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IBCTR
INTERNATIONAL BIOLOGICAL and CHEMICAL THREAT REDUCTION

# Laboratory Risk Assessment

*Session 2: Creating and Promoting a Culture of Safety and Quality*

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# Risk Assessment

Biological Risk Assessment is the central component of the overall risk analysis process

- Each laboratory is unique, and therefore, its risks will be unique
- All risks should be considered, prioritized, and acceptable risk determined for each laboratory

*A standardized and repeatable risk assessment process is necessary to in order to identify changes over time, facilitate clear risk communication, ensure compliance with biorisk management best practices, and to create a process for laboratory networks to assess and manage risks*

# Risk Characterization: Safety and Security

Biological hazards must be characterized based on agent characteristics and laboratory procedures (safety) and attractiveness to a notional adversary (security)

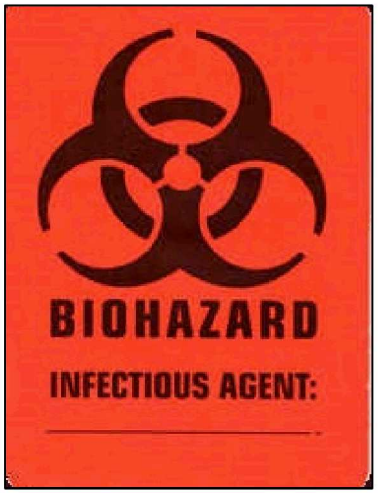
- Security considers the ease or difficulty of malicious use (likelihood) should involve assessing the following:
  - The difficulty of acquiring the agent
  - The difficulty of processing the agent into a suitable quantity in a suitable form
  - The difficulty of disseminating the agent to cause harm

- Safety considers the potential for adverse public, animal and environmental health consequences:
  - Available treatments and vaccines
  - Prevalence of disease in the region
  - Economic impact of disease


# Biosafety and Biosecurity Risk Assessment

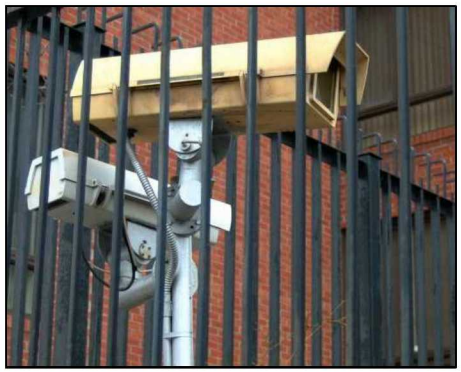
A biosafety risk assessment is an analytical procedure designed to characterize and evaluate safety risks in a laboratory

- A biosafety risk assessment allows a laboratory to determine the relative level of risk its different activities pose, and helps guide risk mitigation decisions so these are targeted to the most important risk



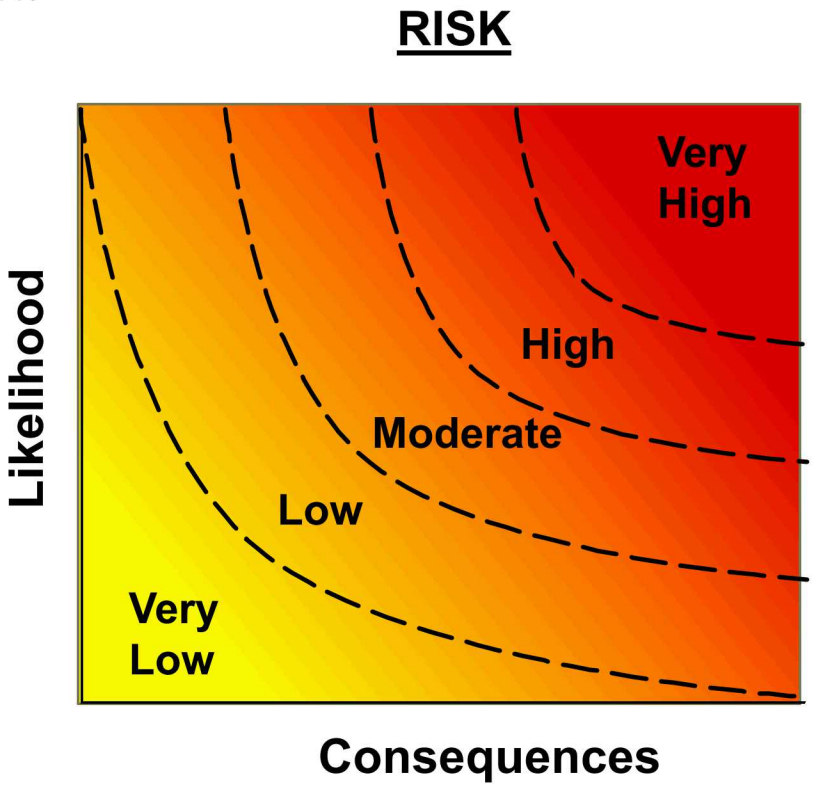

A biosecurity risk assessment is an analytical procedure designed to characterize security risks in a laboratory

- A laboratory biosecurity risk assessment should consider every asset, adversary and vulnerability in an institution and its component laboratories and units.



# Risk

*Risk* is defined as a combination of the likelihood (probability) of the occurrence and the severity of harm (or consequence); the term biological risk is used where the source of harm is a biological agent or toxin.



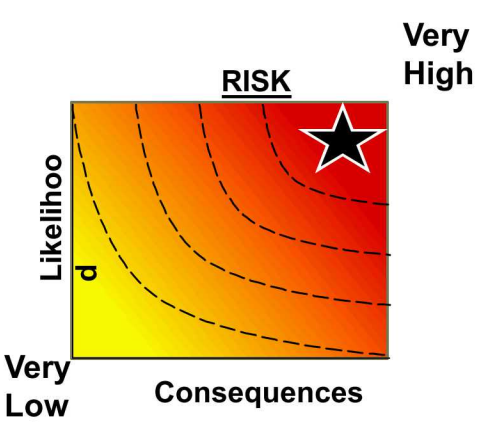

**Risk is the product of Likelihood Consequences:**

$$R = f(L, C)$$

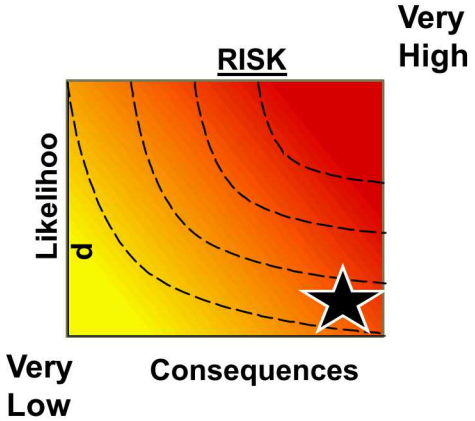
# Risk

**For the following scenarios**, draw a **STAR** where the **risk** would fall on the graph.

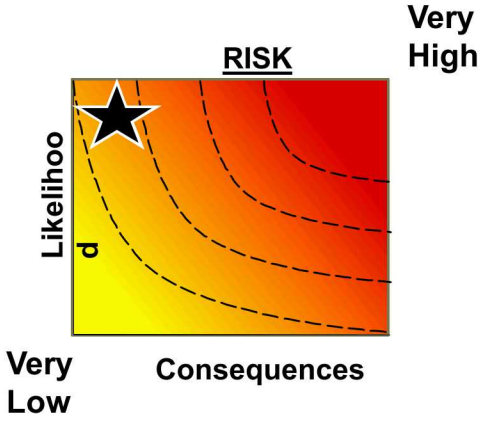
You are in an open field next to a very hungry , aggressive, adult tiger. The tiger is unrestrained and sees you as food.



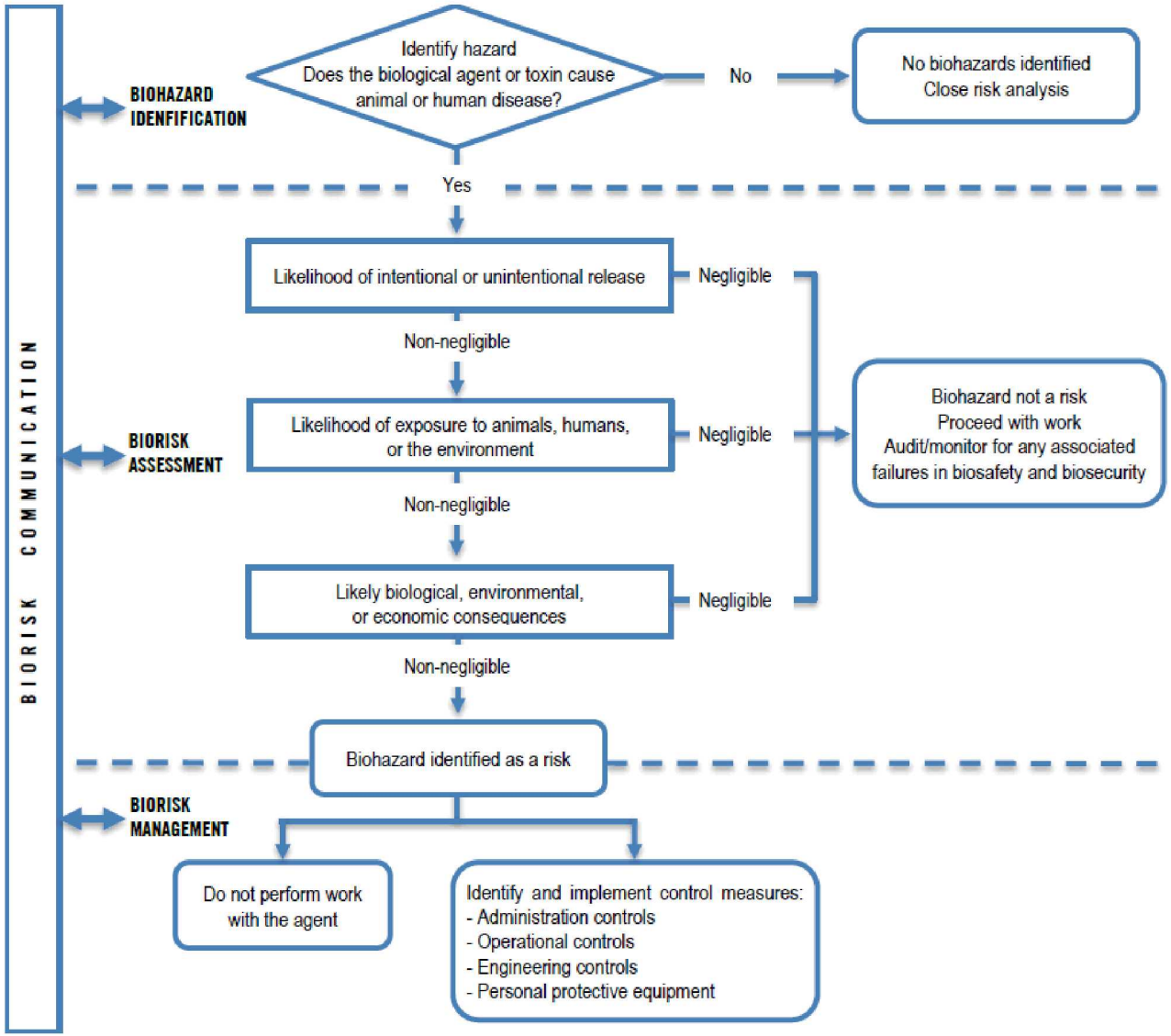

You are in the zoo, observing a caged adult tiger, which is well fed, and has a mild temperament.




You are holding a tiger cub with a playful temperament in your arms.



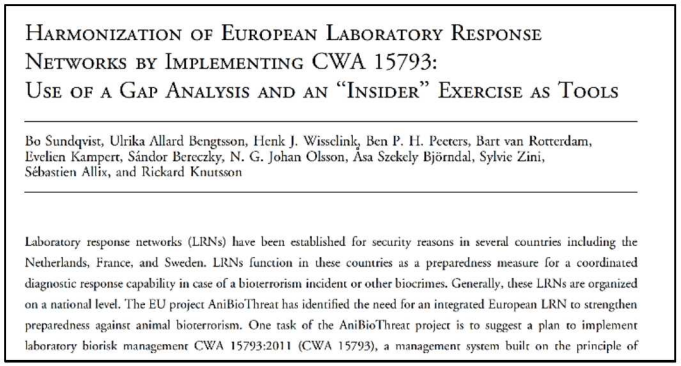
# Risk Analysis Process



# Risk Analysis: Biorisk Management

Execution of risk assessment as part of a larger standardized biorisk management system is essential and is especially important for laboratory networks

- CEN Workshop Agreement (CWA) 15793:2011 provides a framework to establish a standardized implementation plan for laboratory networks
  - Sundqvist, et. al. 2013 describes the harmonization of European Laboratory Response Networks by implementing the CWA 15793
  - Implementation required:
    - *Support from top management*
    - *Knowledge of the CWA 15793*
    - *A compliance audit checklist and gap analysis*
    - *Training and exercises*
    - *Networking in LRNs and other networks*
    - *Interinstitutional audits*



HARMONIZATION OF EUROPEAN LABORATORY RESPONSE NETWORKS BY IMPLEMENTING CWA 15793: USE OF A GAP ANALYSIS AND AN "INSIDER" EXERCISE AS TOOLS

Bo Sundqvist, Ulrika Allard Bengtsson, Henk J. Wisselink, Ben P. H. Peeters, Bart van Rotterdam, Evelien Kampert, Sándor Bereczky, N. G. Johan Olsson, Åsa Szekely Björndal, Sylvie Zini, Sébastien Allix, and Rickard Knutsson

Laboratory response networks (LRNs) have been established for security reasons in several countries including the Netherlands, France, and Sweden. LRNs function in these countries as a preparedness measure for a coordinated diagnostic response capability in case of a bioterrorism incident or other biocrimes. Generally, these LRNs are organized on a national level. The EU project AniBioThreat has identified the need for an integrated European LRN to strengthen preparedness against animal bioterrorism. One task of the AniBioThreat project is to suggest a plan to implement laboratory biorisk management CWA 15793:2011 (CWA 15793), a management system built on the principle of

*Biosecurity and Bioterrorism: Biodefense Strategy, Practice and Science; Volume 11, Supplement 1, 2013; S36 – S44.*

# Implementation Using CWA

Using the CWA 15793 framework a laboratory gap analysis can be done to include all laboratories within a network

- CWA 15793 describes what needs to be achieved
- Organizations and/or laboratory network members determine who to and how to best achieve those objectives
- Standardization is important across network members to ensure robust diagnostic capabilities as well as BRM compliance and consistency in practices


- **Assessment**
  - Hazard Identification
  - Risk Assessment
- **Mitigation**
  - Good microbiological technique
  - Waste management
  - Physical security
- **Performance**
  - Performance measurement and analysis of data
  - Management review

# Planning Example

Table 2. CWA 15793 Gap Analysis at 5 National Reference Laboratories in France, the Netherlands and Sweden

| *Item* | | *Description* | *Supporting Documents Available per Subitem* | | | | | | | | | | *Compliance Status per Subitem* | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 4.1 General requirements | 4.1.1 | Biorisk management system | | | | | | | | | | | | | | | | | | | | |
| | 4.1.2 | Continual improvement | | | | | | | | | | | | | | | | | | | | |
| 4.2 Policy | 4.2.1 | Biorisk management policy | | | | | | | | | | | | | | | | | | | | |
| 4.3 Planning | 4.3.1 | Planning for hazard identification, risk assessment, and risk control | | | | | | | | | | | | | | | | | | | | |
| | 4.3.2 | Conformity and compliance | | | | | | | | | | | | | | | | | | | | |
| | 4.3.3 | Objectives, targets, and program | | | | | | | | | | | | | | | | | | | | |
| 4.4 Implementation and operation | 4.4.1 | Roles, responsibilities, and authorities | | | | | | | | | | | | | | | | | | | | |
| | 4.4.2 | Personnel training, awareness, and competence | | | | | | | | | | | | | | | | | | | | |
| | 4.4.3 | Consultation and communication | | | | | | | | | | | | | | | | | | | | |
| | 4.4.4 | Operational control | | | | | | | | | | | | | | | | | | | | |
| | 4.4.5 | Emergency response and contingency plans | | | | | | | | | | | | | | | | | | | | |
| 4.5 Checking and corrective action | 4.5.1 | Performance measurement and analysis of data | | | | | | | | | | | | | | | | | | | | |
| | 4.5.2 | Record, document, and data control | | | | | | | | | | | | | | | | | | | | |
| | 4.5.3 | Inventory monitoring and control | | | | | | | | | | | | | | | | | | | | |
| | 4.5.4 | Accident and incident investigation, nonconformity, corrective and preventive actions | | | | | | | | | | | | | | | | | | | | |
| | 4.5.5 | Inspection and audit | | | | | | | | | | | | | | | | | | | | |
| 4.6 Review | 4.6.1 | Biorisk management review | | | | | | | | | | | | | | | | | | | | |

*Note.* The results are shown accumulated by the institutes: ANSES, CVI, RIVM, SMI, and SVA (BSL-4, BSL-3 laboratories and animal facilities).
Procedures or compliance are satisfactory (procedures are in place or in compliance with CWA 15793).
Procedures or compliance are developing (procedures are partly in place or partly in compliance with CWA 15793).
Procedures or compliance are challenging (procedures are not available or not in compliance with CWA 15793).
See color graphics online at www.liebertonline.com/bsp

*Biosecurity and Bioterrorism: Biodefense Strategy, Practice and Science; Volume 11, Supplement 1, 2013; S36 – S44.*

** SNL is currently working on CWA 15793 implementation software tool because of its importance

# Summary

- Hazard analysis and risk assessment are central to successful implementation of a biorisk management program
- Risk is determined by likelihood and consequences of an adverse event happening
- Biosafety and biosecurity risks assessments are done separately but often target similar hazards
- The CWA 15793 can be used as a framework to facilitate the implementation of biorisk management systems, to include assessment, mitigation and performance