# CWA 15793: 2008
# Laboratory Biorisk Management Standard

Northern BSOs Meeting, Glasgow 15th May 2009

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# Summary

- How the standard arose
- Content
- How it is used/should be used in practice
- Application in HE sector
- Future developments

# Why develop the Standard?

- Many reference documents available:
  - Standards
  - Guidelines
  - Codes
- Can be largely technical in nature and often prescriptive
- Often national/regional in nature
- Management systems successful in other areas (Safety/Quality/Environment)
- Assurance to the international community

# Development of the Standard

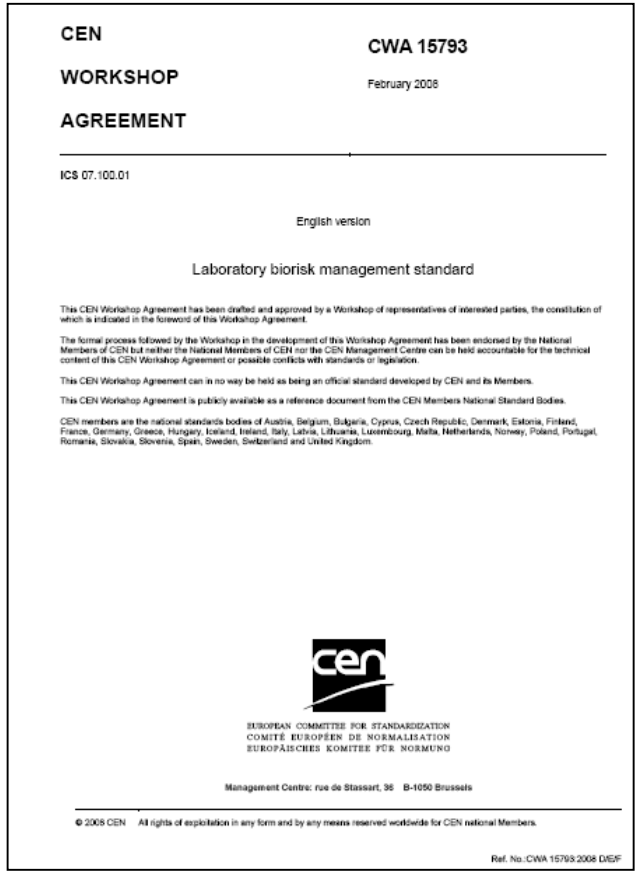
- Oslo February 2005 –concept discussion
- Attended by representatives from EBSA, ABSA, DNV, WHO and others
- Reviewed existing Standards/ Guidelines/Codes
  - Can be largely technical in nature and often prescriptive
  - Often national / regional in nature
- Recognition that management systems successful in other areas (Safety/Quality/Environment)
- Agreement that a performance-oriented international standard would drive improvement in standards especially in regions with less well-developed regulatory framework
- Steering Group set up to look at options

# Options considered

- ANSI/EN/ISO Standard
  - Slow process, long timescale
  - Expensive
  - ANSI perceived as US-focused?
- CEN Workshop Agreement – quicker and cheaper. Despite European flavour in the title, CWA's can be developed with an international basis

European Biosafety Society • American Biological Safety Association • Det Norske Veritas

# International Biosafety and Biosecurity Laboratory Standard Development Initiative



CEN

WORKSHOP

AGREEMENT

CWA 15793

February 2006

ICS 07.100.01

English version

Laboratory biorisk management standard

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.

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 Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

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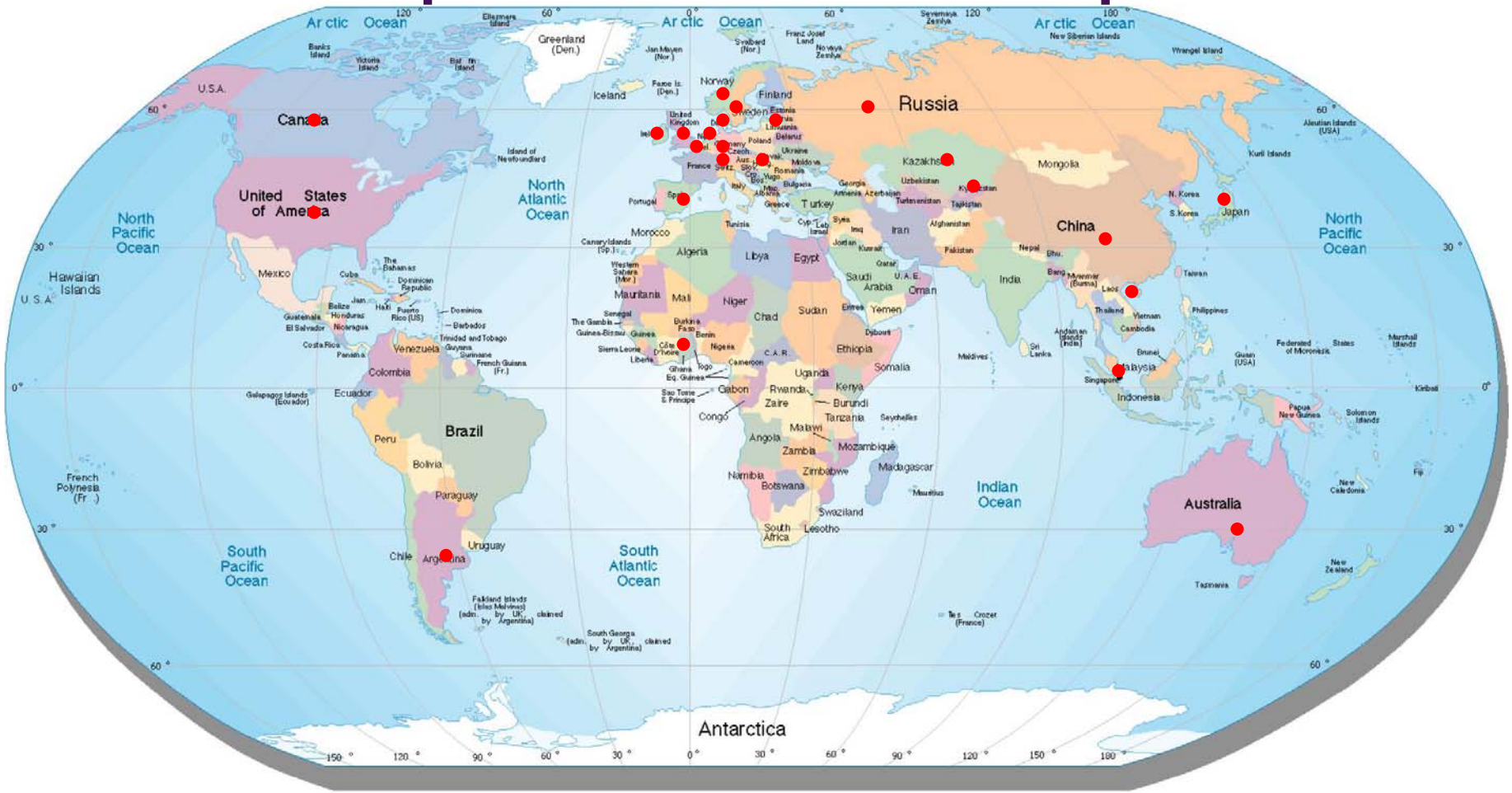
# Key stakeholders

- European Commission
- American, European and Asia Pacific Biosafety Associations
- Standards organisations
- WHO
- Universities
- Research Institutes
- Funding agencies
- Regulators

# Funding & Stakeholder Engagement

- Business plan/budget developed by Steering Group
- Funding application to European Commission (European Programme for Critical Infrastructure Protection)
- Approval 2006
- ~75% of budget from EC, remainder from other sources including participant registration fees
- Steering group develop initial draft
- 2000 organisations/individuals contacted
- 3 workshops scheduled in 2007 (Brussels/Boston).
- Public consultation between 2nd and final meetings.
- Consensus reached on a final draft at last meeting (Nov 07)
- CWA  15793 published Feb 08

# Participation in development




72 participants from 24 countries

WORLD FEDERATION FOR CULTURE COLLECTIONS
Newsletter–JANUARY 2009

# The CEN Workshop Agreement (CWA 15793:2008) and its consequences on science and research

*Dr Christine Rohde*
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*E-mail: chr@dsmz.de*

http://wdcm.nig.ac.jp/wfcc/NEWSLETTER/WFCC-NL-January-2009.pdf

*Article by Christine Rohde from the German Collection of Microorganisms and Cell Cultures*

•Apprehension that smaller institutions or universities cannot implement the CWA because of lack of financial resources.
• The CWA does not need to be fully implemented in every laboratory - individual labs should determine to what extent the CWA is applicable for them.
• Implementation of the document should help discover weaknesses in an institution's practices and prevent misuse of biological resources, data and know-how
• CWA is certainly an additional helpful tool for culture collections
• The pros and cons of the CWA should be carefully weighed and comments on the document should be directed to the CEN management centre or CEN Workshop 31 Secretariat.

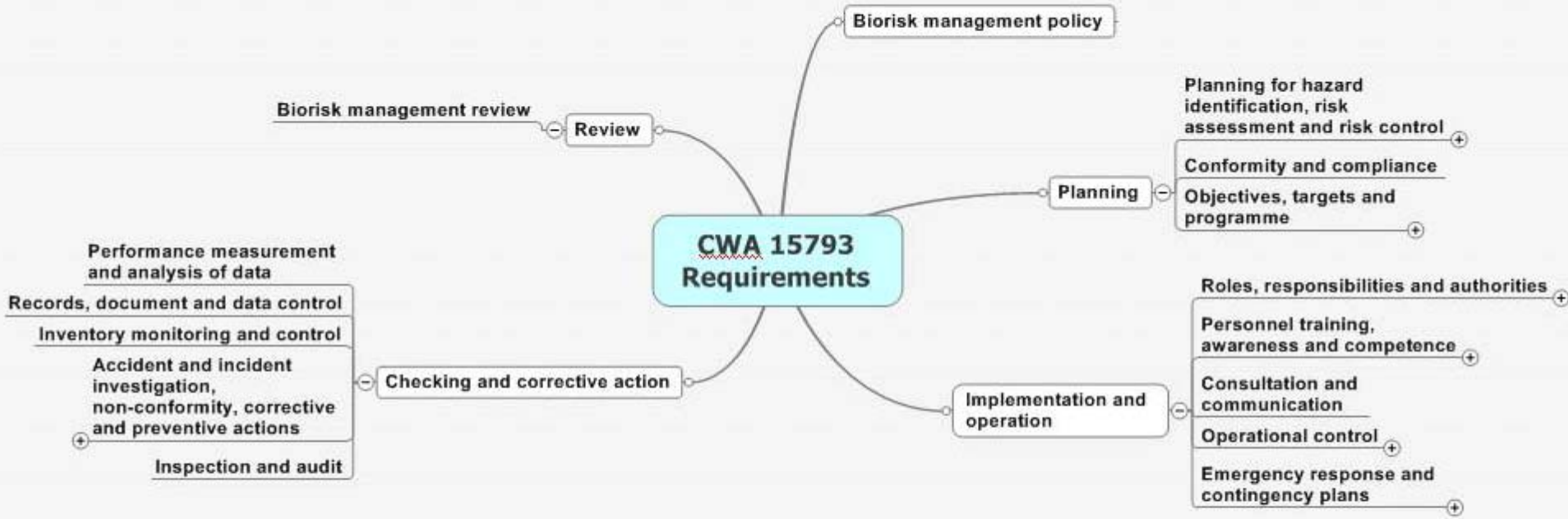
# Laboratory Biorisk Management Standard

- Addresses both biosafety and biosecurity – “Biorisk”
- Performance-orientated and risk-based
- Consistent with other international standards such as ISO 9001 / 14001 and OSHAS18001
- Integrates biosafety and biosecurity under common all hazards approach
- Contains definitions, requirements and notes for guidance
- Objective to be used at a variety of levels and controls will mirror the threat / risk associated with the activity  undertaken

# Application

- Voluntary
- Applicable to all organizations handling biological agents and/or toxins, regardless of type, size and biological agents handled.
- Does not employ biological agent risk classification or laboratory safety containment levels, although such approaches can be entirely compatible with this standard.
- If any part of the standard is in conflict with any national legal requirement or local regulatory standards, the conflicting part of the standard may be eligible for exemption.

# Overview of requirements



# Key elements/outcomes

- Management is responsible and ensures risk is managed responsibly
- Activities are proactively planned, conducted and reviewed
- Risks are identified, assessed and managed in a structured way using recognised approaches and the controls are reasonable and proportionate to the risk
- Appropriate standards and norms must be identified, used and complied with (e.g. laws, codes, BWC, WHO LBM3, WHO LBG)

# Elements/Outcomes cont'd……

- Roles, responsibilities and authorities are clearly defined –helps understanding of required competencies
- Combines controls related to engineering, instructions and people
- Links between related and dependent activities – i.e. a systematic approach
- Workers understand and can comply with requirements
- Proactive approach leading to continuous improvement

# Biosecurity concerns addressed

- Polices and management controls
- Defining and approving projects
- Selection and vetting of workers
- Control of inventories
- General security controls

# Potential applications

- Framework for biorisk management systems
- Internal or external audits and inspections
- Customised protocols and other tools
- Certification and accreditation activities – assurance to stakeholders
- Demonstration of compliance as a pre-requisite for funding projects?
- Could facilitate international collaboration

# Future…

- Review in 2011
  - Retain/Promote to EN/ISO Standard
  - Revise
  - Withdraw
- Development of Guidance on implementation
- Development of an Accreditation/ Certification process

# Conclusions

- The Laboratory Biorisk Management Standard has been developed by the user community for the user community
- Addresses biorisk holistically and is directly applicable to control measures for hazardous biological agents and toxins
- Can be used a basis to demonstrate responsible management of biorisk

# Breakdown of Topics Covered

# Planning


Planning for hazard identification, risk assessment and risk control
Planning and resources
Risk assessment timing and scope
Hazard identification
Risk assessment
Risk management
Conformity and compliance
Objectives, targets and programme
Biorisk control objectives and targets
Monitoring controls

# Implementation and Operation


# Operational Control

# Emergency Response and Contingency Plans

# Checking and Corrective Action