53)

I. Summary

A current demand exists to establish requirements for competency and technical qualification/s in particular within the scope of the BioStoffV. It would be desirable to achieve this during revision of the Biological Agents Ordinance (BioStoffV) or in a subordinate Technical Rule for Biological Agents (TRBA).

The contents of CWA 16335 could deliver some input for this purpose. CWA 16335 aims at specifying the professional competence and therefore also the training required for “biosafety professionals”. The European directives in this area and national regulations such as the German Biological Agents Ordinance do not currently contain any detailed requirements concerning technical qualifications.

However, CWA 16335 specifies an extensive set of responsibilities and tasks focussed on one person. German law does not provide for such a concentration of tasks. It is also questionable whether this concentration is in fact reasonable, as it must be doubted that one single person possesses the expertise to cover such a broad catalogue of tasks. The fact that many of the tasks assigned to the biosafety professional (BSP) are related to health and safety at work may lead to overlaps with existing regulations in this area. Addressing health and safety aspects in CEN Workshop Agreements is therefore not generally useful.

CWA 16335 may be useful in countries in which corresponding legal provisions do not yet exist. The CWA 16335 is not necessary in Germany because a large number of rules and regulations already exist.

II. General characteristics of CEN Workshop Agreements

A CEN Workshop Agreement (CWA) is a CEN document which is developed in a CEN Workshop by a group of interested people within a relatively short space of time. The usual rules of standardisation (e.g. mirror committees and involvement of all stakeholders) do not apply for CWAs. Being fast to produce, these documents were originally intended as a response to the rapid changes in fast-moving sectors such as information and communication technology. In principle, anyone is invited to participate in the development of a CWA. The draft CWA is however only made available to registered and paying workshop participants. The chairman decides when consensus has been reached among the registered participants on the working draft. A

public comment phase is only obligatory where projects receive public funding (which was the case for CWA 16335).

The current version of the CEN Guidance paper on the development of CWAs[1] points out that CWAs are not suitable for addressing significant health and safety issues. However, a procedure to prevent this does not exist. Compared with standards, the overall transparency of the processes is reduced considerably owing to less clear rules and restricted public access.

III. CWA 16335: Background and contents

The initiative for CWA 16335 was led by the EBSA[2] after a need had been recognised at international level to define the competences of a "Biosafety Professional". What is striking in this European (CEN) Workshop is the large number of non-European participants.

The term "Biosafety Professional" (BSP) is used throughout the document; however, in the definitions other terms are referred to, e.g. "biosafety officer", "biosafety advisor", "biosafety manager", "biosafety coordinator" or "biorisk management advisor"[3].

Besides competences in "biosafety" the BSP definition furthermore includes competences in „biosecurity". "Biosafety" – a term from the area of occupational safety and health – focuses on the protection of people and the environment, whereas "biosecurity" aims at securing biological material and information against misuse and criminal acts[4]. Both terms are defined accordingly in the CWA, which means that the title "Biosafety Professional" in the CWA is incompatible with this person's tasks and therefore contradictory. There is no problem with the content of the task description however, since biosafety measures frequently include biosecurity aspects. What is however missing in CWA 16335 is a distinction between **bio**security aspects and normal security measures not specifically targeted on biological hazards.

The target group addressed by the document includes all organisations, regardless of type or size, where the management has identified the need to appoint a BSP. To support the management with this identification, it is explained that a BSP should be appointed when the risk posed by the work with biological materials requires biosafety and biosecurity measures. The document gives no indication however, how the risk assessment should be performed.

The main point of the document is the task description of the BSP within an organisation. Two core competences are defined: firstly, the BSP should advise and guide the management and personnel on biosafety and biosecurity issues, and secondly the BSP should support the design and implementation of efficient biosafety and biosecurity management programmes. To fulfil these two tasks, the BSP must have relevant training and qualifications concerning the safe and secure handling of biological material. In addition, s/he should have relevant experience working at (or overseeing) facilities using biological materials at the highest biosafety containment level established at the workplace.

The definition of the competences which are required is based on a distinction between "core competences", which all BSPs should fulfil, and "specialized competences", which are required for work in more complex and/or higher risk environments.

The core competences are listed in 25 sub-clauses and range from general principles of microbiology to audits and bioethics. Very general examples are given of work environments, e.g.

[1] Guidance - Characteristics of the CEN/CENELEC Workshop Agreement and CEN/CENELEC Workshop guidelines, Version 2 (2009); ftp://ftp.cen.eu/BOSS/Various/Others/Draft_GD_CWA.pdf
[2] EBSA= European Biosafety Association
[3] "biorisk management advisor" is the term used in CWA 15793:2008 'Laboratory biorisk management', which is cited as a central guidance document in the informative references of this CWA
[4] See also the position paper of ABAS UA1 on Biosecurity

“activities with plants”, “activities with animals” or “gene therapy”, without any further definition. Similarly, general examples of work environments are given for the “specialized competences”.

The required knowledge for both areas of competence can be acquired by different means (training and/or relevant practical experience). For *training*, model training specifications are listed in the informative Annex C. Again, this annex includes areas that are not directly related to the tasks of a BSP (e.g. ergonomics and “National biothreat response”). This model curriculum could be used as a basis for certification. The introduction to the document states that the CWA is not primarily intended for certification purposes, but it is structured in such a way that it could serve as a basis for future certification. Demonstration of *knowledge and competence* can also be achieved by different means. Examples given in the CWA include: an evidence portfolio of all relevant areas (portfolio from Great Britain in the informative Annex D), a dossier of practical examples or completion of a risk assessment case.

Further informative annexes deal with model role profiles and tasks of a BSP in an organisation. The latter cover a very broad range of topics, including for example ergonomics, waste management and transport.

IV. European and national legislative context

a) Existing European and national statutory regulations

Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work does not contain any requirements concerning the professional competences of individual people, nor any provision requiring particular knowledge for specific tasks. It only contains a requirement to include information on the name and capabilities of the person responsible *for safety and health at work* in the notification to the competent authority (art. 13, paragraph 4, point b).

The German **Biological Agents Ordinance (BioStoffV)** is based on that directive and has therefore contained only general requirements concerning expert knowledge. These are related to

- Execution of risk assessment (Section 8)
- The assignment and performance of activities involving biological agents of risk group 3 or 4 (Section 10 para. 5).

The notification provided for in Section 13 para. 1 must include information on the qualification of the persons responsible for safety and health at work, too.

In **Directive 2009/41/EC** on the contained use of genetically modified micro-organisms, one of the minimum requirements for protective measures is that appropriate training of personnel be provided (Annex IV, para.1, point v). Information on the *training and qualifications of the persons responsible for supervision and safety* must be included in the notification to the competent authorities provided for in Articles 6, 8 and 9 of the directive.

According to the German **Genetic Engineering Act (GenTG)**, the appointment of a project manager and a biosafety officer by the operator is a basic prerequisite for the performance of genetic engineering operations (Section 6, para. 4). The fact that the project manager and the biosafety officer shall possess the specialized expert knowledge requisite for their functions is explicitly stated as an authorisation requirement for the construction and operation of genetic engineering installations where activities at safety levels 3 or 4 are to be performed (Section 8 in conjunction with Section 11).

According to the German **Genetic Engineering Safety Ordinance (GenTSV)** (Section 14), comprehensive responsibilities are assigned to the project manager which go beyond actual biosafety aspects and include the protection of all legal interests according to Section 1, para.1 of the GenTG. The biosafety officer (Section 18) is to supervise the project manager with regard to the fulfilment of safety-relevant tasks. The same requirements concerning specialized expert knowledge apply to project managers and biosafety officers (Section 15 in conjunction with Section 17). The specialized expert knowledge must be demonstrated by a university degree in a natural science, medicine or veterinary medicine and at least three years’ work experience in the area of genetic engineering, particularly in microbiology, cytology, virology or molecular biology, and a certificate of attendance of an advanced training course recognised by the competent regional authority.

For genetic engineering activities in production areas, the required specialized expert knowledge may also be demonstrated by a university or university of applied sciences degree in engineering, at least three years’ work experience in the area of biological process engineering and the advanced training course mentioned above.

Specifications exist for the content of the advanced training courses. Subjects covered must include the hazard potential of organisms with particular consideration given to microbiology, safety measures for genetic engineering laboratories/genetic engineering production areas, and statutory provisions governing safety measures for genetic engineering laboratories/production areas and occupational safety and health. The GenTSV makes no clear statement on whether the advanced training course must be attended once or repeatedly. In practice, the course is attended only once.

The German **Infectious Diseases Control Law (IfSG)** calls for a personal authorisation (Section 44) for any person intending to export, store, release or work with pathogens. This authorisation (Section 47) requires a university degree in human, dental or veterinary medicine or pharmacy, or a university or university of applied sciences degree in a natural science including microbiological contents and at least two years’ full-time work with pathogens under the supervision of a person authorised to work with pathogens. Limited authorisations may be granted to persons with a university or university of applied sciences degree in a natural science without microbiological contents or a university or university of applied sciences degree in engineering with microbiological contents. The authorisation requirement is lifted for certain medical areas, e.g. for certain types diagnostics or for sterility testing (Section 45). It does also not apply to persons working under the supervision of a person holding an authorisation (Section 46).

b) Comparison of the statutory regulations with the content of CWA 16335

The Biological Substances Ordinance does not currently contain any requirements concerning professional competences.

With the functions of biosafety officer and project manager, genetic engineering legislation stipulates a wide range of duties and responsibilities focusing on biosafety. It also touches marginally on the area of biosecurity. The specialized expert knowledge requirements set out in the GenTSV cover the entire spectrum, but are not formulated in detail. Attendance of advanced training courses at regular intervals or practical exercises are not a requirement. *Note: The training contents and their time frame have been specified by the Bund-/Länderarbeitsgemeinschaft Gentechnik (LAG) and constitute the criteria for recognition of the course.*

The IfSG aims at preventing contagious diseases in human beings, recognizing infections at an early stage and preventing their propagation. This means that the act itself focuses on biosecurity issues, whereas it touches only marginally on biosafety. No supporting rules and regulations setting out further details exist. The competence is based purely on the university degree and practical experience. Special advanced training is not required.

A current demand exists to establish requirements for competency and technical qualification/s in particular within the scope of the BioStoffV. Current plans are to achieve this during revision of the BioStoffV and in a subordinate Technical Rule for Biological Agents (TRBA). CWA 16335 could provide some input for this purpose. However, CWA 16335 specifies an extensive set of responsibilities and tasks focussed on one person. German law does not provide for such a concentration of tasks. It is also questionable whether this concentration is in fact reasonable, as it must be doubted that a single person possesses the expertise to cover such a broad catalogue of tasks.

V. Possible implications of CWA 16335

a) General

As a matter of principle, application of a document such as CWA 16335, which is developed by a random group of people, is voluntary. Nevertheless, the CWA constitutes an official paper by CEN, the European standards organisation, and can therefore easily be confused with a standard. A CWA can become binding in cases where regulations, legal acts or directives make reference to the CWA as constituting the “state of the art in Europe”, or where its contents are incorporated into revisions of such provisions, as was the case for example with the GMP guidelines for the manufacture of medicinal products[5], which also governs personnel and management aspects, or as is theoretically conceivable for the revision of the Biological Agents Ordinance (BioStoffV). An example of a reference to a (different) CWA in an official document can be found in the CBRN Action Plan of the European Union, which calls for application of CWA 15793:2008 “Laboratory Biorisk Management Standard” or comparable documents for certain organisations unless binding statutory provisions exist.[6]

b) Certification

As already mentioned, the document is structured in such a way that it could be used as a basis for future certification. As a result, it increases the significance of certification bodies and other commercial institutions. Running the required advanced training courses for BSPs and certifying and auditing CWA-compliant organisations opens up new business opportunities to these institutions and serves commercial interests. This might become a problem for small organisations in particular, as they possess neither the required structures nor the financial means for certification.

[5] GMP = Good Manufacturing Practice based on Directive 2003/94/EC:
http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

[6] Action B.4 of the Council conclusions on strengthening chemical, biological, radiological and nuclear (CBRN) security in the European Union – an EU CBRN Action Plan, 15505/1/09 REV 1 of 12 November 2009.