

# Restricted Use of Select Agents and Toxins

- The term "biological agent" DOES NOT encompass any biological agent that is in its naturally occurring environment, if the biological agent has not been cultivated, collected, or otherwise extracted from its natural source.

# Biosecurity Of Select Agents And Toxins

**World Health Organization**



## **Biosecurity Of Select Agents And Toxins:**

Responsible Research with Biological Select Agents and Toxins National Research Council, Division on Earth and Life Studies, Board on Life Sciences, Committee on Laboratory Security and Personnel Reliability Assurance Systems for Laboratories Conducting Research on Biological Select Agents and Toxins, 2010-01-12 The effort to understand and combat infectious diseases has during the centuries produced many key advances in science and medicine including the development of vaccines drugs and other treatments A subset of this research is conducted with agents that like anthrax not only pose a severe threat to the health of humans plants and animals but can also be used for ill intended purposes Such agents have been listed by the government as biological select agents and toxins The 2001 anthrax letter attacks prompted the creation of new regulations aimed at increasing security for research with dangerous pathogens The outcome of the anthrax letter investigation has raised concern about whether these measures are adequate *Responsible Research with Biological Select Agents and Toxins* evaluates both the physical security of select agent laboratories and personnel reliability measures designed to ensure the trustworthiness of those with access to biological select agents and toxins The book offers a set of guiding principles and recommended changes to minimize security risk and facilitate the productivity of research The book recommends fostering a culture of trust and responsibility in the laboratory engaging the community in oversight of the Select Agent Program and enhancing the operation of the Select Agent Program *Biosecurity of Select Agents and Toxins* Thomas E. Engells, 2005 Summary the concept of biosecurity as it pertains to Biological Select Agents and Toxins in American biomedical institutions is explored in some depth How can specific public biomedical research universities securely use and store biological select agents The thesis outlines the dynamics of the select agent and toxin list the relevant history of the control of biological agents both in the international and domestic settings including federal regulations pertaining to biosecurity 42CFR73 Two specific case studies are presented The biosecurity strategies and tactics at these two distinct biomedical research studies are compared An answer to the research question is proposed and additional areas for research are outlined

**Sequence-Based Classification of Select Agents** National Research Council, Division on Earth and Life Studies, Board on Life Sciences, Committee on Scientific Milestones for the Development of a Gene Sequence-Based Classification System for the Oversight of Select Agents, 2010-11-08 Select Agents are defined in regulations through a list of names of particularly dangerous known bacteria viruses toxins and fungi However natural variation and intentional genetic modification blur the boundaries of any discrete Select Agent list based on names Access to technologies that can generate or synthesize any DNA sequence is expanding making it easier and less expensive for researchers industry scientists and amateur users to create organisms without needing to obtain samples of existing stocks or cultures This has led to growing concerns that these DNA synthesis technologies might be used to synthesize Select Agents modify such agents by introducing small changes to the genetic sequence or create entirely new pathogens Amid these concerns the National Institutes of

Health requested that the Research Council investigate the science and technology needed to replace the current Select Agent list with an oversight system that predicts if a DNA sequence could be used to produce an organism that should be regulated as a Select Agent A DNA sequence based system to better define when a pathogen or toxin is subject to Select Agent regulations could be developed This could be coupled with a yellow flag system that would recognize requests to synthesize suspicious sequences and serve as a reference to anyone with relevant questions allowing for appropriate follow up Sequence Based Classification of Select Agents finds that replacing the current list of Select Agents with a system that could predict if fragments of DNA sequences could be used to produce novel pathogens with Select Agent characteristics is not feasible However it emphasized that for the foreseeable future any threat from synthetic biology and synthetic genomics is far more likely to come from assembling known Select Agents or modifications of them rather than construction of previously unknown agents Therefore the book recommends modernizing the regulations to define Select Agents in terms of their gene sequences not by their names and called this sequence based classification

*Biosecurity in UK Research Laboratories* Great Britain: Parliament: House of Commons: Innovation, Universities, Science and Skills Committee, 2008 Biosecurity in UK research Laboratories Sixth report of session 2007 08 Vol 2 Oral and written Evidence Laboratory biosecurity guidance World Health Organization, 2024-06-21 The Laboratory biosecurity guidance is a revision of the first edition of the WHO Biorisk management Laboratory biosecurity guidance 2006 As introduced in the 4th edition of the Laboratory biosafety manual LBM4 the novel risk and evidence based approach is applied for biosecurity in this guidance The guidance is intended to help researchers biosafety biosecurity officers and other laboratory personnel properly assess and manage risks inherent to high consequence research Furthermore it contains a template for biosecurity risk assessment in the laboratory to prevent theft misuse and unauthorized access to biological material and also includes a two tier approach for national oversight of biological risk management as well as a hybrid approach with risk and list based elements to regulate high consequence material

**Ensuring National Biosecurity** Carole R Baskin, Alan Zelicoff, 2016-02-03 Ensuring National Biosecurity Institutional Biosafety Committees reviews the various responsibilities and associated challenges Institutional Biosafety Committees IBCs face and proposes changes that may help improve this system and increase national biosecurity and worker safety In recent years IBCs in academic and other institutions have been tasked with increasing levels of responsibility overseeing work with recombinant genetic material and hazardous agents IBC members often lack the training to effectively ensure that the work performed is truly safe for scientists and the general community and so increasingly rely upon the expertise of the researchers themselves With the proposed US dual use research policies soon to be implemented this strain may increase This book provides readers with the necessary information to be able to enhance national biosecurity within the US EU Australia New Zealand Japan and more Ensuring National Biosecurity is as an invaluable reference for biosafety professionals or for researchers who need to understand the regulatory landscape that

impacts their research Examines and assesses the current state of Institutional Biosafety Committees IBCs Collates contributions from world renowned experts in fields as diverse as research compliance law and astrobiology Reflects an international perspective on regulatory biosecurity and biosafety

**Biosecurity** Ryan Burnette, 2013-07-22 Learn how to assess and prevent biosecurity threats to protect public health and national security With contributions from experts in all facets of biosecurity this book explains the fundamental elements of biosecurity as well as the related concepts of biosafety and biosurety detailing how all three concepts fit within the framework of biodefense Readers are then given the tools needed to assess and prevent biosecurity threats and vulnerabilities The book explores the nature of biosecurity threats to research laboratories as well as to agriculture food and mass transit Moreover readers will learn how to apply principles of biosecurity to assess epidemics and protect public health Biosecurity takes a detailed look at today's biosecurity policy explaining how it is likely to evolve given current and potential threats to national security The authors stress the importance of education and advocacy helping readers develop effective programs to build public awareness and preparedness The book also presents a novel tool to assess the effectiveness of laboratory biosafety and biosecurity programs Biosecurity is divided into four parts Part I An Introduction to Biosecurity Part II Elements of Biosecurity Part III Biosecurity in Various Sectors Part IV Biosecurity Policy Bioterrorism and the Future This book will instill a deep understanding of what biosecurity is and what it is not It urges readers to think about the importance of biosecurity as it relates to national security safety and health By exposing major flaws in global biosecurity thinking Biosecurity sets forth a clear pathway to correct those errors and build stronger biosecurity programs

**Biosafety in Microbiological and Biomedical Laboratories**, 2009 **Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories** National Research Council, National Academy of Sciences, Division on Earth and Life Studies, Board on Life Sciences, Policy and Global Affairs, Committee on International Security and Arms Control, Committee on Anticipating Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories, 2012-04-02 During July 10-13, 2011, 68 participants from 32 countries gathered in Istanbul, Turkey for a workshop organized by the United States National Research Council on Anticipating Biosecurity Challenges of the Global Expansion of High-containment Biological Laboratories The United States Department of State's Biosecurity Engagement Program sponsored the workshop which was held in partnership with the Turkish Academy of Sciences The international workshop examined biosafety and biosecurity issues related to the design, construction, maintenance, and operation of high-containment biological laboratories equivalent to United States Centers for Disease Control and Prevention biological safety level 3 or 4 labs Although these laboratories are needed to characterize highly dangerous human and animal pathogens, assist in disease surveillance, and produce vaccines, they are complex systems with inherent risks Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories summarizes the workshop discussion which included the following topics: Technological options to meet diagnostic research and other

goals Laboratory construction and commissioning Operational maintenance to provide sustainable capabilities safety and security and Measures for encouraging a culture of responsible conduct Workshop attendees described the history and current challenges they face in their individual laboratories Speakers recounted steps they were taking to improve safety and security from running training programs to implementing a variety of personnel reliability measures Many also spoke about physical security access controls and monitoring pathogen inventories Workshop participants also identified tensions in the field and suggested possible areas for action      *Laboratory Biosecurity Handbook* Reynolds M. Salerno, Jennifer Gaudioso, Benjamin H. Brodsky, 2007-06-21 By achieving a delicate balance between systems and practices proper laboratory biosecurity reduces the risk of legitimate bioscience facilities becoming sources of pathogens and toxins for malicious use Effective design and implementation of laboratory biosecurity depends on cooperation among individuals from diverse communities including scien

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