Laboratory Biorisk Management Standard
CWA 15793:2008

Towards laboratory biorisk certification in Germany?

Medizinische Hochschule
Hannover

Juergen Mertsching

Statement 1:

A quality management system for safety issues can only be implemented successfully if there is a clear advantage for the day-to-day laboratory business!

Statement 2:

"We are already over-regulated!"

"Bio-Regulations" in force in Germany:

- "Workers Protection Directive"
  (Biostoffverordnung)
- "Protection Against Infection Act"
  (Infektionsschutzgesetz)
- "Genetic Engineering Act"
  (Gentechnikgesetz)
- Safety at Work Act
  (Betriebssicherheitsgesetz)
- Statutory Regulation of Working Hours
  (Arbeitszeitgesetz)
- Medical Products and Drugs Act
  (Medizinproduktegesetz)
- …

Is it that simple?

Laws, ordinances, guidelines in Germany for working with biological materials

- **ArbSchG** - Gesetz über die Durchführung von Maßnahmen des Arbeitsschutzes zur Verbesserung der Sicherheit und des Gesundheitsschutzes der Beschäftigten bei der Arbeit (Arbeitsschutzgesetz) vom 07.08.1996
- **ArbMedVV** - Verordnung zur arbeitsmedizinischen Vorsorge vom18.12.2008
- **ASiG** - Gesetz über Betriebsärzte, Sicherheitsingenieure und andere Fachkräfte für Arbeitssicherheit vom 12.12.1973
- **AWG** – Außenwirtschaftsgesetz vom 28.04.1961
- **BioStoffV** - Verordnung über Sicherheit und Gesundheitsschutz bei Tätigkeiten mit biologischen Arbeitsstoffen (Biostoffverordnung) vom 27.01.1999
- **BetrSichV** - Verordnung über Sicherheit und Gesundheitsschutz bei der Bereitstellung von Arbeitsmitteln und deren Benutzung bei der Arbeit, über Sicherheit beim Betrieb überwachungsbedürftiger Anlagen und über die Organisation des betrieblichen Arbeitsschutzes (Betriebssicherheitsverordnung) vom 27.09.2002
- **GenTG** - Gesetz zur Regelung der Gentechnik (Gentechnikgesetz) vom 20.06.1990
- **GenTSV** - Verordnung über die Sicherheitsstufen und Sicherheitsmaßnahmen bei gentechnischen Arbeiten in gentechnischen Anlagen (Gentechnik-Sicherheitsverordnung) vom 24.10.1990
- **GenTAufzV** - Verordnung über Aufzeichnungen bei gentechnischen Arbeiten und bei Freisetzungen (Gentechnik-Aufzeichnungsverordnung) vom 24.10.1990
- **GenTNotfV** - Verordnung über die Erstellung von außerbetrieblichen Notfallplänen und über Informations-, Melde- und Unterrichtungspflichten (Gentechnik-Notfallverordnung) vom 10.12.1997

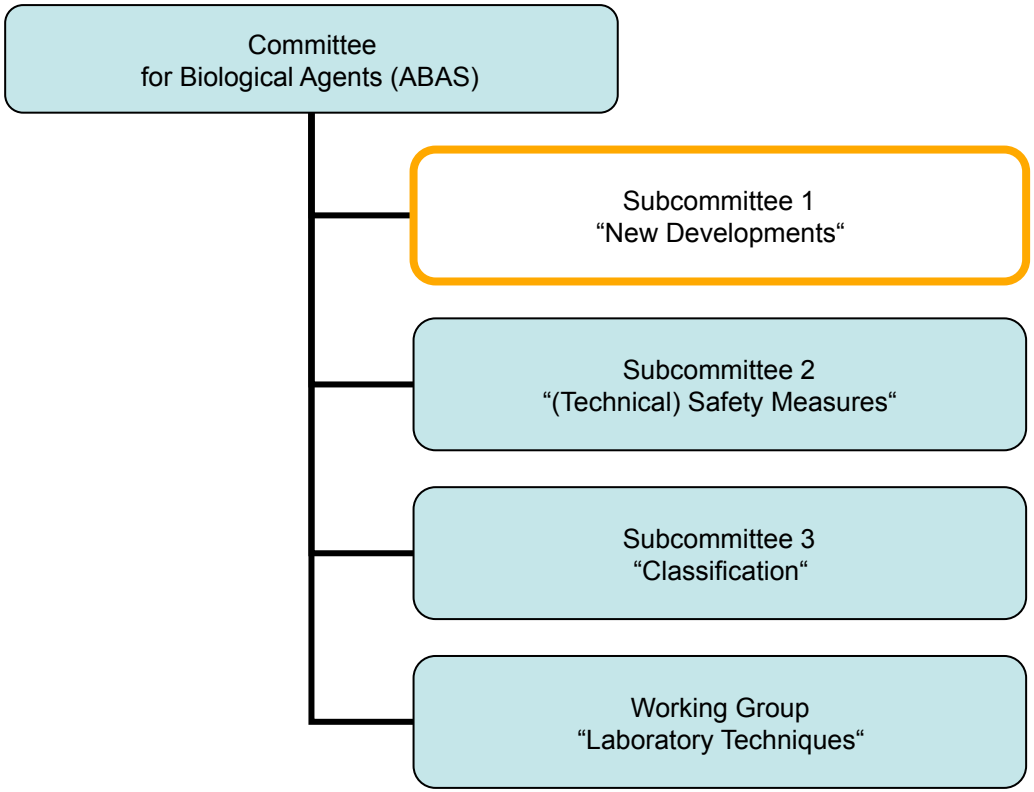
Laws, ordinances, guidelines in Germany for working with biological materials

- **IfSG** - Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen (Infektionsschutzgesetz) vom 20.07.2000
- **TierSchG** – Tierschutzgesetz vom Juli 1972
- **TierSeuchErV** - Verordnung über das Arbeiten mit Tierseuchenerregern (Tierseuchenerreger-Verordnung) vom 25.11.1985
- **TRBA 100** - Technische Regel für Biologische Arbeitsstoffe 100, Schutzmaßnahmen für gezielte und nicht gezielte Tätigkeiten mit biologischen Arbeitsstoffen in Laboratorien vom Dezember 2006
- **TRBA 250** - Technische Regel für Biologische Arbeitsstoffe 250, Biologische Arbeitsstoffe im Gesundheitswesen und in der Wohlfahrtspflege vom November 2003
- **TRBA 400** - Technische Regel für Biologische Arbeitsstoffe 400, Handlungsanleitung zur Gefährdungsbeurteilung und für die Unterrichtung der Beschäftigten bei Tätigkeiten mit biologischen Arbeitsstoffen vom April 2006
- **SÜG** - Gesetz über die Voraussetzungen und das Verfahren von Sicherheitsüberprüfungen des Bundes (Sicherheitsüberprüfungsgesetz) vom 20.04.1994
- **SÜFV** - Verordnung zur Feststellung der Behörden des Bundes mit Aufgaben von vergleichbarer Sicherheitsempfindlichkeit wie die der Nachrichtendienste des Bundes und zur Feststellung der öffentlichen Stellen des Bundes und der nichtöffentlichen Stellen mit lebens- oder verteidigungswichtigen Einrichtungen (Sicherheitsüberprüfungsfeststellungsverordnung) vom 30.07.2003

- **...**

How does CWA 15793:2008 fit in with the large number of German laws and guidelines?

Committee for Biological Agents (ABAS)



Comparison of CWA 15793 with German legal basis

	A	B	C	D	E	F	G
42	CWA 15793 Structure	CWA 15793 heading	CWA 15793 Requirements	Legal Basis Germany	Additional requirements according to TRBAen 100, 250, 400, 500 and other guidelines of workers protection	Comments	Yes / No
43	**4.4.2**	**Personnel training, awareness and competence**	The organization shall ensure that personnel that have responsibilities and/or perform tasks that may impact biorisk management in the workplace are competent to do so. Competence levels shall be judged on appropriate education, training and experience. The organization shall define required competency levels and shall maintain records verifying that staff members have attained and demonstrated those levels of competency.	ArbSchG § 9, 12 BioStoffV § 8, 12 GenTSV §§ 12, 15, 17 ASiG §§ 4, 7 IfSG § 47 TierSeuchErV § 4	TRBA 100 (Ziffern 5.1; 5.1; 5.1) BGV-A1 §4	Qualifikation FaSi, Betriebsarzt, BBS und Unterweisung der Beschäftigten (E.G.) BioStoffV fordert, dass Arbeitgeber ggf. fachkundige Personen zur Gefährdungsbeurteilung hinzuziehen muss. (R.J.)	
44	4.4.2.1	Recruitment	The organization shall ensure that qualifications, experience and aptitudes relating to biorisk are considered as part of the recruitment process.	BioStoffV §10 GenTSV § 12 SÜG §§ 1, 2 SÜFV §§ 8, 9, 11	TRBA 250 (Ziffer 4.1.2.1) BGV-A 1 §7	Der Arbeitgeber darf Tätigkeiten im Anwendungsbereich dieser TRBA nur Personen übertragen, die eine abgeschlossene Ausbildung in Berufen des Gesundheitswesens haben oder die von einer fachlich geeigneten Person unterwiesen sind und beaufsichtigt werden. (C.H.)	
45	4.4.2.2	Competence	The organization shall ensure that personnel conduct activities within the facility under close supervision until competency has been demonstrated.	ArbSchG § 7 BioStoffV § 10 GenTSV § 12, 14, 15, 17 IfSG § 47 TierSeuchErV §§ 3, 4	TRBA 250) (Ziffern 4.1.2.1; 4.1.2.2) BGV-A1 § 8, § 12	In der BiostoffV indirekt über Unterweisung gefordert, nicht durch Überwachung. (R.J.)	
46	4.4.2.3	Continuity and succession planning	The organization shall ensure that adequate back-up and contingency measures are in place to address the need for continuity and succession planning.	BioStoffV § 8 GenTSV § 8 TierSeuchErV §§ 5, 6	BGV-A1 § 2		
47	4.4.2.4	Training	The organization shall ensure that requirements and procedures for biorisk-related training of personnel are identified, established and maintained.	ArbSchG § 7, 12 BioStoffV § 12 GenTSV § 12, 15	TRBA 100 (Ziffern 5.1; 5.1; 5.1) TRBA 250 (Ziffern 5.1; 5.1.3; 5.2; 7.4.1; 7.4.2; 7.6) TRBA 400 (Ziffer 5) BGV-A1 § 31		
48	**4.4.3**	**Consultation and communication**	The organization shall ensure that relevant biorisk information relating to its activities is communicated to and from employees and other relevant parties. Employee involvement and consultation arrangements shall be documented. Personnel shall have access to adequate and up-to-date information pertaining to the biorisks of the organization.	ArbSchG § 3 (2); BioStoffV § 16 GentG § 18, 21, 28 GenTSV §§ 12, 14, 15, 17, 18 GenTNotfV § 4 TierSEV §§ 5, 6 IfSG §§ 49, 50	TRBA 250 (Ziffern 4.2.4; 5.1.2)		
	4.4.4	**Operational control**	The organization shall identify those operations and activities that are associated with possible biological risk and where control measures shall be applied. The organization shall plan these activities, including maintenance, and ensure that they are carried out under	BioStoffV §§ 5-8, 10-12 GenTG §§ 8-10, 12, 25 GenTSV § 18 ASiG §§ 3, 6	TRBA 250 (Ziffer 4.2.4) BGV-A1 §8	Aufgaben von FaSi, Betriebsarzt, BBS sowie Projektleiter. (E.G.)	

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Comparison of CWA 15793 with German legal basis Results:

1. In Germany most of the requirements of the CWA15793:2008 are covered by one or another law, ordinance, guideline, etc.

2. Points to be considered as a positive addition to German legal basis:
   - Biosecurity
   - Toxins
   - Biorisk adviser
   - Ongoing training

3. Points in conflict with German legal basis:
   - Certification of workers protection measures

Definitions

1. ISO 17000 defines **ACCREDITATION** as “third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks”

2. ISO 17000 defines **CERTIFICATION** as “third-party attestation related to products, processes, systems or persons assessment except for conformity assessment bodies themselves, to which accreditation is applicable”

Why is certification of workers protection measures in conflict with German legal requirements?

General Conditions in Germany: I. The European Community

C 115/116 EN Official Journal of the European Union 9.5.2008

Article 153
(ex Article 137 TEC)

1. With a view to achieving the objectives of Article 151, the Union shall support and complement the activities of the Member States in the following fields:

(a) improvement in particular of the working environment to protect workers' health and safety;

(b) working conditions;

(c) social security and social protection of workers;

(d) protection of workers where their employment contract is terminated;

(e) the information and consultation of workers;

...

[Treaty establishing the European Community, Title X: Social Policy – Article 153 (ex Article 137)]

General Conditions in Germany: I. The European Community

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4. The provisions adopted pursuant to this Article:

— shall not affect the right of Member States to define the fundamental principles of their social security systems and must not significantly affect the financial equilibrium thereof,

— shall not prevent any Member State from maintaining or introducing more stringent protective measures compatible with the Treaties.

[Treaty establishing the European Community, Title X: Social Policy – Article 153 (ex Article 137)]

CEN Resolution BT 22/1997
Standardization policy in the area covered by Article 137 of the EU Treaty

1. Article 137 of the EU Treaty provides for the development of Community measures to set minimum levels of protection for Health and Safety at work. This paper sets out the CEN policy in this area.

2. CEN acknowledges that on the basis of the EU Treaty the **improvement of Occupational Health and Safety lies primarily with the Member States**. In particular the right to set up limiting values for occupational exposure must be reserved for the political decision-making process.

…

11.

The “German Consensus Statement”

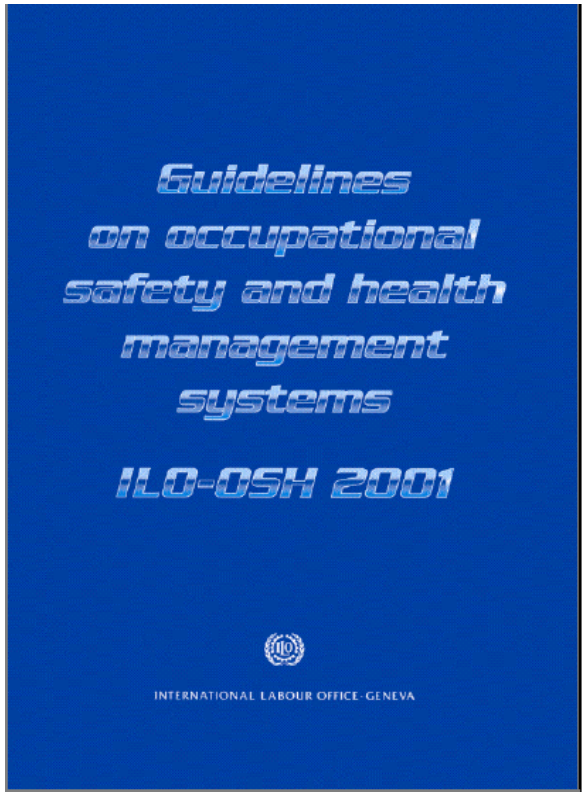
"German Consensus Statement concerning standardization within the scope of directives pursuant to Article153 of the Treaty on the Functioning of the European Union (TFEU)"

“Improvement of Occupational Health and Safety lies primarily with the EU Member States and shall not be subject to standardization.“

Adopted by all relevant parties

- Federal Ministry of Labour and Social Affairs
- Ministries of Labour and Social Affairs of the “Länder“
- German Social Accident Insurance (DGUV)
- Representatives of employer
- Representatives of worker (Trade Union)

General Conditions in Germany
II. Guidelines of the International Labour Organization



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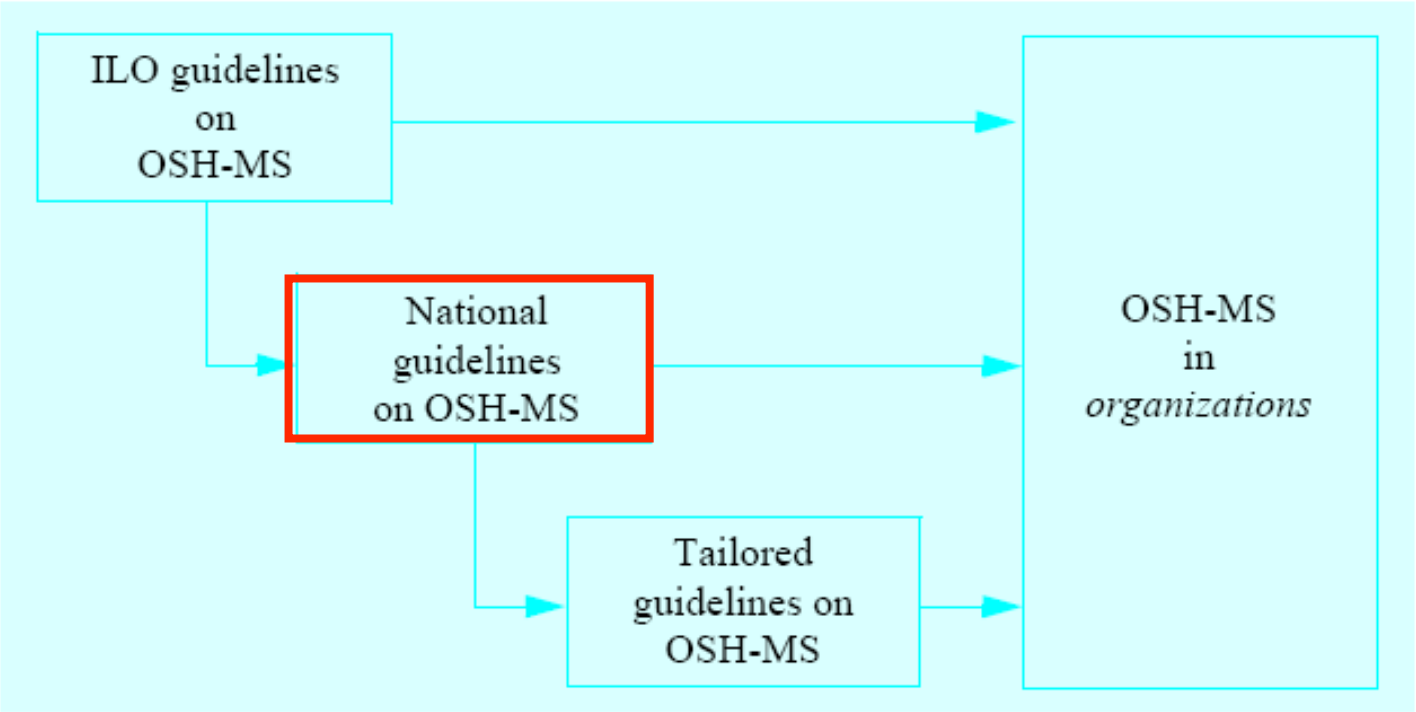
Guidelines on occupational safety and health management systems (ILO-OSH 2001)

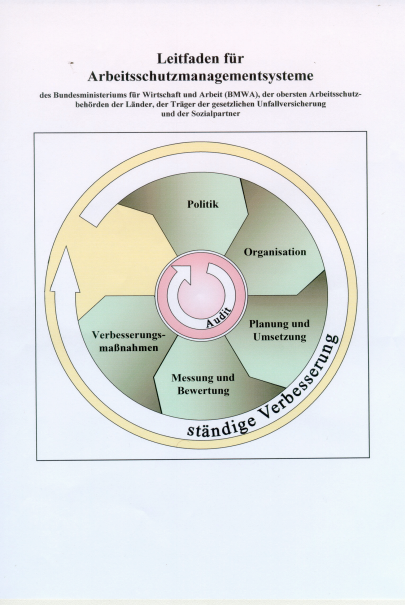
Figure 1. Elements of the national framework for OSH management systems



German OSH-Guidelines, 2002
(Leitfaden für Arbeitsschutzmanagementysysteme)

These national guidelines

- provide guidance for the development of voluntary arrangements
- are not legally binding
- are not intended to replace national laws, regulations or accepted standards
- are comparable with
  EN ISO 9001:2000 (Quality),
  EN ISO 14001:2004 (Environmental) and
  OHSAS 18001:2007 (Occupational Health and Safety).



Their application does not require certification.

One step further:

Biorisk education at universities in Germany

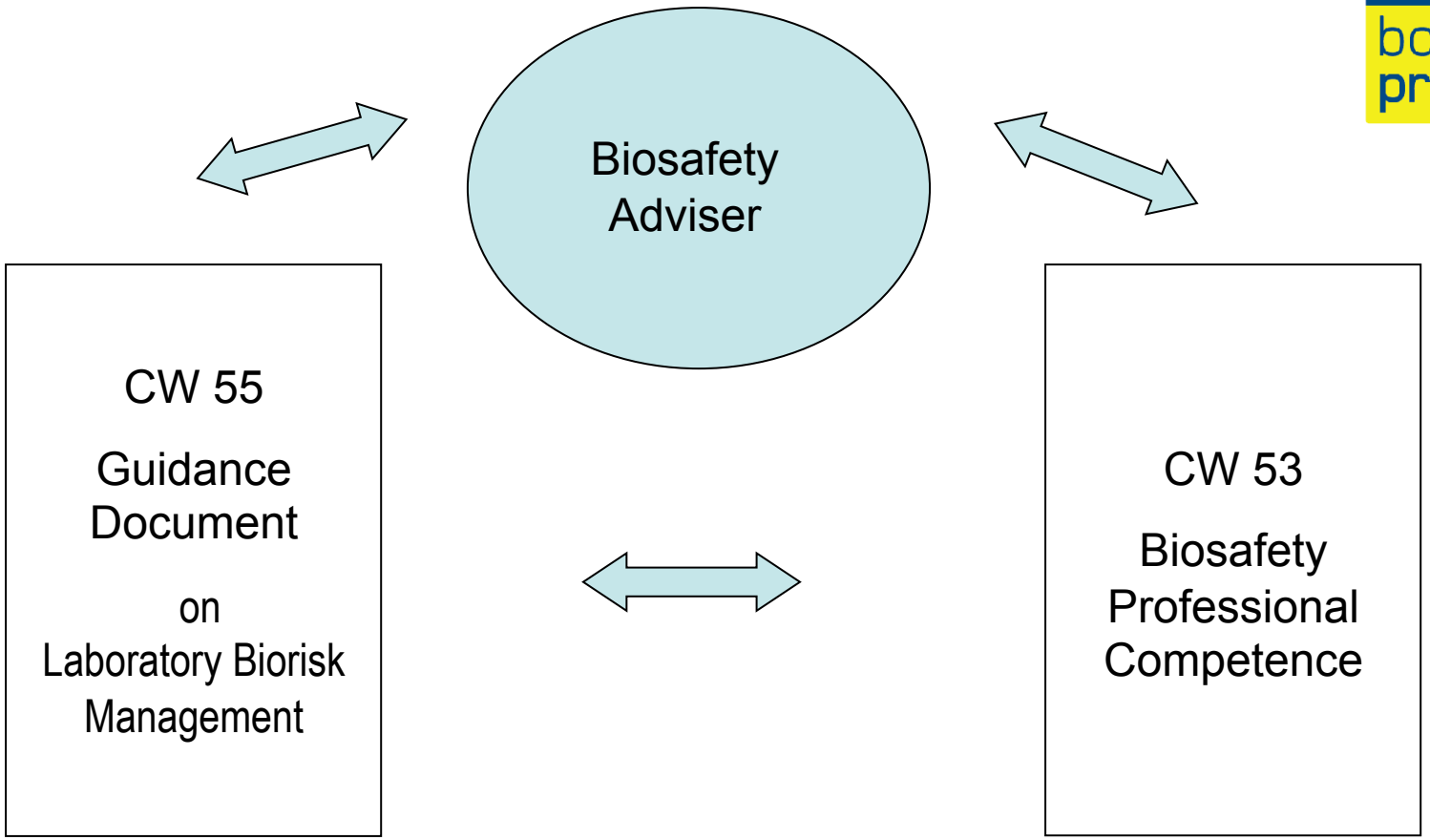
CBRN Action Plan - Biological

ACTIONS
Goal 4: Improve Training

Action B.16
The Member States together with the Commission should consider and, where appropriate, develop:
…
in conjunction with universities and professional associations, minimum requirements for academic training on biosafety, potential misuse of information and biological agents and toxins and bio-ethics **for undergraduate, graduate and postgraduate students.**

[EU CBRN Action Plan, Nov. 2009, page 73]

One step further:
Biorisk education at universities in Germany



Accreditation Council **(Akkreditierungsrat), 2004**
(Foundation for the Accreditation of Study Programs in Germany)

AHPGS – Accreditation Agency for Study Programs in Special Education, Care, Health Sciences and Social Work

AKAST – Agency for Quality Assurance and Accreditation of Canonical Study Programs

AQUIN – Accreditation, Certification and Quality Assurance Institute

AQAS – Agency for Quality Assurance by Accreditation of Study Programs

ASIIN – Accreditation Agency for Degree Programs in Engineering, Computer Science, the Natural Sciences and Mathematics

FIBAA - Foundation for International Business Administration Accreditation

ZevA – Central Evaluation- and Accreditation Agency Hannover

These agencies accredit programs of study for Bachelor and Master degrees from state or state recognized Higher Education Institutions in Germany.

Towards laboratory biorisk certification in Germany?

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Proposal for the Guidance Document CWA 15793:2008

Scope

Organisations that wish to demonstrate conformity with this laboratory biorisk management standard can choose one of the following options:

1) Providing confirmation of its conformance by relevant state agencies, or

2) making a declaration based on a legal accreditation/licencing process and regular control by state agencies issuing such accreditations/licenses, or

3) making a self-determination and self-declaration and seeking verification of it by an external party, or

4) seeking certification of its conformance by an external organization in case of working with valuable biological agents (according to WHO, Laboratory Biosecurity Guidance) or with dual-use biological material.

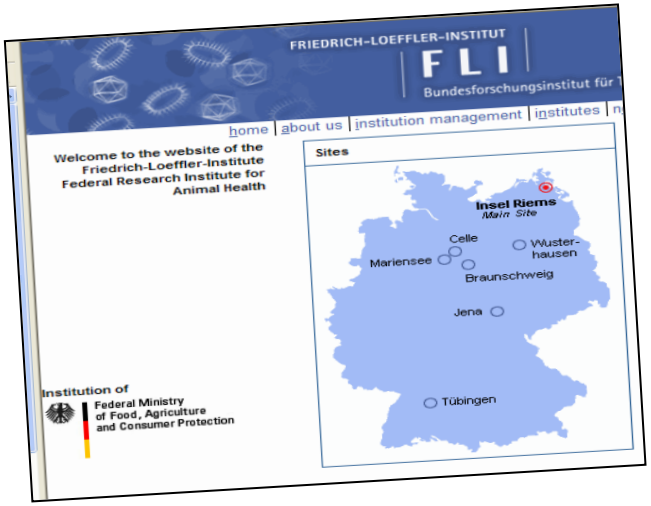
Compliance with requirements of the CWA 15793 on the basis of equal or more significant national regulations together with checkable documentation is of the same value as certification.

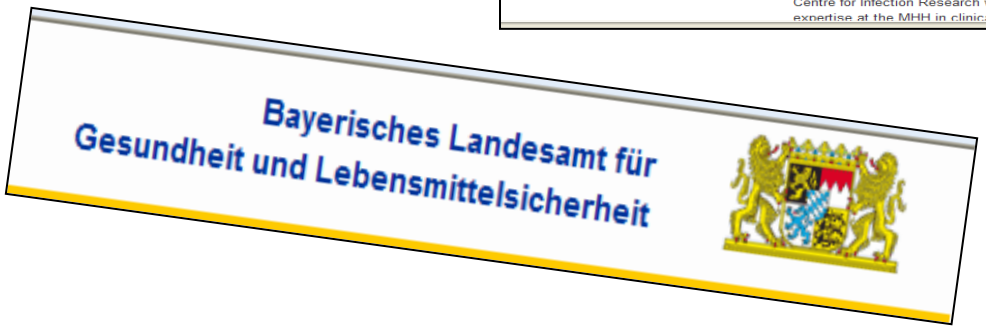
Conclusion:

The CWA 15793:2008 is the only internationally recognized document on a management system specific for Laboratory Biosafety and Biosecurity.

Let's use it to improve the biosafety and biosecurity culture in our laboratories.

On their way to implement CWA 15793:2008 in Germany





Thank you for your attention !