

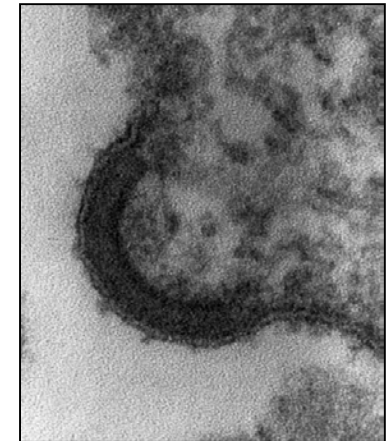


CENTRE FOR
**BIOSECURITY AND
BIOPREPAREDNESS**

Biosecurity regulation of dual use technology

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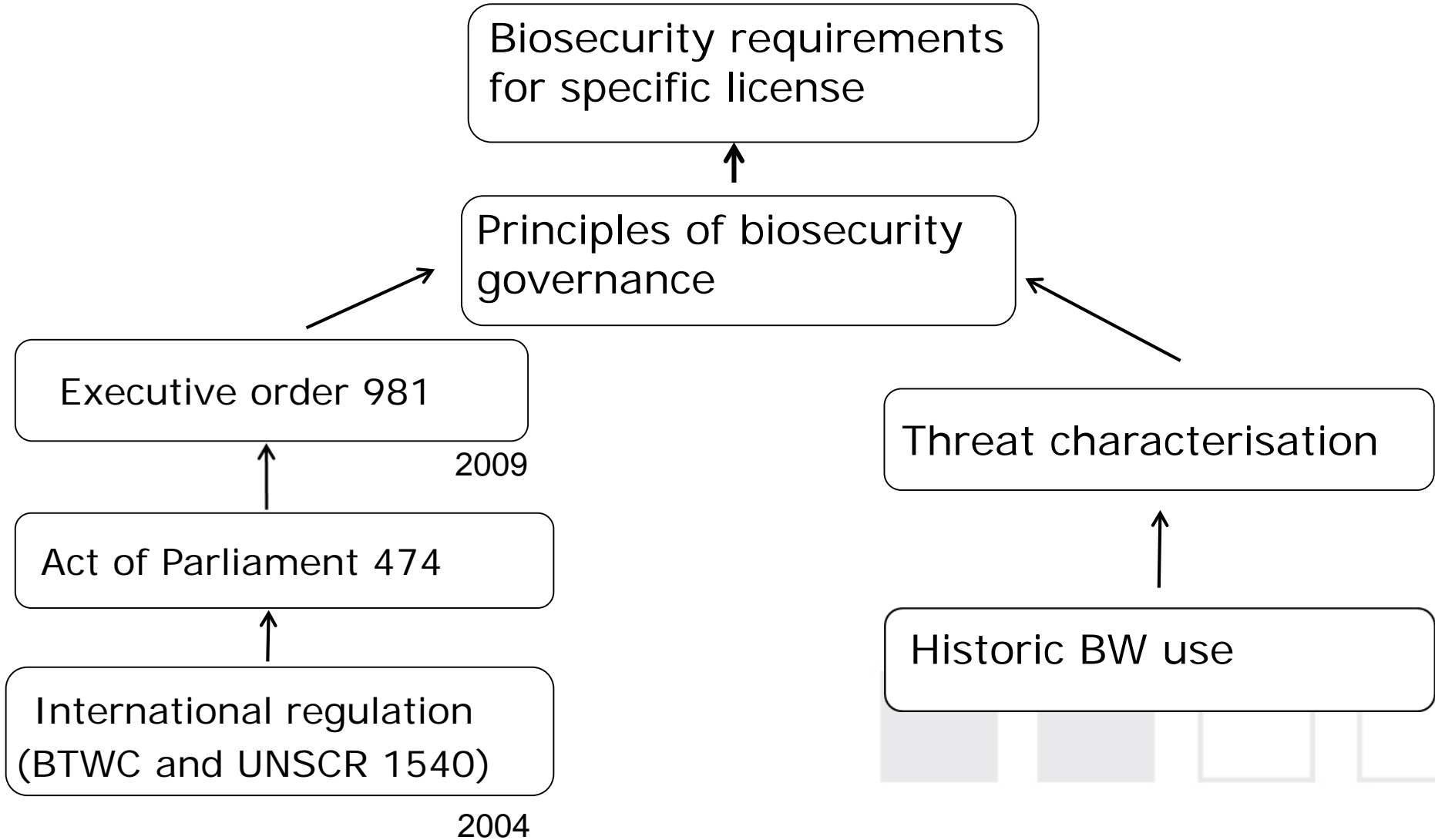
Director

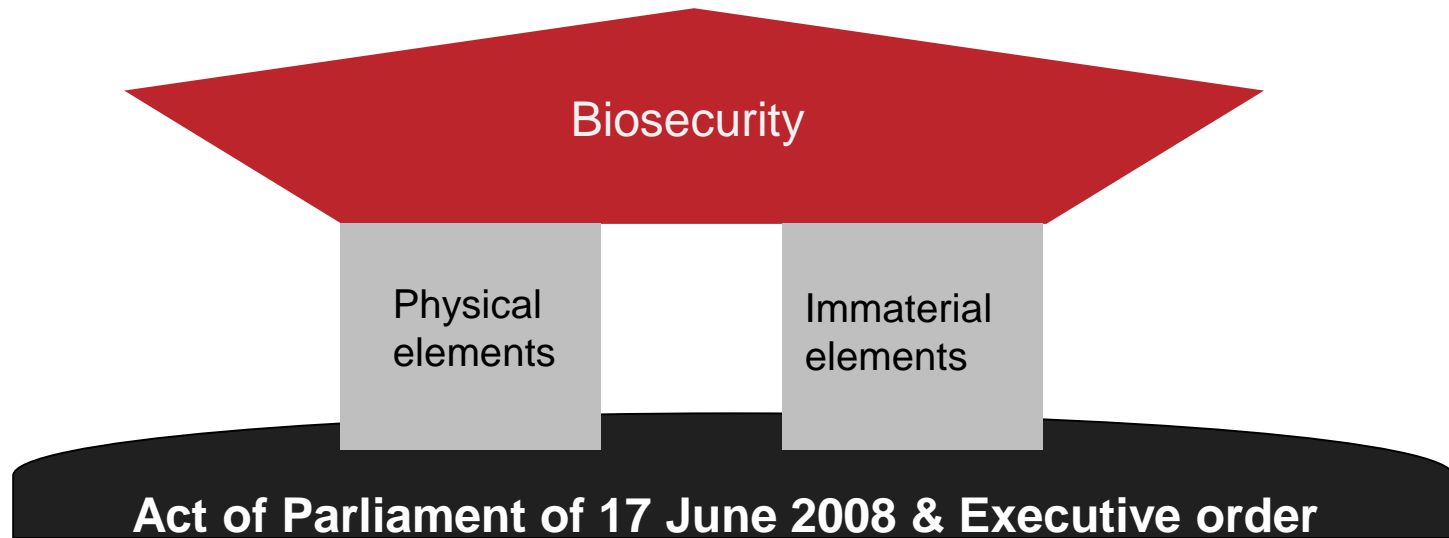


Retrovirus emerging from
infected cell



The basis for the Danish biosecurity system





License required before work!

- Security installations
- Access control
- Stock management
- Transport security
- Security culture
- Information security
- Technology control
- Ethical code



Requirements for a license

Mandatory elements

- Legitimate purpose
- Vulnerability assessment
- Security plan
- Security procedures
- Biosecurity officer (local)
- Mandatory training at CBB

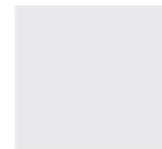
Control & sanctions:

- Inspections
- Withdrawal of license
- Penal sanctions



www.biosikring.dk/eng

Executive Order in 22 languages



Biological weapons components

- **Biological agents**

- Virus
- Bacteria
- Fungi
- Toxins



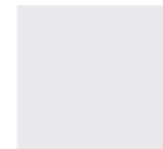
- **Know how = technology**

- Knowledge
- Skills
- Documentation

- **Equipment**

- Fermentors
- Spray-dryer
- Delivery vehicle

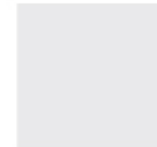
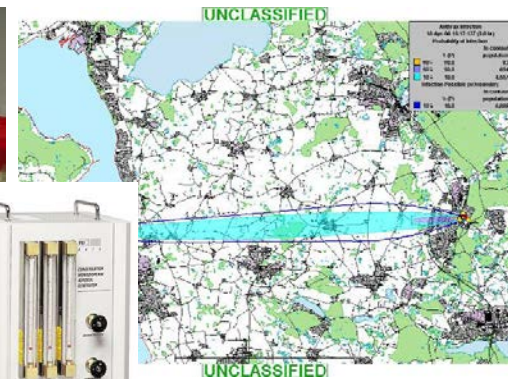
”Related materials: ...*technology* ... which could be used for the design, development, production or use of ... biological weapons and their means of delivery”
UNSCR 1540



Threat characterization

Preparation----->Weaponization----->Execution

Planning	Equipment	Production	Assembly	Deployment	Attack	Exploitation
Motive-objective Know-how Financing Facility	Hardware Precursors Consumables Containment	Methods Validation Storage Protection	Delivery device Testing	Reconnaissance Transport Communication	Access Co-ordination Release	Extraction Media & PR Protection



Technology and biosecurity

In connection with Danish biosecurity, "technology" refers to information used to develop, produce or use a product. Information can be in the form of *technical data*, or *technical assistance*.

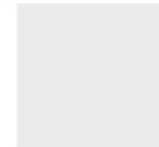
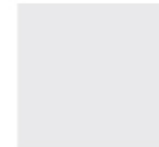
Research (results)

Technical data, i.e.: drawings, plans, diagrams, formulas, tables, construction plans, specifications, procedures, manuals and instructions, written or stored on medias or devices such as discs, tapes or ROM

Skills

Technical assistance, i.e.: instructions, skills, training, practical experience, and consultancy services

- Control corresponds with Australia Group and EU export control lists
- Does not apply to information already in the public domain



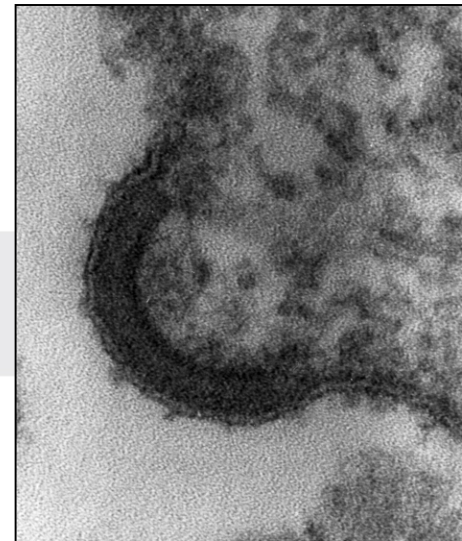
Control of dual use technology of concern

Three categories of immaterial technology

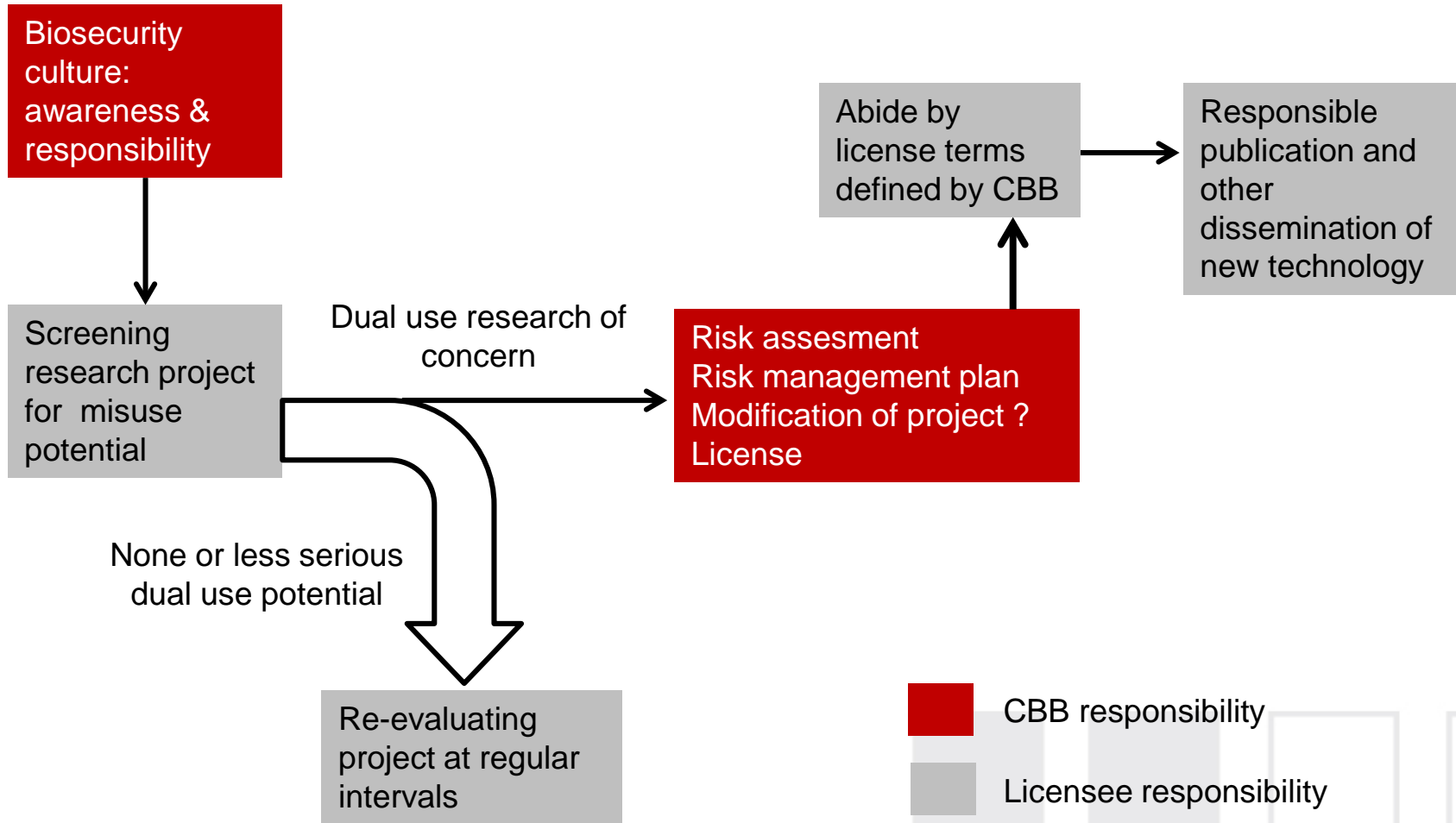
1. *Can be used in biological weapons production without further modifications* – mandatory license must be obtained from the Centre for Biosecurity and Biopreparedness and biosecurity requirements fulfilled prior to starting the project

2. *Serious potential for misuse in relation to offensive use* – mandatory guidance from the Centre for Biosecurity and Biopreparedness prior to starting the project or when potential is realised

3. *Less grave and more general dual-use potential* – awareness and biosecurity culture at the company or institution



Secure technology: A shared responsibility



Dual use technology of concern indicators

1. Virulence of pathogens increase
2. Transmissibility of pathogens increase
3. Toxins become more potent
4. Host specificity is altered
5. Resistance of pathogens to medical treatments increases
6. Resistance of pathogens to environmental stress increases
7. Improved methods of dissemination in air, food or water
8. Human immune response is compromised
9. New pathogens or toxins arise
10. Extinct pathogens are recreated
11. Diagnostic methods are undermined
12. Other technologies with outcome similar to the above

Dual use **skills** of concern indicators

Examples:

1. Production of bacteria or viruses
2. Environmental stabilization of microorganisms
3. Microencapsulation of microorganisms
4. Aerosolization of microparticles
5. Genetic engineering of microorganisms



CBB's technology assessment

1. Benefits must outweigh risks
2. New, non-public TMP in category A requires a license from CBB

I. TMP category A, B, C (or none) is assessed on the basis of:

- Biological weapons relevance (i.e. Australia Group criteria)
- Previously part of biological weapons programme
- Obvious BW potential (e.g. classified information)
- Unique importance for weapons development (technology not easily substituted by alternative technology)
- Clear and precise delimitation/definition of subject for control

II. Regarding new, non-public TMP in category A, it must be assessed if a license can be issued, taking into consideration:

- Accessibility of the information (scope of dissemination)
- Number of people with access to the information/skills (i.e. how large is the research group?)
- Possibilities for application

III. If a license cannot be issued because the risks are larger than the benefits, it may be considered if risk reduction can be achieved by:

- Reduction of accessibility (i.e. limited publication)
- Project adjustment (i.e. research conducted with non-dangerous materials)

Status after seven years

Licenses (approx. 150) to professional institutions:

- Laboratories working with controlled agents
- Industrial companies with dual-use equipment
- Diagnostic laboratories in clinical microbiology
- Retailers of agents and/or related materials



Out-reach activities:

- Education of biosecurity officers
- Inspections & guidance/consultancy visits
- Awareness raising among students and scientists



Unauthorised acquisition of biological dual use material in Denmark significantly harder than earlier



CBB options for enforcement

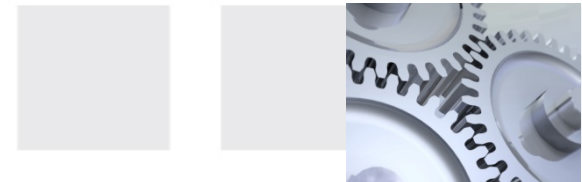
Executive order 981

- Set up special license requirements (§ 8)
- Background security check of personnel (§ 14)
- Security plan must include specifications on how sensitive information is secured (§ 17)
- Withdraw license, close the project (§ 22)
- Sanctions: fines or imprisonment (§ 24)

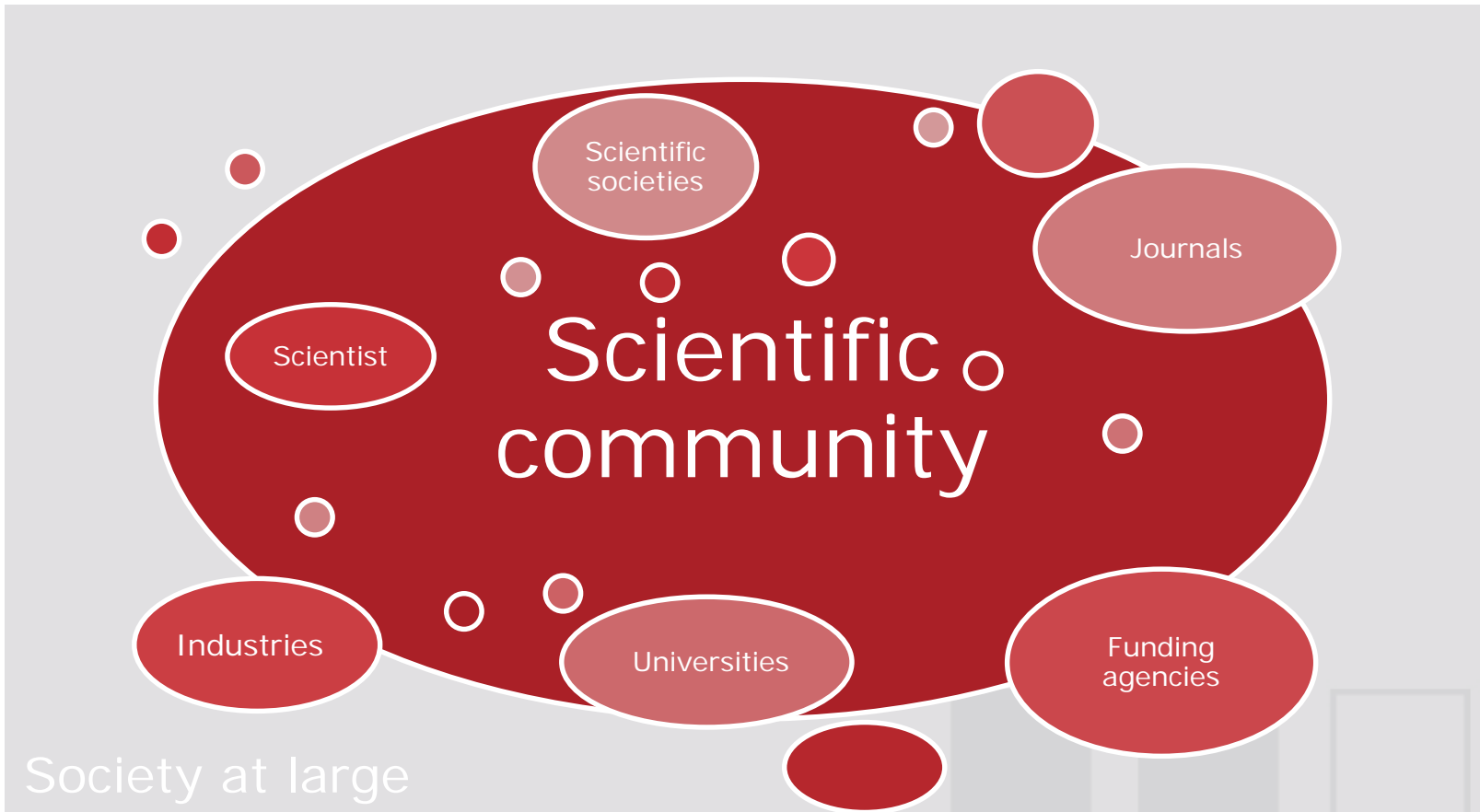


Technology intervention in practice

- Change experimental design (decrease pathogenecity, use kill switches ect.)
- Omit key information from publication
- Do not publish
- Prohibit project

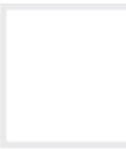
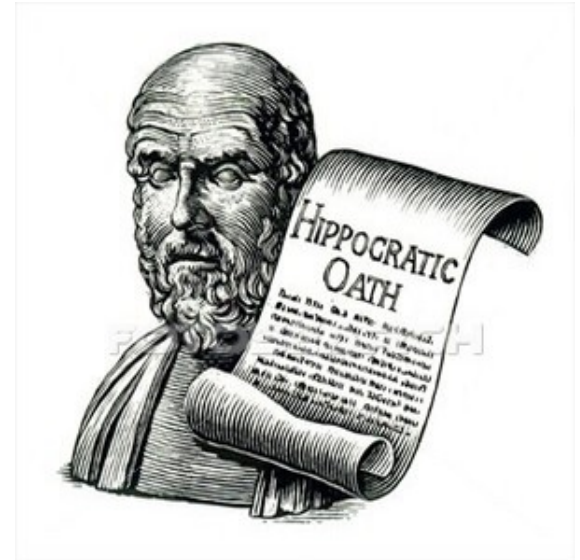


Responsible science is a community paradigm

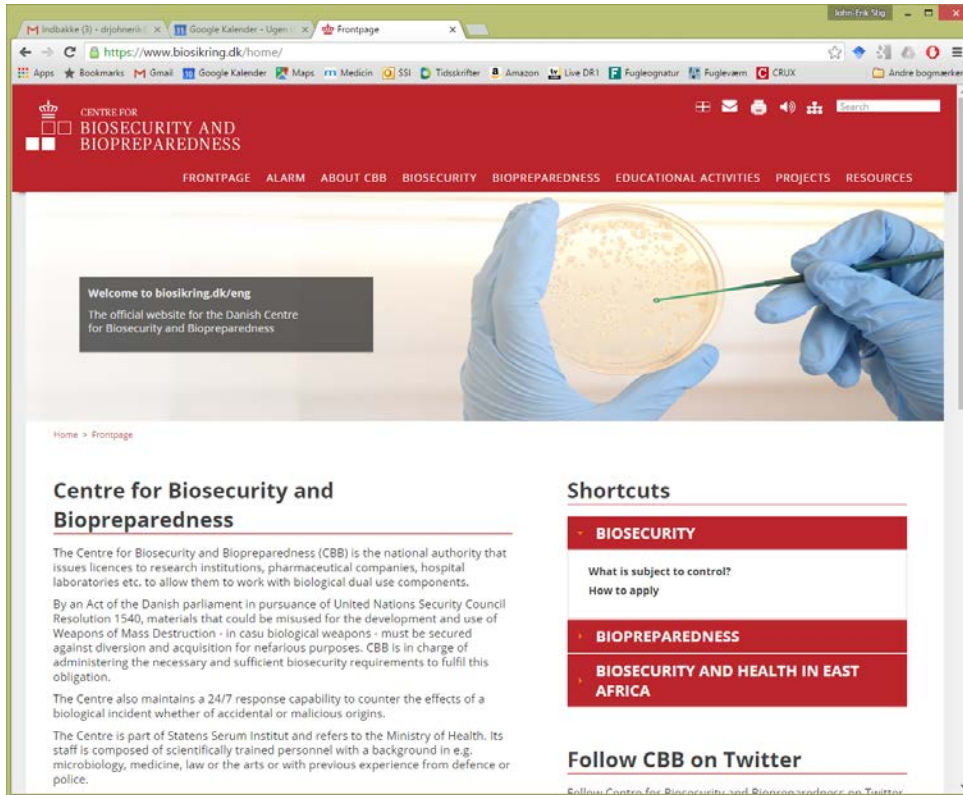


Ethics of Life Sciences

- A scientist should do no harm
- A scientist has a responsibility for the use of his research results
- Placing humans at risk in relation to research requires:
 - Informed consent
 - Benefit outweighs risk



Thank you for your attention!



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