

Biosafety and Biosecurity Regulations in Germany

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“Laboratory Biosafety” aspects are covered in Germany since 1999 by the Ordinance on safety and health protection at work involving biological agents (Biological agents ordinance - BioStoffV). The purpose of the ordinance is to protect workers from risks to their safety and health while performing these activities. The ordinance is based on guidelines of the European legislation. Biological agents are classified into four risk groups according to their level of risk or infection emanating from them. On the basis of these risk groups, work-related information on operational processes and work procedures and type and duration of activities and possible infection routes as well as information on the exposure of workers, the employer performs the risk assessment in case of specific activities. In the light of the risk assessment and in accordance with other provisions of the ordinance, the employer takes then the required protection measures for the workers' safety and health protection. The Technical Rule 100 “Specific and Non-specific Activities involving Biological Agents in Laboratories” lays down the structural, technical and organisational minimum requirements for biological safety in laboratories for four protection levels needed for activities involving the handling of biological agents of various risk groups. The requirements are intended to minimise hazards which may arise for workers from activities involving the handling of biological agents.

In contrast to “Laboratory Biosafety”, “Laboratory biosecurity” is the physical and administrative measures that secures biological material and information that could cause harm to health or economic loss as a result of malicious release, intentional loss, theft or misappropriation. Biosecurity has become a major international issue and it was recommended that the Annual Meeting of States Parties urge expansion of existing biosecurity guidelines by the World Health Organization (WHO), Office Internationale des Epizooties (OIE), and the Food and Agriculture Organization (FAO). In the European area, the CEN (Comité Européen de Normalisation) has published the CEN Workshop Agreement (CWA) 15793 “Laboratory Biorisk Management Standard” in 2008, containing several recommendations in regard to Biosafety and Biosecurity measures. In addition, the European Union has released a CBRN actionplan in 2009, in which several biosafety and biosecurity goals of prevention, like the development of EU lists of high-risk CBRN materials and risk-based approaches to security, enhancement of control over high risk CBRN materials, contribution to the development of a high security culture of staff, improvement of identification and reporting of suspicious transactions and behaviour, enhancement of the security of transport, improvement of information exchange and strengthening the import/export regime, are clearly addressed

The integration of these recommendations into the framework of the existing regulations is currently discussed in Germany and an overview of the state-of-the art will be reported.