THE INTERNATIONAL EXPERTS GROUP OF BIOSAFETY AND BIOSECURITY REGULATORS

Insights into Inventory Management and Laboratory Inspections within the IEGBBR Membership

Virgilio Cadete (he|il)
IEGBBR Secretariat

Logistics

- Please mute your microphone to ensure that all participants can hear the speakers
- During the Question & Answer session following each presentation, please ask all questions by entering them into the chat function

Principles of Conduct

- The IEGBBR strives to maximize participation by diverse groups of people
- We encourage self-identification of personal pronouns to promote an inclusive environment
- We aim to reduce potential barriers experienced by some individuals and groups by:
  - ✓ Providing for virtual attendance
  - ✓ Adhering to schedules
- All participants shall conduct themselves professionally and respectfully

Outline of Virtual Event

Presentation 1

- Dr. Virgilio Cadete - Introduction

Presentation 2

- Dr. Dirk Hamburger – Cantonal Laboratory Inspections in Switzerland

Presentation 3

- Dr. Enitra Jones Sprouse – Inventory Management and Accountability Best Practices

IEGBBR

Outline: Introduction

- About the IEGBBR
- Capacity-building through the IEGBBR:
  - IEGBBR website
  - IEGBBR Mobile Application
  - The Incident reporting Model
  - The Technical Expertise (and Exchange) Program

About the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR)

- A group of national government authorities with established regulatory oversight systems in place for biosafety and biosecurity
- World Health Organization (WHO) and the World Organisation for Animal Health (OIE) participate as non-member observers

- Created in 2007 under the leadership of the Public Health Agency of Canada with support from Global Affairs Canada

IEGBBR

Objectives of the IEGBBR

To strengthen and advance global biosafety and biosecurity by:

- Sharing of knowledge and experience of human and zoonotic animal pathogen biosafety and biosecurity oversight issues
- Promoting international co-operation and convergence among regulatory authorities
- Developing reference tools and materials that are universal in nature and can benefit the international community, regardless of the national level of development or resources

www.iegbbr.org

IEGBBR

The IEGBBR website

IEGBBR Mobile Application of Biosafety, Biosecurity and Dual-Use Oversight

- Reference tool for countries that aim to develop or strengthen:
  - ✓ Compliance with international biosafety and biosecurity commitments
  - ✓ National biosafety, biosecurity, and DU oversight capacities
- Two modules:
  - ✓ The Compendium of International Biosafety and Biosecurity Oversight Systems for Human and Animal Pathogens and Toxins
  - ✓ The Review of Oversight of Dual-Use in Life Sciences

www.iegbbr.org

IEGBBR

IEGBBR Mobile Application of Biosafety, Biosecurity and Dual-Use Oversight

IEGBBR

INTERNATIONAL EXPERTS GROUP OF BIOSAFETY AND BIOSECURITY REGULATORS

The IEGBBR Model of Standardized Regulatory Practices for Biosafety and Biosecurity Incidents

- 12 biosafety and biosecurity incident types
- 12 standardized practices
- 7 optional enhancements

[IEGBBR Model of Standardized Regulatory Practices for Biosafety and Biosecurity Incidents - phac-aspc.gc.ca]

IEGBBR

IEGBBR Capacity Building And Technical Expertise (and Exchange) Program

IEGBBR BIOSAFETY AND BIOSECURITY EXPERTISE TOPICS

1. Inspections: laboratory, biosafety, biosecurity
2. Inspector training
3. Biological Safety Officers: training, qualifications and responsibilities
4. Laboratory personnel training
5. Developing a national inventory of pathogens
6. Biological agent inventory requirements for laboratories
7. Pathogen risk assessments
8. Biosecurity program
9. Biosecurity risk assessments
10. Licensing/authorizations
11. Secure information systems
12. Biocontainment
13. Engineering, maintenance and calibration of laboratory biosafety equipment
14. Outreach, engagement and communication
15. Mandatory reporting/ notification obligations (including incidents)
16. Compliance and enforcement
17. Regulatory and non-regulatory oversight measures for dual-use in the life sciences
18. Dual-Use risk analysis
19. Raising awareness of dual-use

Thank you!

Are there any questions?

www.iegbbr.org

Canada

Download on the App Store

GET IT ON Google Play

IEGBBR

Survey and Contact Us

- Please complete the 3 question survey about this event
  https://forms.office.com/r/0RawhhsvFB
- It will help us to provide the information that is the most useful to you

- You can reach the IEGBBR by emailing contact@iegbbr.org

Kanton Basel-Stadt

IEGBBR

Switzerland

Insights into Inventory Management and Laboratory Inspections within the IEGBBR Membership

Cantonal Laboratory Inspections in Switzerland

IEGBBR, March 26, 2024, VIRTUAL EVENT

Dr. Dirk Hamburger, Biosafety Inspector, Basel-Stadt, Switzerland
Direction of Public Health
Cantonal Laboratory Basel-Stadt
Enforcement Agency for Chemical and Biosafety
(Kontrollstelle für Chemie- und Biosicherheit, KCB)

Focus

Enforcement of Biosafety and Biosecurity in Contained Systems

Duties and Responsibilities

Scope of biosafety ordinances
- Protection aims
- Classification
- Safety measures
- Biosecurity

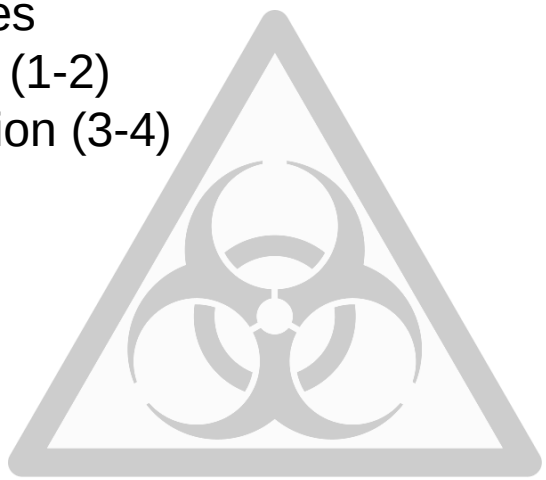
Control mechanisms
- Procedures
- Inspections

Summary, Discussion, Weblinks

Duties and Responsibilities

Persons/Establishments carrying out activities with organisms:

- No risk to public and environment
- Implement measures
- Hand in notification (1-2)
- Demand authorization (3-4)



Federal agencies:

Federal Office for the Environment (FOEN)
Federal Office of Public Health (FOPH)

- Laws / Ordinances
- Enforcement of **CO**
  - Authorizing authority / classification
  - Safety measures

Cantonal agencies:

- Enforcement of **CO**
- Enforcement of **MAO**
  - Authorizing authority
  - Safety measures

Scope of Swiss Biosafety Ordinances

Aim: Protection of collaborators

Normal operating state: SAMV*

Regulates the exposition when working with **human pathogenic micro organisms**.

Risk groups of organisms 1, 2, **3**, **4** (SR 832.321)

*Ordinance on the protection of workers from risks posed by microorganisms

Enforcement: Cantons: cantonal workers protection agencies
CH: Swiss National Accident Insurance Fund

Scope of Swiss Biosafety Ordinances

Aim: Protection of population, environment, biodiversity

Normal operating state: Containment Ordinance

Regulates the contained use of organisms, particularly genetically modified or pathogenic organisms

Activities risk class 1, 2, **3, 4** (SR 814.912)

Exceptional event: Major Accident Ordinance

Generally regulates the prevention of an exceptional event occurring in an establishment which has significant impact **outside** of the operating area

Micro organisms: Establishments where an activity assigned to risk class **3** or **4** is carried out (SR 814.012)

Containment Ordinance (CO, SR 814.912)

Handling organisms in the contained system:

- Pathogens, GMO, animals, plants, invasive species (not only select agents)
- Contained systems: laboratories (research, diagnostics), Biotech-Production, animal stations, green houses

Classification of activities: Establishments → Federal office

- **Risk group** (RG) of organisms **AND activities** result in the **classification**
  - Class 1: negligible risk → Global notification if RG1-GMO
  - Class 2: low risk → Notification
  - Class 3: moderate risk
  - Class 4: high risk

  } Authorization

- The competent federal agency: issue final classification and authorization

→ The class of the activity defines the safety measures

→ Biosafety level of the laboratory (BSL)

Safety measures (CO art. 4 annex 12)

General safety measures: apply for each level of activity

- Solid construction (fire protection, earth quake, emergency exits, …)
- Safety concept
- Biosafety officer (BSO)
- Good microbial practice (SAMV): e.g. no consumption, windows/doors closed, cleaning, disinfection, adequate personal protective equipment (PPE)

BSL specific safety measures (table)

- **BSL1: basic needs**, apply to every type of installation
- **BSL2: additional measures**, like controlling access, biosafety cabinet, higher demands for inactivation
- **BSL3: high requirements**, like negative pressure, exhaust air with HEPA filters
- **BLS4: very high requirements**, e.g. complete change of working clothes

Safety measures (CO art. 4 annex 12)

…must correspond to the state of the art in safety technology…

Table:
36 spec. safety measures

No	Safety measures	Safety level			
		1	2	3	4
	Building				
1	Separate work area	– – – –	P – – –	P L G V	P L G V
	Equipment				
19	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontaminants	P L G V	P L G V	P L G V	P L G V
	Work Organisation				
27	Suitable clothing for the work area	P L G V For laboratory activities: laboratory clothing	P L G V For laboratory activities: laboratory clothing	P L G V Suitable protective clothing and, if applicable, shoes	P L G V Change all clothing and shoes before entering or leaving

Major Accidents Ordinance (MAO, SR 814.012, ann. 2.3)

Safety measures

a) Reduce hazard potential

b) Laboratory has to be equipped with reliable technical safety measures and control technology, including **redundancies**

c) Technical and organizational safety measurements have to be in place

d) Periodical surveillance of organizational and technical safety measures and maintenance; **documentation of these surveillances → self control**

e) Alarm system

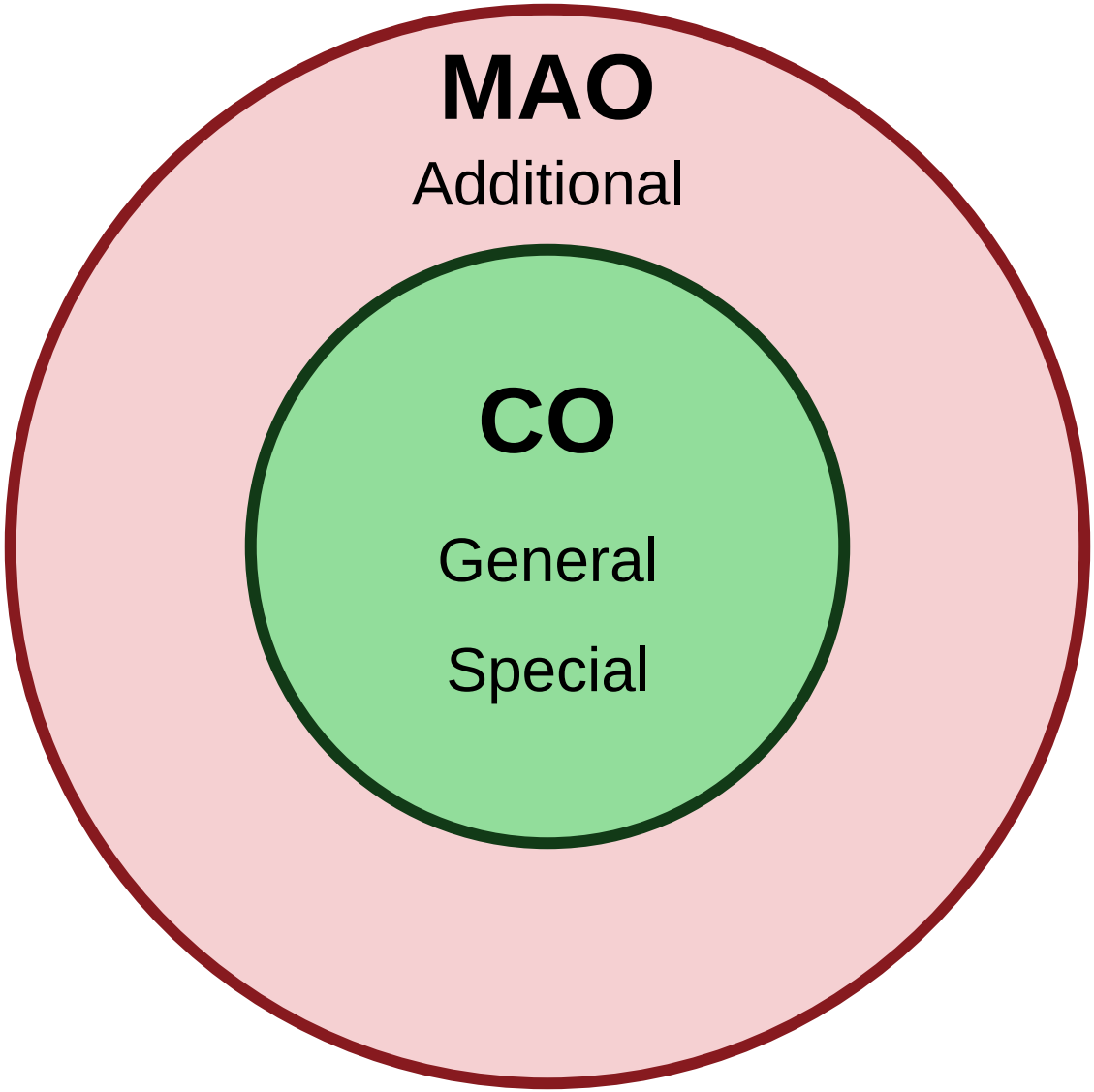
f) Storage of organisms and waste management: Inventory

g) Training of personnel to handle risky tasks

h) Documentation of relevant perturbations and incidences

i) Be prepared for respond to major accidents: Training; **Liaise with emergency services**, etc.

Comply with safety measures



Implement safety measures

Reach protection goal

CO: Safety measures in Appendix 4

- Example “negative pressure”
  - How much is needed?
  - Is -50 Pa better than -20 Pa?

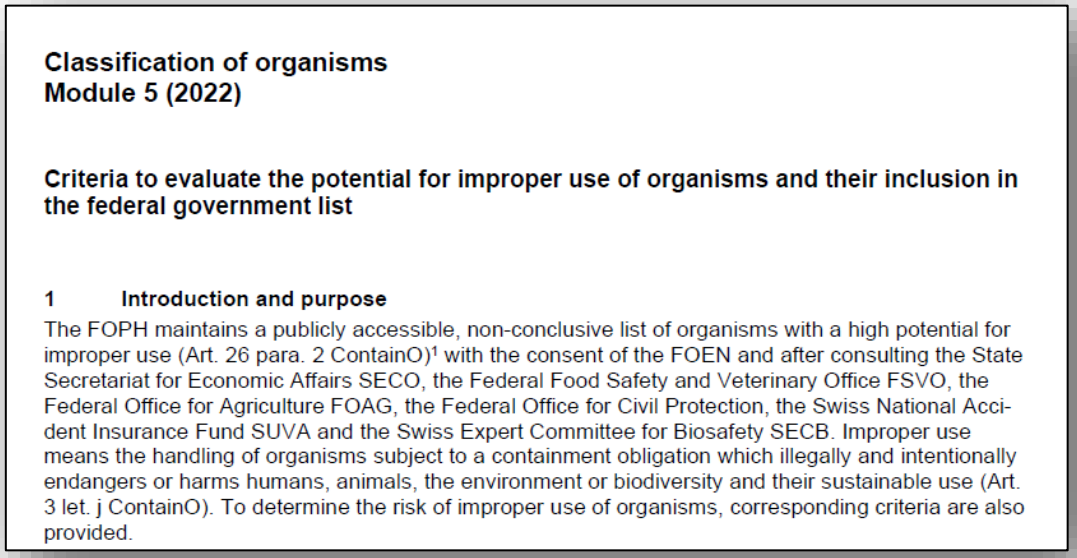
MAO: Safety measures in Appendix 2.1 and 2.3

- “Summary Report”
  - More detailed description of safety measures, e.g. “negative pressure”:
    - Values
    - How is it maintained
  - Risk evaluation, scenarios

Biosecurity

Containment Ordinance:

- Organisms with the potential for improper use **(select agents)**
- Publication by Federal Office of Public Health:



Classification of organisms
Module 5 (2022)

Criteria to evaluate the potential for improper use of organisms and their inclusion in the federal government list

1 Introduction and purpose

The FOPH maintains a publicly accessible, non-conclusive list of organisms with a high potential for improper use (Art. 26 para. 2 ContainO)[1] with the consent of the FOEN and after consulting the State Secretariat for Economic Affairs SECO, the Federal Food Safety and Veterinary Office FSVO, the Federal Office for Agriculture FOAG, the Federal Office for Civil Protection, the Swiss National Accident Insurance Fund SUVA and the Swiss Expert Committee for Biosafety SECB. Improper use means the handling of organisms subject to a containment obligation which illegally and intentionally endangers or harms humans, animals, the environment or biodiversity and their sustainable use (Art. 3 let. j ContainO). To determine the risk of improper use of organisms, corresponding criteria are also provided.

- If you work with these organisms, you have to take additional safety measures.

Control Mechanisms

1) CO: Classification of activity (1 through 4)

- Cantons take position
- Competent federal office takes decision or grants authorization

2) MAO: Risk evaluation and measures against major accidents

- Risk evaluation based on classification CO (3 and 4)
- Evaluation of hazard potential
- Canton decides if additional safety measures are needed

3) Construction permits

- Cantons evaluate construction demands
- Biosafety and Biosecurity is only one part of it

4) Inspection on site: Cantons (states)

- End of construction
- **During operations**

Biosafety and Biosecurity Routine Inspections

CO	Art. 23
MAO	Art. 8b

Preparation (office)

- Check actual status of notifications
- **Evaluate safety documents**
- History: consult earlier inspection reports

Procedure on site

Initial discussion

- Activities (notification / authorization)
- Organization (BSO / safety concept / SOPs / training records / incidence reports)

Visit laboratories / operating area

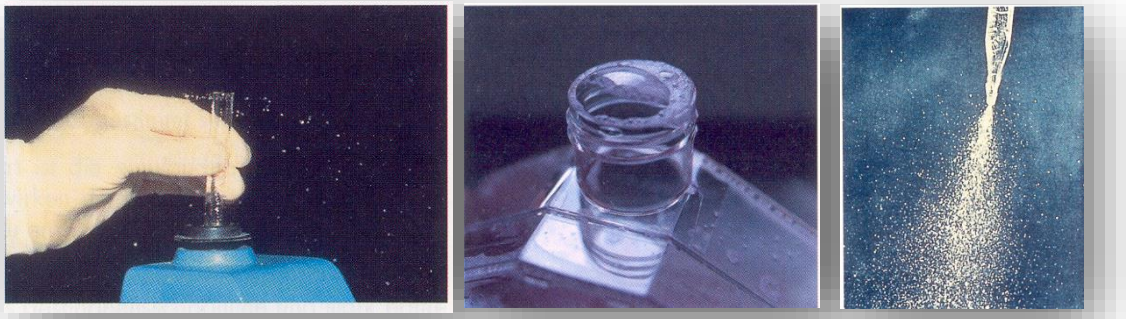
Final discussion → measures

Back in office

- If necessary, evaluation of safety documents
- Inspection report, if necessary with measures:
  - Agreements
  - Official decree

Routine Inspections: Aerosol protection

Aerosols are a source for contamination / infection



Instruments with aerosol protection

- Cell sorting devices
- Centrifuges

Abbildung 7: Rundbecher mit Schraubdeckel und O-Ring

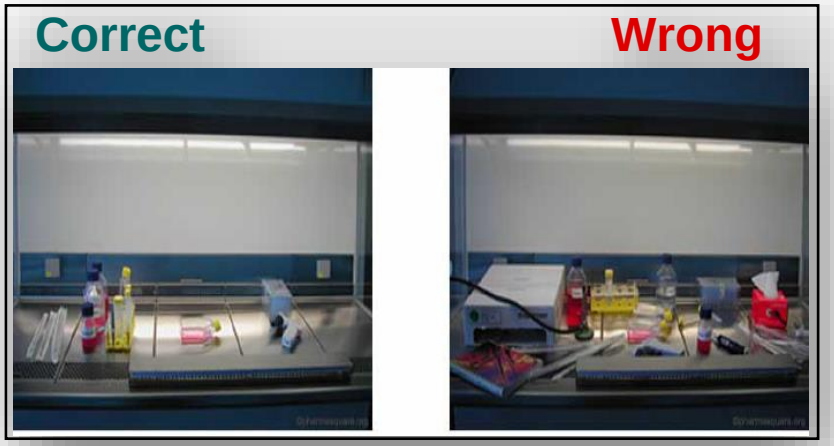
Abbildung 8: Tragringrotor mit hermetisch schließendem Deckel

Routine Inspections: Aerosol protection

Biosafety cabinet class II (BSC II)

- State of the art in safety technology
- Maintenance
- Placement (distance, not next to a door, etc.)

- Appropriate working
- Clean
- Air conducts have to be free
  → not overloaded



Routine Inspections: Waste treatment

Storage of infectious waste

- Closed containers
- Leak prove
- Labelled
- Access restricted

Inactivation in autoclave (heat / steam)

- State of the art in safety technology
- Filter / sterilization of condensate
- Correct operating (loading / sterilization program)
- Maintenance
- Independent functionality test
- Documentation

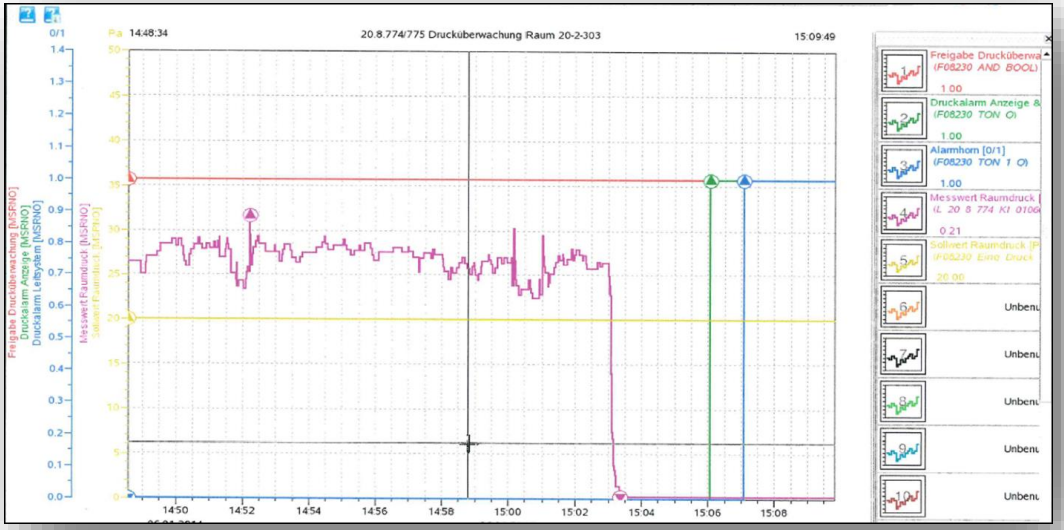
Chemical inactivation

- Prove of efficacy / validation (biocide, concentration, mixing, reacting time)

Routine Inspections: BSL3

Technical safety measures

- Negative pressure
- Alarming
- Access
- BSC II or III



Training and incident prevention

- Training plan
- Training records
- Spill kit
- PPE, handling of it
- Entrance and Exit procedures

Liaise with emergency services (fire brigade)

- Intervention plan
- Alarming (automatic)
- Access for emergency services
- Contact list
- Emergency exit / meeting points

Routine Inspections: Consequences

Inspection report

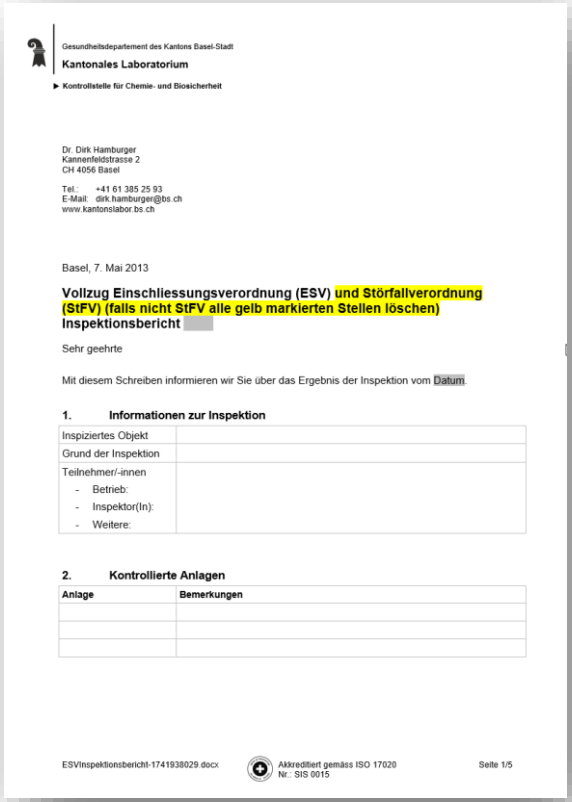
- Persons involved
- Notifications / authorizations inspected
- Facilities inspected
- Special findings
- Measures
- Recommendations

Measures (official decree or agreements)

- Dead lines to remediate the shortcomings
- Establishments have to report implementation of measures

Next inspection

- Basel-Stadt …



Gesundheitsdepartement des Kantons Basel-Stadt
Kantonales Laboratorium
▶ Kontrollstelle für Chemie- und Biosicherheit

Dr. Dirk Hamburger
Kannenfeldstrasse 2
CH 4056 Basel

Tel.: +41 61 385 25 93
E-Mail: dirk.hamburger@bs.ch
www.kantonslabor.bs.ch

Basel, 7. Mai 2013

Vollzug Einschliessungsverordnung (ESV) und Störfallverordnung (StFV) (falls nicht StFV alle gelb markierten Stellen löschen)
Inspektionsbericht

Sehr geehrte

Mit diesem Schreiben informieren wir Sie über das Ergebnis der Inspektion vom Datum.

1. Informationen zur Inspektion

Inspiziertes Objekt	
Grund der Inspektion	
Teilnehmer/-innen - Betrieb: - Inspektor(In): - Weitere:	

2. Kontrollierte Anlagen

Anlage	Bemerkungen

ESVInspektionsbericht-1741938029.docx Akkreditiert gemäss ISO 17020 Nr.: SIS 0015 Seite 1/5

Routine Inspections: Frequency

Basel-Stadt: ISO 17020 accredited inspection institution

- In general announced inspections

- Risk based inspection frequency (equal treatment of establishments)
  - BSL3 = 2 years
  - BSL2 = 3 or 5 years
  - BSL1 = upon need
  - Higher frequency if measures had to be ordered

- Reactive inspections are possible …

Reactive Inspections

Upon repeated shortcomings

- Check implementation of ordered measures
- Insufficient implementation of ordered measures
- Spot checks without announcement

Upon incident reporting of establishment

- Dealing with incident
  - Reason
  - Handling
  - Measures taken (direct and preventive)

- Evaluate situation and demand additional safety measures, if there was…
  - … a breach in technical safety measures
  - … a breach of organizational safety measures
  - … insufficient safety documents and training

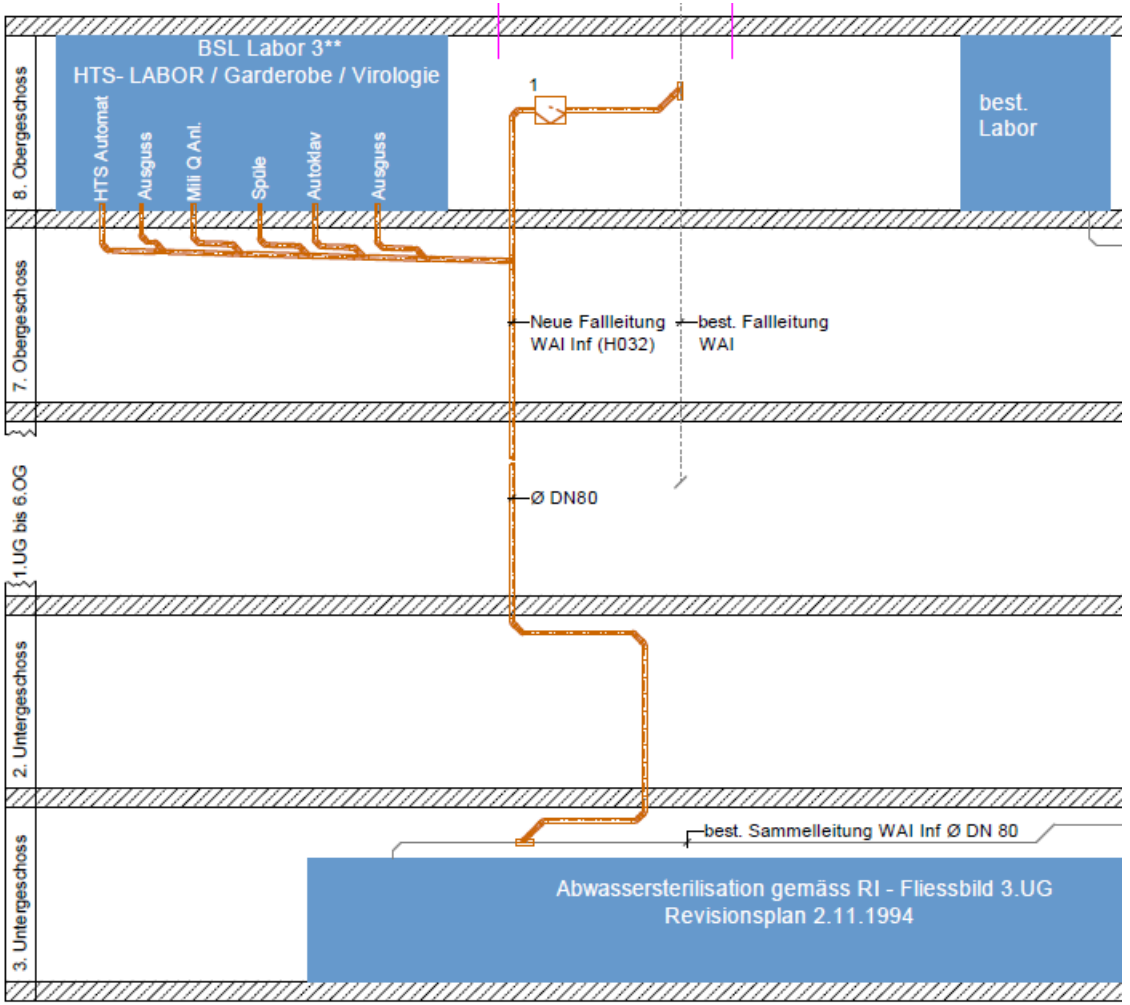
Example: Release of (contaminated) water from BSL3

Technical installation

8th Floor:
BSL3-Laboratory
with HTS unit

down pipe

-3 Basement:
Heat inactivation installation
“kill tanks”
with 2x 250 L capacity



Example: Release of (contaminated) water from BSL3

Technical installation

- HTS unit: automatic transfer of contaminated liquids into down pipe
- Additional manual transfer of contaminated liquids from vacuum bottles into down pipe
- Reason for “kill tanks”: 200 L cont. liquids per day

Example: Release of (contaminated) water from BSL3

Incident:

- Release of possibly contaminated water from BSL3-laboratory into hallway and BSL2-Laboratory underneath (estimated 300 L)
- No release into environment

Handling of incident:

- Fire brigade collected all water
- Water was chemically inactivated
- Floors were decontaminated and disinfected

Reasons for incident:

- Tube clogged siphon
- Faucet was left open for hours

Example: Release of (contaminated) water from BSL3

Measures taken by establishment:

- Tubing has to be fixed in a manner to not to clog the siphon
- Faucet will be self-closing
- Organizational measures and training (e.g. SOP handling liquid waste)
- Automatic seals of doors
- Internal recommendation: water detectors

Evaluation by enforcement:

- No harm to environment or population
- Incident was appropriately tackled
- Establishment fulfilled due diligence by reporting immediately (phone call, updates by e-mail, incident report)
- Correctional measures take are appropriate
- Measure ordered: Obligation to install water detectors

Inspector Training: Biosafety Networking in Switzerland

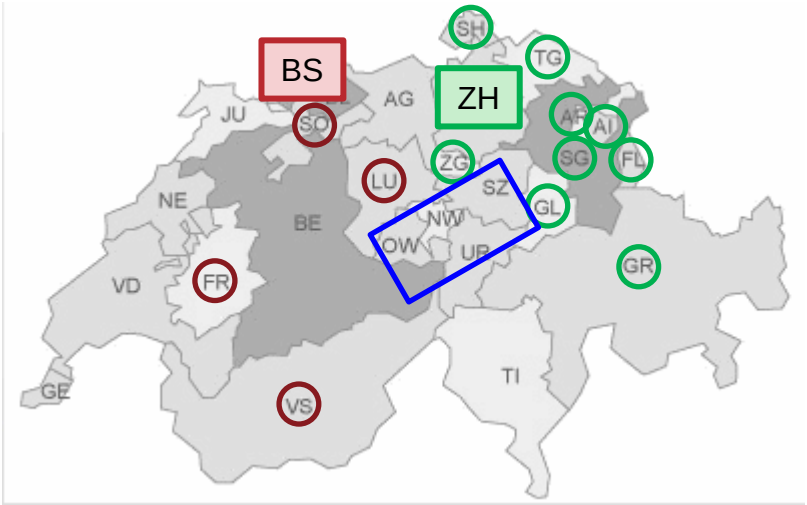
Inter cantonal exchange group

ERFA BIO

Interkantonale Erfahrungsaustauschgruppe von Fachstellen im Bereich der Bio- und Gentechnologie

- Cantonal agencies
- Federal office of public health and Federal office of environment

Consulting contracts between cantons



Swiss Biosafety Network
SBNet

Concluding Remarks

Responsibilities

- Establishments → due diligence
- Federal and cantonal agencies → Regulations, safety measures, controlling

Implement safety measures

- Achieve protection goal
- **Keep up awareness** of people involved through inspections

Control mechanisms

- During construction, when starting with the activities, during operation
- Encourage establishments to dare to get into contact with federal and cantonal agencies

Inspections: Discussion Points

Inspections (Art. 23 CO)

- “At random” means not a profound audit
- Announced vs. not announced inspection
- Inspection frequency: too short, too long?

Inspector training

- Good exchange between authorities
- Federal BSO-training accessible for inspectors

Web Links

FOEN: Contained use

https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/info-specialists/activities-in-contained-use.html

FOEN: Activities with organisms in contained system

https://www.bag.admin.ch/bag/en/home/gesund-leben/umwelt-und-gesundheit/biosafety/geschlossenes-system.html

Ordinances:

SAMV (French version): https://www.fedlex.admin.ch/eli/cc/1999/445/fr

CO (English version): https://www.fedlex.admin.ch/eli/cc/2012/329/en

MAO (English version): https://www.fedlex.admin.ch/eli/cc/1991/748_748_748/en

Inventory Management and Accountability Best Practices

Enitra Jones Sprouse, PhD, RBP, CBSP
Senior Biological Safety Advisor

Samuel S. Edwin, PhD
Director

Division of Regulatory Science and Compliance
Office of Readiness and Response
Centers for Disease Control and Prevention

IEGBBR Virtual Event

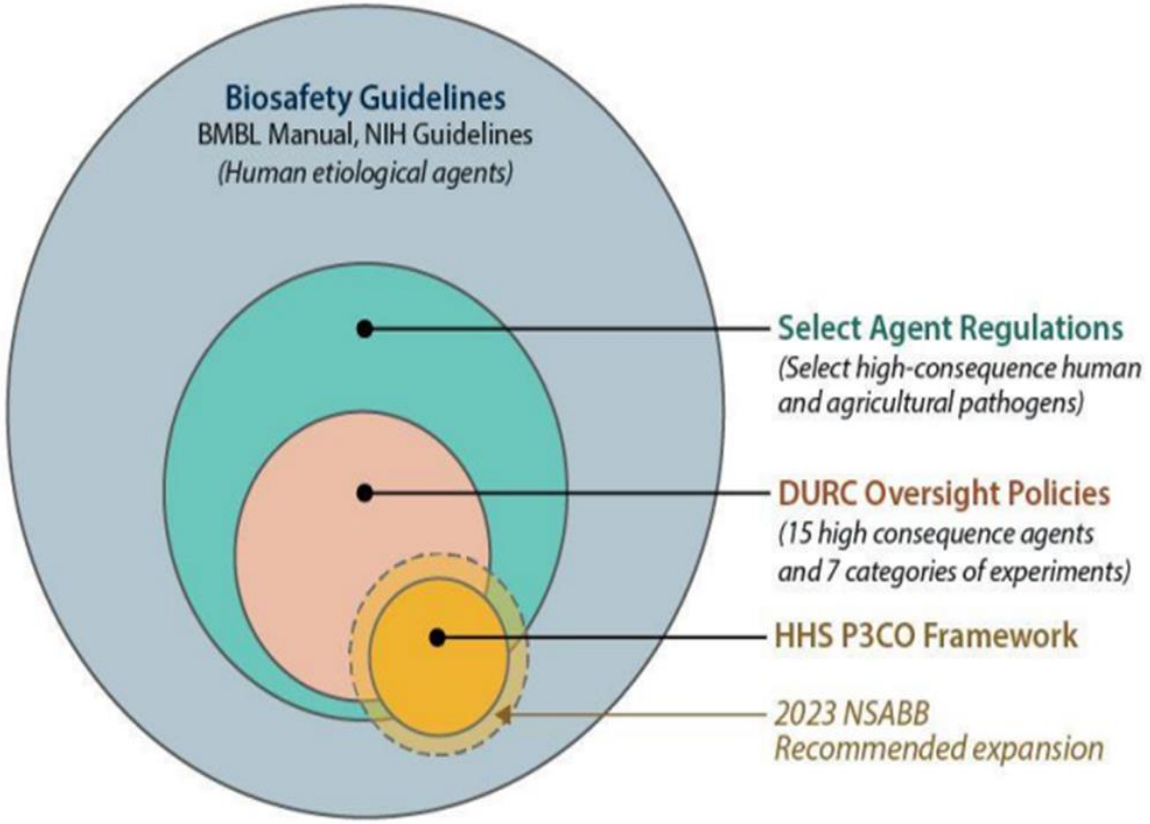
26 March 2024

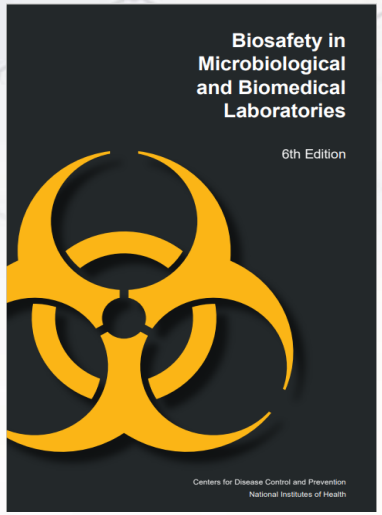
Outline

- United States Biosafety and Biosecurity Oversight
  - Federal Select Agent Program
- Select Agents and Toxins Regulations Overview
- Select Agents and Toxins Inventory Regulations
  - Inventory Considerations
- Resources

U.S. Biosafety and Biosecurity Oversight

U.S. Federal Biosafety & Biosecurity Oversight





CDC USDA

FEDERAL SELECT AGENT PROGRAM

Figure 1: Overlap of Select U.S. Policies for Biosafety and Biosecurity Oversight: Oversight Applies to Specific Agents and/or Types of Experiments Congressional Research Service, 15 September 2023
https://crsreports.congress.gov

Federal Select Agent Program (FSAP)

Regulates the possession, use, and transfer of biological select agents and toxins (BSAT) with the potential to pose a severe threat to public, animal or plant health, or to animal or plant products

Managed jointly by:

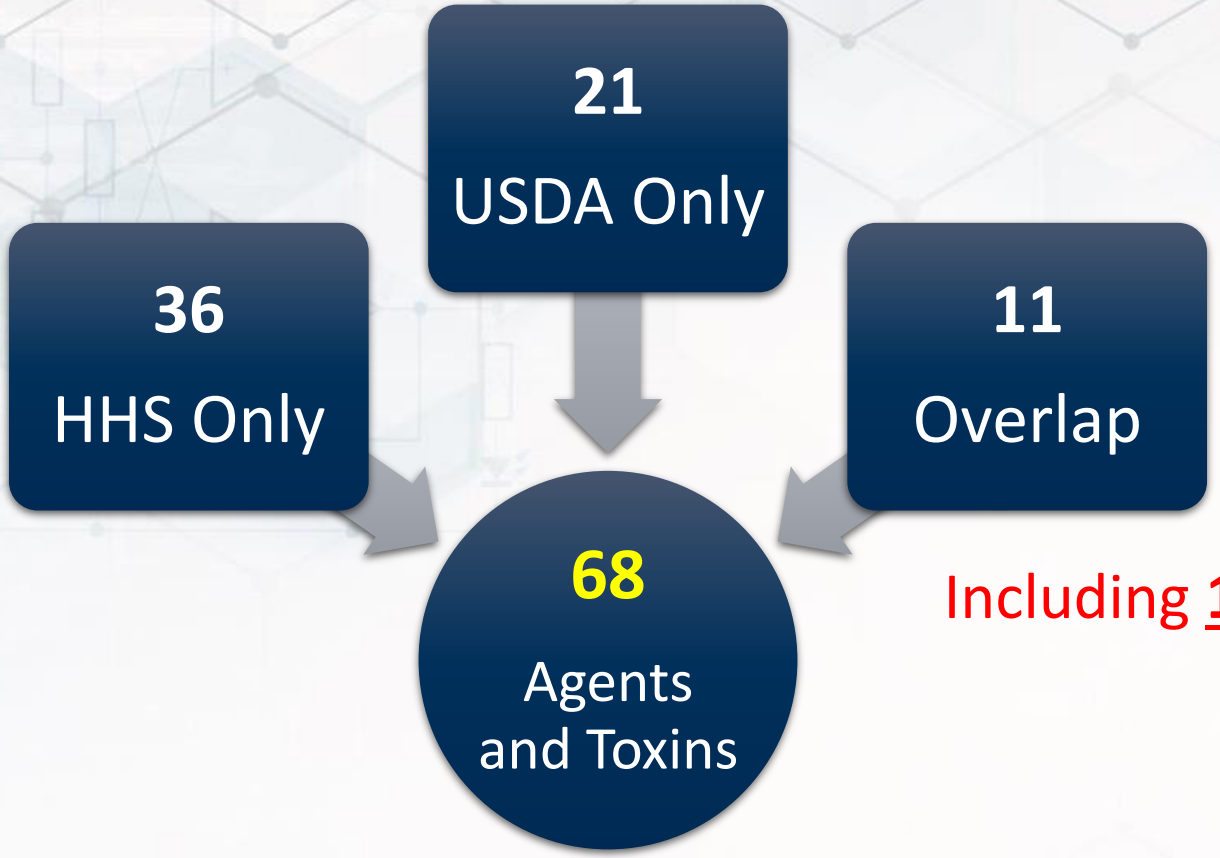
- The Division of Regulatory Science and Compliance (DRSC), Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS)
- The Division of Agricultural Select Agents and Toxins (DASAT), Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA)

FSAP: Key Regulatory Functions & Activities

- Promulgate the select agent regulations
- Provide oversight of possession, use, and transfer
- Conduct inspections and approve registrations
- Approve individual access to select agents & toxins
- Receive reports of a theft, loss, or release
- Take appropriate enforcement actions
- Serve as a resource on compliance with the regulations

U.S. Select Agents and Toxins Regulations

Select Agents and Toxins List Description



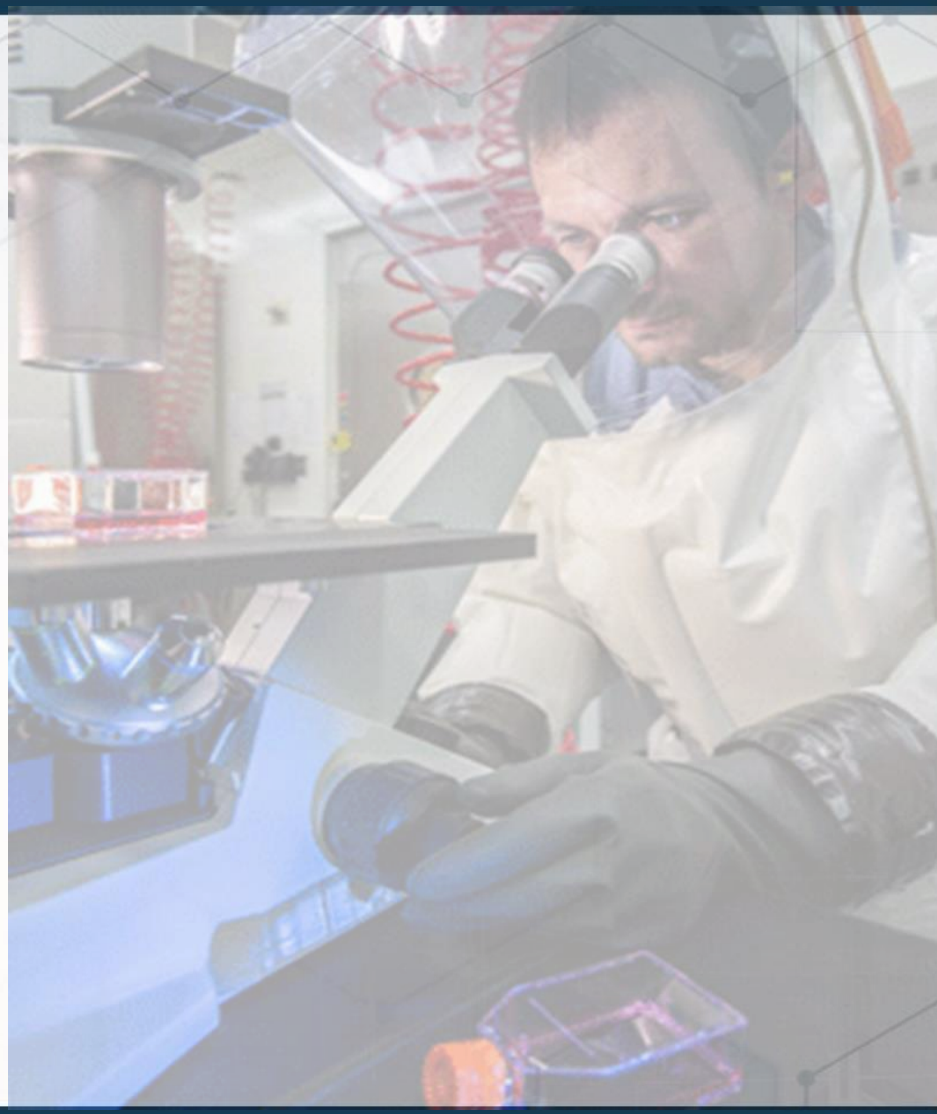
Including **14** Tier 1 Agents

Select Agents and Toxins List

https://www.selectagents.gov/sat/list.htm

FSAP Metrics

- Since 2003, there have been:
  - **No** reported thefts of a select agent or toxin from a registered entity.
  - **No** deaths among laboratory workers.
  - **No** reported cases of illness or death in the general public due to work with these agents in regulated laboratories.
  - **No** animal or plant disease outbreaks due to work with these agents in regulated laboratories



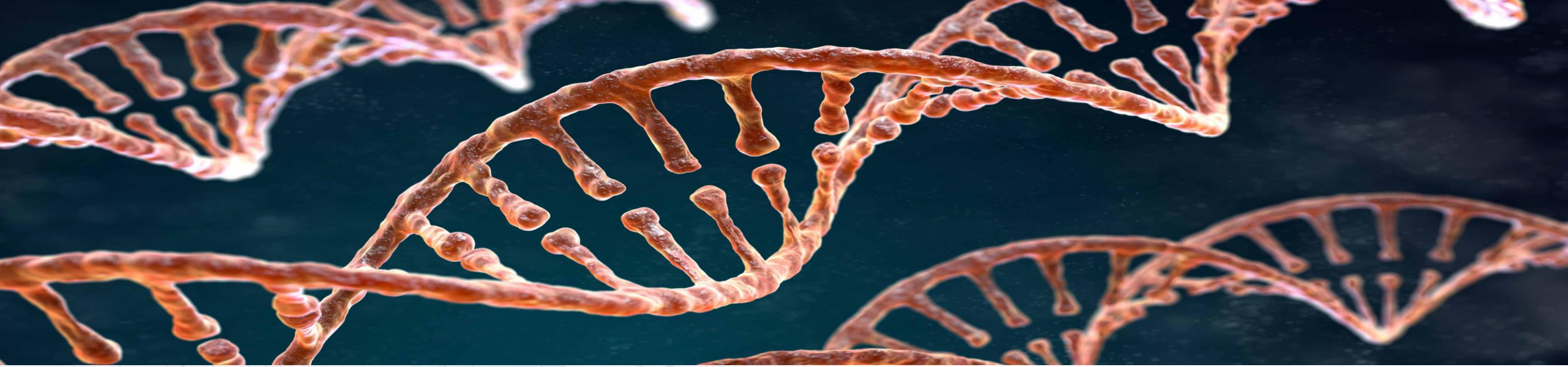
Inventory Regulations

Biological Agent - Definition

- **Biological Agent** means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, to other living organism; deterioration of food, water, equipment, supplies, or material of any kind, or deleterious alteration of the environment.

Toxin – Definition

- **Toxin** means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substances of biological product that may be engineered as a result of biotechnology, produces by a living organism; or any poisonous isomer or biological product, homolog or derivative of such a substance.



Nucleic Acids - Definition(s)

- **Recombinant nucleic acids** means:
  - (1) molecules that constructed by joining nucleic acid molecules and that can replicate in a living cell or
  - (2) molecules that result from the replication of those described in paragraph (1) of this definition.
- **Synthetic nucleic acids** means:
  - (1) Molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids) or
  - (2) Molecules that result from the replication of those described in (1) of this definition.

Select Agent and Toxin Regulations

- The Select Agent Regulations [42 CFR 73.17(a), 7 CFR 331.17 (a), and 9 CFR 121.17(a)] require an **accurate and current inventory** for:
  - Each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms held in long-term storage);
  - Any animal or plants intentionally or accidentally exposed to or infected with a select agent;
  - Each toxin held

Long-Term Storage Criteria

- **Placement of select agents and toxins in a system designed to ensure viability for future use,** such as a refrigerators, freezers, liquid nitrogen storage tanks, room temperature storage containers or lyophilized materials
- As a general rule, long-term storage materials are **not part of an ongoing experiment** or have not been accessed for a significant period of time (e.g., 30 calendar days or in accordance with entity policies)
- All select agent materials stored long-term must be **kept in a secure location** registered with FSAP. Only **FSAP-approved individuals** with current Security Risk Assessment (SRA) can access these materials.

Indicators of Long-Term Storage Materials

- The material is in a highly concentrated state and would not be used in its current form without dilution to a less concentrated state.
- The material is not part of an ongoing experiment and will not be used for any work by the entity within a defined period of time (e.g., 30 calendar days or in accordance with entity policy)
- The material is not consumed within a defined period of time by the entity (e.g., 30 calendar days or in accordance with entity policy; an aliquot from an experimental protocol preserved for future use)
- The material is placed in an environment where there is infrequent access to the environment (e.g., viral stocks in LN2 tanks)

Long-Term Storage Materials-Management

- **Long-term select agents and toxins not frequently accessed** containers can be sealed with tamper-proof material (e.g., security tape) following inventory verification. These sealed containers can be verified during entity (self) audits.
- Every entity should have a written policy for management of select agent and toxin inventory held in long-term storage, including:
  - Identifying specific individual responsibilities for inventory oversight
  - An internal audit system to ensure appropriate procedures are followed to document changes to the inventory
  - Procedures in place to transfer select agent and toxin inventory (intra-, inter-entity transfers)
  - Procedures in place when Principal investigators with holding leave the entity

Working Stock Criteria

- **Select agents are considered working stock if**:
  - The materials are part of an ongoing experiment
  - Accessed frequently
  - Not stored for extended period of time
- Entities must document the purpose of use of select agents and their final disposition
- All select agent working stock materials are used in secure location registered with FSAP
- Only FSAP-approved individuals with current Security Risk Assessment (SRA) can access these materials

Indicators of Working Stock Materials

- The material has been diluted from a concentrated state and placed into multiple aliquots in the less concentrated form for immediate use (less than 30 calendar days or as needed by the ongoing experiment)
- The material is part of an ongoing experiment and will be used for work by the entity within a defined period of time (less than 30 calendar days or as needed by the ongoing experiment)
- The material is consumed as part of an ongoing experiment within a defined period of time by the entity (less than 30 calendar days or as needed by the ongoing experiment)
- The material is placed in an environment where there is frequent access to the material, such as a refrigerator or incubator in an active laboratory, to support ongoing experiments.

Long-Term Storage Verses Working Stock

	Long Term	Working Stock
Highly concentrated	✓	✗
Part of an ongoing experiment	✗	✓
Consumed within a defined period of time	✗	✓
Placed in an environment with infrequent access to the material	✓	✗

Labeling Guidance

- **Labels on agent or toxin containers (e.g., tubes) should:**
  - Be legible
  - Be permanently affixed to the container
  - Be indelible and able to survive surface decontamination with appropriate disinfectant and time and temperature extremes expected during storage
  - Contain enough information for a rapid, visual assessment of the contents by a knowledgeable viewer
  - Have a unique identifier/linkage to the inventory record that contains the full amount of information on the sample/specimen (e.g., agent/toxin name, viable or inactivated material, strain information)

Select Agent and Toxin Inventory Records (1 of 2)

- **An accurate and current inventory for each select agent and toxin** held in long-term storage.
- Name and characteristics (e.g., strain designation)
- Quantity acquired from another individual or entity (containers, vials, tubes, etc.) date of acquisition and the source
- Where stored (e.g., building, room, and freezer or other storage container)
- When moved from storage and by whom and when returned to the storage and by whom
- The select agent used, purpose of use, and when applicable, final disposition
- Details of inter- and intra-entity transfers

Select Agent and Toxin Inventory Records (2 of 2)

Select Agent materials include: (a) Confirmed clinical specimens; (b) Laboratory cultures containing select agents; (c) Recombinant and/or synthetic select agent organisms; (d) Genetic elements and recombinant and/or synthetic nucleic acids encoding regulated genetic material; and (e) animals, animal tissues, plants, plant tissues intentionally or accidentally exposed to or infected with select agent.

Each select agent material stored long-term must correspond to a written record containing all the information.

An entity is responsible for maintaining an accurate and current inventory of all **toxins** possessed.

Final disposition of the select agent and toxin materials is required to be recorded (material consumption, transfer, and/or subjected to destruction).

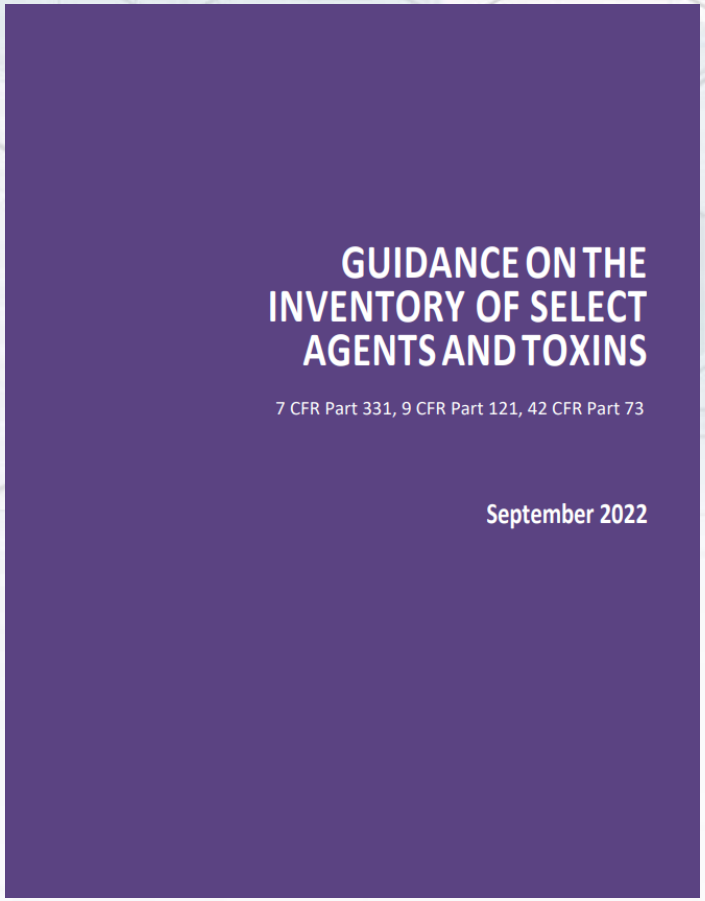
Select Agent and Toxin Exposed Animals and Tissues

- **Toxin records** must be maintained. For select toxins, there is no differentiation between working stocks and long-term storage materials. All regulated toxin materials must be captured under the inventory records.
- Once an animal has been injected with or exposed to a select toxin (e.g., by inhalation, dermal absorption, or ingestion), the animal is not considered a 'select toxin' and does not need to be housed in an FSAP-registered space. Animal tissues from toxin-exposed animals do not fall under Select Agent Regulations.
- An accurate and current accounting (record) are required for any animals or plants intentionally or accidentally exposed to or infected with select agent and or toxin
- Until the select toxin is injected into or exposed to the animal, the select toxin is subject to Select Agent Regulations

Inventory Best Practices

- Frequently take stock of your laboratory inventory
- Develop and maintain a centralized inventory record, integrating experimental notes (e.g., laboratory notebooks) with your inventory management system of record
- Ensure all approved personnel, with access to your inventory, are aware of the labelling and recording requirements
  - Inventory accuracy is everyone's responsibility
- Ask colleagues what has worked for them

Resources



- Guidance On The Inventory of Select Agents and Toxins
  https://www.selectagents.gov/compliance/guidance/inventory/docs/Inventory_Guidance.pdf
- Long-Term Storage Criteria for Select Agent-Infected Arthropods
  https://www.selectagents.gov/compliance/guidance/inventory/long-term.htm
- Long-Term Storage Criteria for Select Agent-Infected Plants
  https://www.selectagents.gov/compliance/guidance/inventory/long-term.htm

www.selectagents.gov

CDC Contact Information
Division of Regulatory Science
and Compliance
LRSAT@cdc.gov
404-718-2000

APHIS Contact Information
Division of Agricultural
Select Agents and Toxins
DASAT@usda.gov
301-851-2070

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention or the Animal and Plant Health Inspection Service.