

BIOSAFETY-EUROPE

**Extended definition of terms including
the use of biosafety and biosecurity**



Version month 27

Effective **biosafety practices** are the very foundation of **laboratory biosecurity** activities. The main difference between biosafety and biosecurity is that biosafety aims at protection from *unintentional* release, while laboratory biosecurity shall protect from *intentional* release.

For the purpose of this project we have defined laboratory biosafety, laboratory biosecurity and the relationship between them as follows:

- **Laboratory biosafety** describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release.
- **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. NOTE: In the context of this standard, *biosecurity* is restricted to laboratory biosecurity (laboratory includes animal, plants and manufacturing facilities) and does not include all aspects of biosecurity in the sense of national or regional control measures to prevent the dissemination of alien species and pathogens.
- **Biological agents** shall mean micro-organisms, cell cultures and parasites, which may be able to provoke any infection, allergy or toxicity in humans, animals or plants and includes any of these materials which have been genetically modified.
- **Containment level** designations are based on a composite of design features, construction of containment facilities, equipment, practices and operational procedures; all required for working with biological agents and based on risk assessment.

These definitions are based on WHO guidelines and are used as working definitions for our project activities.

Biosecurity and Biosafety are separate concepts in English and other languages (including French). However, in many European tongues they translate to the same term. This causes confusion. For this reason, WHO has limited its definition of biosecurity to laboratory biosecurity. In animal health, biosecurity is a different concept which includes biosafety, quarantine and restrictions in animal movement. Politicians and law enforcement bodies have their own interpretation of the term, which may not coincide with the scientific interpretation. The ambiguity surrounding the term biosecurity may result in its meaning becoming so degraded that an alternative term is warranted. (“*Biocrime prevention*”?)

In the following, we further address the language issue by providing translations of the English definitions we propose above for biosafety and biosecurity into French, German and Italian:

Version française:

Biosécurité de laboratoire décrit les principes, les technologies et les pratiques en matière de système confiné, qui doivent être appliqués afin d’éviter une dissémination ou une exposition involontaire à des agents biologiques.

Biosûreté de laboratoire consiste en des mesures physiques et administratives destinées à sécuriser du matériel biologique et des informations qui, par une dissémination malveillante, la perte volontaire, le vol ou la soustraction (détournement), pourraient nuire à la santé et/ou causer des dommages économiques.

Remarque: Dans le contexte de ce standard, biosûreté est limité à la biosûreté du laboratoire. Cela inclut des installations d'expérimentation animale, végétale et de production. Tous les aspects de la biosûreté d'après les mesures de control nationales et regionales pour empêcher la dissémination d'espèces ou pathogènes étranges n'y sont pas inclus.

Deutsche Fassung:

Labor-Biosafety beschreibt die Prinzipien, Technologien und Praktiken für das geschlossene System, die implementiert werden müssen, um eine unabsichtliche Exposition oder Freisetzung von biologischen Agenzien zu verhindern.

Labor-Biosecurity sind die physikalischen und administrativen Maßnahmen, die biologisches Material und Informationen sichern, welches durch böswillige Freisetzung, durch absichtlichen Verlust, Diebstahl oder Unterschlagung die Gesundheit schädigen und/oder wirtschaftlichen Schaden anrichten können.

Anmerkung: „*Biosecurity*“ ist in Zusammenhang mit dem vorliegenden Standard begrenzt auf laborbezogene *biosecurity*. Dabei beinhaltet „*Labor*“ hier auch Tier- und Pflanzenversuchs- sowie Produktionsanlagen. Nicht eingeschlossen hingegen sind alle Aspekte der *biosecurity* im Sinne von nationalen und regionalen Kontrollmaßnahmen zur Verhinderung der Ausbreitung von fremden Arten und Pathogenen.

Versione italiana:

Con il termine “**Laboratory Biosafety**” si descrivono i principi, le tecnologie e le pratiche di contenimento messe in opera al fine di prevenire esposizioni non intenzionali o un rilascio accidentale di agenti biologici e tossine.

Con il termine “**Laboratory Biosecurity**” si descrivono le misure fisiche ed amministrative atte a garantire la sicurezza di materiale biologico e informazioni, che - in seguito a smarrimento, uso improprio, furto, modifica o appropriazione indebita - potrebbero nuocere alla salute e/o all'economia.

Nota: nel contesto di questi standard, il termine “*Biosecurity*” viene inteso come “*Biosecurity*” di laboratorio, intendono dunque stabilimenti per la sperimentazione animale, vegetale o di fabbricazione. Tutti gli aspetti di “*Biosecurity*” che riguardano misure di controllo regionali o nazionali atte a prevenire la disséminazione di specie aliene o patogene, non sono dunque inclusi.

Version Month 12

For the purpose of this project we have defined laboratory biosafety, laboratory biosecurity and the relationship between them as:

- Effective **biosafety practices** are the very foundation of **laboratory biosecurity** activities.
- **Laboratory biosafety** describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents, or their accidental release.
- **Biological agents** shall mean micro-organisms, including those which have been genetically modified, cell cultures and parasites, which may be able to provoke any infection, allergy or toxicity.

These definitions are based on WHO guidelines and are used as working definitions for our project activities.

Based on the detailed analysis of our questionnaire 1 (WP2) we will propose further definitions, e.g. for containment levels. Already now, upon a first glance, it became apparent that the differences between the countries are large and linguistic as well as cultural roots play an important role in the wording used. While the terminology we used preparing the questionnaire is homogeneous and based on European guidelines, the terminology used in the responses shows a substantial diversity.